

REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: ADM.03500.F.2.B
(alternative codes: ADM.3500.F.2.B; MCW-2075)

Product name(s): see part A

Chemical active substance:

Prothioconazole, 250 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation / representative
as specified in Part A

Submission date: June 2021, updated February 2022

Finalisation date: November 2022 (initial Core Assessment)

March 2023 (final Core Assessment)

Version history

| When | What |
|---------------|--|
| June 2021 | Version 1 submitted by Applicant |
| February 2022 | Version 2 submitted by Applicant |
| November 2022 | <p>Initial zRMS assessment.</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.</p> |
| March 2023 | <p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p> |

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03500.F.2.B. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03500.F.2.B. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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¹ JAU 6476 EC 250 is the formulation development code of Bayer for its formulation of prothioconazole 250 g/l EC.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation ADM.03500.F.2.B are presented in Table 7.1- 1. They have been selected from the individual GAPs in the central zone for wheat, rye, triticale, barley, oat, and oilseed rape.

A list of all intended uses within the central zone is given in Part B, Section 0.

Three critical GAP uses, one for wheat, rye, triticale, one for barley and oat and one for oilseed rape were selected based on the highest application rate and the latest application timing (BBCH) per season of the active substance. For the cGAPs intended for wheat, rye and triticale as well as for barley and oat, general extrapolation rules apply from wheat to rye and from barley to oat for prothioconazole.

According to Commission regulation (EU) No 752/2014 replacing Annex I to Regulation (EC) No 396/2005 triticale (code number: 0500090-006) can be grouped to wheat (code number: 0500090).

Overall conclusion

The data available for prothioconazole are considered sufficient for risk assessment. An exceedance of the current EU-MRLs for prothioconazole (prothioconazole-desthio (sum of isomers)) of 0.1 mg/kg (wheat, triticale), 0.05 mg/kg (rye), 0.2 mg/kg (barley) and 0.15 mg/kg (rapeseeds) as laid down in Reg. (EU) 396/2005 (last update Comm. Reg. (EU) No 2019/552) is not expected.

Considering the intended use on oat, an exceedance of the MRL of 0.05 mg/kg for prothioconazole, as established in Commission Regulation (EU) 2019/552, is expected.

The chronic and the short-term intakes of prothioconazole residues according to the residue definition for risk assessment are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorisation of the intended use(s): wheat, rye, triticale, barley and oilseed rape, except oat.

According to available data, no specific mitigation measures should apply.

Regarding the data for triazole derivative metabolites (TDMs) which were newly included in the prothioconazole residue definition for risk assessment (EFSA, 2018b and EFSA 2020), relevant studies (residue studies and storage stability studies) have been conducted. Study reports and final risk assessments on TDMs are submitted with this dRR update.

Data gaps

Noticed data gaps are:

- None.

Table 7.1- 1: Acceptability of critical GAPS (and respective fall-back GAPS, if applicable)

| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | | 8 | | | | 9 | | 10 | 11 |
|---------------------|---|---|-------------------------|---|-------------------------------|--|-------------|-------------|--------------------------|-----------------------|---|---|--------------------------------|--|------------|--------------------------|
| Critical GAP number | Use number (see part B.0)* | Crop and/or situation ** | dRR zone (residue zone) | Product code | F, Fn, Fpn G, Gn, Gpn or I*** | Pests or Group of pests controlled | Formulation | | Application | | | | Application rate per treatment | | PHI (days) | Conclusion |
| | | | | | | | Type | Conc. of as | method kind | growth stage & season | Max. number a) per use b) per crop/season | Min. interval between applications (days) | water L/ha min max | kg as/ha a) max. rate per appl. b) max. total rate per crop/season | | |
| Critical GAP (1) | 1, 3, 4, 6, 8, 9, 11, 13, 14, 17, 19, 20, 28, 30, 31, 33, 35, 36, 38, 40, 42, 45, 52, 54, 169 | Spring and winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS) | C-EU (N-EU) | ADM.03500.F.2.B (alternative codes: ADM.3500.F.2.B; MCW-2075) | F | <i>Septoria tritici</i> , <i>Drechslera tritici-repentis</i> (DTR), <i>Puccinia striiformis</i> , <i>Puccinia recondita</i> , <i>Fusarium</i> + <i>microdochium</i> , <i>Rhynchosporium secalis</i> , <i>Erysiphe graminis</i> | EC | 250 g/L | Foliar spraying, overall | BBCH 30-69 Spring | a) 1 b) 1 | - | 100-400 | a) 0.200 b) 0.200 | n/a | A |
| Critical GAP (2) | 2, 7, 12, 15, 18, 21, 29, 34, 39, 43, 46, 53 | Spring and winter barley (HORVS, HORVW), oat (AVESS) | C-EU (N-EU) | ADM.03500.F.2.B (alternative codes: ADM.3500.F.2.B; MCW-2075) | F | <i>Rhynchosporium secalis</i> , <i>Helminthosporium gramineum</i> (<i>Pyrenophora teres</i>), <i>Ramularia collo-cygni</i> , <i>Puccinia hordei</i> , <i>Puccinia coronata</i> | EC | 250 g/L | Foliar spraying, overall | BBCH 30-65 Spring | a) 1 b) 1 | - | 100-400 | a) 0.200 b) 0.200 | n/a | A for barley |
| | | | | | | | | | | | | | | | | N for oat MRL exceedance |
| Critical GAP (3) | 5, 10, 16, 22, 32, 37, 41, 44, 47, 55 | Winter oilseed rape (BRSNW), spring oilseed rape (BRSNS) | C-EU (N-EU) | ADM.03500.F.2.B (alternative codes: ADM.3500.F.2.B; MCW-2075) | F | <i>Sclerotinia sclerotiorum</i> , <i>Alternaria</i> spp. | EC | 250 g/L | Foliar spraying, overall | BBCH 50-73 Spring | a) 1 b) 1 | - | 100-400 | a) 0.175 b) 0.175 | n/a | A |

* Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

*** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional

and non-professional greenhouse use, I: indoor application
n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Explanation for Column 11 “Conclusion”

| | |
|---|--|
| A | Exposure acceptable without risk mitigation measures, safe use |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable, no safe use |

7.1.2 Summary of the evaluation

The preparation ADM.03500.F.2.B is composed of prothioconazole 250 g/L

Table 7.1- 2: Toxicological reference values for the dietary risk assessment

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
|----------------------------|---|------|------------------|---|---------------|
| Prothioconazole-desthio | | | | | |
| ADI | EFSA Scientific Report (2007) 106, 1-98 | 2007 | 0.01 mg/kg bw/d | Rat – oncogenicity | 100 |
| ARfD | | | 0.01 mg/kg bw | Rat – oncogenicity | 100 |
| Prothioconazole (JAU 6476) | | | | | |
| ADI | EFSA Scientific Report (2007) 106, 1-98 | 2007 | 0.05 mg/kg bw/d | Rat – oncogenicity | 100 |
| ARfD | | | 0.2 mg/kg bw | Rat – oncogenicity | 100 |
| 1,2,4-triazole (1,2,4-T) | | | | | |
| ADI | EFSA Journal 2018;16(7):5376; EC Review Report 2021 | 2018 | 0.023 mg/kg bw/d | Rat 12-month study | 300 |
| ARfD | | | 0.1 mg/kg bw | Rabbit developmental study | 300 |
| Triazole alanine (TA) | | | | | |
| ADI | EFSA Journal 2018;16(7):5376; EC Review Report 2021 | 2018 | 0.3 mg/kg bw/d | Rabbit developmental study | 100 |
| ARfD | | | 0.3 mg/kg bw | Rabbit developmental study | 100 |
| Triazole acetic acid (TAA) | | | | | |
| ADI | EFSA Journal 2018;16(7):5376; EC Review Report 2021 | 2018 | 1.0 mg/kg bw/d | Rat 2-generation and rabbit developmental studies | 100 |
| ARfD | | | 1.0 mg/kg bw | Rat 2-generation and rabbit developmental studies | 100 |
| Triazole lactic acid (TLA) | | | | | |
| ADI | EFSA Journal 2018;16(7):5376; EC Review Report 2021 | 2018 | 0.3 mg/kg bw/d | Bridging from TA | |
| ARfD | | | 0.3 mg/kg bw | Bridging from TA | |

7.1.2.1 Summary for prothioconazole

Table 7.1- 3: Summary for prothioconazole

| Critical GAP number | Use-No.* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample storage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
|---------------------|---|---|---------------------------|----------------------------|-----------------------------|---|---------------------------------|--|--------------------------------------|
| Critical GAP (1) | 1, 3, 4, 6, 8, 9, 11, 13, 14, 17, 19, 20, 23, 25, 26, 28, 30, 31, 33, 35, 36, 38, 40, 42, 45, 48, 50, 52, 54, 56, 58, 59, 169 | Spring and winter wheat (TRZAS, TRZAW), winter rye (SECCW), triticale (TTLSS) | Yes | Yes | n.a. | Yes | Yes | No | No |
| Critical GAP (2) | 2, 7, 12, 15, 18, 21, 24, 29, 34, 39, 43, 46, 49, 53, 57, 60 | Spring and winter barley (HORVS, HORVW), oat (AVESS) | Yes | Yes | n.a. | Yes | Yes (barley) No (oat) | No | No |
| Critical GAP (3) | 5, 10, 16, 22, 27, 32, 37, 41, 44, 47, 51, 55, 61 | Winter oilseed rape (BRSNW), spring oilseed rape (BRSNS) | Yes | Yes | n.a. | Yes | Yes | No | No |

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a.: not applicable

The effects of processing on the nature of prothioconazole residues have been investigated. As residues of prothioconazole do not exceed the trigger values defined in Reg (EU) No 283/2013 (except TDMs), there is no need to investigate the effect of industrial and/or household processing on prothioconazole residues except for TDMs.

Residues of prothioconazole (including TDMs) in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues exceeding residues in primary crops will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No chronic and acute dietary risk has been identified for wheat, rye, triticale, barley and oilseed rape.

The uses of ADM.03500.F.2.B on wheat, rye, triticale, barley and oilseed rape is therefore acceptable. The proposed use on oat is not considered acceptable.

7.1.2.2 Summary for ADM.03500.F.2.B

Table 7.1- 4: Information on ADM.03500.F.2.B (KCA 6.8)

| Crop | PHI for ADM.03500.F.2.B proposed by applicant | PHI sufficiently supported for | PHI for ADM.03500.F.2.B proposed by zRMS | zRMS Comments (if different PHI proposed) |
|-----------------------|---|--------------------------------|--|---|
| | | Prothioconazole | | |
| Wheat, rye, triticale | n/a [#] | Yes | n/a | - |
| Barley-oat | n/a [#] | Yes | n/a | - |
| Oilseed rape | n/a [#] | Yes | n/a | - |

n/a[#] : The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Table 7.1- 5: Waiting periods before planting succeeding crops

| Waiting period before planting succeeding crops | | Overall waiting period proposed by zRMS for ADM.03500.F.2.B |
|---|------------------------|---|
| Crop group | Led by prothioconazole | |
| Wheat, rye, triticale | NR | NR |
| Barley-oat | NR | NR |
| Oilseed rape | NR | NR |

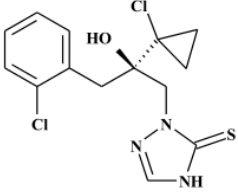
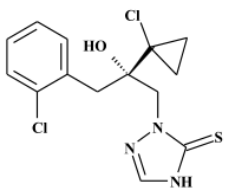
NR: not relevant

Assessment

7.2 Prothioconazole

General data on prothioconazole are summarised in the table below (last updated 2021/06/22)

Table 7.2- 1: General information on prothioconazole

| | |
|---|---|
| Active substance (ISO Common Name) | Prothioconazole |
| IUPAC | (<i>RS</i>)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione |
| Chemical structure | <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>R - enantiomer</p> </div> <div style="text-align: center;">  <p>S - enantiomer</p> </div> </div> |
| Molecular formula | C ₁₄ H ₁₅ Cl ₂ N ₃ O S |
| Molar mass | 344.26 g/mol |
| Chemical group | Triazole fungicides |
| Mode of action (if available) | Steroid demethylation (ergosterol biosynthesis) |
| Systemic | Yes |
| Company (ies) | Bayer Crop Science* |
| Rapporteur Member State (RMS) | Poland (previously United Kingdom) |
| Approval status | Approved. Date of approval: 01/08/2008 COMMISSION DIRECTIVE 2008/44/EC COMMISSION IMPLEMENTING REGULATION (EU) 2020/869 COMMISSION IMPLEMENTING REGULATION (EU) 2021/745 COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 |
| Restriction (e.g. is restricted to use as "...") | Only uses as fungicide may be authorised. |
| Review Report | SANCO/3923/07 – final (10/12/2007) and revised version (26/01/2021) involving confirmatory data |
| Current MRL regulation | COMMISSION REGULATION (EU) No 2019/552 of 04 April 2019 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal : Conclusion on the peer review | Yes (Prothioconazole: EFSA, 2007, TDMs (confirmatory data): 2018)**; |
| EFSA Journal : conclusion on article 12 | Yes (EFSA, 2014 and EFSA 2020)** |
| Current MRL applications on intended uses | None |

* Notifier in the EU process

** If yes: see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

In addition, two new stability studies (KCA 6.1/01 and KCA 6.1/02) are submitted by the applicant in the framework of this application demonstrating stability of prothioconazole metabolites including triazole derivative metabolites (TDMs). Results are summarized in the tables below. The detailed assessments of these studies are presented in Appendix 2.

Further, two new stability studies (KCA 6.1/03 and KCA 6.1/04) analysing the stability of 1,2,4-T and TA in oilseed rape seeds and of prothioconazole and prothioconazole-desthio in pollen, nectar, flowers and honey are submitted in the framework of this application. Results are summarized in the tables below. The detailed assessments of these studies are presented in Appendix 2.

Applicant has access to a new residue analytical method study in honey (Kalathoor, 2021) demonstrating short term stability of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey via letter of access (KCA 6.1/05).

Table 7.2- 2: Summary of stability data for prothioconazole-desthio, prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio and prothioconazole-6-hydroxy-desthio achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Compounds covered | Reference |
|-----------------------------|-------------------------------|-------------------------------------|--|--|
| Data relied on in EU | | | | |
| Plant products | | | | |
| Wheat grain | High starch content | 180 days | Prothioconazole (JAU 6476) | Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014 |
| | | 540 days | Prothioconazole -desthio (JAU 6476-desthio) | |
| Potatoes | High starch content | 24 months | Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio | EFSA, 2020 |
| Wheat straw | Difficult commodity | 360 days | Prothioconazole | Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014 |
| | | 540 days | Prothioconazole -desthio | |

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Compounds covered | Reference |
|--------------------------------|-------------------------------|-------------------------------------|--|--|
| Wheat green material | High water content | 120 days | Prothioconazole | Heinemann, O. (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.0/01; EFSA, 2007; EFSA, 2014 |
| | | 540 days | Prothioconazole -desthio | |
| Tomatoes | High water content | 24 months | Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio | EFSA, 2020 |
| Rapeseeds | High oil content | 24 months | Prothioconazole -desthio | EFSA, 2014 |
| Soya beans, rapeseeds | High oil content | 24 months | Prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio | EFSA, 2020 |
| Animal Products | | | | |
| All relevant ruminant matrices | Animal tissues | 1 month | Prothioconazole -desthio, prothioconazole-3 hydroxy-desthio (M14), and prothioconazole-4 hydroxy-desthio (M15) | xxxxxxxxxxxxx (2001), DAR UK, 2004, Vol. 3, B.7, IIA, 6.4/01; EFSA, 2014 |
| New data | | | | |
| Plant Products | | | | |
| Wheat whole plant | High water content | 24 months | Prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio | Lefresne, S., 2020 (KCA 6.1/02) |
| Wheat grain | High starch content | 24 months | | |
| Wheat straw | Difficult commodity | 24 months | | |
| Oilseed rape | High oil content | 24 months | | |
| Strawberry | High acid content | 24 months | | |
| Dry bean | High protein content | 24 months | | |
| Pollen, nectar, flowers, honey | - | 13 months | Prothioconazole-desthio | Lindner, M., 2022, (KCA 6.1/04) |

n.a.: not applicable

Table 7.2- 3: Summary of stability data for TDMs (1,2,4-triazole, triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) achieved at $\leq -18^{\circ}\text{C}$ (unless stated otherwise)

| Matrix | Characteristic s of the matrix | Acceptable Maximum Storage duration (months) | | | | Reference |
|--|---|--|--|---------|---|---------------------------------------|
| | | 1,2,4- Triazole | TA | TAA | TLA | |
| Data relied on in EU | | | | | | |
| Plant products | | | | | | |
| Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces | High water content | 6 | 53 | 53 | 48 (lettuce only) | EFSA, 2018b (amended 2019); EFSA 2020 |
| Barley, wheat grain | Dry commodity ¹ - High starch content | 12 | 26 | 26 | 48 | EFSA 2018b (amended 2019); EFSA 2020 |
| Rapeseeds, soya beans | High oil content | 12 (soya bean only; not stable in rape seed) | 26 (soya bean only; not stable in rape seed) | 53 | 48 | EFSA 2018b (amended 2019); EFSA 2020 |
| Peas, dry; Navy beans | Dry commodity ¹ - High protein content | No data | 15 | 25 | 48 | EFSA 2018b (amended 2019); EFSA 2020 |
| Oranges | High acid content | No data | No data | No data | 48 | EFSA 2018b (amended 2019); EFSA 2020 |
| Barley, wheat straw | Dry ¹ commodity | 12 | 53 | 40 | Covered by 5 matrices and dry commodity data ¹ | EFSA 2018b (amended 2019); EFSA 2020 |
| Animal Products | | | | | | |
| Animal products and tissues | Milk | 18 | No data | No data | No data | EFSA 2018b (amended 2019) |
| | Eggs | 12 | No data | No data | No data | |
| | Liver | 12 | No data | No data | No data | |
| | Muscle | 12 | No data | No data | No data | |
| | Fat | 12 | No data | No data | No data | |

| Matrix | Characteristic s of the matrix | Acceptable Maximum Storage duration (months) | | | | Reference |
|-------------------|--------------------------------------|---|----|-----|-----|--|
| | | 1,2,4-Triazole | TA | TAA | TLA | |
| New data | | | | | | |
| Plant Products | | | | | | |
| Cucumber | High water content | 12 | 36 | 36 | 36 | Klimmek, S., 2017 (KCA 6.1/01) |
| Grapes | High acid content | 36 | 36 | 36 | 36 | |
| Dried beans | High protein content | 36 | 36 | 36 | 36 | |
| Oilseed rape seed | High oil content | 2 | 9 | - | - | Yozgatli, H., 2022 (KCA 6.1/03) |
| Honey | - | Short-term stability study of TDMG* exists. Access via Letter of Access from owner. Stability in honey was proven for 153 days. | | | | Kalathoor, R., 2021 (KCA 6.1/05) Access via LoA. |

*TDMG = Triazole Derivative Metabolite Group

¹: New matrix characteristic acc. to SANTE/2020/12830, Rev.1 February 2021 additionally given here.

Conclusion on stability of residues during storage

Prothioconazole except TDMs

In addition to the storage stability data evaluated during EU review (EFSA, 2007), the storage stability of prothioconazole-desthio in plant samples stored under frozen conditions was investigated in the framework of the Art. 12 MRL review. A data gap was noted by EFSA during the MRL review for the need of further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition in the relevant commodity groups (i.e. high water, high oil content commodities and dry (high starch/high protein) commodities) (EFSA, 2014).

This data gap is addressed with the new storage stability study submitted with this dossier (Lefresne, 2020, KCA 6.1/02) where storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio is demonstrated in all matrix groups for 24 months.

In addition, in order to address this data gap, during evaluation of confirmatory data following the Article 12 MRL review (EFSA, 2020), the EMS UK referred to storage stability studies submitted in the framework of the renewal of the approval (United Kingdom, 2018). EFSA assessed the submitted studies, noting that the renewal of the approval has not been finalised yet:

“Freezer storage stability of prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxydesthio was investigated in high water content (tomatoes), high starch content (potatoes), high oil content (soya beans, oilseed rape) and high acid content (oranges) commodities for a period of 24 months. Samples were fortified with a mixture containing all five analytes at a level of 0.1 mg/kg each. Since all these compounds are included in the residue definition for risk assessment, spiking with a mixture was considered acceptable. Results demonstrate stability of all compounds in all matrices for a maximum of 24 months (duration of study) when stored at $\leq 18^{\circ}\text{C}$.

It is noted that according to EU guidelines (European Commission, 1997 [Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997]), applicable for the current assessment, cereals are considered as dry matrix, for which the storage stability of hydroxylated metabolites of prothioconazole-desthio has not been investigated. However, it is noted that the applicant has generated data according to the OECD guidelines (OECD, 2007 [Test No 506: Stability of pesticide residues in stored commodities]) in the framework of the renewal of the approval of prothioconazole. According to OECD guideline, cereals are considered as high starch matrix. EFSA accepted the storage stability data on potatoes (high starch

matrix) to address the storage stability in cereals.” (EFSA 2020).

One new study demonstrating stability of prothioconazole-desthio in pollen, nectar, flowers and honey is submitted in the framework of this application.

TDMs

The freezer storage stability of various TDMs was investigated in the framework of the peer review of TDMs (UK, 2018b, EFSA, 2018b, amended 2019). The data is additionally included in the evaluation of confirmatory data following the Article 12 MRL review of prothioconazole (EFSA 2020): In the commodity groups relevant for the envisaged GAP uses, the stability of all TDMs has been demonstrated, except that of 1,2,4-T and TA in rapeseeds (refer to Table 7.2- 3).

A new storage stability study analysing the stability of 1,2,4-T and TA in oilseed rape seeds is submitted (KCA 6.1/03), showing stability of two and nine months for 1,2,4-T and TA, respectively. Additionally, a letter of access exists to a new residue analytical method study in honey (Kalathoor, 2021) demonstrating short term stability of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey (KCA 6.1/05).

In addition, storage stability in cucumber, grapes and dried bean was demonstrated in the new storage stability studies submitted with this dossier (Klimmek, 2017, KCA 6.1/01): Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months. Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months. Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored at -18°C or below for at least 36 months.

Storage stability of TLA in straw is covered according to OECD guidance 506 as stability for 48 months was demonstrated in each of the relevant five matrix categories. This was also agreed in the Peer Review Report on triazole derivate metabolites (confirmatory data) of Pesticides Peer Review Meeting 171 (13-15 December 2017) (EFSA, 2018a). Since this time SANTE/2020/12830, Rev.1 February 2021 has defined cereal straws as a dry commodity which further supports the acceptability of the existing storage stability data for TLA and that no further data is required.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

Studies on the storage stability of prothioconazole and its metabolites in crop and animal tissues under frozen conditions were assessed in the framework at the EU level.

Residues of prothioconazole-desthio are stable for 18 months under deep-freeze storage in high water content matrices (wheat green matter), dry commodities (cereal grain) and straw and for 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw.

EFSA in EFSA Journal 2014;12(5):3689 concluded that

(...) Furthermore, storage stability of prothioconazole-desthio residues was subsequently demonstrated for a period of 24 months at – 18 °C in commodities with high water content (spinach, sugar beet, tomatoes), high oil content (canola seeds), dry commodities (dried peas) and canola straw (EFSA, 2009, 2010a, 2010b, 2012; Netherlands, 2007). According to the RMS and the Member States which submitted additional data during the MS consultation, all residue trial samples reported in the PROFile were stored in compliance with the storage conditions reported above. Degradation of prothioconazole-desthio residues during storage of the trial samples is therefore not expected. However, storage stability was demonstrated for prothioconazole and prothioconazole-desthio only, while further metabolites are included in the residue definition for risk assessment. Therefore, further storage stability data for at least one hydroxylated metabolite included in the risk assessment residue definition are still required in the relevant commodity groups.

As the proposed residue definitions for enforcement and risk assessment are different (see also Section 3.1.1.1), conversion factors (CF) for enforcement to risk assessment of 2 in cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 in cereal straw were derived on the basis of the available metabolism data on wheat, peanut and sugar beet (roots, tops) (EFSA, 2007b, 2009, 2010a, 2010b, 2012; United Kingdom, 2007).

New studies on the storage stability of prothioconazole-desthio and its hydroxies metabolites in different matrices were submitted by the Applicant:

- the results of new study of Lefresne, S. (2020; Report No.: B18S-A4-P-02) demonstrate the stability of residues of prothioconazole-desthio, prothioconazole- α -hydroxy-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, and prothioconazole-6-hydroxy-desthio upon deep frozen storage at – 18 °C for up to 24 months in in wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content).
- the storage stability of prothioconazole-desthio was demonstrated in pollen, nectar surrogate, flowers and honey at ≤ -18 °C in the dark over a storage period of up to 13 months (Lindner, M., 2022; Study no.: S19-02145).

In EFSA Journal 2014;12(5):3689 it is stated that *in the framework of the reported feeding study, the **storage stability of prothioconazole-desthio, M14 and M15** was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.*

TDMs

Maximum storage time periods for TDMs in several commodities (EFSA, 2018):

| Plant products (category) | Commodity | Storage stability (months) | | | |
|------------------------------|--|--|--|---------|-------------------|
| | | 1,2,4 Triazole | TA | TAA | TLA |
| High water content | Apples, tomatoes, mustard leaves, wheat forage, radishes tops/roots, turnips roots, sugar beet roots, cabbages, lettuces | 6 | 53 | 53 | 48 (lettuce only) |
| High starch content | Barley, wheat | 12 | 26 | 26 | 48 |
| High oil content | Rapeseeds, soyabeans | 12 (soya bean only; not stable in rape seed) | 26 (soya bean only; not stable in rape seed) | 53 | 48 |
| High protein content | Peas, dry; Navy beans | No data | 15 | 25 | 48 |
| High acid content | Oranges | No data | No data | No data | 48 |
| Cereal straw | Barley, wheat | 12 | 53 | 40 | No data |
| Animal products | | | | | |
| | Milk | 18 | No data | No data | No data |
| | Eggs | 12 | No data | No data | No data |
| | Liver | 12 | No data | No data | No data |
| | Muscle | 12 | No data | No data | No data |
| | Fat | 12 | No data | No data | No data |

New studies on the storage stability of prothioconazole-desthio and the triazole derivative metabolites in different matrices were submitted by the Applicant:

- Klimmek, S and Gizler, A. (2017, Report No.: S12-00072) - the storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months, for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored for at least 36 months, 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored for at least 36 months.
- Yozgatli, H. (2022a; Study no.: S20-08247) - the storage stability was demonstrated in homogenates of oilseed rape (seeds) upon storage at ≤ -18 °C in the dark for 2 months for 1,2,4-triazole and for 9 months for triazole alanine.
- Kalathoor, R. (2021 Study no.: M-680825-03-1) - the study results demonstrate that the residues of TDMs are stable in honey for at least 5 months under deep-freezer storage conditions (≤ -18 °C).

Sufficient stability data are available to support the residue data presented in this dossier.
No further data are required.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

The stability of crop sample extracts was checked as part of the field residue studies. The stability of prothioconazole metabolites in the specimen extracts during the analytical procedure was proven by the corresponding procedural recovery specimen which were stored under the same conditions together with the field specimens. The results do not indicate any residue decrease within this period of storage and subsequent analytical measurements.

Conclusion on stability of residues in sample extracts

The stability of prothioconazole metabolites in the specimen extracts is sufficiently demonstrated in the frame of the available supervised residue trials.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

No further data are required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

No new data are submitted in the framework of this application.

Metabolism of prothioconazole was investigated for foliar application on pulses and oilseeds (peanuts) and cereals (wheat) as well as for seed treatment in cereals (wheat) using [U-¹⁴C-phenyl]-labelled prothioconazole. The metabolism of prothioconazole-desthio was also investigated for foliar application on cereals (wheat) using [3,5-¹⁴C-triazole]-labelled prothioconazole-desthio (United Kingdom, 2004, 2007; EFSA, 2007). Furthermore, additional metabolism studies were conducted on pulses and oilseeds (peanut) and cereals (wheat) by foliar application using [3,5-¹⁴C-triazole]-labelled prothioconazole (EFSA, 2014; FAO, 2008a, 2008b). The characteristics of all these studies are summarised in the following table.

Table 7.2- 4: Summary of plant metabolism studies

| Crop Group | Crop | Label position | Application and sampling details | | | | Reference |
|---------------------|---------|---|------------------------------------|----------------------|--------------------------|---------------------------------------|--|
| | | | Method, F or G ^(a) | Rate (kg a.s./ha) | No (Interval in days) | Sampling (DAT) | |
| EU data | | | | | | | |
| Pulses and oilseeds | Peanuts | [Phenyl-UL- ¹⁴ C]-prothioconazole | Foliar treatment, G | 0.300 ^(b) | 3 (21 days) (BBCH 66-75) | Hay & nuts without shells: 14 days | Haas, M. (2001), DAR UK, 2004 and 2007, Vol. 3, B.7, IIA, 6.1.2/01; EFSA, 2007 |
| | | [3,5- ¹⁴ C-triazole]-prothioconazole | Foliar treatment, G | 0.300 | 3 (21 days) (BBCH 66-75) | Hay & nuts without shells: 14 days | JMPR: FAO, 2008a, 2008b EFSA, 2014 |
| Cereals | Wheat | [Phenyl-UL- ¹⁴ C]-prothioconazole | Foliar treatment, G ^(c) | 0.200 | 2 | Forage: 6, Hay: 26, Grain & straw: 48 | Haas, M., Bornatsch, W. (2000), DAR UK, 2004 and 2007, |

| Crop Group | Crop | Label position | Application and sampling details | | | | Reference |
|------------|-------|---|---|--|-----------------------|---|--|
| | | | Method, F or G ^(a) | Rate (kg a.s./ha) | No (Interval in days) | Sampling (DAT) | |
| | | | | | | DAT | Vol. 3, B7, IIA, 6.1.1/01; EFSA, 2007 |
| | Wheat | [3,5- ¹⁴ C-triazole] JAU6476-desthio | Foliar treatment, G ^(c) | 0.250 | 2 | Forage: 0, 14 Grain & straw: 48 DAT | Vogeler, K., Sakamoto, H., Brauner, A. (1993), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.1.1/03; EFSA, 2007 |
| | Wheat | [Phenyl-UL- ¹⁴ C]-prothioconazole | Seed treatment, G | 0.020 kg a.s./100 kg seed (1N) or 0.100 kg a.s./100 kg seed (5N) | 1 | Fodder: 57, Hay: 110, Straw: 153 DAT | Haas, M. (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.1.1/02; EFSA, 2007 |
| | | [3,5- ¹⁴ C-triazole] prothioconazole | Foliar, F (spring wheat) ^(d) | 0.18 and 0.29 | 2 (BBCH 32-65) | Forage, hay, grain, straw | JMPR: FAO, 2008a, 2008b EFSA, 2014 |

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

(b): In the JMPR report, it is stated, that a 5x application was also tested in order to collect sufficient amounts of radioactivity to identify metabolites.

(c): The plants were grown under environmental conditions (sunlight and temperatures). A glass roof protected the plants from rainfall. The soil was surface irrigated.

(d): 1 day after application, the soil tub was moved to the outside of the greenhouse.

Summary of plant metabolism studies reported in the EU

According to EFSA, 2007: “Prothioconazole is extensively metabolised. In a first step the sulphur group of the triazolinethione ring is oxydised to the corresponding sulfonic acid. Subsequent elimination of the sulfonic acid moiety results in prothioconazole-desthio (metabolite M04) which is consistently the major prothioconazole-structurally related metabolite in all plant parts and for all growth stages, except in nutmeat, where it was not found. This metabolite is further hydroxylated in the chlorophenyl ring forming various hydroxyl-desthio isomers and dihydroxy-olefins. Similarly, α -hydroxylation of prothioconazole-desthio was also observed. A dimerisation product and other metabolites resulting from combined oxidation of the sulphur atom and hydroxylation of the chlorophenyl ring were also identified. Cleavage of the triazole moiety is also observed resulting in the ‘triazole derivative metabolites’ which consist essentially in triazole alanine and triazole acetic acid. These compounds are common, unspecific metabolites of triazole fungicides. Triazole alanine and triazole acetic acid are massively translocated to wheat grains where they represent 90% of the Total Radioactive Residues (TRR). Although the metabolism study in peanut did not use radiolabelling in the triazole ring, it is expected from studies carried out with other triazole fungicides that these triazole derivative metabolites are also present as major constituent of the residue in oilseeds.”

According to EFSA, 2014: “The metabolic pattern of prothioconazole and prothioconazole-desthio was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues with further hydroxylation and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of triazole derivative metabolites (TDMs). A global residue definition for enforcement was proposed as prothioconazole-desthio (sum of isomers) only whilst for risk assessment, the residue was defined as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). As the residue definitions for enforcement and risk assessment are different, conversion factors for enforcement to risk assessment of 2

for cereal grain, pulses and oilseeds, leafy vegetables and root and tuber vegetables and of 3 for cereal straw were derived on the basis of the available plant metabolism data.”

According to EFSA, 2020: “The metabolism of prothioconazole was investigated by foliar applications on root, pulses/oilseeds and cereal/grass crop groups and by seed treatment on cereals (spring wheat). The metabolic pattern of prothioconazole was shown to be similar with prothioconazole-desthio being the predominant compound of the total residues. Besides prothioconazole-desthio, other metabolites, which are structurally closely related to this compound, and the main triazole derivative metabolites (TDMs) were identified. [...] Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as ‘prothioconazole-desthio (sum of isomers)’ for enforcement and, as follows, for the risk assessment:

- 1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
- 2) Triazole alanine (TA) and triazole lactic acid (TLA)
- 3) Triazole acetic acid (TAA)
- 4) 1,2,4-triazole (1,2,4-T).

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.”

Summary of new plant metabolism studies

Not applicable/ no new studies are submitted.

Conclusion on metabolism in primary crops

Based on the evaluations of EFSA 2018b, amended 2019 and EFSA 2020, the following residue definitions are proposed:

Residue definition for enforcement:

- Prothioconazole-desthio (sum of isomers).

Residue definition for risk assessment:

- Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole)

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In the framework of the peer review under Directive 91/414/EEC and the Art.12 MRL review (EFSA, 2007, 2014), the metabolism of prothioconazole was investigated by foliar applications on root (sugar beet), pulses/oilseeds (peanut) and cereal/grass (wheat) crop groups and by seed treatment on cereal (wheat) (EFSA, 2007). In addition, the metabolism of prothioconazole-desthio labelled in the triazole moiety was investigated after foliar applications on cereals (EFSA, 2007).

Prothioconazole is extensively metabolised and the metabolic pathway was similar in all crops investigated. Prothioconazole-desthio was the predominant compound of the total residues with further hydroxylation (with the formation of several closely related metabolites) and glucosidation steps, whilst cleavage of the triazole bound of prothioconazole-desthio molecule resulted in the formation of TDMs.

In EFSA Journal 2018;16(7):5376 it is stated that *Primary crops metabolism data are reported for a total of 16 approved triazole compounds, and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops.(...) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*

The residue definitions

Taking into account conclusions EFSA regarding residue definitions presented in EFSA Journal 2020;18(2):5999, EFSA Journal 2014;12(5):3689 and EFSA Journal 2018;16(7):5376, based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definitions for plant products were proposed as ‘**prothioconazole-desthio (sum of isomers)**’ for **enforcement** and, as follows, for **the risk assessment**:

- 1) sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
- 2) Triazole alanine (TA) and triazole lactic acid (TLA)
- 3) Triazole acetic acid (TAA)
- 4) 1,2,4-triazole (1,2,4-T).

These residue definitions are applicable to primary crops, rotational crops and processed products and for both foliar and seed treatments.

Since all compounds included in the residue definitions are a mixture of enantiomers and since there are no enantiospecific analytical methods, the residue definitions are expressed as “sum of isomers”.

Although the residue definition for risk assessment includes consideration of all metabolites containing a common moiety, it is not possible to develop a common moiety method to meet the residue definition for risk assessment. For this reason, all the analytes have to be determined separately. 6 analytes, representing the major portion of the TRR (Total Radioactive Residue) for prothioconazole in the plant metabolism studies, should be determined in residue trials. These are: prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio (including all their acid-hydrolysable conjugates).

No further data are required.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

No new data are submitted in the framework of this application.

Prothioconazole except TDMs

Table 7.2- 5: Summary of metabolism studies in rotational crops

| Crop group | Crop | Commodities sampled | Label position | Application and sampling details | | | | | Reference |
|---------------------------|-------------|--------------------------------------|--|----------------------------------|-------------------|---------------------------|---|---------|---|
| | | | | Method | Rate (kg a.s./ha) | Planting intervals* (DAT) | Harvest Intervals (DAT) | Remarks | |
| EU data | | | | | | | | | |
| Leafy vegetables | Swiss chard | Swiss chard | [Phenyl-UL- ¹⁴ C]-prothioconazole | Soil treatment | 0.58 | 28, 146, 269 | 80, 188, 348 | -- | Haas, M. (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.6/01; EFSA, 2007 |
| Root and tuber vegetables | Turnip | Roots and tops | [Phenyl-UL- ¹⁴ C]-prothioconazole | Soil treatment | 0.58 | 28, 146, 269 | 94, 201, 349 | -- | |
| Cereals | Wheat | Green material, hay, straw and grain | [Phenyl-UL- ¹⁴ C]-prothioconazole | Soil treatment | 0.58 | 28, 146, 269 | 73, 178, 327 (green mat.); 111, 231, 377 (hay); 145, 269, | -- | |

| | | | | | | | | | |
|--|--|--|--|--|--|--|---------------------------|--|--|
| | | | | | | | 412 (grain & straw) | | |
|--|--|--|--|--|--|--|---------------------------|--|--|

* Planting of seedlings.

Summary of rotational crop metabolism studies reported in the EU

UK, 2007 (Final Addendum to the DAR (Addendum 10, pp. 216): “A study of uptake and metabolism in spring wheat, Swiss chard and turnip grown as rotational crops under worst case conditions in a confined study showed that residues declined between first and third rotations. Significant residues (>0.1 mg/kg) were only found in wheat straw and hay and these were at similar or lower levels than those recorded for the directly treated spring wheat. The profile of metabolites was found to be very similar in directly treated wheat and wheat grown as a rotational crop. The level of prothioconazole-desthio (M04, residue of concern), in Swiss chard was 0.014 mg/kg at the shortest plant back interval (30 days). No other single metabolite was present. In turnip leaves and turnip roots, no single metabolite was present at a level greater than 0.01mg/kg.”

Conclusion on metabolism in rotational crops

According to UK, 2007 (Final Addendum to the DAR (Addendum 10, pp. 216), the following was concluded: “The Rapporteur concludes that residues in rotational crops will not lead to any additional exposure to JAU 6476-desthio above that from directly treated crops. Therefore, a field rotational crop study is not considered necessary, since any significant additional exposure of the consumer by the uptake of prothioconazole residues from rotated crops can be excluded.”

According to EFSA, 2014 (Art. 12 MRL review), the following was concluded: “In wheat grain, the total radioactive residues were recovered at a trace level at all DATs (≤ 0.007 mg eq/kg) and no further metabolites’ identification was attempted. In wheat green material, hay and straw, TRR ranged from 0.021 mg eq/kg (green material, DAT 28) to 0.450 mg eq/kg (straw, DAT 28). In turnip roots, tops and Swiss chard, the highest residue levels ranged from 0.043 mg eq/kg (turnip root, DAT 28) to 0.053 mg eq/kg (Swiss chard, DAT 146). No significant decline of the residue levels was observed for any crop part throughout the first, second and third rotation.

In the edible parts of the crops at harvest 61 to 87 % of the total residues were extracted and the level of identification ranged between 34.4 % TRR (swiss chard, DAT 269) to 77.2 % TRR (turnip leaves, DAT 28). The major compounds of the total residues were identified as prothioconazole-desthio, its hydroxylated derivative metabolites, either free or conjugated (M14, M15, M16, M17), M27, free and conjugated and M02 (prothioconazole-sulfonic acid). Residue levels of the main metabolites recovered in wheat were in general higher in straw than in hay. In straw, they reached the following levels: prothioconazole-desthio (0.066 mg eq/kg) (DAT 28), M02 (0.063 mg eq/kg) (DAT 269), glucoside of M27 (0.056 mg eq/kg) (DAT 269) and glucosides of the hydroxylated metabolites of prothioconazole-desthio (0.097 mg eq/kg) (DAT 28). In Swiss chard, levels of prothioconazole-desthio reached 0.014 mg eq/kg at 28 DAT, while levels of M27 glucosides were below 0.01 mg eq/kg at all sowing intervals. In turnip roots and leaves, the residue levels of the identified major metabolites were always below 0.01 mg eq/kg.

Consequently, the metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

No rotational crop studies with prothioconazole radiolabelled on the triazole ring were assessed in the framework of the peer review but such studies were reported and assessed by the JMPR (FAO, 2008a, 2008b). These indicated a cleavage of the triazole linkage with the formation of the major metabolites found in all rotational crop matrices as triazole alanine [TA], triazole lactic acid [TLA] and triazole acetic acid [TAA]. Both the parent prothioconazole and prothioconazole-desthio were identified as minor metabolites.”

TDMs

During the peer review of TDMs, the metabolism of various triazole compounds in rotational and primary crops was investigated. It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops. For details, please refer to the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (EFSA, 2018b).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2020;18(2):5999 it is stated that *The metabolism of prothioconazole in rotational crops was investigated in the framework of the EU pesticides peer review in Swiss chards, turnips and spring wheat following the treatment of bare soil with prothioconazole at an application rate of 580 g/ha using the compound labelled in the phenyl ring. The main compounds identified were prothioconazole-desthio and its hydroxylated derivative metabolites, either free or conjugated.*

The MRL review concluded that metabolism of prothioconazole in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not necessary (EFSA, 2014).

The metabolism of prothioconazole labelled in triazole ring was assessed by the JMPR (FAO, 2009a) as reported in the MRL review. The studies indicate the cleavage of triazole linkage to form major metabolites TA, TLA and TAA (EFSA, 2014). During the peer review of TDMs in light of confirmatory data, the metabolism of various triazole compounds in rotational and primary crops was investigated.

It was concluded that for TDMs similar metabolic patterns were depicted both in primary and rotational crops (EFSA, 2018b).

Triazole Derivate Metabolites, addendum – confirmatory data (UK, 2018)

“For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12 approved triazole active substances and one non approved triazole active substance (flusilazole).

The rotational crop metabolism studies for the triazole active substances demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and/or triazole lactic acid (TLA) were often found to represent a significant portion of the total radioactive residue in the rotational crops; in addition 1,2,4-triazole (T) was detected but usually at much lower levels. Therefore, a number of field rotational crop trials have been conducted to investigate the magnitude of triazole derivative metabolite (TDM) residues in rotational crops after the use of triazole active substances”.

No further data are required.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

A new processing hydrolysis study with prothioconazole-desthio is submitted in the framework of this application.

Nature of the residues of prothioconazole and prothioconazole-desthio in processed commodities

| Nature of the residues of prothioconazole and prothioconazole-desthio in processed commodities | | | |
|--|--------|--|---------------------------|
| Conditions (Duration, Temperature, pH) | Stable | Comment | Reference |
| EU data | | | |
| Pasteurisation (20 minutes, 90°C, pH 4) | Yes | Prothioconazole degrades to prothioconazole-desthio under sterilisation process (≤ 11% AR). Prothioconazole-desthio remains stable (99.4 - 99.9% of AR) | EFSA, 2014; EFSA, 2020 |
| Baking, boiling, brewing (60 minutes, 100°C, pH 5) | Yes | | |
| Sterilisation (20 minutes, 120°C, pH 6) | Yes | | |
| New data | | | |
| Pasteurisation (20 minutes, 90°C, pH 4) | Yes | Prothioconazole-desthio remains stable (98.9 - 102.8% of AR) under the different hydrolytic conditions. | KCA 6.5.1/01 |
| Baking, boiling, brewing (60 minutes, 100°C, pH 5) | Yes | | |
| Sterilisation (20 minutes, 120°C, pH 6) | Yes | | |

Conclusion on nature of residues in processed commodities

Prothioconazole except TDMs

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review (EFSA, 2007). According to UK, 2004, residues in all treated commodities at harvest were at or near the limit of quantification and thus determination of the nature of residues in processed commodities was not considered relevant.

During MRL review it was referred to studies with prothioconazole investigated by the JMPR (FAO, 2008a, 2008b) and to studies with prothioconazole-desthio reported by Germany (EFSA, 2014; Germany, 2014). Prothioconazole-desthio was reported to be stable under all standard hydrolysis steps (99.4 - 99.9% applied radioactivity (AR)), whereas parent prothioconazole slightly degraded to prothioconazole-desthio under sterilisation process ($\leq 11\%$ AR).

The remaining compounds included in the risk assessment residue definition were concluded to be stable under standard hydrolysis conditions, considering their structural similarity to parent compound (EFSA, 2014).

A new processing hydrolysis study with prothioconazole-desthio is submitted in the framework of this application showing that [^{14}C]prothioconazole-desthio was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative for simulating pasteurisation, baking/brewing/boiling and sterilisation.

The relevant residues for enforcement and risk assessment in processed commodities are expected to be the same as for primary crops.

TDMs

According to EFSA, 2018b the TDMs are stable under hydrolysis conditions simulating baking/brewing/boiling, pasteurisation and sterilisation. For details, please refer to the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

The effect on the nature of prothioconazole and prothioconazole-desthio has not been investigated in the framework of the EU pesticides peer review.

In EFSA Journal 2014;12(5):3689 it is stated that *The effect of processing on the nature of prothioconazole residues was not investigated in the framework of the peer review. Nevertheless, studies were assessed by the JMPR (FAO, 2008a, 2008b), simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90 °C, pH 4), boiling/brewing/baking (60 minutes at 100 °C, pH 5) and sterilisation (20 minutes at 120 °C, pH 6). From these studies, it was concluded that parent compound prothioconazole is stable under processing by pasteurisation and baking/brewing/boiling. However, under sterilisation, prothioconazole slightly degrades ($\leq 11\%$) to prothioconazole-desthio.*

The Applicant submitted new hydrolysis study for prothioconazole-desthio (Bloß, K., 2019; Report No.: S18-07655). The results of study showed that prothioconazole-desthio was stable during all processing conditions. No significant hydrolysis or degradation products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

The data confirm previously evaluated data by JMPR (2008) and EFSA (2014, 2020).

The TDMs are stable under hydrolysis studies simulating baking/brewing/boiling, pasteurisation and sterilisation (EFSA, 2018).

No further data are required.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2- 6: Summary of the nature of prothioconazole residues in commodities of plant origin

| Endpoints | |
|----------------------|---|
| Plant groups covered | Pulses and oilseeds (peanuts); foliar application |

| | |
|---|--|
| | Cereals (Wheat): foliar and seed application |
| Rotational crops covered | Swiss chard (leafy vegetables), turnip (root and tuber vegetables), spring wheat (cereals) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Prothioconazole-desthio is stable under standard hydrolysis conditions |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Prothioconazole: prothioconazole-desthio (sum of isomers) (Commission Regulation (EU) 2019/552) |
| Plant residue definition for risk assessment | <p>a) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA 2014, EFSA, 2020)</p> <p>b) TDMs (EFSA, 2018b), with separate assessment of:</p> <ul style="list-style-type: none"> • Triazole alanine (TA) and triazole lactic acid (TLA) • Triazole acetic acid (TAA) • 1,2,4-triazole (1,2,4-triazole) (EFSA, 2020) |
| Conversion factor from enforcement to RA a) (Except TDMs) | <p>EFSA, 2007: 2 (cereal grain and oilseeds)</p> <p>EFSA, 2014: Based on metabolism study results, the MRL review derived the following tentative conversion factors to account for hydroxy metabolites of prothioconazole-desthio: 2 in cereal grains, pulses and oilseeds, leafy vegetables and tuber vegetables and 3 in cereal straw.</p> |

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

No new data are submitted in the framework of this application.

Reported metabolism studies include two studies in lactating goats using respectively [U-¹⁴C-phenyl]-labelled prothioconazole and prothioconazole-desthio and one study in laying hens using [U-¹⁴C-phenyl]-labelled prothioconazole. Besides, two additional studies were assessed by the JMPR (FAO, 2008a, 2008b) on lactating goats and laying hens, using both [3,5-¹⁴C-triazole]-labelled prothioconazole. The characteristics of these studies are summarised in the following table.

Summary of animal metabolism studies reported in the EU

Prothioconazole except TDMs

Table 7.2- 7: Summary of animal metabolism studies

| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
|---------------------|---|---|--------------|--------------------------|-----------------|------------------|--|---|
| | | | | Rate (mg/kg bw/d) | Duration (days) | Commodity | Time of sampling | |
| EU data | | | | | | | | |
| Lactating ruminants | Goat | [U- ¹⁴ C-phenyl] prothioconazole | 1 | 10 (250 mg a.s./kg feed) | 3 | Milk | Twice daily | Xxxxxx (2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.1/01; EFSA, 2007 |
| | | | | | | Urine and faeces | Daily and at sacrifice | |
| | | | | | | Tissues | At sacrifice | |
| | | [U- ¹⁴ C-phenyl] prothioconazole-desthio | 1 | 10 (195 mg a.s./kg feed) | 3 | Milk | Twice daily | xxxxx (2002), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.2/01; EFSA, 2007 |
| | | | | | | Urine and faeces | Daily and at sacrifice | |
| | | | | | | Tissues | At sacrifice | |
| | | [3,5- ¹⁴ C-triazole] prothioconazole | 1 | 10 | 3 | Milk | Twice daily | JMPR: FAO, 2008a, 2008b EFSA, 2014 |
| | | | | | | Urine and faeces | Daily and at sacrifice | |
| | | | | | | Tissues | At sacrifice | |
| Laying poultry | Hens | [U- ¹⁴ C-phenyl] prothioconazole | 6 | 10 | 3 | Eggs | Once daily | xxxxx.(2001), DAR UK, 2004 and 2007, Vol. 3, B7, IIA, 6.2.2.3/01; EFSA, 2007 |
| | | | | | | Excreta | At regular intervals | |
| | | | | | | Tissues | At sacrifice (5 h after last administration) | |
| | | [3,5- ¹⁴ C-triazole] prothioconazole | 6 | 10 | 3 | Eggs | Once daily | JMPR: FAO, 2008a, 2008b EFSA, 2014 |
| | | | | | | Excreta | At regular intervals | |
| | | | | | | Tissues | At sacrifice (5 h after last administration) | |
| Pigs | “Following prothioconazole administration to rats, metabolite 1,2,4-triazole was recovered in urine at minor amounts (2.3 % AR), whilst it was not recovered in goats. Therefore, meanwhile a harmonized approach on how to consider TDMs in the risk assessment, the general metabolic pathways in rodents and ruminants can be considered as comparable, mainly involving various types of hydroxylation affecting the chlorophenyl ring and leading to the formation of metabolites both under their free and glucuronide or sulphate conjugated forms. The metabolic pathway of prothioconazole-desthio depicted in ruminants can therefore be extrapolated to pigs.” | | | | | | | EFSA, 2014 |

EFSA, 2014: “It is noted that in poultry no study was performed with prothioconazole-desthio and that the fate of the triazole moiety in livestock was only investigated for prothioconazole. However, the available studies indicate similar metabolic patterns for the different compounds and moieties investigated. Additional studies addressing these requirements are therefore not expected to provide different results. It is also noted that no livestock metabolism study was performed with administration of all the metabolites included in the residue definition set for risk assessment in plants. Nevertheless, EFSA assumes that the administration of prothioconazole-desthio only in the livestock metabolism studies is acceptable since no different metabolic route of degradation would be expected if all the metabolites containing the moiety of the residue definition for risk assessment in plants were considered. Therefore, no additional metabolism data are deemed necessary.

Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices. It is noted that although only the glucuronide conjugates of prothioconazole-desthio were detected in milk, the actual residue levels are expected at a trace level at the calculated dietary burden (< 0.01 mg/kg) and EFSA considers that analysing the conjugates of prothioconazole-desthio would have a negligible impact on the residue levels enforced in milk. In case the livestock dietary burden is further increased in the future due to additional uses on feed items, the residue definition for enforcement might have to be revised by including the glucuronide conjugates of prothioconazole-desthio for all livestock matrices.

For risk assessment, since all the metabolites are structurally related to prothioconazole-desthio and consist mainly in hydroxylated derivatives, EFSA assumes as a worst case that the toxicological end points allocated to prothioconazole-desthio should also be applied to these metabolites. The residue is therefore defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). [...] The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble.”

TDMs

According to EFSA, 2018b: “The compilation of the poultry and ruminant metabolism studies conducted with the triazole pesticide active substances with the ^{14}C labelling on the triazole moiety showed that besides the parent compound that was detected in significant proportions in all animal matrices ranging between 27% and 81% TRR in milk, eggs and tissues, 1,2,4-T was also found to be a predominant compound of the total residues with levels ranging from 31% to 86% TRR in those matrices. TA was identified at very low levels in poultry muscle only (< 10% TRR) and at levels between 22% and 39% TRR in ruminant matrices. Since TA is a major component in feed items, the potential transfer of this compound in poultry and ruminant matrices was further investigated in a metabolism study conducted with ^{14}C -TA. TA remains the major compound of the total residues in all poultry matrices (84–97.2% TRR) and in ruminant tissues (56–76% TRR) while TA and 1,2,4-T accounted for 8% and 86% TRR, respectively, in milk. TLA and TAA were detected in very low levels in all matrices (< 1% TRR). The potential transfer of TAA, TLA and 1,2,4-T present in feed items to the animal matrices was not further investigated. Although there are indications from the ruminant metabolism study conducted with the ^{14}C -TA, that there is no accumulation of TAA and TLA (4.2% and < 1% of the total administered dose in urine, respectively), these metabolites were however detected in the ruminant matrices from the feeding study conducted with TA. Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions”:

RD for enforcement: Triazole parent compound only

RDs for risk assessment: 1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;
2) TA and TLA, since these compounds share the same toxicity;
3) TAA;
4) 1,2,4-triazole

Summary of new animal metabolism studies

No new data considered to be required.

Conclusion on metabolism in livestock

Prothioconazole except TDMs

Metabolism studies with prothioconazole (ruminants and poultry) labelled in the triazole-moiety as well as in the phenyl ring are available. In addition, a study with phenyl-labelled prothioconazole-desthio in

ruminants has been conducted. The available studies indicate similar metabolic patterns for the different compounds and moieties used in the metabolism studies.

Based on the overall metabolic pattern of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products is proposed as prothioconazole-desthio (sum of isomers) for all livestock matrices.

For risk assessment the residue definition is defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014).

The log $P_{o/w}$ of prothioconazole-desthio equals 3.04 (EFSA, 2007). Since higher prothioconazole-desthio residue levels were found in fat compared to fat free muscle, EFSA concludes that the residue definition for enforcement in commodities of animal origin is fat soluble (EFSA 2014).

TDMs

“Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions” (EFSA, 2018b):

RD for enforcement: Triazole parent compound only (prothioconazole-desthio (sum of isomers), see prothioconazole above)

RDs for risk assessment: 1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers), see prothioconazole above;
2) TA and TLA, since these compounds share the same toxicity;
3) TAA;
4) 1,2,4-triazole

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

In EFSA Journal 2014;12(5):3689 it is stated that *Based on the overall metabolic picture of prothioconazole and prothioconazole-desthio in animals, the residue definition for enforcement in animal products was set as prothioconazole-desthio (sum of isomers) for all the livestock matrices. This compound is fat soluble. (...) For risk assessment, the residue was defined in all commodities of animal origin as the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers).*

According to the EFSA Journal 2018;16(7):5376: *Ruminant and poultry metabolism studies labelled on the triazole ring are available.*

(...) Based on the metabolism studies conducted, respectively, with triazole pesticide active substances and TA and considering the results of the livestock feeding studies carried out with TA and TAA, respectively, the experts agreed on the following residue definitions:

- *Residue definition for enforcement: triazole parent compound only*
- *Residue definition for risk assessment:*
 1. *Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound;*
 2. *TA and TLA, since these compounds share the same toxicity;*
 3. *TAA;*
 4. *1,2,4-triazole.*

No further data are required.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2- 8: Summary on the nature of residues in commodities of animal origin

| | Endpoints |
|---|--|
| Animals covered | Lactating ruminants (goat) |
| | Laying hens (chicken) |
| Time needed to reach a plateau concentration | 1-2 days in milk |
| Animal residue definition for monitoring (Prothioconazole) | Old: -Sum of prothioconazole-desthio and its glucuronide conjugate, expressed as prothioconazole-desthio (JAU 4676-desthio) (EFSA, 2007) New: -Prothioconazole-desthio (sum of isomers) (EFSA, 2014 and Reg. (EU) 2019/552) |
| Animal residue definition for monitoring (Triazole derivative metabolites (TDMs)) | Triazole parent compound only (EFSA, 2018b) |
| Animal residue definition for risk assessment (Prothioconazole) | Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014) |
| Animal residue definition for risk assessment (Triazole derivative metabolites) | 1) Triazole parent compound and any other relevant metabolite exclusively linked to the parent compound; 2) TA and TLA, since these compounds share the same toxicity; 3) TAA; 4) 1,2,4-triazole (EFSA, 2018b) |
| Conversion factor from enforcement to RA (Prothioconazole without TDMs) | 2 (liver); 9 (kidney) not necessary for milk, ruminant muscle and ruminant fat (EFSA, 2014) |
| Metabolism in rat and ruminant similar | Yes The metabolic pathway of prothioconazole-desthio depicted in ruminants can be extrapolated to pigs |
| Fat soluble residue | Yes, log P _{ow} for prothioconazole-desthio (JAU 6476-desthio) = 3.04 |

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

Available data

Where applicable, reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

In addition, new studies on the magnitude of residue are submitted by the applicant in the framework of this application. All studies are summarised in the summary tables below. The detailed assessment of the new studies is presented in Appendix 2.

Prothioconazole except TDMs

The intended critical GAPs in cereals and oilseeds are covered by the representative EU GAP uses of prothioconazole in cereals and oilseeds as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR UK, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement) and studies were conducted at more critical GAPs than envisaged in this dossier.

Therefore, the respective data are not used for risk assessment in this dossier but new studies analysing for

prothioconazole-desthio (sum of isomers) as well as for the sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) are submitted with this dossier.

TDMs

Residue studies with prothioconazole analysing for TDMs were evaluated during the peer review of the triazole derivative metabolites (UK, 2018b, EFSA, 2018b, amended 2019) but were considered not to be sufficiently supported by acceptable stability data.

Therefore, the respective data are not cited here again but new residue studies analysing for all TDMs and supported by storage stability data are submitted with this dossier. It is noted that significant residue levels of TDMs were often found in untreated control samples of the residue trials suggesting the use of triazole pesticide active substances in previous seasons. However, these trials were considered for risk assessment with the purpose of performing a ‘worst case’ consumer dietary intake calculation.

Thus, to address all relevant potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed:

Residue definition for enforcement:

- Prothioconazole-desthio (sum of isomers).

Residue definition for risk assessment:

- Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole)

Wheat, rye, triticale (KCA 6.3.1)

Table 7.2- 9: Comparison of intended and critical EU GAPs in wheat, rye and triticale

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Wheat, rye, triticale | | | | | |
| cGAP EU (EFSA, 2007) | 3 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| cGAP EU (Art. 12, EFSA, 2014) | 3 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| Intended cGAP (1)* | 1 | 0.2 kg as/ha | - | 69 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

According to the available data, the intended outdoor uses on wheat, rye and triticale in C-EU are considered acceptable. According to EU guideline [SANCO 7525/V1/95 rev. 10.3 \(13/06/2017\)](#); [SANTE/2019/12752](#), extrapolation from wheat to rye (and triticale) is possible without restriction.

The intended critical GAPs in wheat, rye and triticale (spring and winter wheat, winter rye, triticale) are covered by the representative EU GAP uses of prothioconazole in cereals (wheat, rye and triticale) as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level (EFSA, 2007, DAR UK, 2004) were only analysed for prothioconazole-desthio (residue definition for enforcement), and studies were conducted

at more critical GAPs than envisaged in this dossier. Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed.

The data submitted show that no exceedance of the current EU MRLs will occur. The uses are considered acceptable.

Table 7.2- 10: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03500.F.2.B in wheat and conformity to existing MRLs

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|--|--|---|---|---|------------|---------------------------------------|--------------------------|----------------|
| E: Prothioconazole-desthio (sum of isomers). RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers); (B) Triazole alanine (TA) and triazole lactic acid (TLA); (C) Triazole acetic acid (TAA); (D) 1,2,4-triazole (1,2,4-triazole) | | | | | | | | |
| Spring and winter wheat, grain and straw Extrapolation from wheat → rye and triticale Extrapolation from spring cereals ↔ winter cereals due to late application timing Critical GAP (1) | EFSA, 2007, DAR UK, 2004 | N-EU | GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 26-29 up to BBCH 69, 14-21 days interval, PHI 35 days, outdoor. Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged. | N/A | | | | |
| | New trials KCA 6.3.1/01 KCA 6.3.1/02 KCA 6.3.1/03 KCA 6.3.1/04 KCA 6.3.1/05 KCA 6.3.1/06 | N-EU | Trials GAP: 1× 0.15 - 0.20 kg a.s./ha applied in wheat at BBCH 69 Wheat grain: E: 11× <0.01, 14× <0.01*, 0.013 RA: (A): 12× <0.06, 14× <0.06 (B): TA: (0.08), 0.14, 0.14, 0.22, 0.26, (0.29), 0.29, 0.29, 0.31, 0.31, (0.32), 0.34, 0.34, 0.37, 0.38, 0.54, 0.58, 0.61 TLA: 16× <0.01, 0.01, 0.03 (C): TAA: (0.02), 0.13, (0.04), 0.04, (0.05), 0.05, 0.06, 0.06, 0.06, 0.07, 0.07, 0.09, 0.09, 0.09, 0.11, 0.12, 0.21, 0.39 (D): 1,2,4-T: 6× <0.01, 8 x <0.01**, (12× <0.01) For livestock dietary burden assessment only: Wheat straw: | *Values in italics were derived using RAR method 00979/M001, LC-MS/MS (in contrast to other results derived using methods based on QuEChERS method EN 15662:2009-02). Values E_{all} (prothioconazole-desthio (sum of isomers)) and (A) RA_{all} (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) below in bold show STMR and HR of prothioconazole residues involving residues from all studies. | | | | |

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|-----------|------------------------------------|---|---|-----------------|---------------|---|-----------------------------------|---|
| | KCA 6.3.1/07 KCA 6.3.1/08 | | E: 0.015, 0.018, 0.021, 0.022, 0.028, 0.039, 0.047, 0.050, 0.062, 0.064, 0.071, 0.072, 0.076, 0.078, 0.13, 0.16, 0.18, 0.29, 0.31, 0.43, 0.49, 0.51, 0.52, 0.53, 0.54, 0.73 RA: (A): 0.065, 0.068, 0.082, 0.095, 0.12, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.16, 0.17, 0.20, 0.26, 0.30, 0.31, 0.45, 0.49, 0.53, 0.70, 0.74, 0.87, 0.88, 1.2, 1.4 (B): TA: 9× <0.01, 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.04, 0.06, 0.08 TLA: 4× <0.01, 4× 0.01, 0.02, 0.03, 0.04, 0.04, 0.05, 0.05, 0.06, 0.07, 0.16, 0.25 (C): TAA: <0.01, 0.01, 0.01, 7x 0.02, 0.03, 0.03, 0.04, 0.04, 0.06, 0.07, 0.12, 0.13 (D): 1,2,4-T: 6× <0.01, 8 x <0.01**, (12× <0.01) | | | | | () Values in brackets indicate residues outside acceptable storage stability period and have therefore been removed from the overall supporting data. ** 8 additional trials using mixture product prothioconazole and difenoconazole (KCA 6.3.1/08) are included |

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|-----------|----------------------------------|---|--|--|---|---|---------------------------------------|----------------|
| | Overall supporting data for cGAP | N-EU | <p>Wheat grain: E: $11 \times <0.01$, $14 \times <0.01$, 0.013 RA: (A): $12 \times <0.06$, $14 \times <0.06$ (B): TA: 0.14, 0.14, 0.22, 0.26, 0.29, 0.29, 0.31, 0.31, 0.34, 0.34, 0.37, 0.38, 0.54, 0.58, 0.61 TLA: $16 \times <0.01$, 0.01, 0.03 (C): TAA: 0.04, 0.05, 0.06, 0.06, 0.06, 0.07, 0.07, 0.09, 0.09, 0.09, 0.11, 0.12, 0.13, 0.21, 0.39 (D): 1,2,4-T: $14 \times <0.01$</p> <p>For livestock dietary burden assessment only: Wheat straw: E: 0.015, 0.018, 0.021, 0.022, 0.028, 0.039, 0.047, 0.050, 0.062, 0.064, 0.071, 0.072, 0.076, 0.078, 0.13, 0.16, 0.18, 0.29, 0.31, 0.43, 0.49, 0.51, 0.52, 0.53, 0.54, 0.73 RA: (A): 0.065, 0.068, 0.082, 0.095, 0.12, 0.13, 0.14, 0.14, 0.15, 0.15, 0.16, 0.16, 0.17, 0.20, 0.26, 0.30, 0.31, 0.45, 0.49, 0.53, 0.70, 0.74, 0.87, 0.88, 1.2, 1.4 (B): TA: $9 \times <0.01$, 0.01, 0.01, 0.02, 0.02, 0.03, 0.03, 0.04, 0.06, 0.08 TLA: $4 \times <0.01$, 4×0.01, 0.02, 0.03, 0.04, 0.04, 0.05, 0.05, 0.06, 0.07, 0.16, 0.25 (C): TAA: <0.01, 0.01, 0.01, 7×0.02, 0.03, 0.03, 0.04, 0.04, 0.06, 0.07, 0.12, 0.13 (D): 1,2,4-T: $14 \times <0.01$</p> | <p>Grain: E: 0.010 E: 0.010* E_{all}: 0.010 RA: (A): 0.06 0.06 RA_{all}: 0.06 (B): 0.31 (TA) 0.01 (TLA) (C): 0.09 (D): 0.01</p> <p>Straw: RA: (A): 0.250 0.165 RA_{all}: 0.185 (B): 0.01 (TA) 0.025 (TLA) (C): 0.02 (D): 0.01</p> | <p>E: 0.013 E: 0.010 E_{all}: 0.013 RA: (A): 0.06 0.06 RA_{all}: 0.06 (B): 0.61 (TA) 0.03 (TLA) (C): 0.39 (D): 0.01</p> <p>RA: (A): 1.40 1.20 RA_{all}: 1.40 (B): 0.08 (TA) 0.25 (TLA) (C): 0.13 (D): 0.01</p> | <p>E: 0.014 E: 0.010 E_{all}: 0.013 RA: n.r. RA: n.r.</p> | <p>Wheat grain: 0.1 Rye: 0.05</p> | Yes |

* Source of EU MRL: Reg. (EU) 2019/552

Barley and oat (KCA 6.3.2)

Table 7.2- 11: Comparison of intended and critical EU GAPs in barley and oat

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Barley, oat | | | | | |
| cGAP EU (EFSA, 2007) | 2 | 0.2 kg as/ha | 14-21 days | 61 | 35 |
| cGAP EU (Art. 12, EFSA, 2014) | 2 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| Intended cGAP (2)* | 1 | 0.2 kg as/ha | - | 65 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

According to the available data, the intended outdoor uses on barley in C-EU are considered acceptable. According to EU guideline [SANCO 7525/VL/95 rev. 10.3 \(13/06/2017\)](#), [SANTE/2019/12752](#), extrapolation from barley to oat is possible without restriction.

The intended critical GAPs in barley and oat (spring and winter barley, oat) are covered by the representative EU GAP uses of prothioconazole in cereals (barley and oat) as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level EFSA, 2007, DAR UK, 2004 were only analysed for prothioconazole-desthio (residue definition for enforcement), and studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed.

The data submitted show that no exceedance of the current EU MRL for barley will occur.

The uses on barley are considered acceptable.

Considering the intended use on oat, an exceedance of the MRL for prothioconazole is expected. The proposed use on oat is not considered acceptable.

Table 7.2- 12: Summary of EU reported and new data on prothioconazole metabolites supporting the intended uses of ADM.03500.F.2.B in barley and conformity to existing MRLs

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|---|--|---|---|---|------------|---------------------------------------|--------------------------|----------------|
| E: Prothioconazole-desthio (sum of isomers). RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers); (B) Triazole alanine (TA) and triazole lactic acid (TLA); (C) Triazole acetic acid (TAA); (D) 1,2,4-triazole (1,2,4-triazole) | | | | | | | | |
| Spring and winter barley, grain and straw | EFSA, 2007, DAR UK, 2004 | N-EU | GAP on which EU a.s. assessment is based: 3× 0.2 kg as/ha, start BBCH 30 up to BBCH 61, 14-21 days interval, PHI 35 days, outdoor Studies not relevant for envisaged GAP uses due to more critical GAP than envisaged. | N/A | | | | |
| Extrapolation from barley → oat Extrapolation from spring cereals ↔ Winter cereals due to late application timing Critical GAP (2) | New trials KCA 6.3.2/01 KCA 6.3.2/02 KCA 6.3.2/03 KCA 6.3.2/04 KCA 6.3.2/05 KCA 6.3.2/06 KCA 6.3.2/07 KCA 6.3.2/08 KCA 6.3.2/09 KCA 6.3.2/10 KCA 6.3.2/11 KCA 6.3.2/12 KCA 6.3.2/13 | N-EU | Trials GAP: 1× 0.15 - 0.20 kg a.s./ha applied in barley at BBCH 65 - 69 Barley grain: E: 15× <0.01, 11× <0.01*, 0.010, 0.010, 0.013, 0.014, 0.015, 0.026, 0.027, 0.027, 0.030, 0.033, 0.054, 0.061 RA: (A): 19× <0.06, 16× <0.06, 0.061, 0.087, 0.095 (B): TA: 0.05, 0.06, 0.07, 0.07, 0.08, 0.09, (0.10), 0.11, 0.11, 0.12, 0.12, 0.13, 0.12, 0.13, 0.14, 0.15, (0.17), 0.19, (0.20), 0.29 TLA: 20× <0.01, (C): TAA: 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.04, 0.04, (0.05), 0.05, 0.05, 0.06, 0.07, 0.07, (0.10), (0.11), 0.11, 0.12 (D): 1,2,4-T: 20× <0.01 For livestock dietary burden assessment only: Barley straw: E: 0.015, 0.015, 0.041, 0.041, 0.049, 0.052, 0.055, 0.056, 0.063, 0.068, 0.070, 2× 0.083, 0.083, 0.084, 0.085, 0.092, 0.092, 0.11, 0.12, 0.12, 0.13, 0.14, 0.15, 0.20, 0.21, 0.21, 0.24, 0.25, 0.27, 0.28, 0.31, 0.34, 0.49, 0.49, 0.93, 1.1, 1.7 RA: (A): <0.06, <0.06, 0.061, 0.069, 0.11, 0.11, 0.11, 0.12, 0.14, 0.14, 0.15, 2× 0.16, 0.17, 0.17, 0.18, 0.19, 0.20, 0.24, 0.25, 0.27, 0.33, | *Values in italics were derived using RAR method 00979/M001, LC-MS/MS (in contrast to other results derived using methods based on QuEChERS method EN 15662:2009-02). Values E_{all} (prothioconazole-desthio (sum of isomers)) and (A) RA_{all} (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) below in bold show STMR and HR of prothioconazole residues involving residues from all studies. () Values in brackets indicate residues outside acceptable storage stability period and have therefore been removed from the overall supporting data. | | | | |

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|-----------|----------------------------------|---|---|--|--|---|--------------------------------|---------------------------------|
| | | | 0.36, 0.37, 0.44, 0.48, 0.49, 0.53, 0.58, 0.61, 0.77, 0.84, 0.93, 1.0, 1.3, 1.3, 1.6, 2.2 (B): TA: 15× <0.01, 0.02, 0.02, 0.02, 0.02, 0.05 TLA: <0.01, 0.01, 6× 0.02, 4× 0.03, 0.04, 0.04, 0.05, 0.05, 0.05, 0.06, 0.08, 0.26 (C): TAA: 2× <0.01, 0.01, 9× 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.07, 0.12 (D): 1,2,4-T: 19× <0.01, 0.02 | | | | | |
| | Overall supporting data for cGAP | N-EU | Trials GAP: 1× 0.15 - 0.20 kg a.s./ha applied in barley at BBCH 65 - 69 Barley grain: E: 15× <0.01, 11× <0.01, 0.010, 0.010, 0.013, 0.014, 0.015, 0.026, 0.027, 0.027, 0.030, 0.033, 0.054, 0.061 RA: (A): 19× <0.06, 16× <0.06, 0.061, 0.087, 0.095 (B): TA: 0.05, 0.06, 0.07, 0.07, 0.08, 0.09, 0.11, 0.11, 0.12, 0.12, 0.13, 0.12, 0.13, 0.14, 0.15, 0.19, 0.29 TLA: 20× <0.01, (C): TAA: 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.04, 0.04, , 0.05, 0.05, 0.06, 0.07, 0.07, 0.11, 0.12 (D): 1,2,4-T: 20× <0.01 For livestock dietary burden assessment only: Barley straw: E: 0.015, 0.015, 0.041, 0.041, 0.049, 0.052, 0.055, 0.056, 0.063, 0.068, 0.070, 2× 0.083, 0.083, 0.084, 0.085, 0.092, 0.092, 0.11, 0.12, 0.12, 0.13, 0.14, 0.15, 0.20, 0.21, 0.21, 0.24, 0.25, 0.27, 0.28, 0.31, 0.34, 0.49, 0.49, 0.93, 1.1, 1.7 RA: (A): <0.06, <0.06, 0.061, 0.069, 0.11, 0.11, 0.11, 0.12, 0.14, 0.14, 0.15, 2× 0.16, 0.17, 0.17, 0.18, 0.19, 0.20, 0.24, 0.25, 0.27, 0.33, 0.36, 0.37, 0.44, 0.48, 0.49, 0.53, 0.58, 0.61, 0.77, 0.84, 0.93, 1.0, 1.3, 1.3, 1.6, 2.2 (B): TA: 12× <0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.05, TLA: <0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, | Grain: E: 0.010 E: 0.010* E_{all}: 0.010 RA: (A): 0.06 0.06 0.06 RA_{all}: 0.06 (B): 0.12 (TA) 0.01 (TLA) (C): 0.040 (D): 0.01 Straw: RA: (A): 0.245 0.265 RA_{all}: 0.245 (B): 0.01 (TA) 0.03 (TLA) | E: 0.033 E: 0.061 E_{all}: 0.061 RA: (A): 0.061 0.095 RA_{all}: 0.095 (B): 0.29 (TA) 0.01 (TLA) (C): 0.12 (D): 0.01 RA: n.r. | E: 0.041 E: 0.080 E_{all}: 0.063 RA: n.r. RA: n.r. | Barley grain: 0.2 Oat: 0.05 | Yes (Barley) No (oat) |

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|-----------|--------|---|---|------------------------|------------------------|---------------------------------------|-----------------------------|----------------|
| | | | 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.05, 0.06, 0.08, 0.26 (C): TAA: 2× <0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.07, 0.12 (D): 1,2,4-T: 19× <0.01, 0.02 | (C): 0.02 (D): 0.01 | (C): 0.12 (D): 0.02 | | | |

* Source of EU MRL: Reg. (EU) 2019/552

Oilseed rape (KCA 6.3.3)

Table 7.2- 13: Comparison of intended and critical EU GAPs in oilseeds

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Oilseed rape | | | | | |
| cGAP EU (EFSA, 2007) | 2 | 0.175 kg as/ha | 14-28 days | Not stated, start at BBCH 53 | 56 |
| cGAP EU (Art. 12, EFSA, 2014) | 2 | 0.12 kg as/ha | 14 days | Not stated | 28 |
| Intended cGAP (3)* | 1 | 0.175 kg as/ha | - | 73 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

According to the available data, the intended outdoor uses on oilseed rape in C-EU are considered acceptable.

The intended critical GAPs in oilseed rape (spring and winter oilseed rape) are covered by the representative EU GAP use of prothioconazole in rape as evaluated during AIR process (EFSA 2007).

However, samples in residue studies already evaluated at EU level EFSA, 2007, DAR UK, 2004 were only analysed for prothioconazole-desthio (residue definition for enforcement), and studies were conducted at more critical GAPs than envisaged in this dossier. Therefore, studies are considered not relevant.

Thus, to address all potential residues, new supplementary studies are presented in the following. In these studies residues according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA 2018b and EFSA 2020 were analysed.

The data submitted show that no exceedance of the current EU MRL will occur. The uses are considered acceptable.

Table 7.2- 14: Summary of EU reported and new data supporting the intended uses of ADM.03500.F.2.B in oilseed rape and conformity to existing MRL

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|---|----------------------------------|---|---|--|--|--|--|----------------|
| E: Prothioconazole-desthio (sum of isomers). RA: (A) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers); (B) Triazole alanine (TA) and triazole lactic acid (TLA); (C) Triazole acetic acid (TAA); (D) 1,2,4-triazole (1,2,4-triazole) | | | | | | | | |
| Spring oilseed rape | EFSA, 2007, DAR UK, 2004 | N-EU | GAP on which EU a.s. assessment is based: 2× 0.2 kg as/ha, start BBCH 53, 14-28 days interval, PHI 56 days, outdoor | N/A | | | | |
| Extrapolation from spring oilseed rape ↔ winter oilseed rape due to late application timing | New trials | N-EU | Trials GAP: 1× 0.15 – 0.20 kg a.s./ha applied in oilseedst at BBCH 73 - 75 Seeds: E: 9× <0.01, 7× <0.01*, 0.019, 0.021, 0.028, 0.037, 0.072 RA: (A): 12× <0.06, 7× <0.06, 0.073, 0.103 (B): TA: (0.08), 0.08, 0.08, 0.09, (0.1), 0.13, 0.21, (0.22), (0.23), (0.26), 0.30, (0.33), 0.33, (0.35), (0.39), (0.60), (0.83), (1.2), (1.5), 2.42, (2.8) TLA: 7× <0.01, 0.01, 0.01, 0.01, 0.01, 0.01, 0.014, 0.015, 0.023, 0.029, 0.048, 0.06, 0.10, 0.12, 0.14 (C): TAA: 17× <0.01, 0.018, 0.02, 0.02, 0.039 (D): 1,2,4-T: 8× <0.01, (13 x <0.01) | <i>*Values in italics were derived using RAR method 00979/M001, LC-MS/MS (in contrast to other results derived using methods based on QuEChERS method EN 15662:2009-02).</i> Values E_{all} (prothioconazole-desthio (sum of isomers)) and (A) RA_{all} (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) below in bold show STMR and HR of prothioconazole residues involving residues from all studies. () Values in brackets indicate residues outside acceptable storage stability period and have therefore been removed from the overall supporting data. | | | | |
| Critical GAP (3) | Overall supporting data for cGAP | N-EU | Seeds: E: 9× <0.01, 7× <0.01, 0.019, 0.021, 0.028, 0.037, 0.072 RA: (A): 12× <0.06, 7× <0.06, 0.073, 0.103 (B): TA: 0.08, 0.08, 0.09, 0.13, 0.21, 0.30, 0.33, 2.42 TLA: 7× <0.01, 5× 0.01, 0.01, 0.01, 0.01, 0.01, 0.014, 0.015, 0.023, 0.029, 0.048, 0.06, 0.10, 0.12, 0.14 (C): TAA: 17× <0.01, 0.018, 0.02, 0.02, 0.039 (D): 1,2,4-T: 8× <0.01 | Seeds: E: 0.010 <i>E: 0.01*</i> E_{all}: 0.010 RA: (A): 0.06 <i>0.06</i> | E: 0.072 <i>E: 0.021</i> E_{all}: 0.072 RA: (A) 0.103 <i>0.073</i> | E: 0.091 <i>E: 0.028</i> E_{all}: 0.076 RA: n.r. | 0.15 (0.20 proposed in EFSA, 2020) | Yes |

| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL (mg/kg) * | MRL compliance |
|-----------|--------|---|--|--|--|---|-----------------------------------|-------------------|
| | | | | RA_{all}: 0.06 (B): 0.17 (TA) 0.01 (TLA) (C): 0.01 (D): 0.01 | RA_{all}: 0.103 (B): 2.42 (TA) 0.14 (TLA) (C): 0.039 (D): 0.01 | | | |

* Source of EU MRL: Reg. (EU) 2019/552

7.2.3.2 Conclusion on the magnitude of residues in plants

Wheat, rye, triticale

According to the available data, the intended uses on wheat, rye and triticale are considered acceptable. 26 trials in wheat in Northern Europe showed no residues at harvest according to the residue definition for enforcement in wheat grains (below the LOQ of 0.01 mg/kg) except for one trial showing low residues of 0.013 mg/kg.

Therefore, the supplementary data submitted show that no exceedance of the current EU-MRLs of 0.1 mg/kg for wheat and 0.05 mg/kg for rye will occur.

For risk assessment, residues have also been determined as sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Residues were always below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites at harvest.

Residues of TDMs according to the residue definition for risk assessment and covered by storage stability data were determined for TA, TLA, TAA and 1,2,4-T in samples from 15, 18, 15 and 14 trials, respectively.

Extrapolation from trials conducted in wheat (grain and straw) to rye and triticale is not restricted according to SANTE/2019/12752 (replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3).

Barley, oat

According to the available data, the intended uses on barley are considered acceptable. 38 trials in barley in Northern Europe showed no or only low residues at harvest according to the residue definition for enforcement in barley grains up to 0.061 mg/kg.

Therefore, the supplementary data submitted show that no exceedance of the current EU-MRL of 0.2 mg/kg for barley will occur.

For risk assessment, residues have also been determined as sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Residues were below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites in 35 trials at harvest and exceeded the LOQ in only three trials with a HR of 0.095 mg/kg.

Residues of TDMs according to the residue definition for risk assessment and covered by storage stability data were determined for TA, TLA, TAA and 1,2,4-T in samples from 17, 20, 17 and 20 trials, respectively.

Oilseed rape

According to the available data, the intended uses on oilseed rape are considered acceptable. 21 trials in oilseed rape in Northern Europe showed no (below the LOQ of 0.01 mg/kg) or only low residues at harvest according to the residue definition for enforcement in oilseed rape at <0.01 mg/kg to 0.072 mg/kg.

Therefore, the supplementary data submitted show that no exceedance of the current EU-MRL of 0.15 mg/kg for oilseed rape will occur.

For risk assessment, residues have also been determined as sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers). Residues were always below the cumulative LOQ of 0.06 mg/kg for the sum of metabolites at harvest except for two trials showing cumulative residues of 0.073 and 0.103 mg/kg.

Residues of TDMs according to the residue definition for risk assessment and covered by storage stability data were determined for TA, TLA, TAA and 1,2,4-T in samples from 8, 21, 21 and 8 trials, respectively.

zRMS comments:

Residue Definitions (EFSA 2020; Reg EU 2019/552):

Monitoring (Mo): Prothioconazole-desthio (sum of isomers)

Risk Assessment (RA):

- 1) Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) (EFSA, 2014)
- 2) TDMs (EFSA, 2018), with separate assessment of:
 - Triazole alanine (TA) and triazole lactic acid (TLA)
 - Triazole acetic acid (TAA)
 - 1,2,4-triazole (1,2,4-T)

Trials on wheat, barley and oilseed rape previously presented and evaluated in DAR (2004) were conducted according to the residue definition for monitoring only (trials measuring levels of prothioconazole-desthio only; there are no data on prothioconazole-hydroxy-destio) and were conducted at more critical GAPs than envisaged in this dossier.

To address all potential residues, new additionally residue studies conducted according to the plant residue definitions for enforcement and for risk assessment as proposed by EFSA (2018 and 2020) were submitted by Applicant in the framework of this application.

Wheat, triticale and rye

Wheat and rye are the major crops in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on wheat can be used for extrapolation to rye and triticale before and after forming of the edible part.

Sufficient trials on wheat were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 150-200 g a.s. /ha, application at BBCH 69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in wheat grain at harvest were <0.01 mg/kg except for one trial for which residues equal 0.013 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were <0.06 mg/kg.

Available results show that the in force MRL of prothioconazole on wheat of 0.1 mg/kg and on rye of 0.05 (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed uses.

Residues of 1,2,4-T were <LOQ.

Residues of TLA in grain between <0.01 mg/kg and 0.03 mg/kg.

Residues of TA in grain were between 0.14 and 0.61 mg/kg.

Residues of TAA in grain were between 0.04 and 0.39 mg/kg.

More details of the residue studies on wheat are provided in Appendix 2.

The proposed uses on wheat, triticale and rye are considered acceptable.

Barley

Barley is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient trials on barley were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 150-200 g a.s. /ha, application at BBCH 65-69, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in barley grain at harvest were between <0.01 mg/kg and 0.061 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.06 mg/kg and 0.095 mg/kg.

Available results show that the in force MRL of prothioconazole on barley of 0.2 mg/kg (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

Residues of 1,2,4-T and TLA in grain were <LOQ.

Residues of TA in grain were between 0.05 and 0.29 mg/kg.

Residues of TAA in grain were between 0.02 and 0.12 mg/kg.

More details of the residue studies on wheat are provided in Appendix 2.

The proposed use on barley is considered acceptable.

Oat

Oat is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required. Based on the SANTE/2019/12752, 8 residue trials on barley can be used for extrapolation to oat before and after forming of the edible part.

Sufficient trials on barley were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 150-200 g a.s. /ha, application at BBCH 65-69, outdoor. See zRMS comments above. The residue trials on barley can be used for extrapolation to oat.

Residues of prothioconazole-desthio (RD-Mo) in barley grain at harvest were between <0.01 mg/kg and 0.061 mg/kg.

Considering the intended use on oat, an exceedance of the MRL of 0.05 mg/kg for prothioconazole, as established in Commission Regulation (EU) 2019/552, is expected. Therefore until the new MRL for oat come into force, authorization of the GAP (oat) will not be possible.

The proposed use on oat is not considered acceptable.

Oilseed rape

Oilseed rape is the major crop in northern Europe (SANTE/2019/12752). A minimum of eight trials are required.

Sufficient trials on oilseed rape were conducted according to the residue definition for monitoring and risk assessment with the following GAP: 1 x 150-200 g a.s. /ha, application at BBCH 73-75, outdoor. The trials are supported by valid storage stability data (for TDMs, not all submitted trials were covered by the storage stability data for the metabolites – see boxes with zRMS comments in Appendix 2) and validated analytical methods.

Residues of prothioconazole-desthio (RD-Mo) in oilseed rape seed at harvest were between <0.01 mg/kg and 0.072 mg/kg.

Total residue for prothioconazole (prothioconazole-desthio and all 5 hydroxy metabolites) in grain at harvest were between <0.06 and 0.103 mg/kg.

Available results show that the in force MRL of prothioconazole on oilseed rape of 0.15 mg/kg (Reg. (EU) 2019/552) will not be exceeded. The current EU MRL for prothioconazole is sufficient to support the proposed use.

Residues of 1,2,4-T were <LOQ.

Residues of TLA in grain between <0.01 mg/kg and 0.14 mg/kg.

Residues of TA in grain were between 0.08 mg/kg and 2.42 mg/kg.

Residues of TAA in grain were between <0.01 mg/kg and 0.039 mg/kg.

More details of the residue studies on wheat are provided in Appendix 2.

The proposed use on oilseed rape is considered acceptable.

7.2.4 Magnitude of residues in livestock

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

7.2.4.1 Dietary burden calculation

Prothioconazole except TDMs

The dietary burden calculation made by EFSA in the framework of the Article 12 evaluation is available for prothioconazole (see EFSA, 2014). Prothioconazole is authorised for use on several crops that might be fed to livestock. EFSA calculated the livestock dietary burdens for different groups of livestock using the agreed European methodology (European Commission, 1996). The envisaged GAP uses are covered by this calculation.

In addition, new dietary burden calculations were conducted in EFSA, 2020. According to EFSA, 2020 “[...] new data on carrots, swedes, turnips and wheat were submitted in the framework of the assessment of the Article 12 confirmatory data application (UK, 2019a). The most recent livestock dietary burden was calculated in the EFSA opinion on the modification of prothioconazole residues in sunflower seeds (EFSA, 2015b), updating the calculation done by the MRL review (EFSA, 2014).

However, due to the fact that existing EU MRLs for livestock and for various feed commodities are set on the basis of CXLs, instead of proposals made by the MRL review, the livestock dietary burden was calculated using Animal Model (OECD methodology), considering the actual existing EU MRLs for feed commodities. The input values for rapeseeds and carrots, swedes, turnips were as derived from the current assessment; for remaining feed commodities the input values were corresponding to the existing EU MRLs and were as reported in the MRL review, or in JMPR reports (in particular for cereals, cotton, maize, peanuts and soya beans, since for these crops the existing EU MRLs are set on the basis of CXLs) (FAO, 2009a, b, 2014, 2018) and in previous EFSA reasoned opinions (for sunflower seeds, EFSA, 2015b). Where residue data according to the risk assessment residue definition were not available, default conversion factors for risk assessment as derived by the MRL review, were applied.”

The input values as used in EFSA, 2020 for the latest exposure calculations for livestock are presented in the table below together with STMRs/HRs derived from the submitted residue studies covering the envisaged GAP uses of this dossier. The more critical value (input values EFSA 2020 versus STMRs/HRs derived from the residue studies submitted with this dossier) was used for new intake calculations. The corresponding results can be found in Table 7.2- 16.

Table 7.2- 15: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|-----------------------|---|------------------------|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | |
| Rape seed meal (<i>EFSA 2020</i>) | 0.16 | STMR × PF (2) ^(a) | 0.16 | STMR × PF (2) ^(a) |
| Rape seed meal (<i>new</i>) | 0.12 | STMR × PF (2) (new trials submitted, refer to Table 7.2- 14, but covered by higher input value used in EFSA 2020 in the line above) | 0.12 | STMR × PF (2) (new trials submitted, refer to Table 7.2- 14, but covered by higher input value used in EFSA 2020 in the line above) |
| Sunflower seed meal (<i>EFSA 2020</i>) | 0.04 | STMR × CF (2) × PF (2) ^(a) (EFSA, 2015a,b) | 0.04 | STMR × CF (2) × PF (2) ^(a) (EFSA, 2015a,b) |
| Head cabbage (<i>EFSA 2020</i>) | 0.02 | STMR × CF (EFSA, 2014) | 0.12 | HR × CF (EFSA, 2014) |
| Maize silage (<i>EFSA 2020</i>) | 0.01 | STMR (EFSA, 2014) | 0.01 | HR (EFSA, 2014) |
| Maize grain (<i>EFSA 2020</i>) | 0.02 | STMR (FAO, 2014) × CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2014) × CF (2) (EFSA, 2014) |
| Maize, milled by-products ^(b) ; Maize, hominy meal ^(b) ; Maize gluten feed/gluten meal ^(b) ; Distiller's grain ^(b) (<i>EFSA 2020</i>) | 0.02 | STMR (FAO, 2014) × CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2014) × CF (2) (EFSA, 2014) |

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|-----------------------|--|------------------------|--|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Barley grain (EFSA 2020) | 0.07 | STMR (FAO, 2009b) × CF (2) (EFSA, 2014) | 0.07 | STMR (FAO, 2009b) × CF (2) (EFSA, 2014) |
| Barley grain <i>new</i> | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) |
| Brewer`s grain (EFSA 2020) | 0.23 | STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3) ^(a) | 0.23 | STMR barley grain (FAO, 2009b) × CF (2) (EFSA, 2014) × PF (3.3) ^(a) |
| Oat grain (EFSA 2020) | 0.02 | STMR (FAO, 2008a) × CF (2) (EFSA, 2014) | 0.02 | STMR (FAO, 2008a) × CF (2) (EFSA, 2014) |
| Oat grain <i>new</i> | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley) | 0.06 (RD for RA) | STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley) |
| Wheat grain (EFSA 2020) | 0.04 | STMR (FAO, 2009b) × CF (2) (EFSA, 2014) | 0.04 | STMR (FAO, 2009b) × CF (2) (EFSA, 2014) |
| Wheat grain <i>new</i> | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10) |
| Wheat gluten meal ^(b) (EFSA 2020) | 0.04 | STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8) ^(a) | 0.04 | STMR wheat grain (FAO, 2009b) × CF (2) × PF (1.8) ^(a) |
| Wheat milled by-products ^(b) (EFSA 2020) | 0.28 | STMR wheat grain (FAO, 2009b) × CF (2) × PF (7) ^(a) | 0.28 | STMR wheat grain (FAO, 2009b) × CF (2) × PF (7) ^(a) |
| Rye grain (EFSA 2020) | 0.02 | STMR (FAO, 2008a) × CF (2) | 0.02 | STMR (FAO, 2008a) × CF (2) |
| Rye grain <i>new</i> | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) |
| Triticale grain <i>new</i> | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) |
| Barley straw (EFSA 2020) | 1.96 | STMR (FAO, 2009b) × CF (3) (EFSA, 2014) | 7.50 | HR ^(d) × CF (3) (EFSA, 2014) |
| Barley straw (<i>new</i>) | 0.245 | STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) | 2.2 | HR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) |
| Oats straw (EFSA 2020) | 1.26 | STMR ^(d) × CF (3) (EFSA, 2014) | 7.50 | HR ^(d) × CF (3) (EFSA, 2014) |
| Oat straw (<i>new</i>) | 0.245 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from barley, but covered by higher input value used in EFSA 2020 in the line above) | 2.2 | HR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley, but covered by higher input value used in EFSA 2020 in the line above) |
| Wheat straw (EFSA 2020) | 2.69 | STMR | 5.52 | HR ^(d) (EFSA, 2014) × CF (2.3) |

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
|---|-----------------------|---|------------------------|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Wheat straw (<i>new</i>) | 0.185 | STMR (new trials submitted, refer to Table 7.2- 10, but covered by higher input value used in EFSA 2020 in the line above) | 1.4 | HR (new trials submitted, refer to Table 7.2- 10, but covered by higher input value used in EFSA 2020 in the line above) |
| Rye straw (<i>EFSA 2020</i>) | 2.25 | STMR ^(d) × CF (3) (EFSA, 2014) | 5.52 | HR ^(d) (EFSA, 2014) × CF (2.3) |
| Rye straw (<i>new</i>) | 0.185 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above) | 1.4 | HR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat, but covered by higher input value used in EFSA 2020 in the line above) |
| Triticale straw <i>new</i> | *0.185 | STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from wheat) | *1.4 | HR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) |
| Cotton seed (<i>EFSA 2020</i>) | 0.10 | STMR (FAO, 2018) × CF (2) | 0.10 | STMR (FAO, 2018) × CF (2) |
| Cotton seed meal (<i>EFSA 2020</i>) | 0.14 | STMR (FAO, 2018) × CF (2) × PF (1.3) ^(a) | 0.14 | STMR (FAO, 2018) × CF (2) × PF (1.3) ^(a) |
| Beans (dry) (<i>EFSA 2020</i>) | 0.02 | STMR × CF (2) (EFSA, 2014) | 0.02 | STMR × CF (2) (EFSA, 2014) |
| Peas, lupins (dry) (<i>EFSA 2020</i>) | 0.10 | STMR (FAO, 2009b) × CF (2) | 0.10 | STMR (FAO, 2009b) × CF (2) |
| Lupin seed meal (<i>EFSA 2020</i>) | 0.11 | STMR (FAO, 2009b) × CF (2) × PF (1.1) ^(a) | 0.11 | STMR (FAO, 2009b) × CF (2) × PF (1.1) ^(a) |
| Potatoes (<i>EFSA 2020</i>) | 0.01 | STMR (EFSA, 2014) | 0.01 | HR (EFSA, 2014) |
| Potato process waste ^(b) ; Potato dried pulp ^(b) (<i>EFSA 2020</i>) | 0.01 | STMR potato (EFSA, 2014) × PF (1) ^(c) | 0.01 | HR potato (EFSA, 2014) × PF (1) ^(c) |
| Turnips, swedes, carrot culls (<i>EFSA 2020</i>) | 0.08 | STMR | 0.10 | HR |
| Peanut meal (<i>EFSA 2020</i>) | 0.04 | STMR (FAO, 2009b) × CF (2) × PF (2) | 0.04 | STMR (FAO, 2009b) × CF (2) × PF (2) |
| Linseed meal (<i>EFSA 2020</i>) | 0.12 | STMR × CF (2) × PF (2) ^(a) (EFSA, 2015a,b) | 0.12 | STMR × CF (2) × PF (2) ^(a) (EFSA, 2015a,b) |
| Soybean seed (<i>EFSA 2020</i>) | 0.10 | STMR (FAO, 2014) × CF (2) | 0.10 | STMR (FAO, 2014) × CF (2) |
| Soybean seed meal (<i>EFSA 2020</i>) | 0.13 | STMR (FAO, 2014) × CF (2) × PF (1.3) ^(a) | 0.13 | STMR (FAO, 2014) × CF (2) × PF (1.3) ^(a) |
| Soybean hulls ^(b) (<i>EFSA 2020</i>) | 1.30 | STMR soybean (FAO, 2014) × CF (2) × PF (13) ^(a) | 1.30 | STMR soybean (FAO, 2014) × CF (2) × PF (13) ^(a) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition.

(a): For rape seed meal/sunflower seed meal, brewer's grain, wheat gluten meal, wheat milled by-products, cotton seed meal, lupin seed meal, soybean meal, lupin seed meal, and soybean hulls in the absence of processing factors supported by data, default processing factors of 2, 3.3, 1.8, 7, 1.3, 1.1, 1.3 and 13 were, respectively, included in the calculation to consider the potential

concentration of residues in these commodities.

- (b): New commodities (OECD methodology), not considered in MRL review.
- (c): Default processing factors were not applied because prothioconazole and its metabolites were below LOQ both in maize and potatoes, indicating no-residue situation. Thus, concentration of residues in these commodities is therefore not expected.
- (d): The STMR and HR values derived by the JMPR (FAO, 2009a,b) are lower than the values derived for cereals straws for the authorised EU uses reported in the MRL review.

* In the original dRR version, STMR and HR of wheat straw acc. to residue definition for enforcement instead of residue definition for risk assessment was given here erroneously. The values have now been replaced by newly calculated STMR and HR of wheat straw from all trials now available and acc. to residue definition for risk assessment. However, results given in Table 7.2- 16 below are not affected by this change.

Table 7.2- 16: Results of the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

| Relevant groups | Dietary burden expressed in | | | | Most critical diet ^(a) | Most critical commodity ^(b) | | Trigger exceeded (Yes/No) 0.004 mg/kg bw Max burden | Previous assessment (EFSA 2020) Max burden mg/kg DM |
|--|-----------------------------|-------|----------|------|-----------------------------------|--|-------|--|---|
| | mg/kg bw/d | | mg/kg DM | | | | | | |
| | Median | Max. | Median | Max. | | | | | |
| Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | | | | | | |
| Cattle (all diets) | 0.038 | 0.111 | 1.14 | 3.10 | Dairy cattle | Barley | straw | Yes | 3.10 |
| Cattle (dairy only) | 0.038 | 0.111 | 0.98 | 2.89 | Dairy cattle | Barley | straw | Yes | 2.85 |
| Sheep (all diets) | 0.075 | 0.236 | 1.76 | 5.55 | Lamb | Barley | straw | Yes | 5.55 |
| Sheep (ewe only) | 0.059 | 0.185 | 1.76 | 5.55 | Ram/Ewe | Barley | straw | Yes | 5.55 |
| Swine (all diets) | 0.017 | 0.020 | 0.57 | 0.72 | Swine (finishing) | Swede | roots | Yes | 0.64 |
| Poultry (all diets) | 0.036 | 0.060 | 0.53 | 0.87 | Poultry layer | Wheat | straw | Yes | 0.86 |
| Poultry (layer only) | 0.036 | 0.060 | 0.53 | 0.87 | Poultry layer | Wheat | straw | Yes | 0.86 |

bw: body weight; DM: dry matter.

(a): When several diets are relevant (e.g. cattle, sheep and poultry ‘all diets’), the most critical diet is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

The above intake calculations for the maximum dietary burden of livestock demonstrate that residues of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) are significant in the diets of livestock (> 0.1 mg/kg dry matter in the diet).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

Prothioconazole

The median and maximum dietary burdens for livestock were estimated for prothioconazole and were calculated using the animal model calculator developed by EFSA (Animal model 2017).

The calculated dietary burdens for prothioconazole were found to exceed the trigger value of 0.1 mg/kg DM (or 0.004 mg/kg bw/d, respectively) for all livestock groups. Further investigation of residues is therefore required.

Remark on residue behaviour in fish (B.7.2.2.5 and B.7.2.4)

According to the new Working Documents on the nature and magnitude of pesticide residues in fish (SANTE/10254/2021, SANTE/10252/2021) as well as on the dietary burden calculator for pesticide residues in fish (SANTE/10250/2021), data on residue behaviour in fish are required when the pesticide use may lead to residues >0.1 mg/kg in the total diet (dry weight basis) and when the active substances and/or metabolites are fat soluble, i.e. have a $\log Po/w \geq 3$.

For prothioconazole-desthio the $\log Po/w$ is 3.04 and EFSA concluded that prothioconazole-desthio is fat soluble due to higher residue levels found in fat than in fat free muscle. Rape seed meal and cereal grains are used as a fish feeding stuff. However, residues of prothioconazole-desthio ranged from below the LOQ to 0.072 mg/kg in cereals grain and rape seeds. Residues above the trigger value of 0.1 mg/kg are therefore not expected. Further data are not required.

TDMs

No new calculations were submitted in the framework of this application. Livestock dietary intake calculations for TDMs have been performed during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b and EFSA 2018b, amended 2019) and reference is made to the respective evaluation of EFSA 2018b: “The livestock dietary burden calculation has been performed respectively for each TDM compound and triggered livestock feeding studies for 1,2,4-T, TA, TAA and TLA, see chapter B.7.4 of the addendum (United Kingdom, 2015, 2018).” The envisaged GAP uses are considered to be covered by these calculations as input values are considered/expected to cover the highest residues found in the relevant primary and rotational crop residue trials. The respective input values can be found in the confirmatory data assessment on pp 354 to 363 (UK, 2018b).

Input values used in UK, 2018b directly relevant to the envisaged GAP uses are given below and compared with the respective values derived from the new studies (TDM primary and rotational crop studies) submitted with this application.

Table 7.2- 17: Comparison of input values for dietary burden calculation from confirmatory data assessment (UK 2018b, pp 354 to 363) with values derived from new supplementary primary and rotational crop field residue studies

| Crop | Source of data | HR or STMR-P | Residue (mg/kg) | | | | HR or STMR-P | Residue (mg/kg) | | | |
|---------------------|---------------------------|--|-----------------|-------|-------|------|-----------------------|--|------|------|------|
| | | | T | TA | TAA | TLA | | T | TA | TAA | TLA |
| | | Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | | | Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | |
| Forages | | | | | | | | | | | |
| Alfalfa forage | Wheat or barley plant | HR | 0.06 | 0.524 | 0.434 | 1.43 | STMR | 0.05 | 0.16 | 0.1 | 0.4 |
| Alfalfa hay | Wheat or barley plant | HR * default PF (2.5) | 0.15 | 1.31 | 1.085 | 3.58 | HR * default PF (2.5) | 0.3 | 0.4 | 0.25 | 1 |
| Alfalfa meal | Wheat or barley plant | HR * default PF (2.5) | 0.15 | 1.31 | 1.085 | 3.58 | HR * default PF (2.5) | 0.3 | 0.4 | 0.25 | 1 |
| Alfalfa silage | Wheat or barley plant | HR * default PF (1.1) | 0.066 | 0.576 | 0.477 | 1.57 | HR * default PF (1.1) | 0.06 | 0.18 | 0.11 | 0.44 |
| Beet, mangel fodder | HR of beet leaves or root | HR | 0.12 | 0.239 | 0.05 | 0.14 | STMR | 0.05 | 0.18 | 0.05 | 0.05 |
| Beet tops | Sugar beet leaves | HR | 0.12 | 0.218 | 0.02 | 0.14 | STMR | 0.03 | 0.04 | 0.01 | 0.05 |
| Cabbage heads | brassica | HR | 0.113 | 0.5 | 0.01 | 0.01 | STMR | 0.04 | 0.17 | 0.01 | 0.01 |
| Clover forage | Wheat or barley plant | HR | 0.06 | 0.524 | 0.434 | 1.43 | STMR | 0.05 | 0.16 | 0.1 | 0.4 |
| Clover hay | Wheat or barley plant | HR * default PF (3) | 0.18 | 1.57 | 1.3 | 4.29 | STMR * default PF (3) | 0.15 | 0.48 | 0.3 | 1.2 |
| Clover silage | Wheat or barley plant | HR * default PF (1) | 0.06 | 0.524 | 0.434 | 1.43 | STMR * default PF (1) | 0.05 | 0.16 | 0.1 | 0.4 |

| Crop | Source of data | HR or STMR-P | Residue (mg/kg) | | | | HR or STMR-P | Residue (mg/kg) | | | |
|----------------------------------|------------------------|--|--------------------------------|-----------------------------------|--------------------------------|--------------------------------|--|-------------------------------|----------------------------------|---------------------------------|--------------------------------|
| | | | T | TA | TAA | TLA | | T | TA | TAA | TLA |
| | | Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | | Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | |
| Grass forage | Wheat or barley plant | HR | 0.06 | 0.524 | 0.434 | 1.43 | STMR | 0.05 | 0.16 | 0.1 | 0.4 |
| Grass hay | Wheat or barley plant | HR * default PF (3.5) | 0.21 | 1.83 | 1.5 | 5 | STMR * default PF (3.5) | 0.18 | 0.56 | 0.35 | 1.4 |
| Grass silage | Wheat or barley plant | HR * default PF (1.6) | 0.096 | 0.838 | 0.694 | 2.3 | STMR * default PF (1.6) | 0.08 | 0.26 | 0.16 | 0.64 |
| Kale | brassica | HR | 0.113 | 0.5 | 0.01 | 0.01 | STMR | 0.04 | 0.17 | 0.01 | 0.01 |
| Rape forage | Oilseed rape plant | HR | 0.023 | 0.913 | 0.034 | 0.04 | STMR | 0.01 | 0.1 | 0.01 | 0.04 |
| Cereal straws/stover | Cereal data | HR | 0.05 (0.02) | 0.65 (0.08) | 0.78 (0.40) | 1.1 (0.45) | STMR | 0.05 (0.01) | 0.12 (0.03) | 0.24 (0.105) | 0.37 (0.13) |
| Turnip leaves | Sugar beet leaves data | HR | 0.12 | 0.218 | 0.02 | 0.14 | STMR | 0.03 | 0.04 | 0.01 | 0.05 |
| Root and tubers | | | | | | | | | | | |
| Carrot | Root vegetable | HR | 0.06 (0.01) | 0.239 (0.12) | 0.05 (0.01) | 0.13 (0.02) | STMR | 0.05 (0.01) | 0.18 (0.06) | 0.05 (0.01) | 0.02 (0.01) |
| Potato | Root vegetable | HR | 0.06 (0.01) | 0.239 (0.12) | 0.05 (0.01) | 0.13 (0.02) | STMR | 0.05 (0.01) | 0.18 (0.06) | 0.05 (0.01) | 0.02 (0.01) |
| Swede | Root vegetable | HR | 0.06 (0.01) | 0.239 (0.12) | 0.05 (0.01) | 0.13 (0.02) | STMR | 0.05 (0.01) | 0.18 (0.06) | 0.05 (0.01) | 0.02 (0.01) |
| Turnip | Root vegetable | HR | 0.06 (0.01) | 0.239 (0.12) | 0.05 (0.01) | 0.13 (0.02) | STMR | 0.05 (0.01) | 0.18 (0.06) | 0.05 (0.01) | 0.02 (0.01) |
| Cereal grains/ crop seeds | | | | | | | | | | | |
| All cereal grains | Cereal data | STMR | 0.05 (0.01) | 0.621 (0.31) | 0.79 (0.235) | 0.02 (0.01) | STMR | 0.05 (0.01) | 0.62 (0.31) | 0.79 (0.235) | 0.022 (0.01) |
| Pulses | Pulse data | STMR | 0.05 | 0.17 | 0.05 | 0.01 | STMR | 0.05 | 0.17 | 0.05 | 0.01 |
| By products | | | | | | | | | | | |
| Apple pomace | Citrus or apple | STMR-P | 0.25 (STMR* default PF (5)) | 0.167 (STMR*PF) (0.32*0.52) | 0.25 (STMR* default PF (5)) | 0.1 (STMR*PF) (0.04*2.5) | STMR-P | 0.3 (STMR* default PF (5)) | 0.17 (STMR*PF) (0.32*0.52) | 0.13 (STMR*PF) (0.05*2.5) | 0.1 (STMR*PF) (0.04*2.5) |

| Crop | Source of data | HR or STMR-P | Residue (mg/kg) | | | | HR or STMR-P | Residue (mg/kg) | | | |
|--------------------------------|----------------------|--|--|---|-----------------------------------|------------------------------------|--|--|---|-----------------------------------|------------------------------------|
| | | | T | TA | TAA | TLA | | T | TA | TAA | TLA |
| | | Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | | Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | |
| Beet sugar dried pulp | Sugar beet root data | STMR* default PF (18) | 0.9 | 3.3 | 0.9 | 0.38 | STMR* default PF (18) | 0.9 | 3.3 | 0.9 | 0.38 |
| Beet, sugar, ensiled pulp | Sugar beet root data | STMR* default PF (3) | 0.15 | 0.55 | 0.15 | 0.06 | STMR* default PF (3) | 0.15 | 0.55 | 0.15 | 0.06 |
| Beet, sugar molasses | Sugar beet root data | STMR* default PF (28) | 1.4 | 5.1 | 1.4 | 0.59 | STMR* default PF (28) | 1.4 | 5.1 | 1.4 | 0.59 |
| Brewer's grain | Cereal grain data | STMR* default PF (3.3) | 0.165 | 2 | 2.6 | 0.073 | STMR* default PF (3.3) | 0.17 | 2 | 2.6 | 0.073 |
| Canola | Oilseed rape data | STMR* PF | 0.1 (0.02) | 1.45 (0.441) | 0.24 (0.02) | 0.13 (0.02) | STMR* PF | 0.1 (0.02) | 1.45 (0.441) | 0.24 (0.02) | 0.13 (0.02) |
| | | | (STMR * default PF (2)) (0.05* 2) (0.01*2) | (STMR*PF) (1.039*1.4) (0.315*1.4) | (STMR*PF) (0.12*2) (0.01*2) | (STMR*PF) (0.065*2) (0.01*2) | | (STMR * default PF (2)) (0.05* 2) (0.01*2) | (STMR*PF) (1.039*1.4) (0.315*1.4) | (STMR*PF) (0.12*2) (0.01*2) | (STMR*PF) (0.065*2) (0.01*2) |
| Citrus pomace | Citrus or apple | STMR-P | 0.5 (STMR* default PF (10)) | 0.167 (STMR*PF) (0.32*0.52) | 0.5 (STMR* default PF (10)) | 0.1 (STMR*PF) (0.04*2.5) | STMR-P | 0.5 (STMR* default PF (10)) | 0.17 (STMR*PF) (0.32*0.52) | 0.13 (STMR*PF) (0.05*2.5) | 0.1 (STMR*PF) (0.04*2.5) |
| Corn, field milled by-products | Cereal grain data | STMR* default PF (1) | 0.05 | 0.621 | 0.79 | 0.02 | STMR* default PF (1) | 0.05 | 0.62 | 0.79 | 0.02 |
| Corn, field, hominy meal | Cereal grain data | STMR* default PF (6) | 0.3 | 3.73 | 4.74 | 0.13 | STMR* default PF (6) | 0.3 | 3.7 | 4.74 | 0.13 |
| Corn, field gluten feed | Cereal grain data | STMR* default PF (2.5) | 0.125 | 1.55 | 1.98 | 0.06 | STMR* default PF (2.5) | 0.13 | 1.6 | 1.98 | 0.06 |
| Corn field, gluten meal | Cereal grain data | STMR* default PF (1) | 0.05 | 0.621 | 0.79 | 0.02 | STMR* default PF (1) | 0.05 | 0.62 | 0.79 | 0.02 |
| Cotton meal | Oilseed data | STMR* PF | 0.065 | 1.45 | 0.24 | 0.13 | STMR* PF | 0.07 | 1.45 | 0.24 | 0.13 |

| Crop | Source of data | HR or STMR-P | Residue (mg/kg) | | | | HR or STMR-P | Residue (mg/kg) | | | |
|-----------------------|-------------------|--|--|--|---|--|--|--|--|---|--|
| | | | T | TA | TAA | TLA | | T | TA | TAA | TLA |
| | | Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | | Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | |
| | | | (STMR* default PF (1.3)) (0.05*1.3) | (STMR*PF) (1.039*1.4) | (STMR*PF) (0.12*2) | (STMR*PF) (0.065*2) | | (STMR* default PF (1.3)) (0.05*1.3) | (STMR*PF) (1.039*1.4) | (STMR*PF) (0.12*2) | (STMR*PF) (0.065*2) |
| Distiller's grain | Cereal grain data | STMR* default PF | 0.165 | 2 | 2.6 | 0.073 | STMR* default PF (3.3) | 0.17 | 2 | 2.6 | 0.073 |
| | | -3.3 | | | | | | | | | |
| Flaxseed/linseed meal | Oilseed rape data | STMR* PF | 0.1 (STMR * default PF (2)) (0.05*2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) | STMR* PF | 0.1 (STMR * default PF (2)) (0.05*2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) |
| Lupin seed meal | Pulse data | STMR* default PF (1.1) | 0.055 | 0.187 | 0.055 | 0.01 | STMR* default PF (1.1) | 0.06 | 0.19 | 0.06 | 0.01 |
| Potato process waste | Root vegetable | STMR* default PF (20) | 1 | 3.68 | 1 | 0.42 | STMR* default PF (20) | 1 | 3.7 | 1 | 0.42 |
| Potato dried pulp | Root vegetable | STMR* default PF (38) | 1.9 | 6.99 | 1.9 | 0.8 | STMR* default PF (38) | 1.9 | 6.99 | 1.9 | 0.8 |
| Rape meal | Oilseed rape data | STMR* PF | 0.1 (0.02) (STMR * default PF (2)) (0.05*2) (0.01*2) | 1.45 (0.441) (STMR*PF) (1.039*1.4) (0.315*1.4) | 0.24 (0.02) (STMR*PF) (0.12*2) (0.01*2) | 0.13 (0.02) (STMR*PF) (0.065*2) (0.01*2) | STMR* PF | 0.1 (0.02) (STMR * default PF (2)) (0.05*2) (0.01*2) | 1.45 (0.441) (STMR*PF) (1.039*1.4) (0.315*1.4) | 0.24 (0.02) (STMR*PF) (0.12*2) (0.01*2) | 0.13 (0.02) (STMR*PF) (0.065*2) (0.01*2) |
| | | | | | | | | | | | |
| Safflower meal | Oilseed rape data | STMR* PF | 0.1 (STMR * default PF (2)) (0.05*2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) | STMR* PF | 0.1 (STMR * default PF (2)) (0.05*2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) |
| | | | | | | | | | | | |
| Soybean meal | | STMR* PF | 0.065 | 1.45 | 0.24 | 0.13 | STMR* PF | 0.07 | 1.45 | 0.24 | 0.13 |

| Crop | Source of data | HR or STMR-P | Residue (mg/kg) | | | | HR or STMR-P | Residue (mg/kg) | | | |
|--------------------------|-------------------|--|---|----------------------------------|-------------------------------|--------------------------------|--|---|----------------------------------|-------------------------------|--------------------------------|
| | | | T | TA | TAA | TLA | | T | TA | TAA | TLA |
| | | Residues input values for the <u>max.</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | | Residues input values for the <u>median</u> dietary burden calculation (in brackets: HR/STMRs derived from new supplementary residue studies) | | | | |
| | Oilseed rape data | | (STMR * default PF (1.3)) (0.05* 1.3) | (STMR*PF) (1.039*1.4) | (STMR*PF) (0.12*2) | (STMR*PF) (0.065*2) | | (STMR * default PF (1.3)) (0.05* 1.3) | (STMR*PF) (1.039*1.4) | (STMR*PF) (0.12*2) | (STMR*PF) (0.065*2) |
| Soybean hulls | Oilseed rape data | STMR* default PF (13) | 0.65 | 13.5 | 1.56 | 0.85 | STMR* default PF (13) | 0.7 | 13.5 | 1.56 | 0.85 |
| Sugarcane molasses | Sugar plant data | STMR* default PF (32) | 1.6 | 5.89 | 1.6 | 0.67 | STMR* default PF (32) | 1.6 | 5.89 | 1.6 | 0.67 |
| Sunflower meal | Oilseed rape data | STMR* PF | 0.1 (STMR * default PF (2)) (0.05* 2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) | STMR* PF | 0.1 (STMR * default PF (2)) (0.05* 2) | 1.45 (STMR*PF) (1.039*1.4) | 0.24 (STMR*PF) (0.12*2) | 0.13 (STMR*PF) (0.065*2) |
| Wheat gluten meal | Cereal data | STMR* default PF (1.8) | 0.09 | 1.11 | 1.42 | 0.04 | STMR* default PF (1.8) | 0.09 | 1.11 | 1.42 | 0.04 |
| Wheat milled by products | Cereal data | STMR* default PF (7) | 0.035 | 4.35 | 5.53 | 0.15 | STMR* default PF (7) | 0.35 | 4.35 | 5.53 | 0.15 |

Table 7.2- 18: The median and maximum dietary burden for 1,2,4-T

| Relevant groups | Dietary burden expressed in | | | | Most critical diet (a) | Most critical commodity (b) | | Trigger exceeded (Yes/No) | Previous assessment |
|--|-----------------------------|---------|----------|---------|------------------------|-----------------------------|---------------|---------------------------|---------------------|
| | mg/kg bw per day | | mg/kg DM | | | | | 0.004 | Max burden |
| | Median | Maximum | Median | Maximum | | | | mg/kg bw | mg/kg bw |
| Cattle (all diets) | 0.104 | 0.109 | 3.60 | 3.75 | Dairy cattle | Potato | process waste | Yes | |
| Cattle (dairy only) | 0.104 | 0.109 | 2.70 | 2.83 | Dairy cattle | Potato | process waste | Yes | |
| Sheep (all diets) | 0.118 | 0.121 | 3.54 | 3.63 | Ram/Ewe | Potato | process waste | Yes | |
| Sheep (ewe only) | 0.118 | 0.121 | 3.54 | 3.63 | Ram/Ewe | Potato | process waste | Yes | |
| Swine (all diets) | 0.045 | 0.047 | 1.93 | 2.04 | Swine (breeding) | Potato | process waste | Yes | |
| Poultry (all diets) | 0.037 | 0.038 | 0.53 | 0.54 | Poultry broiler | Potato | dried pulp | Yes | |
| Poultry (layer only) | 0.029 | 0.032 | 0.43 | 0.46 | Poultry layer | Potato | dried pulp | Yes | |
| (a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day" | | | | | | | | | |
| (b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day". | | | | | | | | | |

| Relevant groups | Dietary burden expressed in | | | | Most critical diet (a) | Most critical commodity (b) | | Trigger exceeded (Yes/No) | Previous assessment |
|--|-----------------------------|---------|----------|---------|------------------------|-----------------------------|---------------|---------------------------|---------------------|
| | mg/kg bw per day | | mg/kg DM | | | | | 0.004 | Max burden |
| | Median | Maximum | Median | Maximum | | | | mg/kg bw | mg/kg bw |
| Cattle (all diets) | 0.376 | 0.405 | 12.97 | 13.63 | Dairy cattle | Potato | process waste | Yes | |
| Cattle (dairy only) | 0.376 | 0.405 | 9.77 | 10.52 | Dairy cattle | Potato | process waste | Yes | |
| Sheep (all diets) | 0.425 | 0.454 | 12.76 | 13.63 | Ram/Ewe | Potato | process waste | Yes | |
| Sheep (ewe only) | 0.425 | 0.454 | 12.76 | 13.63 | Ram/Ewe | Potato | process waste | Yes | |
| Swine (all diets) | 0.163 | 0.178 | 7.08 | 7.71 | Swine (breeding) | Potato | process waste | Yes | |
| Poultry (all diets) | 0.158 | 0.165 | 2.24 | 2.34 | Poultry broiler | Potato | dried pulp | Yes | |
| Poultry (layer only) | 0.130 | 0.149 | 1.91 | 2.18 | Poultry layer | Potato | dried pulp | Yes | |
| (a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day" | | | | | | | | | |
| (b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day". | | | | | | | | | |

Table 7.2- 20: The median and maximum dietary burden for TAA

| Relevant groups | Dietary burden expressed in | | | | Most critical diet (a) | Most critical commodity (b) | |
|----------------------|-----------------------------|---------|----------|---------|------------------------|-----------------------------|---------------|
| | mg/kg bw per day | | mg/kg DM | | | | |
| | Median | Maximum | Median | Maximum | | | |
| Cattle (all diets) | 0.118 | 0.140 | 3.87 | 4.29 | Dairy cattle | Potato | process waste |
| Cattle (dairy only) | 0.118 | 0.140 | 3.06 | 3.63 | Dairy cattle | Potato | process waste |
| Sheep (all diets) | 0.153 | 0.170 | 3.80 | 4.37 | Lamb | Wheat | milled bypdts |
| Sheep (ewe only) | 0.127 | 0.146 | 3.80 | 4.37 | Ram/Ewe | Potato | process waste |
| Swine (all diets) | 0.108 | 0.109 | 3.60 | 3.76 | Swine (finishing) | Wheat | milled bypdts |
| Poultry (all diets) | 0.138 | 0.140 | 1.98 | 2.05 | Poultry broiler | Wheat | milled bypdts |
| Poultry (layer only) | 0.135 | 0.140 | 1.98 | 2.05 | Poultry layer | Wheat | milled bypdts |

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burden

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Table 7.2- 21: The median and maximum dietary burden for TLA

| Relevant groups | Dietary burden expressed in | | | | Most critical diet (a) | Most critical commodity (b) | |
|--|-----------------------------|---------|----------|---------|------------------------|-----------------------------|----------------|
| | mg/kg bw per day | | mg/kg DM | | | | |
| | Median | Maximum | Median | Maximum | | | |
| Cattle (all diets) | 0.078 | 0.177 | 2.22 | 4.61 | Dairy cattle | Grass | forage (fresh) |
| Cattle (dairy only) | 0.078 | 0.177 | 2.03 | 4.61 | Dairy cattle | Grass | forage (fresh) |
| Sheep (all diets) | 0.079 | 0.187 | 2.36 | 5.61 | Ram/Ewe | Grass | forage (fresh) |
| Sheep (ewe only) | 0.079 | 0.187 | 2.36 | 5.61 | Ram/Ewe | Grass | forage (fresh) |
| Swine (all diets) | 0.026 | 0.055 | 1.11 | 2.37 | Swine (breeding) | Grass | forage (fresh) |
| Poultry (all diets) | 0.021 | 0.055 | 0.31 | 0.77 | Poultry layer | Clover | hay |
| Poultry (layer only) | 0.021 | 0.052 | 0.31 | 0.77 | Poultry layer | Clover | hay |
| (a): When several diets are relevant (e.g. cattl0.052e, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day". | | | | | | | |
| (b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day". | | | | | | | |

The above intake calculations for the maximum dietary burden of livestock demonstrate that residues of T, TA, TAA and TLA are significant in the diets of livestock (>0.1 mg/kg in the diets on an 'as received' basis in accordance with Regulation (EC) 544/2011). The intakes are also above the trigger of 0.1 mg/kg applied on a DM basis (UK, 2018b).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

TDMs

Livestock dietary burden calculation has been performed respectively for each TDM compound in the addendum – confirmatory data on TDMs performed by UK (UK, 2018) using results from residue trials and from rotational crops.

It should be noted that the results of dietary burdens for TDMs taking into account the intended uses of ADM.03500.F.2.B are covered by the dietary burdens calculated by the UK (UK, 2018) for the different groups of livestock.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

Prothioconazole except TDMs

No new data were submitted in the framework of this application.

The magnitude of prothioconazole residues in livestock was evaluated during EU review (UK, 2004 and 2007; EFSA, 2007) and during Article 12 MRL review (EFSA, 2014 and EFSA, 2020) and reference is made to the respective evaluations.

Table 7.2- 22: Overview of livestock feeding studies with prothioconazole-desthio

| Group | Species | No of animal | Test item | Application details | | Sample details | | Reference |
|---------------------|-----------|---|-------------------------|--|-----------------|--------------------------------------|-----------------------|---|
| | | | | Rate | Duration (days) | Commodity | Time of sampling | |
| EU data | | | | | | | | |
| Lactating ruminants | Dairy cow | 10 (3 groups à 3 animals, 1 control animal) | Prothioconazole-desthio | 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d (UK 2007)) | 28 | Milk | 24 times during study | UK, 2004 and 2007 (IIA, 6.4/01); EFSA, 2007, evaluated and accepted (xxxxxxx, 2001); Report no. MR-535/00 |
| | | | | | | Tissues (liver, kidney, muscle, fat) | After sacrifice | |

Ruminants and pigs (EFSA 2014):

“During the peer review under Directive 91/414/EEC, the magnitude of prothioconazole residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2007; FAO, 2008a, 2008b; United Kingdom, 2004, 2007). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with prothioconazole-desthio at levels of 4, 25, and 100 mg/kg in the diet (equivalent to 0.145, 0.909 and 3.636 mg/kg bw per d, respectively). The samples were analysed for prothioconazole-desthio, M14 (prothioconazole-3-hydroxy-desthio) and M15 (prothioconazole-4-hydroxy-desthio). Results of the ruminant livestock feeding study are summarised in [Table 7.2- 23]. In milk, a plateau level was reached after 1 or 2 days of exposure, according to the dose level group. Since neither the metabolites (free and conjugated) containing the common moiety and included in the residue definition for risk assessment nor the glucuronide conjugates of prothioconazole-desthio were analysed, EFSA reported the residue levels for enforcement only (prothioconazole-desthio) and considered the conversion factors for enforcement to risk assessment of 2 and 9 respectively for liver and kidney based on the goat metabolism study with administration of prothioconazole-desthio. No tentative CF was derived for milk, muscle and fat since the residue levels in these matrices are expected to be negligible (<0.01 mg/kg) at the calculated dietary burden. However, conversion factors reported above should in principle be covered by a new feeding study to estimate prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Furthermore, in the framework of the reported feeding study, the storage stability of prothioconazole-desthio, M14 and M15 was demonstrated in all matrices for up to 1 month when stored deep frozen and was shown to cover the storage time interval of the residue samples of the feeding study. Degradation of prothioconazole-desthio residues during storage of the feeding study residue samples is therefore not expected.

Consequently, the available data allow deriving tentative MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009b) and are summarised in [Table 7.2- 23]. Tentative MRLs in all commodities are established at the LOQ, except in liver and kidney of ruminants, where MRLs of 0.05 and 0.02 mg/kg respectively are proposed.”

When using the dietary burdens calculated above (considering the uses evaluated in Art. 12 procedure and the uses under consideration, presented in Table 7.2- 16), estimated residues at 1N dietary burden in ruminant and pig matrices and in milk do not exceed the current MRLs in the respective commodities as given in Com. Reg. (EU) 2019/552 (Table 7.2- 23).

Poultry (EFSA 2014): “Finally, although the maximum dietary burden for poultry exceeds the threshold of 0.1 mg/kg DM, no appropriate feeding study is available and is required, since based on the metabolism study, no residues above the LOQ are expected in poultry matrices at the calculated dietary burden.”

According to EFSA, 2020 the following applies with regard to residues in livestock: “The results of the dietary burden calculation are presented in Section B.2 [see Table 7.2- 16 above] and demonstrate that the exposure of all livestock species exceeds the trigger value of 0.1 mg/kg DM [...]. EFSA notes that since the residue trials on grass (major component of livestock dietary burden) have not been submitted, the EU livestock dietary burden from the existing EU uses including grass could not be properly calculated. However, since the existing EU MRLs for livestock commodities reflect CXLs, which are derived on the basis of significantly higher livestock dietary burdens as calculated by the JMPR in 2017 for cattle and poultry (FAO, 2018), the nature and magnitude of prothioconazole residues in livestock was not investigated further.”

Table 7.2- 23: Overview of the values derived from livestock feeding studies (EFSA, 2014) and the estimated STM/HRs at 1N intake level when using livestock dietary burden as calculated above (Table 7.2- 16)

| Commodity | Dietary burden (EFSA 2020) | | Results of the livestock feeding study (EFSA 2014) | | | | | | Median residue at 1N dietary burden (mg/kg) ^(c) | Highest residue at 1N dietary burden (mg/kg) ^(d) | Current EU-MRL (mg/kg) Com. Reg. (EU) 2019/552 | CF for RA ^(e) |
|---|----------------------------|----------------------------------|--|------|------------------------|--------------|------------------------------|--------------|--|---|--|--------------------------|
| | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) ^(a) | Dose Level (mg/kg bw/d) | No | Result for enforcement | | Result for RA ^(b) | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| EU data (UK, 2004; EFSA, 2014; dietary burden: EFSA 2020) | | | | | | | | | | | | |
| Enforcement residue definition: Prothioconazole-desthio (sum of isomers) | | | | | | | | | | | | |
| Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety expressed as prothioconazole-desthio (sum of isomers). | | | | | | | | | | | | |
| Pig muscle | 0.017 | 0.020 | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01 | 1.0 |
| Pig fat | | | 0.91 | 3 | <0.01 | <0.01 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | <0.01 | <0.01 | n.a. | n.a. | | | | |
| | | | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.02 | 1.0 |
| Pig liver | | | 0.91 | 3 | <0.01 | 0.01 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | 0.02 | 0.04 | n.a. | n.a. | | | | |
| | | | 0.15 | 3 | 0.02 | 0.03 | n.a. | n.a. | <0.01 | <0.01 | 0.5 | 2.0 |
| Pig kidney | | | 0.91 | 3 | 0.14 | 0.18 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | 0.68 | 1.20 | n.a. | n.a. | | | | |
| | | | Ruminant muscle | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.5 |
| 0.91 | | | | 3 | 0.03 | 0.03 | n.a. | n.a. | | | | |
| 3.64 | | | | 3 | 0.13 | 0.24 | n.a. | n.a. | | | | |
| Ruminant fat | 0.038 | 0.111 | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.01 | 1.0 |
| | | | 0.91 | 3 | <0.01 | <0.01 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | <0.01 | <0.01 | n.a. | n.a. | | | | |
| | | | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 | 0.02 | 1.0 |
| | | | 0.91 | 3 | <0.01 | 0.01 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | 0.02 | 0.04 | n.a. | n.a. | | | | |

| Commodity | Dietary burden (EFSA 2020) | | Results of the livestock feeding study (EFSA 2014) | | | | | | Median residue at 1N dietary burden (mg/kg) ^(c) | Highest residue at 1N dietary burden (mg/kg) ^(d) | Current EU-MRL (mg/kg) Com. Reg. (EU) 2019/552 | CF for RA ^(e) |
|--|----------------------------|----------------------------------|--|----|------------------------|--------------|------------------------------|--------------|--|---|--|--------------------------|
| | Med. (mg/kg bw/d) | Max. (mg/kg bw/d) ^(a) | Dose Level (mg/kg bw/d) | No | Result for enforcement | | Result for RA ^(b) | | | | | |
| | | | | | Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) | | | | |
| EU data (UK, 2004; EFSA, 2014; dietary burden: EFSA 2020) | | | | | | | | | | | | |
| Enforcement residue definition: Prothioconazole-desthio (sum of isomers) | | | | | | | | | | | | |
| Risk assessment residue definition: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2- chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety) expressed as prothioconazole-desthio (sum of isomers). | | | | | | | | | | | | |
| Ruminant liver | | | 0.15 | 3 | 0.02 | 0.03 | n.a. | n.a. | <0.01 (0.01 in EFSA 2014) | 0.02 (0.042 in EFSA 2014) | 0.5 | 2.0 |
| | | | 0.91 | 3 | 0.14 | 0.18 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | 0.68 | 1.20 | n.a. | n.a. | | | | |
| Ruminant kidney | | | 0.15 | 3 | <0.01 | <0.01 | n.a. | n.a. | <0.01 | <0.01 (0.012 in EFSA 2014) | 0.5 | 9.0 |
| | | | 0.91 | 3 | 0.03 | 0.03 | n.a. | n.a. | | | | |
| | | | 3.64 | 3 | 0.13 | 0.24 | n.a. | n.a. | | | | |
| Milk | 0.038 | 0.111 | 0.15 | 42 | <0.005 ^(f) | N/A | n.a. | n.a. | <0.005 | <0.005 | 0.01* | 1.0 |
| | | | 0.91 | 42 | <0.005 ^(f) | N/A | n.a. | n.a. | | | | |
| | | | 3.64 | 42 | 0.005 ^(f) | N/A | n.a. | n.a. | | | | |

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.a.: Not reported

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Based on a 560 kg animal consuming 20 kg feed DM/day.

(b): In the feeding study, residues were not determined according to the residue definition for risk assessment. Indeed, only prothioconazole-desthio, M14 and M15 were analysed.

(c): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009). As raw data from the feeding study are not available to the applicant, the given STMRs at 1N dietary burden are only rough estimates rather than derived from detailed calculations.

(d): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009). As raw data from the feeding study are not available to the applicant, the given HRs at 1N dietary burden are only rough estimates rather than derived from detailed calculations.

(e): The tentative conversion factors for enforcement to risk assessment in liver and kidney were derived on the basis of the available metabolism study on ruminants. For muscle, fat and milk, no CF was derived as residue levels are expected at the maximum meat ruminant dietary burden in these matrices are negligible (<0.01 mg/kg) (EFSA, 2014).

(f): Mean residue level from day 1 or 4 until day 29 (3 cows, 13 or 14 sampling days).

TDMs

No new data were submitted in the framework of this application.

The magnitude of residues in livestock with regard to TDMs was evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b and EFSA 2018b, amended 2019) and reference is made to the respective evaluation.

EFSA 2018b: “Poultry and ruminants feeding studies were conducted respectively with TA and TAA and analysed for the magnitude of TA, TAA, 1,2,4-T and TLA residues. The poultry feeding study conducted with TA showed that TA remained predominant in all matrices and a slight metabolisation to 1,2,4-T in whole eggs, liver and muscle at the highest dosing level was noted. When the animals were fed with TAA, this compound was detected in eggs, fat and liver with residues of TA in liver only at all dosing levels. From the ruminant feeding study conducted with TA, TA remained predominant in all tissues but with a significant metabolisation of TA into 1,2,4-T in milk and to a minor extent into 1,2,4-T and TAA in tissues. TLA was identified in fat only but its detection was rather attributed to a contamination as the respective levels were independent from the dosing levels. When ruminants were fed with TAA, this metabolite was only detected at the highest dose level in whole milk and in all tissues whilst TA was identified in liver, muscle and kidney at all the dosing levels. 1,2,4-T and TLA compounds were never detected (< 0.01 mg/kg). Animal tissues, milk and eggs samples were analysed within 30 days of sampling.

Since livestock feeding studies were not conducted to address the potential transfer of 1,2,4-T and TLA in products of animal origin, the experts agreed that transfer factors for TA derived from the feeding studies conducted with TA should be applied to 1,2,4-T, assuming that the absorption and excretion behaviour of TA and 1,2,4-T are similar. Similarly transfer factors for TAA derived from the feeding studies conducted with TAA should be applied to TLA assuming that the absorption and excretion behaviour of TAA and TLA are comparable and because of the similarity of the functional groups. From the available toxicological studies, the absorption and excretion of TA, 1,2,4-T and TAA were shown to be similar and the experts agreed to estimate the 1,2,4-T residue levels in animal matrices by applying transfer factors for TA derived from the feeding study conducted with TA. A feeding study conducted with 1,2,4-T is therefore not required as no further metabolism of this compound in animal matrices is expected. In contrast and since a similar absorption and excretion behaviour of TLA compared to the other TDMs could not be demonstrated, livestock feeding studies conducted with TLA or metabolism studies performed in accordance with the current recommendations as a surrogate to these feeding studies should be provided (data gap). Meanwhile and provisionally, transfer factors for TAA derived from the feeding study conducted with TAA were applied to estimate the residue levels of TLA in animal commodities. The magnitude of residues of each TDM in animal matrices were therefore estimated by using the approach of a separate dietary burden calculation for each TDM and the application of transfer factors respectively to 1,2,4-T and to TLA for which feeding studies are not available.

Furthermore, the residues of the TDMs (mainly 1,2,4-T and to a minor extent, TA) arising from the metabolism of triazole pesticide active substances in livestock should also be considered to derive the total residue levels of the individual TDMs in animal matrices. In the framework of these confirmatory data assessments and since feeding studies conducted with the triazole compounds were not available, the residue levels of 1,2,4-T and TA were estimated from the metabolism studies conducted with the triazole compounds when these were available. For any future assessment of triazole pesticide active substances, livestock feeding studies or, alternatively metabolism studies should be conducted with the triazole compounds to carry out a complete livestock exposure assessment.”

New studies to cover the data gap identified by EFSA 2018b cited above have been conducted by the Triazole Derivative Metabolite Group (TDMG). The data gap will be addressed at EU level and considered to be evaluated in the course of the TDM assessment. Therefore, the relevant studies are not submitted with this dossier.

Conclusion on feeding studies

The requested uses are covered by the referenced intake calculations for livestock. Regarding available feeding data and evaluations in EFSA 2014, and EFSA, 2020, there is no risk for livestock MRLs of prothioconazole-desithio (sum of isomers) to be exceeded.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

The livestock feeding studies was investigated during the peer review of prothioconazole. The intended uses do not modify the theoretical maximum daily intake for animals for prothioconazole and TDMs. The residues in animal commodities will not exceed MRLs (Reg. (EU) 2019/552).

No further data are required to support the intended uses of ADM.03500.F.2.B.

Remark:

It should be noted that EFSA recommended providing a ruminant feeding study to estimate the potential exposure to all the prothioconazole metabolites containing the common moiety in accordance with the residue definition for risk assessment.

Additionally, regarding TDMs EFSA identified livestock exposure assessment as a data gap.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

In addition, a new processing study in oilseed rape seeds has been conducted (KCA 6.5.2/01) and is included in Appendix 2.

Prothioconazole except TDMs

Any studies on the magnitude of residues of prothioconazole (except TDMs) in processed commodities are not required, as residues of

Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

were ≤ 0.1 mg/kg in cereal grains and oilseeds at commercial harvest. Based on the results of residue trials, significant residue levels will not occur in cereals and oilseed rape at harvest. Accordingly, processing studies are not required.

TDMs

Residues of TDMs:

- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole (1,2,4-triazole)

partly exceed 0.1 mg/kg in cereal grains and oilseeds (even though significant background residues in untreated samples were also observed).

In cereal grain, 1,2,4-T and TLA always show residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA (HR and STMR exceed 0.1) and for TAA (only HR exceeds 0.1).

In oilseed rape seeds, 1,2,4-T and TAA always show residues < 0.1 mg/kg, whereas the trigger of 0.1 is partly exceeded for TA (HR and STMR exceed 0.1) and for TLA (only HR exceeds 0.1).

The contribution of cereals and oilseed rape to the IEDIs and IESTIs of the four relevant TDMs is always < 10 % of the ADI and ARfD, respectively. Due to the low residues in the respective commodities and the

low contribution dietary intake, any processing studies are not considered to be required.

However, for the sake of completeness, available processing data is given in the following.

During the peer review of TDMs, processing studies including oilseed rape seed and cereal grain processing have been evaluated and processing factors for bran and rape seed meal for TDMs have been derived (UK, 2018b, pp.464-465):

1,2,4-Triazole

No processing factors are available. Residues in the animal feed items were <0.1 mg/kg and consequently the data requirements for processing are not triggered.

Triazole alanine

| Crop | Processing factors available | Processing factor used in livestock dietary burden calculation (UK 2018b) | Comment |
|----------------|-----------------------------------|---|-----------|
| Rape seed meal | 0.52, 0.81, 2.9, 1.9 | 1.4 | Median PF |
| Bran | 1.9, 2.2, 1.8, 3.0, 3.7, 2.2, 1.4 | 2.2 | Median PF |

Triazole acetic acid

| Crop | Processing factors available | Processing factor used in livestock dietary burden calculation (UK 2018b) | Comment |
|------|----------------------------------|---|-----------|
| Bran | <1, 1.3, 1.3, 1.1, 2.1, 1.4, 1.7 | 1.3 | Median PF |

Triazole lactic acid

| Crop | Processing factors available | Processing factor used in livestock dietary burden calculation (UK 2018b) | Comment |
|----------------|------------------------------|---|------------|
| Rape seed meal | >1, >3, >2 | 2 | Median PF† |

† Owing to the initial residue in the RAC being less than the LOQ these processing factors can only be regarded as indicative only. However, more robust processing factors are not deemed necessary as they are not expected to affect the outcome of the risk assessment.

7.2.5.1 Available data for all crops under consideration

In addition, a new supplementary study on the magnitude of residues in processed commodities of oilseed rape has been conducted and is included in Appendix 2, resulting in the following processing factors for crude oil, pressed cake and refined oil:

Table 7.2- 24: Processing factors for oilseed rape crude oil, pressed cake and refined oil per trial

| Sample type | Plot | Processing factors | | | | | | | | | |
|--------------|---------|--------------------------|-------------|-----------------------|-------------|---------|----------------------------|-------------|----------------------------|-------------|---------|
| | | 1,2,4-triazole (1,2,4-T) | | Triazole alanine (TA) | | | Triazole acetic acid (TAA) | | Triazole lactic acid (TLA) | | |
| | | Trial 01-FR | Trial 02-FR | Trial 01-FR | Trial 02-FR | Mean PF | Trial 01-FR | Trial 02-FR | Trial 01-FR | Trial 02-FR | Mean PF |
| Crude oil | Treated | -* | -* | -* | -* | - | -* | -* | -* | -* | - |
| | Control | -* | -* | 1.11 | -* | - | -* | -* | -* | 1.00 | - |
| Pressed cake | Treated | -* | -* | 1.36 | 1.19 | 1.3 | 2.00 | -* | 1.50 | -* | - |
| | Control | -* | -* | 1.73 | 0.95 | 1.3 | 1.00 | -* | 1.36 | 0.50 | 0.9 |
| Refined oil | Treated | -* | -* | -* | -* | - | -* | -* | -* | -* | - |
| | Control | -* | -* | -* | -* | - | -* | -* | -* | -* | - |

* No processing factor can be calculated as the residue in processed fraction was <LOQ.

The processing factors are calculated using rounded values.

Results of these trials are consistent with those identified during the EU peer review of TDMs.

7.2.5.2 Conclusion on processing studies

Based on the results of residue trials, significant residue levels of prothioconazole (except TDMs) will not occur in cereal grain and oilseed rape at harvest. Accordingly, any processing studies are not considered to be required.

Regarding TDMs, processing factors for TA, TLA and TAA derived from processing studies with cereals and oilseed rape are available, which can be used during risk assessments to account for possible residue concentration during processing.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

As residues of prothioconazole exceeding 0.1 mg/kg are not expected in the treated crops, there is no need to investigate the magnitude of prothioconazole residues in processed commodities.

Regarding TDMs, processing studies on wheat and oilseed rape grain have been evaluated in confirmatory data for Triazole Derivate Metabolites (UK, 2018).

Calculated processing factors show concentration of:

- TA and TAA in wheat bran,
- TA in wheat germ and shorts,
- TA, TAA and TLA in rapeseed meal,
- and TLA in rapeseed press cake.

Applicant submitted new study conducted to determine residue levels of triazole metabolites in processed fractions of oilseed rape seeds following one application of ADM.03503.F.1.A (150 g/L prothioconazole and 75 g/L fluxapyroxad) (Amic, S., 2021; Report no.: BPL21/968/GC). For the common triazole derived metabolites resulting from oilseed rape treated with prothioconazole, in both trials no processing factors could be derived for 1,2,4-Triazole as all residues were below the LOQ in the RAC and in the processed fractions and for TA, TAA and TLA in refined oil and crude oil since all residues were below the LOQ in the processed fraction.

Processing factors could be derived for TA, TAA and TLA for pressed cake.

It should be noted that residues of TDMs were found in control samples. Therefore, for untreated samples of pressed cake and crude oil processing factors could be derived additionally. As processing factors from treated samples of pressed cake exceed those from untreated pressed cake, processing factors from treated pressed cake are considered relevant.

No further data are required.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

Reference is made to the EU peer review (EFSA, 2007, DAR UK, 2004 and 2007) and to the MRL review (EFSA, 2014 and 2020) for prothioconazole, as well as to the peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019).

Two new rotational crop residue studies covering all metabolites of the residue definition for risk assessment residue definition of prothioconazole in plants have been conducted (KCA 6.6.2/01 and KCA 6.6.2/02). The detailed assessments of these studies are presented in Appendix 2.

Table 7.2- 25: Summary of available studies in field rotational crops

| Table 7.2- 25: Summary of available studies in field rotational crops | | | | | |
|---|--|------------------------------------|---|---------------------------|-----------------------------------|
| Primary crop | Rate (kg a.s./ha) (GS at application or PHI) | Residue levels in succeeding crops | | | |
| | | Succeeding crop group | Succeeding crop | Sowing intervals (DAT) | Reference / Remarks |
| EU data | | | | | |
| For a summary of EU data on TDMs in rotational crops please refer to Table 7.2- 26. | | | | | |
| New data | | | | | |
| Bare soil | 0.30 (Bare soil) | Leafy vegetables | Leaf lettuce | 30 120 270 | Semrau, J., 2021, KCA 6.6.2/01 |
| | | Root and tuber vegetables | Radish root Radish top | 30 120 270 | |
| | | Cereals | Barley whole plant Grain Straw | 30 120 270 | |
| Bare soil | 0.30 (Bare soil) | Leafy vegetables | Leaf lettuce | 28 | Semrau, J., 2022, KCA 6.6.2/02 |
| | | Root and tuber vegetables | Radish root Radish top | 28 | |
| | | Cereals | Barley whole plant Grain Straw | 28 | |

Prothioconazole except TDMs

Considering available data dealing with the nature of residues in rotational crops (see 7.2.2.2), no study dealing with the magnitude of these residues in succeeding crops is required.

Since the intended application rates on cereals and oilseeds are within the range of application rates assessed in the MRL review, the same conclusions are applicable that residues of prothioconazole-desthio (sum of isomers) in rotational crops are expected to be covered by the residue levels in primary crops.

TDMs

Rotational crop field trials with prothioconazole in which residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-triazole) were analysed for have been evaluated during EU peer review of the pesticide risk assessment for the triazole derivative metabolites (UK, 2018b, EFSA, 2018b, amended 2019) to which explicit reference is made.

UK 2018b:” Supervised field trials to investigate the residues in rotational crops after the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole were conducted at four test sites in Germany, the Netherlands, southern France and Spain. At each test site three ranges of plant-back intervals (20-35 days, 60-200 days and 270-365 days) and three crop groups (root crops represented by turnip and carrot, leafy crops represented by lettuce, cereals represented by barley) were investigated. In the trials simulating a crop failure (emergency rotation) the EC formulation was applied once to bare soil at the rate of 630 g as/ha of prothioconazole. The rotational crops were sown or planted 21-34 days after the application. In the trials simulating a normal rotation the FS formulation was used to treat wheat seed at the rate of 15 g as/dt. The seed was sown at a nominal rate of 200 kg seed/ha and the wheat plants received 3 spray treatments at the rate of 200 g as/ha with the EC formulation. The treatments were conducted at the growth stages BBCH 32, BBCH 39 and BBCH 65-69, respectively, with intervals of 7-30 days between subsequent treatments. At harvest the wheat straw was ploughed in and the plot was left bare until rotational crops were sown or planted. The plant-back intervals were variable depending on the crop and ranged

between 56 and 200 days for the short crop rotation and between 277 and 345 days for the annual crop rotation. A summary of the median (STMR) and highest residues (HR) of T, TA, TAA and TLA measured in the rotational crops for emergency rotation and normal rotation is given below:

Table 7.2- 26: STMRs and HRs for the triazole derived metabolites in carrot / turnip, lettuce and barley grown as succeeding crops following the use of FS and EC formulations containing 100 g/L and 250 g/L of prothioconazole (UK, 2018b)

| Commodity | No of trials | STMR (mg/kg) | | | | HR (mg/kg) | | | |
|---|--------------|--------------|-------|-------|-------|------------|-------|-------|-------|
| | | T | TA | TAA | TLA | T | TA | TAA | TLA |
| Carrot or turnip leaf – bare soil | 4 | 0.01 | 0.032 | 0.01 | 0.057 | 0.01 | 0.176 | 0.01 | 0.132 |
| Carrot or turnip leaf – normal rotation | 7 | 0.01 | 0.01 | 0.01 | 0.019 | 0.01 | 0.039 | 0.01 | 0.046 |
| Carrot or turnip root – bare soil | 4 | 0.01 | 0.076 | 0.01 | 0.021 | 0.01 | 0.195 | 0.01 | 0.131 |
| Carrot or turnip root – normal rotation | 7 | 0.01 | 0.023 | 0.01 | 0.010 | 0.01 | 0.041 | 0.01 | 0.01 |
| Lettuce – bare soil | 4 | 0.01 | 0.047 | 0.022 | 0.079 | 0.01 | 0.091 | 0.03 | 0.01 |
| Lettuce – normal rotation | 8 | 0.01 | 0.011 | 0.023 | 0.02 | 0.01 | 0.012 | 0.036 | 0.048 |
| Barley plant – bare soil | 4 | 0.01 | 0.068 | 0.01 | 0.078 | 0.01 | 0.082 | 0.01 | 0.165 |
| Barley plant – normal rotation | 8 | 0.01 | 0.037 | 0.01 | 0.032 | 0.01 | 0.057 | 0.01 | 0.208 |
| Barley straw – bare soil | 4 | 0.01 | 0.053 | 0.063 | 0.113 | 0.01 | 0.129 | 0.288 | 0.192 |
| Barley straw – normal rotation | 8 | 0.01 | 0.011 | 0.019 | 0.042 | 0.01 | 0.023 | 0.057 | 0.068 |
| Barley grain – bare soil | 4 | 0.01 | 0.412 | 0.144 | 0.02 | 0.01 | 0.455 | 0.293 | 0.037 |
| Barley grain – normal rotation | 8 | 0.01 | 0.075 | 0.067 | 0.01 | 0.01 | 0.184 | 0.132 | 0.031 |

Note: For the calculation of the STMRs and HRs the residue values measured in the control samples were taken into account whenever they exceeded the values measured in the corresponding treated samples. The STMRs were calculated based on the highest residue levels from each trial. Separate STMRs and HRs were calculated based on the trials involving soil application and based on the trials with application to a preceding crop, respectively. The worst case STMR and the worst case HR were then determined by selecting the greater STMR and the greater HR from the two datasets.”

In addition, two new studies have been conducted and are summarised in Appendix 2. Results for TDMs are shortly summarised in the following:

In study KCA 6.6.2/01, residues of prothioconazole (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio (sum of isomers)), as well as of triazole derivative metabolites (TDMs) (1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) were analysed in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 on bare soil at an exaggerated rate of 300 g prothioconazole/ha. Samples were taken from crops planted at three different plant back intervals of nominal 30-3, 120±5 and 270±10 days. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Four trials were carried out in Poland (2x, N-EU residue zone), Southern France and Italy (S-EU residue zone) in 2018-2019. Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 75 and at normal commercial harvest (grain and straw).

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

Residues of 1,2,4-triazole were always below the LOQ of 0.01 mg/kg. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals (grain and straw). Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found. This is due to the widespread occurrence of the analytes. Background levels of the analytes in are considered to be unavoidable. The following residues were observed in treated samples:

- Highest residues found at 30-3 days PBI in radish (roots) were found at 0.02 mg/kg (TLA) and 0.12 mg/kg (TA), those at 120±5 days PBI were found at 0.02 mg/kg (TLA) and 0.05 mg/kg (TA), whereas at 270±10 days, highest residues varied between 0.02 mg/kg (TLA) and 0.07 mg/kg (TA).
- Highest residues found at 30-3 days PBI in leaf lettuce were found at 0.03 mg/kg TA and 0.19 mg/kg TLA, those at 120±5 days PBI were found at 0.01 mg/kg TA and 0.12 mg/kg TLA, whereas at 270±10 days, highest residues were found to be 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 30-3 days PBI in barley (grain) were found to be 0.01 mg/kg TLA, 0.41 mg/kg TA and 0.55 mg/kg TAA, those at 120±5 days PBI were 0.01 mg/kg TLA, 0.28 mg/kg TA and 0.29 mg/kg TAA, whereas at 270±10 days, highest residues were found at 0.02 mg/kg TLA, 0.28 mg/kg TA and 0.32 mg/kg TAA.
- Highest residues found at 30-3 days PBI in barley (straw) were in 0.04 mg/kg TA, 0.40 TAA and 0.45 mg/kg TLA, those at 120±5 days PBI were 0.05 mg/kg TA, 0.24 mg/kg TAA and 0.21 mg/kg TLA, whereas at 270±10 days, highest residues were found at 0.27 mg/kg TLA, 0.04 mg/kg TA and 0.20 mg/kg TAA.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study. To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study was conducted to verify the no residue situation observed for 1,2,4-T. The rationale for design of this second study is provided in a position paper submitted with this application.

In study KCA 6.6.2/02, residue levels and behaviour of prothioconazole (PTZ) metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), as well as of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil were analysed. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Crops were planted after a plant back interval of 28±2 days. Two rotational crop field trials were conducted in radish, leaf lettuce and barley during 2021, one in Germany (S21-00408-01), and one in Southern France (S21-00408-02).

Residues of prothioconazole (mg/kg) (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

Regarding TDMs, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) in untreated samples were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).
- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.
- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

The freezer storage period of all crop samples was 96 – 105 days for barley grain, 98 - 107 days for barley straw, 141 - 145 days for barley forage, 158 - 165 days for lettuce, 164 - 178 days for radish roots and 169 – 182 days for radish leaves. Therefore, analysis occurred within the acceptable freezer storage stability for 1,2,4-T of 6 months for high water content crops and 12 months for cereal grain and straw. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days.

Conclusion on rotational crops studies

Regarding prothioconazole-desthio (sum of isomers), no study dealing with the magnitude of these residues in succeeding crops is required.

Regarding the TDMs, the application rates used in the rotational crops trials evaluated in UK, 2018b cover the envisaged critical GAPs.

Therefore, any further data investigating the magnitude of prothioconazole residues in rotational crops are not considered to be required.

However, the peer review of TDMs identified a data gap for prothioconazole related to the submission of rotational crop field residue trials supported by acceptable storage stability data on TDMs (EFSA, 2018b). Therefore, two new rotational crop studies comprising six trials in total and covering all metabolites of the residue definition for risk assessment of prothioconazole in plants have been conducted. Derived STMRs and HRs for all four TDMs from the six trials are presented in the following. The detailed assessments of these studies are presented in Appendix 2.

Table 7.2- 27: Overview of the STMRs/HRs of 1,2,4-T in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) (n=6) | | PBI 120 (KCA 6.6.2/01) (n=4) | | PBI 270 (KCA 6.6.2/01) (n=4) | |
|----------------|--------------------------------------|------|------------------------------|------|------------------------------|------|
| Commodity | STMR | HR | STMR | HR | STMR | HR |
| Radish leaves | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Radish roots | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Lettuce leaves | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Barley grain | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Barley straw | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |

Table 7.2- 28: Overview of the STMRs/HRs of TA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) (n=6) | | PBI 120 (KCA 6.6.2/01) (n=4) | | PBI 270 (KCA 6.6.2/01) (n=4) | |
|---------------|--------------------------------------|------|------------------------------|------|------------------------------|------|
| Commodity | STMR | HR | STMR | HR | STMR | HR |
| Radish leaves | 0.11 | 0.27 | 0.08 | 0.14 | 0.095 | 0.22 |

| | PBI 30 (KCA 6.6.2/01 & /02) (n=6) | | PBI 120 (KCA 6.6.2/01) (n=4) | | PBI 270 (KCA 6.6.2/01) (n=4) | |
|----------------|--------------------------------------|-------------|------------------------------|-------------|------------------------------|------|
| Commodity | STMR | HR | STMR | HR | STMR | HR |
| Radish roots | 0.04 | 0.12 | 0.04 | 0.05 | 0.06 | 0.07 |
| Lettuce leaves | 0.015 | 0.03 | 0.01 | 0.02 | 0.01 | 0.02 |
| Barley grain | 0.225 | 0.82 | 0.195 | 0.28 | 0.155 | 0.28 |
| Barley straw | 0.03 | 0.04 | 0.02 | 0.05 | 0.025 | 0.04 |

Table 7.2- 29: Overview of the STMRs/HRs of TAA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) (n=6) | | PBI 120 (KCA 6.6.2/01) (n=4) | | PBI 270 (KCA 6.6.2/01) (n=4) | |
|----------------|--------------------------------------|-------------|------------------------------|------|------------------------------|------|
| Commodity | STMR | HR | STMR | HR | STMR | HR |
| Radish leaves | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Radish roots | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Lettuce leaves | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| Barley grain | 0.235 | 0.57 | 0.19 | 0.29 | 0.145 | 0.32 |
| Barley straw | 0.09 | 0.40 | 0.09 | 0.24 | 0.105 | 0.20 |

Table 7.2- 30: Overview of the STMRs/HRs of TLA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) (n=6) | | PBI 120 (KCA 6.6.2/01) (n=4) | | PBI 270 (KCA 6.6.2/01) (n=4) | |
|----------------|--------------------------------------|--------------------|------------------------------|------|------------------------------|------|
| Commodity | STMR | HR | STMR | HR | STMR | HR |
| Radish leaves | 0.01 | 0.13 | 0.015 | 0.05 | 0.02 | 0.05 |
| Radish roots | 0.01 | 0.02 | 0.01 | 0.02 | 0.01 | 0.02 |
| Lettuce leaves | 0.07 | <u>0.19</u> | 0.07 | 0.12 | 0.065 | 0.1 |
| Barley grain | 0.01 | 0.04 | 0.01 | 0.01 | 0.01 | 0.02 |
| Barley straw | 0.09 | 0.45 | 0.13 | 0.21 | 0.10 | 0.27 |

Underlined value used in consumer RA as higher than the value of 0.14 mg/kg used for leafy vegetables in TDM peer review in the light of confirmatory data submitted (UK, 2018b).

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

Prothioconazole

No residues are expected in rotational crops for the intended uses of ADM.03500.F.2.B, so additional field rotational crop studies are not considered required.

TDMs

Regarding TDMs, rotational crop studies were considered by the UK in the assessment of confirmatory data on TDMs (the UK, 2018).

According to the EU peer review (EFSA, 2018): “Residue trials analysing for all TDMs and compliant with the representative uses on cereals (wheat, rye, barley, oats, triticale) and on rapeseeds together with rotational crops residue field trials were submitted in the framework of this confirmatory data assessment but were not supported by acceptable storage stability data for 1,2,4-T in cereal grain, straw and rapeseeds and for TLA in straw. Sufficient residue trials in primary and rotational crops and supported by acceptable storage stability data are therefore required (data gap).”

The following data gaps were identified for prothioconazole as outlined in section 3 of the peer review conclusion: 14) Residue trials analysing for all TDMs and compliant with the representative use on cereals (wheat, rye, barley, oats, triticale) and on oilseed rapeseeds and supported by acceptable storage stability data on TDMs (prothioconazole).

15) Rotational crops field residue trials supported by acceptable storage stability data on TDMs (prothioconazole).

The applicant provided two rotational crop studies to address the data gap identified in the EFSA peer review.

1. Semrau, J., 2021; Study no.: S18-02513

Four rotational crop field trials were performed in the Northern (two) and Southern (two) residue zone to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L) with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) on bare soil.

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

The trials included analysis of the triazole derivative metabolites.

Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively.

However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

As the analysis of 1,2,4-T was not conducted within the demonstrated stability period in the trials performed in 2018-2019, these were repeated in 2020-2021.

2. Semrau, J., 2022; Study no.: S21-00408

The study (contained two rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B; EC formulation containing 250 g prothioconazole/L) with a target rate of 1.2 L product/ha (300 g prothioconazole /ha) on bare soil. Each trial comprised one plant back interval of 28±2 days.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites and prothioconazole triazole derivative metabolites was 182 days and 92 days, respectively. Sufficient stability data are available to support the residue data presented in this study.

Results from the second study confirmed the findings of the first study (KCA 6.6.2/01); all residues of 1,2,4-T were <0.01 mg/kg in treated and control samples. Other TDMs were also in a similar range, being <0.01 - 0.82 mg/kg for TA, <0.01 - 0.14 mg/kg for TAA and <0.01 - 0.46 mg/kg for TLA. Again, some control samples also contained residues of TA, TAA and TLA but generally at lower levels than in treated samples.

No additional data are required.

7.2.7 Other / special studies (KCA 6.10, 6.10.1)

Regarding potential residues in honey and other apiculture products, the following is to be said:

Prothioconazole is a systemic fungicide applied as a spray at BBCH 30 - 69 in spring and winter wheat, winter rye and triticale, at BBCH 30 - 65 spring and winter barley and oat and at BBCH 50 - 73 in oilseed rape.

Any residues in pollen and bee products collected from treated crops are not to be expected for cereals as these crops have no melliferous capacity.

In contrast, oilseed rape is a melliferous crop foraged by bees and application is foreseen during flowering. Therefore, to address potential residues in honey and other apiculture products relevant for human consumption exceeding the current EU-MRL for prothioconazole of 0.05 mg/kg, new studies determining residues in Phacelia flowers, pollen and nectar have been conducted.

Four new studies determining residues in Phacelia flowers, pollen and nectar after application of prothioconazole containing formulations and covering the envisaged GAPs in oilseed rape (within 25% range) are available and provided with this submission. The studies were conducted in Germany and Spain. Results are summarised in the table below. The detailed assessments of these studies are presented in Appendix 2.

| Sampling time | Mean residues [mg/kg] (3 tunnels) | | | | | |
|--------------------------------|-----------------------------------|-------------------------|-----------------|-------------------------|-------------------------|-------------------------------|
| | Flowers | | Pollen | | Nectar | |
| | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio |
| New data | | | | | | |
| KCA 6.10.1/01 (Germany) | | | | | | |
| DAT 0 | 6.87 | 4.83 | 10.03 | 1.77 | 0.09 | 0.03 |
| DAT 2 | 0.71 | 4.27 | - | - | - | - |
| DAT 4 | - | - | < 0.01 - 0.01 | 0.29 | < 0.003 | 0.02 |
| DAT 7 | 0.02 | 0.64 | < 0.01 - 0.01 | 0.16 | < 0.003 | < 0.01 |
| DAT 10 | < 0.01 - 0.01 | 0.44 | 0.01 | 0.22 | < 0.003 | < 0.003 |
| KCA 6.10.1/02 (Spain) | | | | | | |
| DAT 0 | 3.9 | 7.5 | 34.33 | 6.17 | 0.15 | 0.06 |
| DAT 3 | 0.17 | 3.53 | 0.19 | 1.77 | < 0.003 | < 0.01 |
| DAT 7 | 0.01 | 0.92 | < 0.01 - 0.03 | 0.96 | < 0.003 | < 0.003 - < 0.01 |
| DAT 10 | < 0.003 | 0.31 | < 0.01 - 0.02 | 0.57 | < 0.003 | < 0.003 |
| KCA 6.10.1/03 (Germany) | | | | | | |
| DAT 0 | 12.33 | 4.23 | 27.83 | 2.43 | 0.21 | 0.06 |
| DAT 3 | 2.93 | 3.83 | 0.26 | 0.58 | < 0.01 - 0.01 | < 0.003 - 0.01 |
| DAT 7 | 0.16 | 0.51 | 0.14 | 0.50 | < 0.003 | < 0.003 |
| DAT 10 | 0.05 | 0.21 | 0.12 | 0.35 | < 0.003 | < 0.003 |
| KCA 6.10.1/04 (Spain) | | | | | | |
| DAT 0 | 4.77 | 7.13 | 50.33 | 4.13 | 0.08 | 0.03 |
| DAT 3 | 0.21 | 2.73 | 0.15 | 0.39 | < 0.003 | < 0.01 |
| DAT 7 | 0.14 | 0.89 | 0.04 | 0.24 | < 0.003 | < 0.003 |
| DAT 10 | < 0.01 - 0.01 | 0.30 | < 0.01 - 0.01 | 0.16 | < 0.003 | < 0.003 |

[illegible]

- (1) **DAA:** Days After Application
 - (2) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α -OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)
 - (3) **For each compound:**
 - LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio
 - LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio
- For the sum:**
- LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio
 - LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

Residue results of study KCA 6.10.1/05 for TDMs in honey are summarised in the following table:

Table 7.2- 33: Summary of the TDM residues in honey

| Trial | Matrix | Actual DAA | Residue results (mg/kg) | | | |
|---------------|--------------|------------|-------------------------|----------------------|------------------|----------------------|
| | | | 1,2,4-Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid |
| 555-2021 FR01 | Mature Honey | 10 | <LOD | <LOQ | <LOQ | <LOD |
| 555-2021 GE02 | Mature Honey | 7 | <LOD | <LOQ | <LOD | 0.02 |
| 555-2021 DK03 | Mature Honey | 14 | <LOD | <LOD | <LOQ | <LOD |
| 555-2021 IT04 | Mature Honey | 14 | <LOD | <LOD | <LOD | <LOQ |

DAA: Days After Application

LOQ = 0.01 mg/kg and LOD = 0.003 mg/kg for each analyte

Conclusion on residues in flowers, pollen, nectar and honey

According to EC TG SANTE/11956/2016 rev. 9 (14/09/2018), residue data in aerial parts of the crop can be used for extrapolation to honey. Instead of the relevant crop (oilseed rape), phacelia can be used representing a worst case in terms of residues in honey.

Residues of prothioconazole-desthio found in nectar at 0 days after application are not considered relevant for honey as honey is usually sampled at 7 to 14 days after application. Therefore, it is reasonable to assume significant dilution of residues in honey when residues in nectar are ≤ 0.05 mg/kg at 3 days after application. As residues of prothioconazole-desthio in nectar in the available studies do not exceed the EU-MRL of 0.05 mg/kg for honey at 3 to 10 DAT, any risk for consumer from the consumption of honey from plants (oilseed rape) treated according to the envisaged GAP uses is not to be expected.

This is confirmed by the residue data determined directly in honey: Any residues of prothioconazole expressed as prothioconazole-desthio have not been found in mature honey. All residues were found to be below the LOD of 0.003 mg/kg for each compound and thus do not exceed the EU-MRL of 0.05 mg/kg for honey.

Residues of TDMs in mature honey were found to be below the LOQ of 0.01 mg/kg for each compound except for TLA in one trial, where low residues were found at 0.02 mg/kg with a similar level observed in the control sample.

zRMS comments:

Information given by the Applicant is acceptable and sufficient.

According to SANTE/11956/2016 rev. 9, oilseed rape is considered as melliferous crops. As prothioconazole is proposed to be applied during the flowering stage (BBCH 60-69) and since the active substance is systemic, effects on the residue level in pollen and bee products have been investigated.

The Applicant submitted an additional study (4 trials) to determine residues of prothioconazole-desthio, its hydroxy metabolites and TDMs in Phacelia honey specimens following one foliar application of the formulated product

ADM.03500.F.2.B (prothioconazole 250 g/L; with a nominal concentration of 250 g/L of prothioconazole applied at the target dose rate of 200 g a.s./ha) to Phacelia grown in tunnels.

Any residues of prothioconazole expressed as prothioconazole-desthio have not been found in mature honey. Residues of TDMs in mature honey were below the LOQ of 0.01 mg/kg for each compound except for TLA in one trial, where low residues were found at 0.02 mg/kg with similar level in the control sample. Available results show that the in force MRL of prothioconazole on honey of 0.05 mg/kg (Reg. (EU) 2019/552) will not be exceeded.

Four new ecotoxicological studies in honey bee colonies have been submitted by Applicant. Results of ecotoxicological studies confirmed the above conclusion. In these studies, residues of prothioconazole and prothioconazole-desthio were measured in flower, pollen and nectar. The levels of residues in nectar were below the LOQ after 3, 7 and 10 days of application in all trials.

More details of the residue study in honey, nectar, pollen and flowers of Phacelia ~~plants of oilseed rape~~ are provided in Appendix 2.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Prothioconazole except TDMs

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

Toxicological reference values for prothioconazole-desthio relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

The existing EU MRLs are set according to the residue definition for monitoring of prothioconazole: prothioconazole-desthio (sum of isomers).

For the calculation of chronic exposure, input values as given in Appendix D.2. of EFSA 2020 were used for plant and animal commodities except for dry beans and peanuts (values from EFSA 2014 were used). For wheat, barley, oat, rye and oilseed rape for which new GAPs are envisaged in this dossier, median residues according to the residue definition for risk assessment as derived from the submitted residue trials were used if values used in EFSA 2020 were exceeded. For all other commodities of plant origin the current EU-MRLs (last update Reg. (EU) No 2019/552) and the corresponding conversion factor of 2 for risk assessment were used as input values.

The input values used for the dietary exposure calculation are summarised under 7.2.8.1 below.

TDMs

Consumer exposure assessments for all four TDMs have been conducted by UK, 2018b and EFSA 2018b during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. Input values were derived from the UK, 2018b evaluation.

In addition, new worst case calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies submitted with this dossier if higher were conducted.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

Toxicological reference values for 1,2,4-triazole (1,2,4-T), triazole alanine (TA) and triazole acetic acid (TAA) relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

Any MRLs have not been set for the triazole derivative metabolites at EU-level yet.

The input values used for the dietary exposure calculation are summarised under 7.2.8.1 below.

7.2.8.1 Input values for the consumer risk assessment Prothioconazole except TDMs

Table 7.2- 34: Input values for the consumer risk assessment (according to EFSA, 2020 and new trials submitted)

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|--|-------------------------|--|-----------------------|---|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition in plant commodities: Sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers) | | | | |
| Celeriac | 0.08 | STMR (EFSA 2020) | | |
| Beetroots, carrots, horseradish, parsnips, parsley roots, salsifies, swedes, turnips | 0.08 | STMR (EFSA 2020) | | |
| Rape seed | 0.08 | STMR (EFSA 2020) | 0.08 | STMR (EFSA 2020) |
| Rape seed (<i>new</i>) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 14, but covered by higher input value used in EFSA 2020 in the line above) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 14 but covered by higher input value used in EFSA 2020 in the line above) |
| Cranberries | 0.025 | STMR ^(a) (FAO, 2014) (EFSA 2020) | | |
| Potatoes | 0.01 | STMR (EFSA, 2014) (EFSA 2020) | | |
| Sweet corn | 0.018 | STMR ^(a) (FAO, 2014) (EFSA 2020) | | |
| Onions, shallots | 0.02 | STMR (EFSA, 2014, 2015a) × CF (2) (EFSA 2020) | | |
| Flowering brassica | 0.02 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Brussels sprouts | 0.06 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Head cabbage | 0.02 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Leeks | 0.02 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Beans (dry) | 0.10 | STMR × CF (2) (EFSA, 2014) (EFSA 2014) | | |
| Lentils, peas, lupins (dry) | 0.10 | STMR ^(a) (FAO, 2009b) × CF (2) (EFSA 2020) | | |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|--|-------------------------|--|---|--|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Linseeds, poppy seeds, mustard seeds | 0.06 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Gold of pleasure seeds | 0.02 | STMR × CF (2) (EFSA, 2014) (EFSA 2020) | | |
| Peanuts | 0.04 | STMR (FAO, 2009b) × CF (2) (EFSA 2014) | | |
| Sunflower seeds | 0.02 | STMR (EFSA, 2015b) × CF (2) (EFSA 2020) | | |
| Cotton seed | 0.1 | STMR (FAO, 2018) × CF × 2 (EFSA 2020) | | |
| Soybean | 0.1 | STMR (FAO, 2014) × CF (2) (EFSA 2020) | | |
| Barley grain | 0.07 | STMR ^(a) (FAO, 2009b) × CF (2) (EFSA 2020) | 0.07 | STMR ^(a) (FAO, 2009b) × CF (2) |
| Barley grain (<i>new</i>) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, but covered by higher input value used in EFSA 2020 in the line above) |
| Maize grain | 0.02 | STMR ^(a) (FAO, 2014) × CF (2) (EFSA 2020) | | |
| Oat, rye grain | 0.02 | STMR ^(a) (FAO, 2009a) × CF (2) (EFSA 2020) | 0.02 | STMR ^(a) (FAO, 2009a) × CF (2) |
| Oat grain (<i>new</i>) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 12, extrapolated from barley) |
| Rye grain (<i>new</i>) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10, extrapolated from wheat) |
| Wheat grain | 0.04 | STMR ^(a) (FAO, 2009b) × CF (2) (EFSA 2020) | 0.04 | STMR ^(a) (FAO, 2009b) × CF (2) |
| Wheat grain (<i>new</i>) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10) | 0.06 | STMR (new trials submitted, refer to Table 7.2- 10) |
| Other commodities of plant origin | EU-MRL × CF (2) | Annexes II and IIIB of Regulation (EC) No 396/2005 (last update Comm. Reg. (EU) No 2019/552) | Acute risk assessment was undertaken only with regard to the crops under consideration. | |
| Muscle of swine, bovine, sheep, goat, equine, other farmed animals | 0.01 | STMR ^(b) (FAO, 2018) (EFSA 2020) | 0.01 | HR ^(b) (FAO, 2018) (EFSA 2020) |
| Fat of swine, bovine, sheep, goat, equine, other farmed animals | 0.01 | STMR ^(b) (FAO, 2018) (EFSA 2020) | 0.018 | HR ^(b) (FAO, 2018) (EFSA 2020) |
| Liver of swine, bovine, sheep, goat, equine, other farmed animals | 0.05 | STMR ^(b) (FAO, 2009b) (EFSA 2020) | 0.23 | HR ^(b) (FAO, 2009b) (EFSA 2020) |

| Commodity | Chronic risk assessment | | Acute risk assessment | |
|--|-------------------------|--|-----------------------|--|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Kidney, edible offal of swine, bovine, sheep, goat, equine, other farmed animals | 0.025 | STMR ^(b) (FAO, 2009b) (EFSA 2020) | 0.15 | HR ^(b) (FAO, 2009b) (EFSA 2020) |
| Muscle of poultry | 0.0016 | STMR ^(b) (FAO, 2018) (EFSA 2020) | 0.0016 | HR ^(b) (FAO, 2018) (EFSA 2020) |
| Fat of poultry | 0.008 | STMR ^(b) (FAO, 2018) (EFSA 2020) | 0.008 | HR ^(b) (FAO, 2018) (EFSA 2020) |
| Liver, kidney, edible offal of poultry | 0.071 | STMR ^(b) (FAO, 2018) (EFSA 2020) | 0.071 | HR ^(b) (FAO, 2018) (EFSA 2020) |
| Milks | 0.005 | STMR (EFSA, 2014) (EFSA 2020) | 0.005 | HR (EFSA, 2014) (EFSA 2020) |
| Eggs | 0.01 | STMR (EFSA, 2014) (EFSA 2020) | 0.01 | HR (EFSA, 2014) (EFSA 2020) |

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.

(a): Values refer to the residues of prothioconazole-desthio; data according to EU risk assessment residue definition not available.

(b): Values refer to the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio.

TDMs

Consumer exposure assessments for all four TDMs have been conducted by UK, 2018b and EFSA 2018b during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. Input values were selected according to the following criteria:

EFSA 2018b: "...a 'worst-case' consumer exposure assessment to the TDMs has been carried out in this conclusion taking into consideration the highest residue input values for risk assessment from all the individual residue data sets for plant commodities and the highest residue levels of each TDM arising in products of animal origin from the triazole active substances and from each of the TDMs. [...] The magnitude of the TDMs have been determined in numerous residue trials conducted on crops covering most of the crop categories and for different triazole active substances both in primary and rotational crops. These trials were submitted in the framework of the confirmatory data (United Kingdom, 2015). The submitted residue trials were performed according to specific good agricultural practices (GAPs) authorised for the triazole active substances and residue trials conducted outside Europe were also available. In some cases, these residue trials were compliant with the representative uses of triazole active substances that were approved at EU level. All the residue trials that were used to perform the consumer dietary intake assessment involve only the use of a single triazole active substance, these residue trials do not reflect the situation where several different triazole active substances may be applied on a crop during the same growing season or from treatments with triazole active substances during the previous seasons. However, it is noted that significant residue levels were often found in untreated control samples of residue trials on primary and rotational crops suggesting the use of triazole pesticide active substances in previous seasons. Despite these uncertainties, the experts were of the opinion that these trials should be considered with the purpose of performing a 'worst case' consumer dietary intake calculation. It was, however, emphasised that residue trials analysing all TDMs and compliant with the European authorised uses should be provided in order to conduct a realistic consumer dietary risk assessment and also the need for monitoring data on the occurrence and background levels of all TDMs in plants. For each commodity the input residue values for risk assessment (supervised trials median residues (STMR) and the supervised trials highest residues (HR)) were calculated based on all the residue trials conducted with the same active substance on this commodity

and for a commodity group, the highest STMR and HR values derived from all the individual data sets have been applied to each crop within the commodity group in order to conduct the ‘worst-case’ consumer dietary intake calculation.”

In addition, new calculations for 1,2,4-triazole (1,2,4-T), triazole alanine (TA) and triazole acetic acid (TAA) involving the residue data of the new residue studies submitted with this dossier were conducted. However, residues from new trials submitted were covered by input values used during TDM EU peer review (UK, 2018b) for all four TDMs except for residues in lettuce leaves from rotational crops, which showed a HR of 0.19 mg/kg TLA in new trials exceeding 0.14 mg/kg used in TDM EU peer review.

Table 7.2- 35: 1,2,4-Triazole (T): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--------------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 110010 | Grapefruits | | | 0.05 | STMR-RAC | | |
| 110020 | Oranges | | | 0.05 | STMR-RAC | | |
| 110030 | Lemons | | | 0.05 | STMR-RAC | | |
| 110040 | Limes | | | 0.05 | STMR-RAC | | |
| 110050 | Mandarins | | | 0.05 | STMR-RAC | | |
| 110990 | Other citrus fruit | | | 0.05 | STMR-RAC | | |
| 130010 | Apples | | | 0.01 | STMR-RAC | | |
| 130020 | Pears | | | 0.01 | STMR-RAC | | |
| 130030 | Quinces | | | 0.01 | STMR-RAC | | |
| 130040 | Medlar | | | 0.01 | STMR-RAC | | |
| 130050 | Loquats/Japanese medlars | | | 0.01 | STMR-RAC | | |
| 130990 | Other pome fruit | | | 0.01 | STMR-RAC | | |
| 140010 | Apricots | | | 0.01 | STMR-RAC | | |
| 140020 | Cherries (sweet) | | | 0.01 | STMR-RAC | | |
| 140030 | Peaches | | | 0.01 | STMR-RAC | | |
| 140040 | Plums | | | 0.01 | STMR-RAC | | |
| 140990 | Other stone fruit | | | 0.01 | STMR-RAC | | |
| 151010 | Table grapes | | | 0.01 | STMR-RAC | | |
| 151020 | Wine grapes | | | 0.01 | STMR-RAC | | |
| 152000 | Strawberries | | | 0.01 | STMR-RAC | | |
| 153010 | Blackberries | | | 0.01 | STMR-RAC | | |
| 153020 | Dewberries | | | 0.01 | STMR-RAC | | |
| 153030 | Raspberries (red and yellow) | | | 0.01 | STMR-RAC | | |
| 153990 | Other cane fruit | | | 0.01 | STMR-RAC | | |
| 154010 | Blueberries | | | 0.01 | STMR-RAC | | |
| 154020 | Cranberries | | | 0.01 | STMR-RAC | | |
| 154030 | Currants (red, black and white) | | | 0.01 | STMR-RAC | | |
| 154040 | Gooseberries (green, red and yellow) | | | 0.01 | STMR-RAC | | |
| 154050 | Rose hips | | | 0.01 | STMR-RAC | | |
| 154060 | Mulberries (black and white) | | | 0.01 | STMR-RAC | | |
| 154070 | Azarole/Mediterranean medlar | | | 0.01 | STMR-RAC | | |
| 154080 | Elderberries | | | 0.01 | STMR-RAC | | |
| 154990 | Other other small fruit & berries | | | 0.01 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|---|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 163020 | Bananas | | | 0.05 | STMR-RAC | | |
| 211000 | Potatoes | | | 0.01 | STMR-RAC | | |
| 212010 | Cassava roots/manioc | | | 0.01 | STMR-RAC | | |
| 212020 | Sweet potatoes | | | 0.01 | STMR-RAC | | |
| 212030 | Yams | | | 0.01 | STMR-RAC | | |
| 212040 | Arrowroots | | | 0.01 | STMR-RAC | | |
| 212990 | Other tropical root and tuber vegetables | | | 0.01 | STMR-RAC | | |
| 213010 | Beetroots | | | 0.01 | STMR-RAC | | |
| 213020 | Carrots | | | 0.01 | STMR-RAC | | |
| 213030 | Celeriacs/turnip rooted celeries | | | 0.01 | STMR-RAC | | |
| 213040 | Horseradishes | | | 0.01 | STMR-RAC | | |
| 213050 | Jerusalem artichokes | | | 0.01 | STMR-RAC | | |
| 213060 | Parsnips | | | 0.01 | STMR-RAC | | |
| 213070 | Parsley roots/Hamburg roots parsley | | | 0.01 | STMR-RAC | | |
| 213080 | Radishes | | | 0.01 | STMR-RAC | | |
| 213090 | Salsifies | | | 0.01 | STMR-RAC | | |
| 213100 | Swedes/rutabagas | | | 0.01 | STMR-RAC | | |
| 213110 | Turnips | | | 0.01 | STMR-RAC | | |
| 213990 | Other other root and tuber vegetables | | | 0.01 | STMR-RAC | | |
| 220010 | Garlic | | | 0.01 | STMR-RAC | | |
| 220020 | Onions | | | 0.01 | STMR-RAC | | |
| 220030 | Shallots | | | 0.01 | STMR-RAC | | |
| 220040 | Spring onions/green onions and Welsh onions | | | 0.01 | STMR-RAC | | |
| 220990 | Other bulb vegetables | | | 0.01 | STMR-RAC | | |
| 231010 | Tomatoes | | | 0.01 | STMR-RAC | | |
| 231020 | Sweet peppers/bell peppers | | | 0.01 | STMR-RAC | | |
| 231030 | Aubergines/egg plants | | | 0.01 | STMR-RAC | | |
| 231040 | Okra/lady's fingers | | | 0.01 | STMR-RAC | | |
| 231990 | Other solanacea | | | 0.01 | STMR-RAC | | |
| 232010 | Cucumbers | | | 0.01 | STMR-RAC | | |
| 232020 | Gherkins | | | 0.01 | STMR-RAC | | |
| 232030 | Courgettes | | | 0.01 | STMR-RAC | | |
| 232990 | Other cucurbits - edible peel | | | 0.01 | STMR-RAC | | |
| 233010 | Melons | | | 0.01 | STMR-RAC | | |
| 233020 | Pumpkins | | | 0.01 | STMR-RAC | | |
| 233030 | Watermelons | | | 0.01 | STMR-RAC | | |
| 233990 | Other cucurbits - inedible peel | | | 0.01 | STMR-RAC | | |
| 234000 | Sweet corn | | | 0.01 | STMR-RAC | | |
| 241010 | Broccoli | | | 0.039 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 241020 | Cauliflowers | | | 0.039 | STMR-RAC | | |
| 241990 | Other flowering brassica | | | 0.039 | STMR-RAC | | |
| 242010 | Brussels sprouts | | | 0.039 | STMR-RAC | | |
| 242020 | Head cabbages | | | 0.039 | STMR-RAC | | |
| 242990 | Other head brassica | | | 0.039 | STMR-RAC | | |
| 243010 | Chinese cabbages/pe- tsai | | | 0.039 | STMR-RAC | | |
| 243020 | Kales | | | 0.039 | STMR-RAC | | |
| 243990 | Other leafy brassica | | | 0.039 | STMR-RAC | | |
| 244000 | Kohlrabies | | | 0.039 | STMR-RAC | | |
| 251010 | Lamb's lettuce/corn salads | | | 0.015 | STMR-RAC | | |
| 251020 | Lettuces | | | 0.015 | STMR-RAC | | |
| 251030 | Escaroles/broad- leaved endives | | | 0.015 | STMR-RAC | | |
| 251040 | Cress and other sprouts and shoots | | | 0.015 | STMR-RAC | | |
| 251050 | Land cress | | | 0.015 | STMR-RAC | | |
| 251060 | Roman rocket/rucola | | | 0.015 | STMR-RAC | | |
| 251070 | Red mustards | | | 0.015 | STMR-RAC | | |
| 251080 | Baby leaf crops (including brassica species) | | | 0.015 | STMR-RAC | | |
| 251990 | Other lettuce and other salad plants | | | 0.015 | STMR-RAC | | |
| 252010 | Spinaches | | | 0.015 | STMR-RAC | | |
| 252020 | Purslanes | | | 0.015 | STMR-RAC | | |
| 252030 | Chards/beet leaves | | | 0.015 | STMR-RAC | | |
| 252990 | Other spinach and similar | | | 0.015 | STMR-RAC | | |
| 253000 | Grape leaves and similar species | | | 0.015 | STMR-RAC | | |
| 254000 | Watercress | | | 0.015 | STMR-RAC | | |
| 255000 | Witloofs/Belgian endives | | | 0.015 | STMR-RAC | | |
| 256010 | Chervil | | | 0.015 | STMR-RAC | | |
| 256020 | Chives | | | 0.015 | STMR-RAC | | |
| 256030 | Celery leaves | | | 0.015 | STMR-RAC | | |
| 256040 | Parsley | | | 0.015 | STMR-RAC | | |
| 256050 | Sage | | | 0.015 | STMR-RAC | | |
| 256060 | Rosemary | | | 0.015 | STMR-RAC | | |
| 256070 | Thyme | | | 0.015 | STMR-RAC | | |
| 256080 | Basil and edible flowers | | | 0.015 | STMR-RAC | | |
| 256090 | Laurel/bay leaves | | | 0.015 | STMR-RAC | | |
| 256100 | Tarragon | | | 0.015 | STMR-RAC | | |
| 256990 | Other herbs | | | 0.015 | STMR-RAC | | |
| 260010 | Beans (with pods) | | | 0.01 | STMR-RAC | | |
| 260020 | Beans (without pods) | | | 0.01 | STMR-RAC | | |
| 260030 | Peas (with pods) | | | 0.01 | STMR-RAC | | |
| 260040 | Peas (without pods) | | | 0.01 | STMR-RAC | | |
| 260050 | Lentils (fresh) | | | 0.01 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|------------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 260990 | Other legume vegetables (fresh) | | | 0.01 | STMR-RAC | | |
| 270010 | Asparagus | | | 0.01 | STMR-RAC | | |
| 270020 | Cardoons | | | 0.01 | STMR-RAC | | |
| 270030 | Celeries | | | 0.01 | STMR-RAC | | |
| 270040 | Florence fennels | | | 0.01 | STMR-RAC | | |
| 270050 | Globe artichokes | | | 0.01 | STMR-RAC | | |
| 270060 | Leeks | | | 0.01 | STMR-RAC | | |
| 270070 | Rhubarbs | | | 0.01 | STMR-RAC | | |
| 270080 | Bamboo shoots | | | 0.01 | STMR-RAC | | |
| 270090 | Palm hearts | | | 0.01 | STMR-RAC | | |
| 270990 | Other stem vegetables | | | 0.01 | STMR-RAC | | |
| 300010 | Beans | | | 0.05 | STMR-RAC | | |
| 300020 | Lentils | | | 0.05 | STMR-RAC | | |
| 300030 | Peas | | | 0.05 | STMR-RAC | | |
| 300040 | Lupins/lupini beans | | | 0.05 | STMR-RAC | | |
| 300990 | Other pulses | | | 0.05 | STMR-RAC | | |
| 401010 | Linseeds | | | 0.05 | STMR-RAC | | |
| 401020 | Peanuts/groundnuts | | | 0.05 | STMR-RAC | | |
| 401030 | Poppy seeds | | | 0.05 | STMR-RAC | | |
| 401040 | Sesame seeds | | | 0.05 | STMR-RAC | | |
| 401050 | Sunflower seeds | | | 0.05 | STMR-RAC | | |
| 401060 | Rapeseeds/canola seeds | | | 0.05 | STMR-RAC | 0.05 | STMR-RAC |
| 401070 | Soyabeans | | | 0.05 | STMR-RAC | | |
| 401080 | Mustard seeds | | | 0.05 | STMR-RAC | | |
| 401090 | Cotton seeds | | | 0.05 | STMR-RAC | | |
| 401100 | Pumpkin seeds | | | 0.05 | STMR-RAC | | |
| 401110 | Safflower seeds | | | 0.05 | STMR-RAC | | |
| 401120 | Borage seeds | | | 0.05 | STMR-RAC | | |
| 401130 | Gold of pleasure seeds | | | 0.05 | STMR-RAC | | |
| 401140 | Hemp seeds | | | 0.05 | STMR-RAC | | |
| 401150 | Castor beans | | | 0.05 | STMR-RAC | | |
| 401990 | Other oilseeds | | | 0.05 | STMR-RAC | | |
| 402010 | Olives for oil production | | | 0.05 | STMR-RAC | | |
| 402020 | Oil palm kernels | | | 0.05 | STMR-RAC | | |
| 402030 | Oil palm fruits | | | 0.05 | STMR-RAC | | |
| 402040 | Kapok | | | 0.05 | STMR-RAC | | |
| 402990 | Other oilfruit | | | 0.05 | STMR-RAC | | |
| 500010 | Barley | | | 0.05 | STMR-RAC | 0.05 | STMR-RAC |
| 500020 | Buckwheat and other pseudo-cereals | | | 0.05 | STMR-RAC | | |
| 500030 | Maize/corn | | | 0.05 | STMR-RAC | | |
| 500040 | Common millet/proso millet | | | 0.05 | STMR-RAC | | |
| 500050 | Oat | | | 0.05 | STMR-RAC | 0.05 | STMR-RAC |
| 500060 | Rice | | | 0.05 | STMR-RAC | | |
| 500070 | Rye | | | 0.05 | STMR-RAC | 0.05 | STMR-RAC |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ⁽¹⁾ | | Acute risk assessment ⁽²⁾ | |
|---------|--|------------------------------|---------------------------|--|----------|--------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 500080 | Sorghum | | | 0.05 | STMR-RAC | | |
| 500090 | Wheat | | | 0.05 | STMR-RAC | 0.05 | STMR-RAC |
| 500990 | Other cereals | | | 0.05 | STMR-RAC | | |
| 900010 | Sugar beet roots | | | 0.05 | STMR-RAC | | |
| 900020 | Sugar canes | | | 0.05 | STMR-RAC | | |
| 900030 | Chicory roots | | | 0.05 | STMR-RAC | | |
| 900990 | Other sugar plants | | | 0.05 | STMR-RAC | | |
| 1011010 | Swine: Muscle/meat | | | 0.12 | STMR-RAC | 0.21 | HR-RAC |
| 1011020 | Swine: Fat tissue | | | 0.1 | STMR-RAC | 0.16 | HR-RAC |
| 1011030 | Swine: Liver | | | 0.12 | STMR-RAC | 0.19 | HR-RAC |
| 1011040 | Swine: Kidney | | | 0.13 | STMR-RAC | 0.25 | HR-RAC |
| 1012010 | Bovine: Muscle/meat | | | 0.16 | STMR-RAC | 0.24 | HR-RAC |
| 1012020 | Bovine: Fat tissue | | | 0.12 | STMR-RAC | 0.19 | HR-RAC |
| 1012030 | Bovine: Liver | | | 0.19 | STMR-RAC | 0.25 | HR-RAC |
| 1012040 | Bovine: Kidney | | | 0.2 | STMR-RAC | 0.28 | HR-RAC |
| 1013010 | Sheep: Muscle/meat | | | 0.16 | STMR-RAC | 0.24 | HR-RAC |
| 1013020 | Sheep: Fat tissue | | | 0.12 | STMR-RAC | 0.19 | HR-RAC |
| 1013030 | Sheep: Liver | | | 0.19 | STMR-RAC | 0.25 | HR-RAC |
| 1013040 | Sheep: Kidney | | | 0.2 | STMR-RAC | 0.28 | HR-RAC |
| 1014010 | Goat: Muscle/meat | | | 0.16 | STMR-RAC | 0.24 | HR-RAC |
| 1014020 | Goat: Fat tissue | | | 0.12 | STMR-RAC | 0.19 | HR-RAC |
| 1014030 | Goat: Liver | | | 0.19 | STMR-RAC | 0.25 | HR-RAC |
| 1014040 | Goat: Kidney | | | 0.2 | STMR-RAC | 0.28 | HR-RAC |
| 1016010 | Poultry: Muscle/meat | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1016020 | Poultry: Fat tissue | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1016030 | Poultry: Liver | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1020010 | Milk: Cattle | | | 0.16 | STMR-RAC | 0.16 | STMR-RAC |
| 1020020 | Milk: Sheep | | | 0.16 | STMR-RAC | 0.16 | STMR-RAC |
| 1020030 | Milk: Goat | | | 0.16 | STMR-RAC | 0.16 | STMR-RAC |
| 1020040 | Milk: Horse | | | 0.16 | STMR-RAC | 0.16 | STMR-RAC |
| 1020990 | Milk: Others | | | 0.16 | STMR-RAC | 0.16 | STMR-RAC |
| 1030010 | Eggs: Chicken | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1030020 | Eggs: Duck | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1030030 | Eggs: Goose | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1030040 | Eggs: Quail | | | 0.04 | STMR-RAC | 0.04 | HR-RAC |
| 1030990 | Eggs: Others | | | 0.04 | STMR-RAC | | |
| 1040000 | Honey and other apiculture products | | | 0.01 | STMR-RAC | | |

(1) Normal mode

(2) Assessment of all
crops

Table 7.2- 36: Triazole alanine (TA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ⁽¹⁾ | | Acute risk assessment ⁽²⁾ | |
|--------|-------------|------------------------------|---------------------------|--|----------|--------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 110010 | Grapefruits | | | 0.32 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 110020 | Oranges | | | 0.32 | STMR-RAC | | |
| 110030 | Lemons | | | 0.32 | STMR-RAC | | |
| 110040 | Limes | | | 0.32 | STMR-RAC | | |
| 110050 | Mandarins | | | 0.32 | STMR-RAC | | |
| 110990 | Other citrus fruit | | | 0.32 | STMR-RAC | | |
| 130010 | Apples | | | 0.039 | STMR-RAC | | |
| 130020 | Pears | | | 0.039 | STMR-RAC | | |
| 130030 | Quinces | | | 0.039 | STMR-RAC | | |
| 130040 | Medlar | | | 0.039 | STMR-RAC | | |
| 130050 | Loquats/Japanese medlars | | | 0.039 | STMR-RAC | | |
| 130990 | Other pome fruit | | | 0.039 | STMR-RAC | | |
| 140010 | Apricots | | | 0.32 | STMR-RAC | | |
| 140020 | Cherries (sweet) | | | 0.32 | STMR-RAC | | |
| 140030 | Peaches | | | 0.32 | STMR-RAC | | |
| 140040 | Plums | | | 0.32 | STMR-RAC | | |
| 140990 | Other stone fruit | | | 0.32 | STMR-RAC | | |
| 151010 | Table grapes | | | 0.06 | STMR-RAC | | |
| 151020 | Wine grapes | | | 0.06 | STMR-RAC | | |
| 152000 | Strawberries | | | 0.06 | STMR-RAC | | |
| 153010 | Blackberries | | | 0.06 | STMR-RAC | | |
| 153020 | Dewberries | | | 0.06 | STMR-RAC | | |
| 153030 | Raspberries (red and yellow) | | | 0.06 | STMR-RAC | | |
| 153990 | Other cane fruit | | | 0.06 | STMR-RAC | | |
| 154010 | Blueberries | | | 0.06 | STMR-RAC | | |
| 154020 | Cranberries | | | 0.06 | STMR-RAC | | |
| 154030 | Currants (red, black and white) | | | 0.06 | STMR-RAC | | |
| 154040 | Gooseberries (green, red and yellow) | | | 0.06 | STMR-RAC | | |
| 154050 | Rose hips | | | 0.06 | STMR-RAC | | |
| 154060 | Mulberries (black and white) | | | 0.06 | STMR-RAC | | |
| 154070 | Azarole/Mediterranean medlar | | | 0.06 | STMR-RAC | | |
| 154080 | Elderberries | | | 0.06 | STMR-RAC | | |
| 154990 | Other other small fruit & berries | | | 0.06 | STMR-RAC | | |
| 163020 | Bananas | | | 0.05 | STMR-RAC | | |
| 212010 | Cassava roots/manioc | | | 0.184 | STMR-RAC | | |
| 212020 | Sweet potatoes | | | 0.184 | STMR-RAC | | |
| 212030 | Yams | | | 0.184 | STMR-RAC | | |
| 212040 | Arrowroots | | | 0.184 | STMR-RAC | | |
| 212990 | Other tropical root and tuber vegetables | | | 0.184 | STMR-RAC | | |
| 213010 | Beetroots | | | 0.184 | STMR-RAC | | |
| 213020 | Carrots | | | 0.184 | STMR-RAC | | |
| 213030 | Celeriacs/turnip rooted celeries | | | 0.184 | STMR-RAC | | |
| 213040 | Horseradishes | | | 0.184 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|---|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 213050 | Jerusalem artichokes | | | 0.184 | STMR-RAC | | |
| 213060 | Parsnips | | | 0.184 | STMR-RAC | | |
| 213070 | Parsley roots/Hamburg roots parsley | | | 0.184 | STMR-RAC | | |
| 213080 | Radishes | | | 0.184 | STMR-RAC | | |
| 213090 | Salsifies | | | 0.184 | STMR-RAC | | |
| 213100 | Swedes/rutabagas | | | 0.184 | STMR-RAC | | |
| 213110 | Turnips | | | 0.184 | STMR-RAC | | |
| 213990 | Other other root and tuber vegetables | | | 0.184 | STMR-RAC | | |
| 220010 | Garlic | | | 0.06 | STMR-RAC | | |
| 220020 | Onions | | | 0.06 | STMR-RAC | | |
| 220030 | Shallots | | | 0.06 | STMR-RAC | | |
| 220040 | Spring onions/green onions and Welsh onions | | | 0.06 | STMR-RAC | | |
| 220990 | Other bulb vegetables | | | 0.06 | STMR-RAC | | |
| 231010 | Tomatoes | | | 0.21 | STMR-RAC | | |
| 231020 | Sweet peppers/bell peppers | | | 0.21 | STMR-RAC | | |
| 231030 | Aubergines/egg plants | | | 0.21 | STMR-RAC | | |
| 231040 | Okra/lady's fingers | | | 0.21 | STMR-RAC | | |
| 231990 | Other solanacea | | | 0.21 | STMR-RAC | | |
| 232010 | Cucumbers | | | 0.21 | STMR-RAC | | |
| 232020 | Gherkins | | | 0.21 | STMR-RAC | | |
| 232030 | Courgettes | | | 0.21 | STMR-RAC | | |
| 232990 | Other cucurbits - edible peel | | | 0.21 | STMR-RAC | | |
| 233010 | Melons | | | 0.21 | STMR-RAC | | |
| 233020 | Pumpkins | | | 0.21 | STMR-RAC | | |
| 233030 | Watermelons | | | 0.21 | STMR-RAC | | |
| 233990 | Other cucurbits - inedible peel | | | 0.21 | STMR-RAC | | |
| 234000 | Sweet corn | | | 0.21 | STMR-RAC | | |
| 241010 | Broccoli | | | 0.17 | STMR-RAC | | |
| 241020 | Cauliflowers | | | 0.17 | STMR-RAC | | |
| 241990 | Other flowering brassica | | | 0.17 | STMR-RAC | | |
| 242010 | Brussels sprouts | | | 0.17 | STMR-RAC | | |
| 242020 | Head cabbages | | | 0.17 | STMR-RAC | | |
| 242990 | Other head brassica | | | 0.17 | STMR-RAC | | |
| 243010 | Chinese cabbages/pe- tsai | | | 0.17 | STMR-RAC | | |
| 243020 | Kales | | | 0.17 | STMR-RAC | | |
| 243990 | Other leafy brassica | | | 0.17 | STMR-RAC | | |
| 244000 | Kohlrabies | | | 0.17 | STMR-RAC | | |
| 251010 | Lamb's lettuce/corn salads | | | 0.047 | STMR-RAC | | |
| 251020 | Lettuces | | | 0.047 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 251030 | Escaroles/broad-leaved endives | | | 0.047 | STMR-RAC | | |
| 251040 | Cress and other sprouts and shoots | | | 0.047 | STMR-RAC | | |
| 251050 | Land cress | | | 0.047 | STMR-RAC | | |
| 251060 | Roman rocket/rucola | | | 0.047 | STMR-RAC | | |
| 251070 | Red mustards | | | 0.047 | STMR-RAC | | |
| 251080 | Baby leaf crops (including brassica species) | | | 0.047 | STMR-RAC | | |
| 251990 | Other lettuce and other salad plants | | | 0.047 | STMR-RAC | | |
| 252010 | Spinaches | | | 0.047 | STMR-RAC | | |
| 252020 | Purslanes | | | 0.047 | STMR-RAC | | |
| 252030 | Chards/beet leaves | | | 0.047 | STMR-RAC | | |
| 252990 | Other spinach and similar | | | 0.047 | STMR-RAC | | |
| 253000 | Grape leaves and similar species | | | 0.047 | STMR-RAC | | |
| 254000 | Watercress | | | 0.047 | STMR-RAC | | |
| 255000 | Witloofs/Belgian endives | | | 0.047 | STMR-RAC | | |
| 256010 | Chervil | | | 0.047 | STMR-RAC | | |
| 256020 | Chives | | | 0.047 | STMR-RAC | | |
| 256030 | Celery leaves | | | 0.047 | STMR-RAC | | |
| 256040 | Parsley | | | 0.047 | STMR-RAC | | |
| 256050 | Sage | | | 0.047 | STMR-RAC | | |
| 256060 | Rosemary | | | 0.047 | STMR-RAC | | |
| 256070 | Thyme | | | 0.047 | STMR-RAC | | |
| 256080 | Basil and edible flowers | | | 0.047 | STMR-RAC | | |
| 256090 | Laurel/bay leaves | | | 0.047 | STMR-RAC | | |
| 256100 | Tarragon | | | 0.047 | STMR-RAC | | |
| 256990 | Other herbs | | | 0.047 | STMR-RAC | | |
| 260010 | Beans (with pods) | | | 0.09 | STMR-RAC | | |
| 260020 | Beans (without pods) | | | 0.09 | STMR-RAC | | |
| 260030 | Peas (with pods) | | | 0.09 | STMR-RAC | | |
| 260040 | Peas (without pods) | | | 0.09 | STMR-RAC | | |
| 260050 | Lentils (fresh) | | | 0.09 | STMR-RAC | | |
| 260990 | Other legume vegetables (fresh) | | | 0.09 | STMR-RAC | | |
| 270010 | Asparagus | | | 0.09 | STMR-RAC | | |
| 270020 | Cardoons | | | 0.09 | STMR-RAC | | |
| 270030 | Celeries | | | 0.09 | STMR-RAC | | |
| 270040 | Florence fennels | | | 0.09 | STMR-RAC | | |
| 270050 | Globe artichokes | | | 0.09 | STMR-RAC | | |
| 270060 | Leeks | | | 0.09 | STMR-RAC | | |
| 270070 | Rhubarbs | | | 0.09 | STMR-RAC | | |
| 270080 | Bamboo shoots | | | 0.09 | STMR-RAC | | |
| 270090 | Palm hearts | | | 0.09 | STMR-RAC | | |
| 270990 | Other stem vegetables | | | 0.09 | STMR-RAC | | |
| 300010 | Beans | | | 0.17 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|---------|------------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 300020 | Lentils | | | 0.17 | STMR-RAC | | |
| 300030 | Peas | | | 0.17 | STMR-RAC | | |
| 300040 | Lupins/lupini beans | | | 0.17 | STMR-RAC | | |
| 300990 | Other pulses | | | 0.17 | STMR-RAC | | |
| 401010 | Linseeds | | | 1.039 | STMR-RAC | | |
| 401020 | Peanuts/groundnuts | | | 1.039 | STMR-RAC | | |
| 401030 | Poppy seeds | | | 1.039 | STMR-RAC | | |
| 401040 | Sesame seeds | | | 1.039 | STMR-RAC | | |
| 401050 | Sunflower seeds | | | 1.039 | STMR-RAC | | |
| 401060 | Rapeseeds/canola seeds | | | 1.039 | STMR-RAC | 1.039 | STMR-RAC |
| 401070 | Soyabeans | | | 1.039 | STMR-RAC | | |
| 401080 | Mustard seeds | | | 1.039 | STMR-RAC | | |
| 401090 | Cotton seeds | | | 1.039 | STMR-RAC | | |
| 401100 | Pumpkin seeds | | | 1.039 | STMR-RAC | | |
| 401110 | Safflower seeds | | | 1.039 | STMR-RAC | | |
| 401120 | Borage seeds | | | 1.039 | STMR-RAC | | |
| 401130 | Gold of pleasure seeds | | | 1.039 | STMR-RAC | | |
| 401140 | Hemp seeds | | | 1.039 | STMR-RAC | | |
| 401150 | Castor beans | | | 1.039 | STMR-RAC | | |
| 401990 | Other oilseeds | | | 1.039 | STMR-RAC | | |
| 402010 | Olives for oil production | | | 1.039 | STMR-RAC | | |
| 402020 | Oil palm kernels | | | 1.039 | STMR-RAC | | |
| 402030 | Oil palm fruits | | | 1.039 | STMR-RAC | | |
| 402040 | Kapok | | | 1.039 | STMR-RAC | | |
| 402990 | Other oilfruit | | | 1.039 | STMR-RAC | | |
| 500010 | Barley | | | 0.621 | STMR-RAC | 0.621 | STMR-RAC |
| 500020 | Buckwheat and other pseudo-cereals | | | 0.621 | STMR-RAC | | |
| 500030 | Maize/corn | | | 0.621 | STMR-RAC | | |
| 500040 | Common millet/proso millet | | | 0.621 | STMR-RAC | | |
| 500050 | Oat | | | 0.621 | STMR-RAC | 0.621 | STMR-RAC |
| 500060 | Rice | | | 0.621 | STMR-RAC | | |
| 500070 | Rye | | | 0.621 | STMR-RAC | 0.621 | STMR-RAC |
| 500080 | Sorghum | | | 0.621 | STMR-RAC | | |
| 500090 | Wheat | | | 0.621 | STMR-RAC | 0.621 | STMR-RAC |
| 500990 | Other cereals | | | 0.621 | STMR-RAC | | |
| 900010 | Sugar beet roots | | | 0.05 | STMR-RAC | | |
| 900020 | Sugar canes | | | 0.05 | STMR-RAC | | |
| 900030 | Chicory roots | | | 0.05 | STMR-RAC | | |
| 900990 | Other sugar plants | | | 0.05 | STMR-RAC | | |
| 1011010 | Swine: Muscle/meat | | | 0.06 | STMR-RAC | 0.13 | HR-RAC |
| 1011020 | Swine: Fat tissue | | | 0.03 | STMR-RAC | 0.1 | HR-RAC |
| 1011030 | Swine: Liver | | | 0.13 | STMR-RAC | 0.34 | HR-RAC |
| 1011040 | Swine: Kidney | | | 0.06 | STMR-RAC | 0.22 | HR-RAC |
| 1012010 | Bovine: Muscle/meat | | | 0.06 | STMR-RAC | 0.23 | HR-RAC |
| 1012020 | Bovine: Fat tissue | | | 0.03 | STMR-RAC | 0.11 | HR-RAC |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|---------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 1012030 | Bovine: Liver | | | 0.13 | STMR-RAC | 0.35 | HR-RAC |
| 1012040 | Bovine: Kidney | | | 0.06 | STMR-RAC | 0.22 | HR-RAC |
| 1013010 | Sheep: Muscle/meat | | | 0.06 | STMR-RAC | 0.23 | HR-RAC |
| 1013020 | Sheep: Fat tissue | | | 0.03 | STMR-RAC | 0.11 | HR-RAC |
| 1013030 | Sheep: Liver | | | 0.13 | STMR-RAC | 0.35 | HR-RAC |
| 1013040 | Sheep: Kidney | | | 0.06 | STMR-RAC | 0.22 | HR-RAC |
| 1014010 | Goat: Muscle/meat | | | 0.06 | STMR-RAC | 0.23 | HR-RAC |
| 1014020 | Goat: Fat tissue | | | 0.03 | STMR-RAC | 0.11 | HR-RAC |
| 1014030 | Goat: Liver | | | 0.13 | STMR-RAC | 0.35 | HR-RAC |
| 1014040 | Goat: Kidney | | | 0.06 | STMR-RAC | 0.22 | HR-RAC |
| 1016010 | Poultry: Muscle/meat | | | 0.04 | STMR-RAC | 0.11 | HR-RAC |
| 1016020 | Poultry: Fat tissue | | | 0.03 | STMR-RAC | 0.09 | HR-RAC |
| 1016030 | Poultry: Liver | | | 0.09 | STMR-RAC | 0.22 | HR-RAC |
| 1020010 | Milk: Cattle | | | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| 1020020 | Milk: Sheep | | | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| 1020030 | Milk: Goat | | | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| 1020040 | Milk: Horse | | | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| 1020990 | Milk: Others | | | 0.02 | STMR-RAC | 0.02 | STMR-RAC |
| 1030010 | Eggs: Chicken | | | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| 1030020 | Eggs: Duck | | | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| 1030030 | Eggs: Goose | | | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| 1030040 | Eggs: Quail | | | 0.02 | STMR-RAC | 0.06 | HR-RAC |
| 1030990 | Eggs: Others | | | 0.02 | STMR-RAC | | |
| 1040000 | Honey and other apiculture products | | | 0.01 | STMR-RAC | | |

(1) Normal mode

(2) Assessment of all
crops

Table 7.2- 37: Triazole acetic acid (TAA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|-----------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 110010 | Grapefruits | | | 0.05 | STMR-RAC | | |
| 110020 | Oranges | | | 0.05 | STMR-RAC | | |
| 110030 | Lemons | | | 0.05 | STMR-RAC | | |
| 110040 | Limes | | | 0.05 | STMR-RAC | | |
| 110050 | Mandarins | | | 0.05 | STMR-RAC | | |
| 110990 | Other citrus fruit | | | 0.05 | STMR-RAC | | |
| 130010 | Apples | | | 0.03 | STMR-RAC | | |
| 130020 | Pears | | | 0.03 | STMR-RAC | | |
| 130030 | Quinces | | | 0.03 | STMR-RAC | | |
| 130040 | Medlar | | | 0.03 | STMR-RAC | | |
| 130050 | Loquats/Japanese medlars | | | 0.03 | STMR-RAC | | |
| 130990 | Other pome fruit | | | 0.03 | STMR-RAC | | |
| 140010 | Apricots | | | 0.02 | STMR-RAC | | |
| 140020 | Cherries (sweet) | | | 0.02 | STMR-RAC | | |
| 140030 | Peaches | | | 0.02 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 140040 | Plums | | | 0.02 | STMR-RAC | | |
| 140990 | Other stone fruit | | | 0.02 | STMR-RAC | | |
| 151010 | Table grapes | | | 0.05 | STMR-RAC | | |
| 151020 | Wine grapes | | | 0.05 | STMR-RAC | | |
| 152000 | Strawberries | | | 0.05 | STMR-RAC | | |
| 153010 | Blackberries | | | 0.05 | STMR-RAC | | |
| 153020 | Dewberries | | | 0.05 | STMR-RAC | | |
| 153030 | Raspberries (red and yellow) | | | 0.05 | STMR-RAC | | |
| 153990 | Other cane fruit | | | 0.05 | STMR-RAC | | |
| 154010 | Blueberries | | | 0.05 | STMR-RAC | | |
| 154020 | Cranberries | | | 0.05 | STMR-RAC | | |
| 154030 | Currants (red, black and white) | | | 0.05 | STMR-RAC | | |
| 154040 | Gooseberries (green, red and yellow) | | | 0.05 | STMR-RAC | | |
| 154050 | Rose hips | | | 0.05 | STMR-RAC | | |
| 154060 | Mulberries (black and white) | | | 0.05 | STMR-RAC | | |
| 154070 | Azarole/Mediterranean medlar | | | 0.05 | STMR-RAC | | |
| 154080 | Elderberries | | | 0.05 | STMR-RAC | | |
| 154990 | Other other small fruit & berries | | | 0.05 | STMR-RAC | | |
| 163020 | Bananas | | | 0.05 | STMR-RAC | | |
| 211000 | Potatoes | | | 0.01 | STMR-RAC | | |
| 212010 | Cassava roots/manioc | | | 0.01 | STMR-RAC | | |
| 212020 | Sweet potatoes | | | 0.01 | STMR-RAC | | |
| 212030 | Yams | | | 0.01 | STMR-RAC | | |
| 212040 | Arrowroots | | | 0.01 | STMR-RAC | | |
| 212990 | Other tropical root and tuber vegetables | | | 0.01 | STMR-RAC | | |
| 213010 | Beetroots | | | 0.01 | STMR-RAC | | |
| 213020 | Carrots | | | 0.01 | STMR-RAC | | |
| 213030 | Celeriacs/turnip rooted celeries | | | 0.01 | STMR-RAC | | |
| 213040 | Horseradishes | | | 0.01 | STMR-RAC | | |
| 213050 | Jerusalem artichokes | | | 0.01 | STMR-RAC | | |
| 213060 | Parsnips | | | 0.01 | STMR-RAC | | |
| 213070 | Parsley roots/Hamburg roots parsley | | | 0.01 | STMR-RAC | | |
| 213080 | Radishes | | | 0.01 | STMR-RAC | | |
| 213090 | Salsifies | | | 0.01 | STMR-RAC | | |
| 213100 | Swedes/rutabagas | | | 0.01 | STMR-RAC | | |
| 213110 | Turnips | | | 0.01 | STMR-RAC | | |
| 213990 | Other other root and tuber vegetables | | | 0.01 | STMR-RAC | | |
| 220010 | Garlic | | | 0.01 | STMR-RAC | | |
| 220020 | Onions | | | 0.01 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 220030 | Shallots | | | 0.01 | STMR-RAC | | |
| 220040 | Spring onions/green onions and Welsh onions | | | 0.01 | STMR-RAC | | |
| 220990 | Other bulb vegetables | | | 0.01 | STMR-RAC | | |
| 231010 | Tomatoes | | | 0.01 | STMR-RAC | | |
| 231020 | Sweet peppers/bell peppers | | | 0.01 | STMR-RAC | | |
| 231030 | Aubergines/egg plants | | | 0.01 | STMR-RAC | | |
| 231040 | Okra/lady's fingers | | | 0.01 | STMR-RAC | | |
| 231990 | Other solanacea | | | 0.01 | STMR-RAC | | |
| 232010 | Cucumbers | | | 0.01 | STMR-RAC | | |
| 232020 | Gherkins | | | 0.01 | STMR-RAC | | |
| 232030 | Courgettes | | | 0.01 | STMR-RAC | | |
| 232990 | Other cucurbits - edible peel | | | 0.01 | STMR-RAC | | |
| 233010 | Melons | | | 0.01 | STMR-RAC | | |
| 233020 | Pumpkins | | | 0.01 | STMR-RAC | | |
| 233030 | Watermelons | | | 0.01 | STMR-RAC | | |
| 233990 | Other cucurbits - inedible peel | | | 0.01 | STMR-RAC | | |
| 234000 | Sweet corn | | | 0.01 | STMR-RAC | | |
| 241010 | Broccoli | | | 0.01 | STMR-RAC | | |
| 241020 | Cauliflowers | | | 0.01 | STMR-RAC | | |
| 241990 | Other flowering brassica | | | 0.01 | STMR-RAC | | |
| 242010 | Brussels sprouts | | | 0.01 | STMR-RAC | | |
| 242020 | Head cabbages | | | 0.01 | STMR-RAC | | |
| 242990 | Other head brassica | | | 0.01 | STMR-RAC | | |
| 243010 | Chinese cabbages/pe- tsai | | | 0.01 | STMR-RAC | | |
| 243020 | Kales | | | 0.01 | STMR-RAC | | |
| 243990 | Other leafy brassica | | | 0.01 | STMR-RAC | | |
| 244000 | Kohlrabies | | | 0.01 | STMR-RAC | | |
| 251010 | Lamb's lettuce/corn salads | | | 0.023 | STMR-RAC | | |
| 251020 | Lettuces | | | 0.023 | STMR-RAC | | |
| 251030 | Escaroles/broad- leaved endives | | | 0.023 | STMR-RAC | | |
| 251040 | Cress and other sprouts and shoots | | | 0.023 | STMR-RAC | | |
| 251050 | Land cress | | | 0.023 | STMR-RAC | | |
| 251060 | Roman rocket/rucola | | | 0.023 | STMR-RAC | | |
| 251070 | Red mustards | | | 0.023 | STMR-RAC | | |
| 251080 | Baby leaf crops (including brassica species) | | | 0.023 | STMR-RAC | | |
| 251990 | Other lettuce and other salad plants | | | 0.023 | STMR-RAC | | |
| 252010 | Spinaches | | | 0.023 | STMR-RAC | | |
| 252020 | Purslanes | | | 0.023 | STMR-RAC | | |
| 252030 | Chards/beet leaves | | | 0.023 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|----------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 252990 | Other spinach and similar | | | 0.023 | STMR-RAC | | |
| 253000 | Grape leaves and similar species | | | 0.023 | STMR-RAC | | |
| 254000 | Watercress | | | 0.023 | STMR-RAC | | |
| 255000 | Witloofs/Belgian endives | | | 0.023 | STMR-RAC | | |
| 256010 | Chervil | | | 0.023 | STMR-RAC | | |
| 256020 | Chives | | | 0.023 | STMR-RAC | | |
| 256030 | Celery leaves | | | 0.023 | STMR-RAC | | |
| 256040 | Parsley | | | 0.023 | STMR-RAC | | |
| 256050 | Sage | | | 0.023 | STMR-RAC | | |
| 256060 | Rosemary | | | 0.023 | STMR-RAC | | |
| 256070 | Thyme | | | 0.023 | STMR-RAC | | |
| 256080 | Basil and edible flowers | | | 0.023 | STMR-RAC | | |
| 256090 | Laurel/bay leaves | | | 0.023 | STMR-RAC | | |
| 256100 | Tarragon | | | 0.023 | STMR-RAC | | |
| 256990 | Other herbs | | | 0.023 | STMR-RAC | | |
| 260010 | Beans (with pods) | | | 0.01 | STMR-RAC | | |
| 260020 | Beans (without pods) | | | 0.01 | STMR-RAC | | |
| 260030 | Peas (with pods) | | | 0.01 | STMR-RAC | | |
| 260040 | Peas (without pods) | | | 0.01 | STMR-RAC | | |
| 260050 | Lentils (fresh) | | | 0.01 | STMR-RAC | | |
| 260990 | Other legume vegetables (fresh) | | | 0.01 | STMR-RAC | | |
| 270010 | Asparagus | | | 0.02 | STMR-RAC | | |
| 270020 | Cardoons | | | 0.02 | STMR-RAC | | |
| 270030 | Celeries | | | 0.02 | STMR-RAC | | |
| 270040 | Florence fennels | | | 0.02 | STMR-RAC | | |
| 270050 | Globe artichokes | | | 0.02 | STMR-RAC | | |
| 270060 | Leeks | | | 0.02 | STMR-RAC | | |
| 270070 | Rhubarbs | | | 0.02 | STMR-RAC | | |
| 270080 | Bamboo shoots | | | 0.02 | STMR-RAC | | |
| 270090 | Palm hearts | | | 0.02 | STMR-RAC | | |
| 270990 | Other stem vegetables | | | 0.02 | STMR-RAC | | |
| 300010 | Beans | | | 0.05 | STMR-RAC | | |
| 300020 | Lentils | | | 0.05 | STMR-RAC | | |
| 300030 | Peas | | | 0.05 | STMR-RAC | | |
| 300040 | Lupins/lupini beans | | | 0.05 | STMR-RAC | | |
| 300990 | Other pulses | | | 0.05 | STMR-RAC | | |
| 401010 | Linseeds | | | 0.12 | STMR-RAC | | |
| 401020 | Peanuts/groundnuts | | | 0.12 | STMR-RAC | | |
| 401030 | Poppy seeds | | | 0.12 | STMR-RAC | | |
| 401040 | Sesame seeds | | | 0.12 | STMR-RAC | | |
| 401050 | Sunflower seeds | | | 0.12 | STMR-RAC | | |
| 401060 | Rapeseeds/canola seeds | | | 0.12 | STMR-RAC | 0.12 | STMR-RAC |
| 401070 | Soyabeans | | | 0.12 | STMR-RAC | | |
| 401080 | Mustard seeds | | | 0.12 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|---------|---------------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 401090 | Cotton seeds | | | 0.12 | STMR-RAC | | |
| 401100 | Pumpkin seeds | | | 0.12 | STMR-RAC | | |
| 401110 | Safflower seeds | | | 0.12 | STMR-RAC | | |
| 401120 | Borage seeds | | | 0.12 | STMR-RAC | | |
| 401130 | Gold of pleasure seeds | | | 0.12 | STMR-RAC | | |
| 401140 | Hemp seeds | | | 0.12 | STMR-RAC | | |
| 401150 | Castor beans | | | 0.12 | STMR-RAC | | |
| 401990 | Other oilseeds | | | 0.12 | STMR-RAC | | |
| 402010 | Olives for oil production | | | 0.12 | STMR-RAC | | |
| 402020 | Oil palm kernels | | | 0.12 | STMR-RAC | | |
| 402030 | Oil palm fruits | | | 0.12 | STMR-RAC | | |
| 402040 | Kapok | | | 0.12 | STMR-RAC | | |
| 402990 | Other oilfruit | | | 0.12 | STMR-RAC | | |
| 500010 | Barley | | | 0.79 | STMR-RAC | 0.79 | STMR-RAC |
| 500020 | Buckwheat and other pseudo-cereals | | | 0.79 | STMR-RAC | | |
| 500030 | Maize/corn | | | 0.79 | STMR-RAC | | |
| 500040 | Common millet/proso millet | | | 0.79 | STMR-RAC | | |
| 500050 | Oat | | | 0.79 | STMR-RAC | 0.79 | STMR-RAC |
| 500060 | Rice | | | 0.79 | STMR-RAC | | |
| 500070 | Rye | | | 0.79 | STMR-RAC | 0.79 | STMR-RAC |
| 500080 | Sorghum | | | 0.79 | STMR-RAC | | |
| 500090 | Wheat | | | 0.79 | STMR-RAC | 0.79 | STMR-RAC |
| 500990 | Other cereals | | | 0.79 | STMR-RAC | | |
| 900010 | Sugar beet roots | | | 0.05 | STMR-RAC | 0.05 | HR-RAC |
| 900020 | Sugar canes | | | 0.05 | STMR-RAC | 0.05 | HR-RAC |
| 900030 | Chicory roots | | | 0.05 | STMR-RAC | 0.05 | HR-RAC |
| 900990 | Other sugar plants | | | 0.05 | STMR-RAC | | |
| 1011010 | Swine: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1011020 | Swine: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1011030 | Swine: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1011040 | Swine: Kidney | | | 0.05 | STMR-RAC | 0.1 | HR-RAC |
| 1012010 | Bovine: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1012020 | Bovine: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1012030 | Bovine: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1012040 | Bovine: Kidney | | | 0.05 | STMR-RAC | 0.13 | HR-RAC |
| 1013010 | Sheep: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1013020 | Sheep: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1013030 | Sheep: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1013040 | Sheep: Kidney | | | 0.05 | STMR-RAC | 0.13 | HR-RAC |
| 1014010 | Goat: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1014020 | Goat: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1014030 | Goat: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1014040 | Goat: Kidney | | | 0.05 | STMR-RAC | 0.13 | HR-RAC |
| 1016010 | Poultry: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016020 | Poultry: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|---------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 1016030 | Poultry: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1020010 | Milk: Cattle | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020020 | Milk: Sheep | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020030 | Milk: Goat | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020040 | Milk: Horse | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020990 | Milk: Others | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1030010 | Eggs: Chicken | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030020 | Eggs: Duck | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030030 | Eggs: Goose | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030040 | Eggs: Quail | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030990 | Eggs: Others | | | 0.03 | STMR-RAC | | |
| 1040000 | Honey and other apiculture products | | | 0.01 | STMR-RAC | | |

(1) Normal mode

(2) Assessment of all
crops

Table 7.2- 38: Triazole lactic acid (TLA): Input values for the consumer risk assessment (according to UK, 2018b and new trials submitted)

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|---------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 110010 | Grapefruits | | | 0.04 | STMR-RAC | | |
| 110020 | Oranges | | | 0.04 | STMR-RAC | | |
| 110030 | Lemons | | | 0.04 | STMR-RAC | | |
| 110040 | Limes | | | 0.04 | STMR-RAC | | |
| 110050 | Mandarins | | | 0.04 | STMR-RAC | | |
| 110990 | Other citrus fruit | | | 0.04 | STMR-RAC | | |
| 130010 | Apples | | | 0.03 | STMR-RAC | | |
| 130020 | Pears | | | 0.03 | STMR-RAC | | |
| 130030 | Quinces | | | 0.03 | STMR-RAC | | |
| 130040 | Medlar | | | 0.03 | STMR-RAC | | |
| 130050 | Loquats/Japanese medlars | | | 0.03 | STMR-RAC | | |
| 130990 | Other pome fruit | | | 0.03 | STMR-RAC | | |
| 140010 | Apricots | | | 0.038 | STMR-RAC | | |
| 140020 | Cherries (sweet) | | | 0.038 | STMR-RAC | | |
| 140030 | Peaches | | | 0.038 | STMR-RAC | | |
| 140040 | Plums | | | 0.038 | STMR-RAC | | |
| 140990 | Other stone fruit | | | 0.038 | STMR-RAC | | |
| 151010 | Table grapes | | | 0.04 | STMR-RAC | | |
| 151020 | Wine grapes | | | 0.04 | STMR-RAC | | |
| 152000 | Strawberries | | | 0.04 | STMR-RAC | | |
| 153010 | Blackberries | | | 0.04 | STMR-RAC | | |
| 153020 | Dewberries | | | 0.04 | STMR-RAC | | |
| 153030 | Raspberries (red and yellow) | | | 0.04 | STMR-RAC | | |
| 153990 | Other cane fruit | | | 0.04 | STMR-RAC | | |
| 154010 | Blueberries | | | 0.04 | STMR-RAC | | |
| 154020 | Cranberries | | | 0.04 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|---|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 154030 | Currants (red, black and white) | | | 0.04 | STMR-RAC | | |
| 154040 | Gooseberries (green, red and yellow) | | | 0.04 | STMR-RAC | | |
| 154050 | Rose hips | | | 0.04 | STMR-RAC | | |
| 154060 | Mulberries (black and white) | | | 0.04 | STMR-RAC | | |
| 154070 | Azarole/Mediterranean medlar | | | 0.04 | STMR-RAC | | |
| 154080 | Elderberries | | | 0.04 | STMR-RAC | | |
| 154990 | Other other small fruit & berries | | | 0.04 | STMR-RAC | | |
| 211000 | Potatoes | | | 0.021 | STMR-RAC | | |
| 212010 | Cassava roots/manioc | | | 0.021 | STMR-RAC | | |
| 212020 | Sweet potatoes | | | 0.021 | STMR-RAC | | |
| 212030 | Yams | | | 0.021 | STMR-RAC | | |
| 212040 | Arrowroots | | | 0.021 | STMR-RAC | | |
| 212990 | Other tropical root and tuber vegetables | | | 0.021 | STMR-RAC | | |
| 213010 | Beetroots | | | 0.021 | STMR-RAC | | |
| 213020 | Carrots | | | 0.021 | STMR-RAC | | |
| 213030 | Celeriacs/turnip rooted celeries | | | 0.021 | STMR-RAC | | |
| 213040 | Horseradishes | | | 0.021 | STMR-RAC | | |
| 213050 | Jerusalem artichokes | | | 0.021 | STMR-RAC | | |
| 213060 | Parsnips | | | 0.021 | STMR-RAC | | |
| 213070 | Parsley roots/Hamburg roots parsley | | | 0.021 | STMR-RAC | | |
| 213080 | Radishes | | | 0.021 | STMR-RAC | | |
| 213090 | Salsifies | | | 0.021 | STMR-RAC | | |
| 213100 | Swedes/rutabagas | | | 0.021 | STMR-RAC | | |
| 213110 | Turnips | | | 0.021 | STMR-RAC | | |
| 213990 | Other other root and tuber vegetables | | | 0.021 | STMR-RAC | | |
| 220010 | Garlic | | | 0.01 | STMR-RAC | | |
| 220020 | Onions | | | 0.01 | STMR-RAC | | |
| 220030 | Shallots | | | 0.01 | STMR-RAC | | |
| 220040 | Spring onions/green onions and Welsh onions | | | 0.01 | STMR-RAC | | |
| 220990 | Other bulb vegetables | | | 0.01 | STMR-RAC | | |
| 231010 | Tomatoes | | | 0.03 | STMR-RAC | | |
| 231020 | Sweet peppers/bell peppers | | | 0.03 | STMR-RAC | | |
| 231030 | Aubergines/egg plants | | | 0.03 | STMR-RAC | | |
| 231040 | Okra/lady's fingers | | | 0.03 | STMR-RAC | | |
| 231990 | Other solanacea | | | 0.03 | STMR-RAC | | |
| 232010 | Cucumbers | | | 0.03 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 232020 | Gherkins | | | 0.03 | STMR-RAC | | |
| 232030 | Courgettes | | | 0.03 | STMR-RAC | | |
| 232990 | Other cucurbits - edible peel | | | 0.03 | STMR-RAC | | |
| 233010 | Melons | | | 0.03 | STMR-RAC | | |
| 233020 | Pumpkins | | | 0.03 | STMR-RAC | | |
| 233030 | Watermelons | | | 0.03 | STMR-RAC | | |
| 233990 | Other cucurbits - inedible peel | | | 0.03 | STMR-RAC | | |
| 234000 | Sweet corn | | | 0.03 | STMR-RAC | | |
| 241010 | Broccoli | | | 0.01 | STMR-RAC | | |
| 241020 | Cauliflowers | | | 0.01 | STMR-RAC | | |
| 241990 | Other flowering brassica | | | 0.01 | STMR-RAC | | |
| 242010 | Brussels sprouts | | | 0.01 | STMR-RAC | | |
| 242020 | Head cabbages | | | 0.01 | STMR-RAC | | |
| 242990 | Other head brassica | | | 0.01 | STMR-RAC | | |
| 243010 | Chinese cabbages/pe- tsai | | | 0.01 | STMR-RAC | | |
| 243020 | Kales | | | 0.01 | STMR-RAC | | |
| 243990 | Other leafy brassica | | | 0.01 | STMR-RAC | | |
| 244000 | Kohlrabies | | | 0.01 | STMR-RAC | | |
| 251010 | Lamb's lettuce/corn salads | | | 0.08 | STMR-RAC | | |
| 251020 | Lettuces | | | 0.08 | STMR-RAC | | |
| 251030 | Escaroles/broad- leaved endives | | | 0.08 | STMR-RAC | | |
| 251040 | Cress and other sprouts and shoots | | | 0.08 | STMR-RAC | | |
| 251050 | Land cress | | | 0.08 | STMR-RAC | | |
| 251060 | Roman rocket/rucola | | | 0.08 | STMR-RAC | | |
| 251070 | Red mustards | | | 0.08 | STMR-RAC | | |
| 251080 | Baby leaf crops (including brassica species) | | | 0.08 | STMR-RAC | | |
| 251990 | Other lettuce and other salad plants | | | 0.08 | STMR-RAC | | |
| 252010 | Spinaches | | | 0.08 | STMR-RAC | | |
| 252020 | Purslanes | | | 0.08 | STMR-RAC | | |
| 252030 | Chards/beet leaves | | | 0.08 | STMR-RAC | | |
| 252990 | Other spinach and similar | | | 0.08 | STMR-RAC | | |
| 253000 | Grape leaves and similar species | | | 0.08 | STMR-RAC | | |
| 254000 | Watercress | | | 0.08 | STMR-RAC | | |
| 255000 | Witloofs/Belgian endives | | | 0.08 | STMR-RAC | | |
| 256010 | Chervil | | | 0.08 | STMR-RAC | | |
| 256020 | Chives | | | 0.08 | STMR-RAC | | |
| 256030 | Celery leaves | | | 0.08 | STMR-RAC | | |
| 256040 | Parsley | | | 0.08 | STMR-RAC | | |
| 256050 | Sage | | | 0.08 | STMR-RAC | | |
| 256060 | Rosemary | | | 0.08 | STMR-RAC | | |
| 256070 | Thyme | | | 0.08 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|--------|---------------------------------|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 256080 | Basil and edible flowers | | | 0.08 | STMR-RAC | | |
| 256090 | Laurel/bay leaves | | | 0.08 | STMR-RAC | | |
| 256100 | Tarragon | | | 0.08 | STMR-RAC | | |
| 256990 | Other herbs | | | 0.08 | STMR-RAC | | |
| 260010 | Beans (with pods) | | | 0.01 | STMR-RAC | | |
| 260020 | Beans (without pods) | | | 0.01 | STMR-RAC | | |
| 260030 | Peas (with pods) | | | 0.01 | STMR-RAC | | |
| 260040 | Peas (without pods) | | | 0.01 | STMR-RAC | | |
| 260050 | Lentils (fresh) | | | 0.01 | STMR-RAC | | |
| 260990 | Other legume vegetables (fresh) | | | 0.01 | STMR-RAC | | |
| 270010 | Asparagus | | | 0.01 | STMR-RAC | | |
| 270020 | Cardoons | | | 0.01 | STMR-RAC | | |
| 270030 | Celeries | | | 0.01 | STMR-RAC | | |
| 270040 | Florence fennels | | | 0.01 | STMR-RAC | | |
| 270050 | Globe artichokes | | | 0.01 | STMR-RAC | | |
| 270060 | Leeks | | | 0.01 | STMR-RAC | | |
| 270070 | Rhubarbs | | | 0.01 | STMR-RAC | | |
| 270080 | Bamboo shoots | | | 0.01 | STMR-RAC | | |
| 270090 | Palm hearts | | | 0.01 | STMR-RAC | | |
| 270990 | Other stem vegetables | | | 0.01 | STMR-RAC | | |
| 300010 | Beans | | | 0.01 | STMR-RAC | | |
| 300020 | Lentils | | | 0.01 | STMR-RAC | | |
| 300030 | Peas | | | 0.01 | STMR-RAC | | |
| 300040 | Lupins/lupini beans | | | 0.01 | STMR-RAC | | |
| 300990 | Other pulses | | | 0.01 | STMR-RAC | | |
| 401010 | Linseeds | | | 0.065 | STMR-RAC | | |
| 401020 | Peanuts/groundnuts | | | 0.065 | STMR-RAC | | |
| 401030 | Poppy seeds | | | 0.065 | STMR-RAC | | |
| 401040 | Sesame seeds | | | 0.065 | STMR-RAC | | |
| 401050 | Sunflower seeds | | | 0.065 | STMR-RAC | | |
| 401060 | Rapeseeds/canola seeds | | | 0.065 | STMR-RAC | 0.065 | STMR-RAC |
| 401070 | Soyabeans | | | 0.065 | STMR-RAC | | |
| 401080 | Mustard seeds | | | 0.065 | STMR-RAC | | |
| 401090 | Cotton seeds | | | 0.065 | STMR-RAC | | |
| 401100 | Pumpkin seeds | | | 0.065 | STMR-RAC | | |
| 401110 | Safflower seeds | | | 0.065 | STMR-RAC | | |
| 401120 | Borage seeds | | | 0.065 | STMR-RAC | | |
| 401130 | Gold of pleasure seeds | | | 0.065 | STMR-RAC | | |
| 401140 | Hemp seeds | | | 0.065 | STMR-RAC | | |
| 401150 | Castor beans | | | 0.065 | STMR-RAC | | |
| 401990 | Other oilseeds | | | 0.065 | STMR-RAC | | |
| 402010 | Olives for oil production | | | 0.065 | STMR-RAC | | |
| 402020 | Oil palm kernels | | | 0.065 | STMR-RAC | | |
| 402030 | Oil palm fruits | | | 0.065 | STMR-RAC | | |
| 402040 | Kapok | | | 0.065 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|---------|--|------------------------------|---------------------------|---------------------------------------|----------|-------------------------------------|----------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| 402990 | Other oilfruit | | | 0.065 | STMR-RAC | | |
| 500010 | Barley | | | 0.022 | STMR-RAC | 0.022 | STMR-RAC |
| 500020 | Buckwheat and other pseudo-cereals | | | 0.022 | STMR-RAC | | |
| 500030 | Maize/corn | | | 0.022 | STMR-RAC | | |
| 500040 | Common millet/proso millet | | | 0.022 | STMR-RAC | | |
| 500050 | Oat | | | 0.022 | STMR-RAC | 0.022 | STMR-RAC |
| 500060 | Rice | | | 0.022 | STMR-RAC | | |
| 500070 | Rye | | | 0.022 | STMR-RAC | 0.022 | STMR-RAC |
| 500080 | Sorghum | | | 0.022 | STMR-RAC | | |
| 500090 | Wheat | | | 0.022 | STMR-RAC | 0.022 | STMR-RAC |
| 500990 | Other cereals | | | 0.022 | STMR-RAC | | |
| 900010 | Sugar beet roots | | | 0.01 | STMR-RAC | | |
| 900020 | Sugar canes | | | 0.01 | STMR-RAC | | |
| 900030 | Chicory roots | | | 0.01 | STMR-RAC | | |
| 900990 | Other sugar plants | | | 0.01 | STMR-RAC | | |
| 1012010 | Bovine: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1012020 | Bovine: Fat tissue | | | 0.04 | STMR-RAC | 0.09 | HR-RAC |
| 1012030 | Bovine: Liver | | | 0.03 | STMR-RAC | 0.04 | HR-RAC |
| 1012040 | Bovine: Kidney | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1013010 | Sheep: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1013020 | Sheep: Fat tissue | | | 0.04 | STMR-RAC | 0.09 | HR-RAC |
| 1013030 | Sheep: Liver | | | 0.03 | STMR-RAC | 0.04 | HR-RAC |
| 1013040 | Sheep: Kidney | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1014010 | Goat: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1014020 | Goat: Fat tissue | | | 0.04 | STMR-RAC | 0.09 | HR-RAC |
| 1014030 | Goat: Liver | | | 0.03 | STMR-RAC | 0.04 | HR-RAC |
| 1014040 | Goat: Kidney | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016010 | Poultry: Muscle/meat | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016020 | Poultry: Fat tissue | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016030 | Poultry: Liver | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016040 | Poultry: Kidney | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016050 | Poultry: Edible offals (other than liver and kidney) | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1016990 | Poultry: Other products | | | 0.03 | STMR-RAC | | |
| 1020010 | Milk: Cattle | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020020 | Milk: Sheep | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020030 | Milk: Goat | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020040 | Milk: Horse | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1020990 | Milk: Others | | | 0.03 | STMR-RAC | 0.03 | STMR-RAC |
| 1030010 | Eggs: Chicken | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030020 | Eggs: Duck | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030030 | Eggs: Goose | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030040 | Eggs: Quail | | | 0.03 | STMR-RAC | 0.03 | HR-RAC |
| 1030990 | Eggs: Others | | | 0.03 | STMR-RAC | | |
| 1040000 | Honey and other apiculture products | | | 0.01 | STMR-RAC | | |

| Code | Commodity | existing/ proposed MRL | Source/ type of MRL | Chronic risk assessment ¹⁾ | | Acute risk assessment ²⁾ | |
|------|-----------|------------------------------|---------------------------|---------------------------------------|---------|-------------------------------------|---------|
| | | | | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |

- (1) Normal mode
(2) Assessment of all crops

7.2.8.2 Conclusion on consumer risk assessment

Prothioconazole except TDMs

Extensive calculation sheets are presented in Appendix 3.

Table 7.2- 39: Consumer risk assessment for prothioconazole-desthio (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers))

| | |
|--|--|
| TMDI (% ADI*) according to EFSA PRIMo 3.1 | 43% (based on NL toddler; main contributor: Milk:cattle) |
| IEDI (% ADI*) according to EFSA PRIMo 3.1 | Normal mode: 15% (based on NL toddler; main contributor: milk: cattle); Refined calculation mode: 6% (based on DK child; main contributor: rye) |
| IESTI (% ARfD**) according to EFSA PRIMo 3.1 | Wheat: 9% (based on unprocessed commodities, children) Wheat: 5% (based on unprocessed commodities, adults) Wheat (milling flour): 7% (based on processed commodities, children) Barley / beer: 5% (based on processed commodities, adults) |

* ADI of prothioconazole-desthio

** ARfD of prothioconazole-desthio

The proposed uses of prothioconazole in the formulation ADM.03500.F.2.B do not represent unacceptable acute and chronic risks for the consumer with regard to residues of prothioconazole-desthio (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)).

TDMs:

Consumer exposure assessments for all four TDMs have been conducted by UK, 2018b and EFSA 2018b during evaluation of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data to which explicit reference is made. The EU MS NEDIs and NESTIs for each relevant TDM are below the respective ADIs and ARfDs:

EFSA 2018b: “The ‘worst-case’ consumer dietary intake assessment with regard to the TDMs for the complete group of triazole active substances that were assessed in the framework of these confirmatory data has been conducted by the RMS using the EFSA PRIMo rev.3 and by EFSA using the EFSA PRIMo rev.2A since PRIMo rev.3 is not applicable in the framework of confirmatory data assessed here.

The chronic and acute dietary intakes have been carried out using the highest input residue values for risk assessment (STMR values and the HR values), derived for each TDM for each crop groups and each product of animal origin. Since in most of the residue trials in primary and rotational crops, higher residue levels of the TDMs in the control samples were observed, these levels were also considered in the dietary intake calculation. Using the EFSA PRIMo rev.3, the IEDI accounted for 93% of the ADI (NL toddler) for 1,2,4-T, 6% of the ADI (NL toddler) for TA, 1% of the ADI (NL toddler) for TAA and 1% of the ADI (NL toddler) for TLA. No acute intake concern was identified as the calculated international estimated short-term intake (IESTI) accounted for up to 40% of the ARfD (cattle milk) for 1,2,4-T, 28% of the ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 7% of the ARfD (potatoes) for TLA. Using the EFSA PRIMo rev.2A, the IEDI accounted for 60% of the ADI (FR toddler) for 1,2,4-T, 5% of the ADI (WHO Cluster diet B) for TA, 1% of the ADI (WHO Cluster diet B) for TAA and < 1% of the ADI (FR toddler) for TLA. The acute intake was estimated to be 40% of the ARfD (milk) for 1,2,4-T, 28% of the

ARfD (oranges) for TA, 1% of the ARfD (oranges) for TAA and 6.7% of the ARfD (potatoes) for TLA. Since the toxicological reference values for TLA were derived by bridging with the reference values of TA, a combined dietary risk assessment for TA and TLA was performed. No chronic or acute intake concerns were identified with up to 6% ADI (WHO Cluster diet B), and 34% and 8% ARfD (watermelons) respectively for children and adults.”

calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies submitted with this dossier if higher were conducted.

In addition, new worst case calculations based on input values given in UK, 2018b in Table 7.3.17-16 (for crop commodities) and in Table 7.7-1 of Appendix E thereof (for animal commodities) and involving the residue data of the new residue studies if higher were conducted for the TDMs and results are given in the following:

Extensive calculation sheets are presented in Appendix 3.

Table 7.2- 40: Consumer risk assessment for 1,2,4-triazole

| | |
|--|---|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | Not applicable, no MRLs set. |
| IEDI (% ADI) according to EFSA PRIMo 3.1 | Normal mode: 51 % (based on NL toddler; main contributor: milk: cattle); Refined mode*: 44 % (NL toddler; main contributor: milk: cattle) |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Milk: cattle: 20 % (based on unprocessed commodities, children) Milk: cattle: 6 % (based on unprocessed commodities, adults) Wheat (milling flour): 0.6 % (based on processed commodities, children) Barley / beer: 0.4 % (based on processed commodities, adults) |

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2- 41: Consumer risk assessment for TA

| | |
|--|--|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | Not applicable, no MRLs set. |
| IEDI (% ADI) according to EFSA PRIMo 3.1 | Normal mode: 5 % (based on NL toddler; main contributor: maize/corn); Refined mode*: 2 % (DK child; main contributor: rye) |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Wheat: 3 % (based on unprocessed commodities, children) Wheat: 2 % (based on unprocessed commodities, adults) Wheat (milling flour): 3 % (based on processed commodities, children) Barley / beer: 1 % (based on processed commodities, adults) |

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2- 42: Consumer risk assessment for TLA

| | |
|--|--|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | Not applicable, no MRLs set. |
| IEDI (% ADI) according to EFSA PRIMo 3.1 | Normal mode: 1 % (based on NL toddler; main contributor: milk: cattle); Refined mode*: 0.7 % (based on NL toddler; main contributor: milk: cattle) |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Milk: cattle: 1 % (based on unprocessed commodities, children) Milk: cattle: 0.4 % (based on unprocessed commodities, adults) Wheat (milling flour): 0.1 % (based on processed commodities, children) Barley / beer: 0.1 % (based on processed commodities, adults) |

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

Table 7.2- 43: Consumer risk assessment for TAA

| | |
|--|------------------------------|
| TMDI (% ADI) according to EFSA PRIMo 3.1 | Not applicable, no MRLs set. |
|--|------------------------------|

| | |
|--|--|
| IEDI (% ADI) according to EFSA PRIMo 3.1 | Normal mode: 1 % (based on NL toddler; main contributor: maize/corn); Refined mode*: 0.9 % (DK child; main contributor: rye) |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Wheat: 1 % (based on unprocessed commodities, children) Wheat: 0.7 % (based on unprocessed commodities, adults) Wheat (milling flour): 1 % (based on processed commodities, children) Barley / beer: 0.6 % (based on processed commodities, adults) |

*Refined mode includes GAPs under assessment as well as livestock matrices/products.

TA and TLA can be assigned to a common assessment group. Therefore a combined risk assessment for these TDM can be performed by simple addition of NEDIs and NESTIs of both metabolites.

The combined EU IEDIs are less than the ADI of 0.3 mg/kg bw/day.

The combined EU IESTIs are less than the ARfD of 0.3 mg/kg bw/day.

The proposed uses of prothioconazole in the formulation ADM.03500.F.2.B do not represent unacceptable acute and chronic risks for the consumer with regard to the residues of triazole alanine (TA), triazole lactic acid (TLA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T).

Evaluator comment:

Calculations presented by the Applicant are acceptable.

The data available are considered sufficient for risk assessment. The chronic and the short-term intakes of prothioconazole residues and TDMs are unlikely to present a public health concern.

The intended uses of ADM.03500.F.2.B are accepted.

7.3 Combined exposure and risk assessment

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Not relevant. The product contains only one active substance.

Evaluator comment:

Explanations presented by the Applicant are acceptable.

7.4 References

- EC (European Commission), 2021. Review report for prothioconazole, SANCO/3923 /07 – final (10 December 2007, update 26 January 2021)
- EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. EFSA Scientific Report (2007)106, 1-98.
- EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for prothioconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014; 12(5):3689, 72 pp. doi:10.2903/j.efsa.2014.3689
- EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the modification of the existing maximum residue level (MRL) for prothioconazole in shallots. EFSA Journal 2015; 13(5):4105, 20 pp. <https://doi.org/10.2903/j.efsa.2015.4105>
- EFSA (European Food Safety Authority), 2015b. Reasoned opinion on the modification of the existing maximum residue levels for prothioconazole in sunflower seeds. EFSA Journal 2015;13(12):4371, 24 pp. <https://doi.org/10.2903/j.efsa.2015.4371>
- EFSA (European Food Safety Authority), 2018a. Report of Pesticides Peer Review meeting 171, Triazole derivative metabolites, 13-15 December 2017
- EFSA (European Food Safety Authority), 2018b (amended 2019). Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376, 20 pp. <https://doi.org/10.2903/j.efsa.2018.5376>
- EFSA (European Food Safety Authority), 2020. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds. EFSA Journal 2020;18(2):5999, 50 pp. <https://doi.org/10.2903/j.efsa.2020.5999>
- FAO (Food and Agriculture Organization of the United Nations), 2008b. Prothioconazole. In: Pesticide residues in food – 2008. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 194.
- FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
- FAO (Food and Agriculture Organization of the United Nations), 2009a. Prothioconazole. In: Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 193.
- FAO (Food and Agriculture Organization of the United Nations), 2009b. Prothioconazole. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196.
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- FAO (Food and Agriculture Organization of the United Nations), 2018. Prothioconazole In: Pesticide residues in food - 2018. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 234. FAO 2018
- Germany, 2014. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Report on two studies on the nature of residue of prothioconazole and prothioconazole-desethio under simulated processing conditions, March 2014.
- United Kingdom, 2004. Draft Assessment report (DAR) on the active substance prothioconazole prepared

by the rapporteur Member state United Kingdom in the framework of Council Directive 91/414/EEC, October 2004.

United Kingdom, 2007. Final addendum to the draft assessment report on the active substance prothioconazole prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, May 2007.

United Kingdom, 2018a. Draft renewal assessment report on the active substance prothioconazole prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EU) No 1107/2009, February 2018.

United Kingdom, 2018b. Triazole Derivate Metabolites, addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom in the framework of Regulation (EC) No 1107/2009, revised version of February 2018.

United Kingdom, 2019a. Evaluation report on the confirmatory data assessment and setting of prothioconazole MRLs in oilseed rape. March, 2019, 71pp

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|----------------------|-------------------------------|-------|--|-------------------------|---|
| KCP 8/ KCA 6.1/01 | Klimmek, S. and Gizler, A. | 2017 | Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0, 3, 6, 12, 18, 24 and 36 months. Report No.: S12-00072, sponsor no.: R-30330 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.1/02 | Lefresne, S. | 2020 | Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content). Report No.: B18S-A4-P-02, sponsor no.: R-39653 POLLENIZ/GIRPA, Beaucouzé Cedex, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.1/03 | Yozgatli, H.P. et al. | 2022a | Storage stability of 1,2,4-triazole (1,2,4-T) and triazole alanine (TA) in oilseed rape under deep frozen conditions Report No.: S20-08247, sponsor no.: 000107053 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.1/04 | Lindner, M. | 2022 | Storage stability of prothioconazole and azoxystrobin in pollen, nectar, flowers and honey under deep frozen conditions Study no.: S19-02145, MAC-1931L, sponsor no.: 000104133 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.1/05 | Kalathoor, R. | 2021 | Residue analytical method 01602 and short term storage of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey HPLC DMS-MS/MS, Report Amendment No. 2 Study no.: M-680825-03-1, S19-01126, sponsor no.: Not stated GLP Unpublished | N | Triazole Derivative Metabolite Group |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|------------------|-------------|---|-------------------------------------|--------------|
| KCP 8/ KCA 6.3.1/01 | Huaultmé, J.-M. | 2019a | Residue study of azoxystrobin, prothioconazole and its metabolites in wheat whole plants and Raw Agricultural Commodity after one foliar application of MCW-2073 - 1 harvest and 2 decline trials – Northern Europe (France and Poland) – 2018. Report no.: BPL18/713/GC, sponsor no.: R-39643 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/02 | Yozgatli, H.P. | 2021b | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plant without roots, grain and straw) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France and Poland) 2018 Study No. S18-02654, sponsor no.: R-39643B Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/03 | Amic, S. | 2020a | Residue study of azoxystrobin, prothioconazole and its metabolites in wheat whole plant and Raw Agricultural Commodity after one foliar application of MCW-2073 - 3 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019. Report no.: BPL19/757/GC, sponsor no.: 000102745 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/04 | Yozgatli, H.P. | 2022b | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one application of MCW 2073 (200 g/L of Azoxystrobin and 150 g/L of Prothioconazole) in 5 trials (3 HS + 2 DCS) in Northern EU (France, Hungary and Poland), 2019 Study No. S19-00725, sponsor no.: 000102779 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/05 | Amic, S. | 2020b | Residue study of prothioconazole and its metabolites in wheat whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019. Report no.: BPL19/762/GC, sponsor no.: 000102751 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|-----------------|-------|---|----------------------|-------|
| KCP 8/ KCA 6.3.1/06 | Yozgatli, H.P. | 2021d | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one application of ADM.3500.F.2.B (250g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no: S19-00733, sponsor no.: 000102783 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/07 | Le Mineur, A. | 2022a | Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021 Study no.: BPL21/954/GC, sponsor no.: 000107608 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.1/08 | Le Mineur, A. | 2022b | Residue study of prothioconazole, difenoconazole and their metabolites in wheat whole plant and raw agricultural commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe - 2021 Study no.: S21-02258, BPL21/958/GC, EFSA-2021-00000558, sponsor no.: 000107612 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/01 | Huaultmé, J.-M. | 2019b | Residue study of azoxystrobin, prothioconazole and its metabolites in barley whole plants and Raw Agricultural Commodity after one foliar application of MCW-2073 - 1 harvest and 2 decline trials – Northern Europe (France) – 2018. Report no.: BPL18/715/GC, sponsor no.: R-39645 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/02 | Yozgatli, H.P. | 2021e | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plant without roots, grain and straw) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France) 2018 Study no.: S18-02656, sponsor no.: R-39645B Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|------------------|-------------|---|-------------------------------------|--------------|
| KCP 8/ KCA 6.3.2/03 | Amic, S. | 2020c | Residue study of azoxystrobin, prothioconazole and its metabolites in barley whole plant and Raw Agricultural Commodity after one foliar application of MCW-2073 - 3 harvest and 2 decline trials – Northern Europe (France, Poland and Hungary) – 2019. Report no.: BPL19/759/GC, sponsor no.: 000102749 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/04 | Yozgatli, H.P. | 2021f | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of MCW 2073 (200 g/L of Azoxystrobin and 150 g/L of Prothioconazole) in 5 trials (3 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no.: S19-00727, sponsor no.: 000102781 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/05 | Amic, S. | 2020d | Residue study of prothioconazole and its metabolites in barley whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019. Report no.: BPL19/764/GC, sponsor no.: 000102753 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/06 | Yozgatli, H.P. | 2021g | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 Study no.: S19-00735, sponsor no.: 000102785 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/07 | Huauilmé, J.-M. | 2020 | Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019. Report no.: BPL19/772/GC, sponsor no.: 000102761 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|------------------|-------------|---|-------------------------------------|--------------|
| KCP 8/ KCA 6.3.2/08 | Mahlow, S. | 2021 | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019 Study no.: S19-00752, sponsor no.: 000102794 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/09 | Huaultmé, J.-M. | 2021a | Residue study of Prothioconazole and its metabolites, and Fenpropidin in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020. Report no.: BPL20/844/GC, sponsor no.: 000105350 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/10 | Yozgatli, H.P. | 2021h | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175g a.s./L of prothioconazole and 250 g/L fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2020 Study no.: S20-01302, sponsor no.: 000105545 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/11 | Huaultmé, J.-M. | 2022a | Residue study of fluxapyroxad and prothioconazole and their metabolites in barley raw agricultural commodities after application of ADM.03503.F.1.A under field conditions - Northern Europe - 2021 Study no.: BPL21/962/GC, sponsor no.: 000107616 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.2/12 | Huaultmé, J.-M. | 2022b | Residue study of prothioconazole, difenoconazole and their metabolites in barley raw agricultural commodities after foliar application of ADM.03501.F.1.A under field conditions - Northern Europe - 2021 Study no.: BPL21/960/GC, sponsor no.: 000107614 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|------------------|-------------|--|-------------------------------------|--------------|
| KCP 8/ KCA 6.3.2/13 | Barbier, G. | 2022 | Analysis of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A (prothioconazole and fenpropidin) in trial in Northern - 2020 Study no.: B21G-A4-P-05, sponsor no.: 000108763 GIRPA, Beaucouzé Cedex, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/01 | Roussel, Ch. H. | 2020 | Magnitude of the residues of azoxystrobin + prothioconazole and metabolites in oilseed rape (RAC whole plant and seeds), following one application of MCW-2073 in 3 trials (2 DCS and 1 HS), Northern Europe (Northern France and Poland) – 2018. Report no.: ChR-18-33731, sponsor no.: R-39647 STAPHYT, Inchy en Artois, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/02 | Gustloff, C. | 2021 | Determination of the residue of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in OSR (RAC whole plant and seed) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France and Poland) 2018 Study no.: S18-02650, sponsor no.: R-39647B Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/03 | Peterek, S. | 2020 | Magnitude of the residues of azoxystrobin + prothioconazole and metabolites in oilseed rape (RAC whole plant, seeds and straw), following one application of MCW-2073 in 6 trials (2 DCS, 3 HS and 1 backup HS), Northern Europe (Poland, Northern France and Germany) – 2019. Report no.: SPK-19-38368, sponsor no.: 000102602 STAPHYT, Inchy en Artois, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/04 | Ivanov, E. | 2021a | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in Oilseed rape (RAC whole plant, seeds and straw) following one application of MCW-2073 in Northern Europe (Poland, Northern France and Germany) - 2019 Study no.: S19-01822, sponsor no.: 000102627 Eurofins Agroscience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|------------------------|------------------|-------------|--|-------------------------------------|--------------|
| KCP 8/ KCA 6.3.3/05 | Grall, E. | 2021 | Magnitude of the residues of prothioconazole and metabolites in oilseed rape (RAC whole plant, seeds and straw), following one application of ADM.3500.F.2.B in 4 trials (2 DCS and 2 HS), Northern Europe (Poland, Northern France and Germany) – 2019/2020. Report no.: SPK-19-38370, sponsor no.: 000102604 STAPHYTT Spain S.L., Gines, Spain GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/06 | Ivanov, E. | 2021b | Determination of residue of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in Oilseed rape (RAC whole plant, seeds and straw) following one application of ADM.3500.F.2.B in 4 trials (2 DCS and 2 HS) in Northern Europe (Poland, Northern France and Germany)-2019 Study no.: S19-01824, sponsor no.: 000102629 Eurofins Agrosience Services Chem GmbH, Hamburg, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/07 | Amic, S. | 2021 | Residue study of Prothioconazole and its metabolites in oilseed rape Raw Agricultural Commodities (seeds) after foliar application of ADM.3500.F.2.B (Prothioconazole) under field conditions – harvest trials - Northern Europe - 2021 Study no.: BPL21/964/GC, sponsor no.: 000107621 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.3.3/08 | Amic, S. | 2022 | Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in oilseed rape raw agricultural commodities (seeds) after foliar application of ADM.03503.F.1.A (Prothioconazole and Fluxapyroxad) under field conditions - harvest trials Study no.: BPL21/966/GC, sponsor no.: 000107619 SynTech Research France, La Chapelle de Guinchay, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.5.1/01 | Bloß, K. | 2019 | Prothioconazole-desthio: Aqueous Hydrolysis of [¹⁴ C]Prothioconazole-desthio at 90, 100 and 120 °C. Report no.: S18-07655, sponsor no.: 000101817 Eurofins Agrosience Services EcoChem GmbH, Niefern-Öschelbronn, Germany GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|-------------------------|----------------------|-------------|--|-------------------------------------|--------------|
| KCP 8/ KCA 6.5.2/01 | Amic, S. | 2021 | Residue study of triazole metabolites in oilseed rape seeds processed fractions after foliar application on the crop of ADM.03503.F.1.A (Prothioconazole and Fluxapyroxad) under field conditions - field trials for processing - Northern and Southern Europe Study no.: BPL21/968/GC, sponsor no.: 000107694 BIOTEK Agriculture, Saint-Pouange, France GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.6.2/01 | Semrau, J. | 2021 | Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Study no.: S18-02513, sponsor no.: R-39638 Eurofins Agrosience Services GmbH, Stade, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.6.2/02 | Semrau, J. | 2022 | Determination of residues of prothioconazole metabolites in rotational crops (radish, lettuce, barley) after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil at 1 site in Northern Europe and 1 site in Southern Europe 2021 Study no.: S21-00408, sponsor no.: 000107470 Eurofins Agrosience Services GmbH, Stade, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.6.2/03 | Anonymous | 2022 | Position Paper: 1,2,4-Triazole residues in crop residue trials and rotational crops following the use of Prothioconazole Sponsor no.: 000110079 ADAMA Agricultural Solutions Ltd., Airport City, Israel Not GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.10.1/01 | Persigehl, M. et al. | 2021 | Study on the effect of ADM.3500.F.2.B on honey bee colonies (Apis mellifera L.) under semi-field conditions in Germany Study no.: B19010-3, sponsor no.: 000102470 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.10.1/02 | Persigehl, M. et al. | 2021 | Study on the effect of ADM.3500.F.2.B on honey bee colonies (Apis mellifera L.) under semi-field conditions in Spain Study no.: B19010-4, sponsor no.: 000102471 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished | N | ADM |

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|-------------------------|----------------------|-------------|---|-------------------------------------|--------------|
| KCP 8/ KCA 6.10.1/03 | Persigehl, M. et al. | 2020 | Study on the effect of MCW-2073 on honey bee colonies (<i>Apis mellifera</i> L.) under semi-field conditions in Germany Study no.: B19010-1, sponsor no.: 000102468 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.10.1/04 | Persigehl, M. et al. | 2021 | Study on the effect of MCW-2073 on honey bee colonies (<i>Apis mellifera</i> L.) under semi-field conditions in Spain Study no.: B19010-2, sponsor no.: 000102469 tier3 solutions GmbH, Leverkusen, Germany GLP Unpublished | N | ADM |
| KCP 8/ KCA 6.10.1/05 | Bougrier, M.-A. | 2022 | Magnitude of the residue of prothioconazole and its metabolites in honey after application of ADM.03500.F.2.B on Phacelia crop under semi-field conditions in Europe - 2021 Study no.: 555-2021, EFSA-2021-00003664, sponsor no.: 000108776 Testapi SAS, Gennes, France GLP Unpublished | N | ADM |

ADM = Property of ADAMA Agricultural Solution and all affiliates.

TDMG = Triazole Derivative Metabolite Group.

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review of prothioconazole

| Data point (DAR ref. no) | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|--|--|-------------|---|-------------------------------------|--------------|
| KCP 8/ KCA 6/01 (IIA, 6.0/01) | Heinemann, O. | 2001 | 18 months storage stability of residues of JAU 6476 and JAU 6476-desthio during frozen storage in/on wheat matrices Report No. : MR-282/00 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/02 (IIA, 6.1.2/01) | Haas, M. | 2001 | Metabolism of [phenyl-UL- ¹⁴ C]JAU 6476 in peanuts Report No.: MR-193/01 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/03 (IIA, 6.1.1/01) | Haas, M.; Bornatsch, W. | 2000 | Metabolism of JAU 6476 in spring wheat (after foliar application) Report no.: MR-198/99 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/04 (IIA, 6.1.1/03) | Vogeler, K.; Sakamoto, H.; Brauner, A. | 1993 | Metabolism of SXX 0665 in summer wheat Report No.: PF3906 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/05 (IIA, 6.1.1/02) | Haas, M. | 2001 | Metabolism of JAU 6476 in spring wheat after seed dressing Report No.: MR-467/99 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/06 (IIA, 6.6./01) | Haas, M. | 2001 | Confined rotational crop study with JAU 6476 Report No.: MR-159/00 Bayer AG GLP Unpublished | N | BCS |

| Data point (DAR ref. no) | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|--|------------------|-------------|--|-------------------------------------|--------------|
| KCP 8/ KCA 6/07 (IIA 6.2.2.1/01) | xxxxxxxxxxxx | 2001 | [Phenyl-UL- ¹⁴ C]JAU 6476 Absorption, distribution, excretion and metabolism in the lactating goat Report No.: MR-092/01 GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/08 (IIA, 6.2.2.2/01) | xxxxxxxxxxxx | 2002 | [Phenyl-UL- ¹⁴ C] JAU 6476-desthio Absorption, distribution, excretion, and metabolism in the lactating goat Report no. MR-091/01 GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/09 (IIA, 6.2.2.3/01) | xxxxxxxxxxxx | 2001 | [Phenyl-UL- ¹⁴ C]JAU 6476 Absorption, distribution, excretion and metabolism in laying hens Report No.: MR-309/01 Bayer AG GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/10 (IIA, 6.4/01) | xxxxxxxxxxxx | 2001 | JAU 6476-desthio – Dairy cattle feeding study Report No.: MR-535/00 Report includes trial no.: P 673003007 xxxxxxxxxxxx GLP Unpublished | N | BCS |
| KCP 8/ KCA 6/11 (IIA, 6.5/01) | Gilges, M. | 2001 | Hydrolysis of JAU 6476 under conditions of processing Report No.: MR-166/00 Bayer AG GLP Unpublished | N | BCS |

BCS = Bayer CropScience

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review of triazole derivative metabolites (TDMs)

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|---|------------------|-------------|--|-------------------------------------|--------------|
| For the relevant studies please refer to the EU peer review of the triazole derivative metabolites (TDMs) in the light of confirmatory data submitted (UK, 2018b, EFSA, 2018b, amended 2019). | | | | | |

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| - | - | - | - | - | - |

List of data relied on and not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No. Source (where different from company) GLP or GEP status Published or not | Vertebrate study Y/N | Owner |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| - | - | - | - | - | - |

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Prothioconazole

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

A 2.1.1.1.1.1 Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>A deep-freezer storage stability study was conducted to determine the stability of residues of 1,2,4- Triazole (1,2,4 T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) for up to 36 months during storage at <-18 °C.</p> <p><u>Results:</u></p> <p>Cucumber</p> <ul style="list-style-type: none"> - According to the OECD 506, point 22, in case a significant difference (greater than 20%) exists between the results for the duplicate samples from the same time point, it should be analysing additional samples of the commodity from that time point. This is the case for samples of 1,2,3-triazole (1,2,4 T) after 12 months storage of cucumber. Unfortunately, the additional sample has not been analyzed. - The level of residue 1,2,4-triazole (1,2,4 T) in cucumber declined by more than 30% after 12 months. The procedural recoveries at this time-point were significantly lower than for the earlier time-points. Despite the above, taking into account the recommendation indicated in point 33 of OECD 506 it is considered that the samples are sufficiently stable over 12 months frozen storage in cucumber. - Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months. <p>Grapes</p> <ul style="list-style-type: none"> - Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) stored at -18°C or below for at least 36 months (although it is considered that some decline in the 1,2,4 T stability has been observed after 12 months storage of grapes). <p>Dried beans (seed)</p> <ul style="list-style-type: none"> - Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in dried beans (seed) stored at -18°C or below for at least 36 months. <p>The study is acceptable.</p> |
|-------------------|--|

Reference: KCA 6.1/01

Report Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0, 3, 6,12,18, 24 and 36 months; Klimmek, S and Gizler, A., 2017;
Report No.: S12-00072, Sponsor no.: R-30330

Guideline(s): Yes,
Regulation (EC) No. 1107/2009;
Guidance document SANCO/825/OO rev. 8.1 of 16/11/2010, European Commission;
Guidance document SANCO/3029/99 rev. 4 of 11/07/00, European Commission;
EU Commission Working Document 1607/VI/97, Appendix H: Storage Stability 7032/VI/95, rev. 5 (22/07/97);

U.S. EPA Residue Chemistry Test Guidelines, OPPTS 860.1380, Storage Stability Data

| | |
|----------------|-----|
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Study objective

The study objective was to validate the method for the determination of residues of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) and to investigate their freezer storage stability at < -18°C for up to 36 months.

Materials and methods

For storage stability determination the matrix material was thoroughly homogenised with dry ice using a cutter or knife mill and stored at < -18 °C until start of analysis.

For cucumber (fruit), grapes (bunches) and dried beans (seed) specimens, untreated homogenised material was weighed into glass jars with screw caps. Specimen weight was 5 g for each matrix. Fortification solutions of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) used for cucumber (fruit), grapes (bunches) and dried beans (seed) specimens were prepared in water (HPLC grade) or methanol using an Eppendorf pipette and volumetric flasks.

Fortification of the specimens to be stored was carried out on day 0 by adding the appropriate fortification solution at a level of 0.20 mg/kg to separate samples of the specimens. Afterwards, the glass jars were capped, transferred to a freezer, and then stored at < -18 °C. These specimens were only removed for analysis at the fixed intervals.

Fortified and control samples of cucumber (fruit), grapes (bunches) and dried beans (seed) were analysed at day 0 and after 3, 6, 12, 18, 24 and 36 months of storage at < -18 °C, respectively. At day 0, three specimens of cucumber (fruit), grapes (bunches) and dried beans (seed) fortified with 1,2,4-triazole (1,2,4 T), Triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) were analysed together with one control sample each. At each time point after day 0, one control sample and two stored fortified samples were analysed together with two freshly fortified specimens for each matrix type.

Analysis of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) was performed according to Syngenta method GRM053.01A. For analysis of all analytes, cucumber (fruit), grapes (bunches) and dried beans (seed) specimens were extracted with methanol/water (4/1, v/v). After filtration and evaporation to the aqueous remainder, the volume was adjusted with ultra-pure water. After sonication, final determination took place with liquid chromatography with tandem mass spectrometry (LC-MS/MS) (for validation samples and for storage samples up until the 18 months storage time point) or with high performance liquid chromatography with triple quadrupole mass spectrometric detection equipped with DMS SelexION technology (LC-DMS-MS/MS) (from July 2014 for storage time points 24 and 36 months, and for an additional validation set). All specimen extracts were stored at 3 - 8 °C in the dark until analysis.

For determination of stability in extracts and following analysis, the final extracts of the validation samples fortified at the LOQ along with the control samples were stored in a refrigerator at 5 ± 4°C for at least 10 days. After this period, these samples were re-analysed by single injection against freshly prepared standards.

Successful method validations for all specimens and analytes have been conducted within the study:

A reduced validation for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit), grapes (bunches) and dried beans (seed) was successfully performed within this study using LC-MS/MS and LC-DMS-MS/MS.

For 1,2,4-triazole (1,2,4 T), a reduced validation in cucumber (fruit) and grapes (bunches) was successfully performed within this study using LC-MS/MS and LC-DMS-MS/MS.

For 1,2,4-triazole (1,2,4 T), a full validation in dried beans (seed) was successfully performed within this study using LC-MS/MS and a reduced validation in dried beans (seed) was successfully performed within this study using LC-DMS-MS/MS.

The limit of quantification (LOQ) for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) was 0.01 mg/kg.

For details on method validations, please refer to dRR Part B.5, point KCP 5.1.2.

Results and discussions

Analysis of control specimens by LC-MS/MS and LC-DMS-MS/MS during the validation yielded no residues of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) above the limit of quantification of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in the test systems except for some control specimens for triazole alanine and triazole lactic acid. The residue levels of triazole alanine and triazole lactic acid found in the untreated samples are in line with values found in the latest EU survey of the residue situation of triazole metabolites.

The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T) is stable in cucumber (fruit) stored at -18°C or below for 12 months. Although the level of residue 1,2,4-triazole seems to have declined by more than 30% in cucumber (fruit) after 12 months, it is considered that the samples are sufficiently stable over 12 months frozen storage, as the procedural recoveries at the 12 months time-point were lower than for the earlier time-points (although it is considered that some decline in stability has been observed).

The recoveries of stored samples demonstrate that triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in cucumber (fruit) stored at -18°C or below for at least 36 months.

The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in grapes (bunches) stored at -18°C or below for at least 36 months.

The recoveries of stored samples demonstrate that 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) are stable in dried beans (seed) stored at -18°C or below for at least 36 months.

Extract stability was verified during the study for 1,2,4 T, TA, TAA and TLA in cucumber for 31 days, in grapes for 39 days and in dried beans for 10 (1,2,4 T), 17 (TA) and 50 days (TA, TLA).

Table A 1: Stability of 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber, grapes and dried beans following storage at ≤ -18°C

| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | Actual storage interval (months) | Residues after storage (mg/kg) (mean) | Residues after storage (% of nominal spiking level) (mean) | Procedural recovery of freshly spiked control sample (%) (mean) | Residues after storage (corrected for procedural recovery) (mg/kg) | Residues after storage (corrected for procedural recovery) (%) |
|----------|---------|---------------------------------------|-----------------------------------|----------------------------------|---------------------------------------|--|---|--|--|
| Cucumber | 1,2,4 T | 0.2 | 0 | 0 | 0.200, 0.208, 0.188 (0.199) | 100, 104, 94 (99) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.169, 0.152 (0.161) | 85, 76 (81) | 114, 106 (110) | 0.146 | 73 |
| | | 0.2 | 6 | 6 | 0.167, 0.176 (0.172) | 84, 88 (86) | 104, 99 (102) | 0.169 | 85 |
| | | 0.2 | 12 | 12 | 0.104, 0.133 (0.119) | 52, 67 (60)* | 72, 76 (74) | 0.160 | 80 |
| | | 0.2 | 18 | 19 | 0.085, 0.099 (0.092) | 43, 50 (47) | 105, 101 (103) | 0.089 | 45** |
| | | 0.2 | 24 | 29 | 0.099, 0.089 (0.094) | 50, 45 (48) | 115, 120 (118) | 0.080 | 40** |
| | | 0.2 | 36 | 45 | 0.061, 0.067 (0.064) | 31, 34 (33) | 98, 104 (101) | 0.064 | 32** |
| | TA | 0.2 | 0 | 0 | 0.199, 0.212, 0.189 (0.200) | 100, 106, 95 (100) | NA | 0.199 | 100 |
| | | 0.2 | 3 | 3 | 0.162, 0.148, (0.155) | 81, 74 (78) | 77, - (77) | 0.201 | 101 |
| | | 0.2 | 6 | 6 | 0.216, 0.219 (0.218) | 108, 110 (109) | 108, 111 (110) | 0.199 | 100 |
| | | 0.2 | 12 | 12 | 0.179, 0.166 (0.173) | 90, 83 (87) | 90, 95 (93) | 0.186 | 94 |
| | | 0.2 | 18 | 19 | 0.218, 0.222 (0.220) | 109, 111 (110) | 104, 102 (103) | 0.212 | 107 |
| | | 0.2 | 24 | 28 | 0.221, 0.216 (0.219) | 111, 108 (110) | 107, 112 (110) | 0.200 | 100 |
| | | 0.2 | 36 | 43 | 0.193, 0.206 (0.200) | 97, 103 (100) | 102, 105 (104) | 0.193 | 97 |
| | TAA | 0.2 | 0 | 0 | 0.189, 0.205, 0.194 (0.196) | 95, 103, 97 (98) | NA | 0.199 | 100 |
| | | 0.2 | 3 | 3 | 0.203, 0.214 (0.209) | 102, 107 (105) | 108, 110, (109) | 0.191 | 96 |
| | | 0.2 | 6 | 6 | 0.203, 0.228 (0.216) | 102, 114 (108) | 98, - (98) | 0.220 | 110 |
| | | 0.2 | 12 | 12 | 0.167, 0.109 (0.138) | 84, 55 (70) | 75, 65 (70) | 0.197 | 99 |
| | | 0.2 | 18 | 19 | 0.199, 0.197 (0.198) | 100, 99 (100) | 95, 100 (98) | 0.203 | 102 |
| | | 0.2 | 24 | 29 | 0.212, 0.228 (0.220) | 106, 114 (110) | 108, 107 (108) | 0.205 | 102 |
| | | 0.2 | 36 | 45 | 0.213, 0.216 (0.215) | 107, 108 (108) | 100, 105 (103) | 0.209 | 105 |
| | TLA | 0.2 | 0 | 0 | 0.212, 0.205, 0.210 (0.209) | 106, 103, 105 (105) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.191, 0.212 (0.202) | 96, 106 (101) | 114, 106 (110) | 0.183 | 92 |
| | | 0.2 | 6 | 6 | 0.214, 0.223 (0.219) | 107, 112 (110) | 111, 108 (110) | 0.200 | 100 |
| | | 0.2 | 12 | 12 | 0.226, 0.251 (0.239) | 113, 126 (120) | 114, 122 (118) | 0.202 | 101 |
| | | 0.2 | 18 | 19 | 0.221, 0.218 (0.220) | 111, 109 (110) | 102, 112 (107) | 0.205 | 103 |
| | | 0.2 | 24 | 29 | 0.220, 0.204 (0.212) | 110, 102 (106) | 109, 108 (109) | 0.195 | 98 |
| | | 0.2 | 36 | 45 | 0.224, 0.215 (0.220) | 112, 108 (110) | 103, 107 (105) | 0.209 | 105 |
| Grapes | 1,2,4 T | 0.2 | 0 | 0 | 0.211, 0.211, 0.207 (0.210) | 106, 106, 104 (105) | NA | 0.199 | 100 |
| | | 0.2 | 3 | 3 | 0.174, 0.181 (0.178) | 87, 91 (89) | 106, 106 (106) | 0.167 | 84 |

| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | Actual storage interval (months) | Residues after storage (mg/kg) (mean) | Residues after storage (% of nominal spiking level) (mean) | Procedural recovery of freshly spiked control sample (%) (mean) | Residues after storage (corrected for procedural recovery) (mg/kg) | Residues after storage (corrected for procedural recovery) (%) |
|-------------|---------|--|--|---|---|---|---|---|---|
| | | 0.2 | 6 | 6 | 0.208, 0.198 (0.203) | 104, 99 (102) | 111, 109 (110) | 0.185 | 92 |
| | | 0.2 | 12 | 12 | 0.135, 0.136 (0.136) | 68, 68 (68) | 93, 91 (92) | 0.147 | 74 |
| | | 0.2 | 18 | 19 | 0.147, 0.149 (0.148) | 74, 75 (75) | 109, 105 (107) | 0.138 | 70 |
| | | 0.2 | 24 | 29 | 0.155, 0.149 (0.152) | 78, 75 (77) | 102, 113 (108) | 0.141 | 71 |
| | | 0.2 | 36 | 45 | 0.141, 0.136 (0.139) | 71, 68 (70) | 100, 100 (100) | 0.139 | 70 |
| | TA | 0.2 | 0 | 0 | 0.205, 0.207, 0.199 (0.204) | 103, 104, 100 (102) | NA | 0.199 | 100 |
| | | 0.2 | 3 | 3 | 0.190, 0.200, (0.195) | 95, 100 (98) | 85, 92 (89) | 0.220 | 110 |
| | | 0.2 | 6 | 6 | 0.215, 0.218 (0.217) | 108, 109 (109) | 104, 109 (107) | 0.203 | 102 |
| | | 0.2 | 12 | 12 | 0.177, 0.186 (0.182) | 89, 93 (91) | 99, 101 (100) | 0.182 | 91 |
| | | 0.2 | 18 | 19 | 0.224, 0.215 (0.220) | 112, 108 (110) | 112, 108 (110) | 0.200 | 100 |
| | | 0.2 | 24 | 29 | 0.214, 0.209 (0.212) | 107, 105 (106) | 105, 107 (106) | 0.200 | 100 |
| | | 0.2 | 36 | 44 | 0.220, 0.209 (0.215) | 110, 105 (108) | 107, 105 (106) | 0.202 | 101 |
| | TAA | 0.2 | 0 | 0 | 0.212, 0.190, 0.188 (0.197) | 106, 95, 94 (98) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.235, 0.204 (0.220) | 118, 102 (110) | 111, 105 (108) | 0.203 | 102 |
| | | 0.2 | 6 | 6 | 0.207, 0.231 (0.219) | 104, 116 (110) | 119, 100 (110) | 0.200 | 100 |
| | | 0.2 | 12 | 12 | 0.207, 0.215 (0.211) | 104, 108 (106) | 108, 108 (108) | 0.195 | 98 |
| | | 0.2 | 18 | 19 | 0.200, 0.212 (0.206) | 100, 106 (103) | 107, 113 (110) | 0.187 | 94 |
| | | 0.2 | 24 | 29 | 0.216, 0.216 (0.216) | 108, 108 (108) | 107, 111 (109) | 0.198 | 99 |
| | | 0.2 | 36 | 45 | 0.199, 0.211 (0.205) | 100, 106 (103) | 110, 107 (109) | 0.189 | 95 |
| | TLA | 0.2 | 0 | 0 | 0.212, 0.199, 0.206 (0.206) | 106, 100, 103 (103) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.197, 0.194 (0.196) | 99, 97 (98) | 97, 96 (97) | 0.203 | 102 |
| | | 0.2 | 6 | 6 | 0.201, 0.183 (0.192) | 101, 92 (97) | 114, 106 (110) | 0.175 | 88 |
| | | 0.2 | 12 | 12 | 0.189, 0.188 (0.189) | 95, 94 (95) | 99, 105 (102) | 0.185 | 93 |
| | | 0.2 | 18 | 19 | 0.220, 0.215 (0.218) | 110, 108 (109) | 107, 111 (109) | 0.200 | 100 |
| | | 0.2 | 24 | 29 | 0.214, 0.222 (0.218) | 107, 111 (109) | 109, 108 (109) | 0.201 | 100 |
| | | 0.2 | 36 | 45 | 0.209, 0.203 (0.206) | 105, 102 (104) | 109, 111 (110) | 0.187 | 94 |
| Dried beans | 1,2,4 T | 0.2 | 0 | 0 | 0.197, 0.174, 0.191 (0.187) | 96, 85, 93 (91) | NA | 0.205 | 100 |
| | | 0.2 | 3 | 3 | 0.153, 0.163 (0.158) | 77, 82 (80) | 106, 112 (109) | 0.145 | 73 |
| | | 0.2 | 6 | 6 | 0.145, 0.141 (0.143) | 73, 71 (72) | 74, 91 (83) | 0.173 | 87 |
| | | 0.2 | 12 | 12 | 0.153, 0.145 (0.149) | 77, 73 (75) | 104, 108 (106) | 0.141 | 71 |
| | | 0.2 | 18 | 18 | 0.181, 0.184 (0.183) | 91, 92 (92) | 109, 110 (110) | 0.167 | 84 |
| | | 0.2 | 24 | 24 | 0.140, 0.155 (0.148) | 70, 78 (74) | 86, 84 (85) | 0.174 | 87 |
| | | 0.2 | 36 | 40 | 0.172, 0.153 (0.163) | 86, 77 (82) | 109, 108 (109) | 0.150 | 75 |

| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | Actual storage interval (months) | Residues after storage (mg/kg) (mean) | Residues after storage (% of nominal spiking level) (mean) | Procedural recovery of freshly spiked control sample (%) (mean) | Residues after storage (corrected for procedural recovery) (mg/kg) | Residues after storage (corrected for procedural recovery) (%) |
|--------|---------|---------------------------------------|-----------------------------------|----------------------------------|---------------------------------------|--|---|--|--|
| | TA | 0.2 | 0 | 0 | 0.238, 0.180, 0.194 (0.204) | 119, 90, 97 (102) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.142, 0.145, (0.144) | 71, 73 (72) | 67, 73 (70) | 0.205 | 103 |
| | | 0.2 | 6 | 6 | 0.205, 0.234 (0.220) | 103, 117 (110) | 102, 117 (110) | 0.200 | 100 |
| | | 0.2 | 12 | 12 | 0.147, 0.158 (0.153) | 74, 79 (77) | 84, 79 (82) | 0.187 | 94 |
| | | 0.2 | 18 | 19 | 0.193, 0.212 (0.203) | 97, 106 (102) | 101, 99 (100) | 0.203 | 102 |
| | | 0.2 | 24 | 29 | 0.151, 0.128 (0.140) | 76, 64 (70) | 69, 70 (70) | 0.201 | 101 |
| | | 0.2 | 36 | 44 | 0.195, 0.146 (0.171) | 98, 73 (86) | 77, 93 (85) | 0.201 | 101 |
| | TAA | 0.2 | 0 | 0 | 0.225, 0.209, 0.218 (0.218) | 113, 105, 109 (109) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.203, 0.182 (0.193) | 102, 91 (97) | 115, 100 (108) | 0.179 | 90 |
| | | 0.2 | 6 | 6 | 0.205, 0.212 (0.209) | 103, 106 (105) | 106, 100 (103) | 0.202 | 101 |
| | | 0.2 | 12 | 12 | 0.164, 0.206 (0.185) | 82, 103 (93) | 105, 89 (97) | 0.191 | 95 |
| | | 0.2 | 18 | 19 | 0.160, 0.133 (0.147) | 80, 67 (74) | 58, 69 (64) | 0.231 | 116 |
| | | 0.2 | 24 | 29 | 0.127, 0.152 (0.140) | 64, 76 (70) | 75, 64 (70) | 0.201 | 101 |
| | | 0.2 | 36 | 44 | 0.206, 0.184 (0.195) | 103, 92 (98) | 102, 98 (100) | 0.195 | 98 |
| | TLA | 0.2 | 0 | 0 | 0.203, 0.235, 0.207 (0.215) | 101, 118, 104 (108) | NA | 0.200 | 100 |
| | | 0.2 | 3 | 3 | 0.194, 0.219 (0.207) | 97, 110 (104) | 110, 110 (110) | 0.188 | 94 |
| | | 0.2 | 6 | 6 | 0.160, 0.199 (0.180) | 80, 100 (90) | 83, 96 (90) | 0.201 | 101 |
| | | 0.2 | 12 | 12 | 0.209, 0.142 (0.176) | 105, 71 (88) | 110, 114 (112) | 0.157 | 79 |
| | | 0.2 | 18 | 19 | 0.226, 0.213 (0.220) | 113, 107 (110) | 115, 99 (107) | 0.205 | 103 |
| | | 0.2 | 24 | 29 | 0.154, 0.130 (0.142) | 77, 65 (71) | 78, 71 (75) | 0.191 | 95 |
| | | 0.2 | 36 | 44 | 0.220, 0.212 (0.216) | 110, 106 (108) | 103, 105 (104) | 0.208 | 104 |

^a Corrected percent recovery = (Mean residues after storage (%) / Mean of fresh procedural recoveries (%)) X 100 %

NA = Not Applicable

0-18 months analyses: final determination with LC-MS/MS

24 and 36 months analyses: final determination with LC-DMS-MS/MS

* Although the level of residue 1,2,4-triazole seems to have declined by more than 30%, it is considered that the samples are sufficiently stable over 12 months frozen storage in cucumber (fruit), as the procedural recoveries at the 12 months time-point were lower than for the earlier time-points (although it is considered that some decline in stability has been observed).

** Conversely residues of 1,2,4-triazole are only regarded as sufficiently stable in cucumber (fruit) up to a period of 12 months frozen storage.

Conclusion

Storage stability was demonstrated for 1,2,4-triazole (1,2,4 T) in cucumber (fruit) stored at -18°C or below for 12 months.

Storage stability was demonstrated for triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in cucumber (fruit) stored at -18°C or below for at least 36 months.

Storage stability was also demonstrated for 1,2,4-triazole (1,2,4 T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in grapes (bunches) and in dried beans (seed) stored at -18°C or below for at least 36 months.

A 2.1.1.1.1.2 Study 2

| | |
|-------------------|--|
| Comments of zRMS: | <p>The storage stability was demonstrated for prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole-α-hydroxy-desthio in wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content) upon storage at $\leq -18^\circ\text{C}$ for 24 months.</p> <p>The LOQ of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio and α-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio was 0.010 mg/kg, for each reference item.</p> <p>The LOQ of prothioconazole (sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and α-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg.</p> <p>Remark: For wheat (grain), after 18 and 21 months of storage stability, loss higher than 30% were not confirmed by another analysis at 24 months. Consequently, these analyses were excluded in the conclusion of storage stability with no adverse impact on the study.</p> <p>The study is acceptable.</p> |
|-------------------|--|

Reference: KCA 6.1/02

Report Freezing storage stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and α -hydroxy-prothioconazole-desthio in plant matrices at/below -18°C during 24 months (0, 1, 3, 12, 18 and 24 months): Wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content).
Lefresne, S., 2020
Report No.: B18S-A4-P-02, Sponsor no.: R-39653

Guideline(s): Yes,
Guidance document on pesticide residue analytical methods, ENV/JM/MONO(2007)17,
Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414, SANCO/3029/99 rev.4 of 11/07/2000,

Guidance Document on pesticide residue analytical methods, SANCO/825/00 rev.8.1 of 16/11/2010.
Guideline 7032/VI/95 rev.5, appendix H,
OECD Guideline for the testing of chemical (506/2007) “Stability of Pesticide Residues in Stored Commodities”.

Deviations: No
GLP: Yes
Acceptability: Yes

Study objective

The study objective was to determine the freezing storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio in the following plant matrices (stored at $\leq -18^{\circ}\text{C}$ for 24 months (0, 1, 3, 12, 18, 21 (wheat grain only) and 24 months):

| Group | Matrices |
|----------------------|-----------------------|
| High water content | Whole plant of wheat |
| High acid content | Strawberry |
| High oil content | Grain of oilseed rape |
| High starch content | Grain of wheat |
| High protein content | Dry bean |
| Difficult commodity | Straw of wheat |

Materials and methods

For storage stability determination the matrix material was thoroughly homogenised with dry ice using a mixer and stored at -18°C until start of analysis.

For strawberry, 10 g of sub-specimens were weighed into 50 mL centrifuge tubes. 50 samples were prepared in this way. 12 of them were kept as control sample with addition of 100 μL acetonitrile, the 38 remaining samples were fortified with each metabolite (prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio) at 0.100 mg/kg by addition of 100 μL of a 10 mg/L standard solution of each metabolite using a volumetric pipette.

For the other matrices, 2 g of sub-specimens were weighed into 50 mL centrifuge tubes. 50 samples were prepared in this way. 12 of them were kept as control sample with addition of 20 μL acetonitrile, the 38 remaining samples were fortified with each reference item at 0.100 mg/kg with addition of 20 μL of a 10 mg/L standard solution of each reference item.

All sample containers were labelled with the sample identification number and the study code, and were stored in a freezer at about -18°C .

After a storage period of 0, 1, 3, 12, 18, 21 (only for wheat grain) and 24 months for each matrix, two (or three in the case of 0 month) samples fortified at 0.100 mg/kg and two control samples were removed from the freezer for analysis. One control sample was freshly fortified at 0.100 mg/kg and used as recovery experiment (procedural recovery). This freshly fortified control was analysed together with the second control and with the two or three aged fortified samples.

Control samples used for procedural recoveries were handled and stored in the same way and for the same time period as the analytical sample extracts that were prepared within the same analytical set.

The analytical method principle is based on European Committee for Standardization (CEN): EN 15662:2009-02. “Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE - QuEChERS-method” and summarised as follows:

Residues of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio, all expressed as prothioconazole-desthio were extracted from homogenised matrices by maceration with acetonitrile; water was added if necessary. Then, extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). To ensure unambiguous identification, two mass transitions were monitored for each reference item.

Except for wheat whole plant sample extracts which were analysed within 24 hours following extraction, final sample extracts were stored at about -18°C before injection in LC-MS/MS until analysis. Thus, stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio in final sample extracts was determined during this study.

Therefore, recovery experiments using aged sample sets were conducted. For each metabolite in wheat straw, an aged sample set was injected again with a freshly prepared standard calibration solution. For each metabolite in other matrices, a freshly prepared standard calibration solution was injected with the calibration standard solutions prepared on the day of extraction.

Successful method validations for all specimens and analytes have been conducted within the study: For each matrix and each reference item, a full validation has been performed using 10 spiked samples. 5 recovery experiments fortified at the LOQ level and 5 recovery experiments fortified at ten times the LOQ level, 2 control samples and a reagent blank were prepared.

The LOQ (Limit of quantification) of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-4-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-5-hydroxy-desthio expressed as prothioconazole-desthio, prothioconazole-6-hydroxy-desthio expressed as prothioconazole-desthio and prothioconazole- α -hydroxy-desthio expressed as prothioconazole-desthio was 0.010 mg/kg, for each reference item, corresponding to a LOD (Limit of detection, defined as 30 % of the LOQ) of 0.003 mg/kg.

The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg corresponding to a LOD (Limit of detection, defined as 30 % of the LOQ) of 0.018 mg/kg.

For further details on method validations, please refer to dRR Part B.5, point KCP 5.1.2.

Results and discussions

The aim of this storage stability study was to demonstrate storage stability of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio in wheat (whole plant, grain and straw), oilseed rape (grain), strawberry and dry bean stored under deep frozen conditions $\leq -18^{\circ}\text{C}$) over a storage period up to 24 months.

For each matrix and each analyte, the daily sample sets were validated with the determination of one freshly fortified sample per sample set (procedural recovery). At initial time (0 month), the daily sample sets were validated with the mean of the four fortified samples (fortified and procedural recovery are similar). The results were all well accepted as the procedural recoveries (or mean at 0 month) of each reference item in each matrix from freshly fortified samples were in the range 70-110 % for each sampling point.

Each control sample used to perform each recovery experiment was analysed in order to check for any background interferences at the expected retention time of each analyte. In some cases, background interference below 30% of the level of fortification were detected. In these cases, recoveries were corrected by subtraction of the interferent peak area.

At up to and including 24 months of freezer storage ($\leq -18^{\circ}\text{C}$), there is no significant loss of prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio ($<30\%$) in samples of wheat whole plant (high water content), wheat grain (high starch content), wheat straw (difficult commodity), oilseed rape grain (high oil content), strawberry (high acid content) and dry bean (high protein content) (refer to the table below).

Regarding stability in final sample extracts, extracts of wheat (whole plant) were analysed within 24 hours after initial extraction and thus no experiment on stability was required for this commodity.

For wheat straw, all analytes in final sample extracts were considered stable for at least 10 days when stored at about -18°C . For the other matrices, all analytes in final sample extracts were considered stable for at least 3 days (wheat grain and strawberry) or at least 2 days (oilseed rape seeds and dry bean seeds) when stored at about -18°C , thus covering the storage durations observed within the study.

Table A 2: Stability of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio in wheat (whole plant, grain and straw), in oilseed rape (grain), in strawberry and in dry bean seeds following storage at $\leq -18^{\circ}\text{C}$

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | | |
|-------------------|---|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|---|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| Wheat whole plant | Prothioconazole-desthio | 0.1 | 0 | 0.082 | 0.084 | 0.084 | 0.083 | 83 | 100 | 82 | 0.102 | 102 |
| | | 0.1 | 1 | 0.078 | 0.082 | NA | 0.080 | 80 | 96 | 89 | 0.090 | 90 |
| | | 0.1 | 3 | 0.091 | 0.091 | | 0.091 | 91 | 109 | 90 | 0.101 | 101 |
| | | 0.1 | 12 | 0.092 | 0.089 | | 0.091 | 91 | 109 | 86 | 0.105 | 105 |
| | | 0.1 | 18 | 0.083 | 0.088 | | 0.085 | 85 | 102 | 98 | 0.087 | 87 |
| | | 0.1 | 24 | 0.085 | 0.086 | | 0.086 | 86 | 103 | 89 | 0.096 | 96 |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.081 | 0.084 | 0.083 | 0.083 | 83 | 100 | 82 | 0.101 | 101 |
| | | 0.1 | 1 | 0.075 | 0.078 | NA | 0.077 | 77 | 93 | 87 | 0.088 | 88 |
| | | 0.1 | 3 | 0.089 | 0.089 | | 0.089 | 89 | 108 | 90 | 0.099 | 99 |
| | | 0.1 | 12 | 0.088 | 0.083 | | 0.085 | 85 | 103 | 89 | 0.096 | 96 |
| | | 0.1 | 18 | 0.076 | 0.083 | | 0.080 | 80 | 96 | 96 | 0.083 | 83 |
| | | 0.1 | 24 | 0.096 | 0.095 | | 0.095 | 95 | 115 | 91 | 0.104 | 104 |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.080 | 0.087 | 0.082 | 0.083 | 83 | 100 | 82 | 0.101 | 101 |
| | | 0.1 | 3 | 0.080 | 0.084 | NA | 0.082 | 82 | 99 | 89 | 0.092 | 92 |
| | | 0.1 | 6 | 0.093 | 0.093 | | 0.093 | 93 | 112 | 93 | 0.100 | 100 |
| | | 0.1 | 12 | 0.091 | 0.087 | | 0.089 | 89 | 107 | 90 | 0.099 | 99 |
| | | 0.1 | 18 | 0.084 | 0.092 | | 0.088 | 88 | 106 | 100 | 0.088 | 88 |
| | | 0.1 | 24 | 0.097 | 0.094 | | 0.095 | 95 | 114 | 90 | 0.106 | 106 |
| | Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.081 | 0.085 | 0.084 | 0.083 | 83 | 100 | 82 | 0.102 | 102 |
| | | 0.1 | 3 | 0.084 | 0.087 | NA | 0.086 | 86 | 103 | 88 | 0.097 | 97 |
| | | 0.1 | 6 | 0.092 | 0.091 | | 0.091 | 91 | 109 | 92 | 0.099 | 99 |
| | | 0.1 | 12 | 0.088 | 0.084 | | 0.086 | 86 | 103 | 90 | 0.096 | 96 |
| | | 0.1 | 18 | 0.078 | 0.084 | | 0.081 | 81 | 97 | 96 | 0.084 | 84 |
| | | 0.1 | 24 | 0.100 | 0.091 | | 0.096 | 96 | 115 | 91 | 0.105 | 105 |
| | Prothioconazole-6-hydroxy-desthio, expressed as | 0.1 | 0 | 0.084 | 0.089 | 0.087 | 0.087 | 87 | 100 | 84 | 0.103 | 103 |
| | | 0.1 | 3 | 0.088 | 0.094 | NA | 0.091 | 91 | 105 | 97 | 0.094 | 94 |
| | | 0.1 | 6 | 0.092 | 0.091 | | 0.091 | 91 | 105 | 91 | 0.100 | 100 |
| | | 0.1 | 12 | 0.090 | 0.087 | | 0.089 | 89 | 102 | 90 | 0.098 | 98 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|------------------------------------|--|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|--|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | | Residues after storage mean ³ (mg/kg) |
| | prothioconazole-desthio | 0.1 | 18 | 0.089 | 0.095 | | 0.092 | 92 | 106 | 102 | 0.090 | 90 |
| | | 0.1 | 24 | 0.115 | 0.109 | | 0.112 | 112 | 129 | 106 | 0.106 | 106 |
| | Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.081 | 0.085 | 0.083 | 0.083 | 83 | 100 | 80 | 0.104 | 104 |
| | | 0.1 | 3 | 0.085 | 0.087 | NA | 0.086 | 86 | 104 | 89 | 0.097 | 97 |
| | | 0.1 | 6 | 0.092 | 0.091 | | 0.092 | 92 | 110 | 90 | 0.102 | 102 |
| | | 0.1 | 12 | 0.092 | 0.087 | | 0.089 | 89 | 107 | 89 | 0.100 | 100 |
| | | 0.1 | 18 | 0.084 | 0.093 | | 0.089 | 89 | 107 | 98 | 0.090 | 90 |
| | | 0.1 | 24 | 0.104 | 0.096 | | 0.100 | 100 | 120 | 88 | 0.114 | 114 |
| Wheat grain | Prothioconazole-desthio | 0.1 | 0 | 0.099 | 0.082 | 0.081 | 0.087 | 87 | 100 | 82 | 0.107 | 107 |
| | | 0.1 | 1 | 0.073 | 0.077 | NA | 0.075 | 75 | 86 | 95 | 0.079 | 79 |
| | | 0.1 | 3 | 0.080 | 0.081 | | 0.080 | 80 | 92 | 98 | 0.082 | 82 |
| | | 0.1 | 12 | 0.085 | 0.066 | | 0.076 | 76 | 86 | 89 | 0.085 | 85 |
| | | 0.1 | 18 | 0.069 | 0.055 | | 0.062 | 62 ⁵ | 71 | 105 | 0.059 | 59 |
| | | 0.1 | 21 | 0.067 | 0.059 | | 0.063 | 63 ⁵ | 72 | 90 | 0.070 | 70 |
| | | 0.1 | 24 | 0.091 | 0.080 | 0.086 | 86 | 98 | 100 | 0.086 | 86 | |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.099 | 0.082 | 0.083 | 0.088 | 88 | 100 | 82 | 0.107 | 107 |
| | | 0.1 | 1 | 0.076 | 0.081 | NA | 0.079 | 79 | 89 | 98 | 0.080 | 80 |
| | | 0.1 | 3 | 0.080 | 0.080 | | 0.080 | 80 | 91 | 98 | 0.082 | 82 |
| | | 0.1 | 12 | 0.085 | 0.068 | | 0.077 | 77 | 87 | 90 | 0.085 | 85 |
| | | 0.1 | 18 | 0.068 | 0.055 | | 0.062 | 62 ⁵ | 70 | 106 | 0.058 | 58 |
| | | 0.1 | 21 | 0.070 | 0.064 | | 0.067 | 67 ⁵ | 76 | 88 | 0.076 | 76 |
| | | 0.1 | 24 | 0.097 | 0.085 | 0.091 | 91 | 103 | 99 | 0.092 | 92 | |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.097 | 0.082 | 0.082 | 0.087 | 87 | 100 | 81 | 0.107 | 107 |
| | | 0.1 | 3 | 0.078 | 0.082 | NA | 0.080 | 80 | 92 | 96 | 0.083 | 83 |
| | | 0.1 | 6 | 0.080 | 0.082 | | 0.081 | 81 | 93 | 97 | 0.084 | 84 |
| | | 0.1 | 12 | 0.083 | 0.063 | | 0.073 | 73 | 84 | 88 | 0.083 | 83 |
| | | 0.1 | 18 | 0.069 | 0.056 | | 0.062 | 62 ⁵ | 71 | 101 | 0.061 | 61 |
| | | 0.1 | 21 | 0.069 | 0.063 | | 0.066 | 66 ⁵ | 76 | 89 | 0.074 | 74 |
| | | 0.1 | 24 | 0.095 | 0.085 | 0.090 | 90 | 103 | 95 | 0.095 | 95 | |
| Prothioconazole-5-hydroxy-desthio, | 0.1 | 0 | 0.097 | 0.082 | 0.084 | 0.088 | 88 | 100 | 82 | 0.107 | 107 | |
| | 0.1 | 3 | 0.078 | 0.081 | NA | 0.080 | 80 | 91 | 97 | 0.082 | 82 | |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|-------------|--|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| | expressed as prothioconazole-desthio | 0.1 | 6 | 0.083 | 0.081 | | 0.082 | 82 | 94 | 96 | 0.085 | 85 |
| | | 0.1 | 12 | 0.083 | 0.065 | | 0.074 | 74 | 84 | 89 | 0.083 | 83 |
| | | 0.1 | 18 | 0.066 | 0.057 | | 0.062 | 62 ⁵ | 70 | 105 | 0.059 | 59 |
| | | 0.1 | 21 | 0.070 | 0.063 | | 0.066 | 66 ⁵ | 75 | 86 | 0.077 | 77 |
| | | 0.1 | 24 | 0.103 | 0.091 | | 0.097 | 97 | 111 | 98 | 0.099 | 99 |
| | Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.105 | 0.085 | NA | 0.093 | 93 | 100 | 88 | 0.105 | 105 |
| | | 0.1 | 3 | 0.104 | 0.079 | | 0.092 | 92 | 99 | 102 | 0.090 | 90 |
| | | 0.1 | 6 | 0.081 | 0.082 | | 0.082 | 82 | 88 | 95 | 0.086 | 86 |
| | | 0.1 | 12 | 0.088 | 0.067 | | 0.077 | 77 | 83 | 89 | 0.087 | 87 |
| | | 0.1 | 18 | 0.076 | 0.065 | | 0.070 | 70 | 76 | 108 | 0.065 | 65 |
| | | 0.1 | 21 | 0.083 | 0.075 | | 0.079 | 79 | 85 | 107 | 0.074 | 74 |
| | | 0.1 | 24 | 0.110 | 0.099 | | 0.105 | 105 | 113 | 110 | 0.095 | 95 |
| | Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.101 | 0.083 | 0.086 | 0.090 | 90 | 100 | 84 | 0.107 | 107 |
| | | 0.1 | 3 | 0.086 | 0.092 | NA | 0.089 | 89 | 99 | 98 | 0.091 | 91 |
| | | 0.1 | 6 | 0.090 | 0.091 | | 0.091 | 91 | 101 | 108 | 0.084 | 84 |
| | | 0.1 | 12 | 0.087 | 0.073 | | 0.080 | 80 | 89 | 94 | 0.085 | 85 |
| | | 0.1 | 18 | 0.073 | 0.061 | | 0.067 | 67 ⁵ | 74 | 107 | 0.063 | 63 |
| | | 0.1 | 21 | 0.070 | 0.065 | | 0.067 | 67 ⁵ | 74 | 87 | 0.077 | 77 |
| | | 0.1 | 24 | 0.110 | 0.097 | | 0.104 | 104 | 115 | 103 | 0.100 | 100 |
| Wheat straw | Prothioconazole-desthio | 0.1 | 0 | 0.086 | 0.079 | 0.083 | 0.083 | 83 | 100 | 86 | 0.096 | 96 |
| | | 0.1 | 1 | 0.076 | 0.080 | NA | 0.078 | 78 | 94 | 84 | 0.093 | 93 |
| | | 0.1 | 3 | 0.089 | 0.091 | | 0.090 | 90 | 109 | 84 | 0.107 | 107 |
| | | 0.1 | 12 | 0.088 | 0.096 | | 0.092 | 92 | 111 | 89 | 0.103 | 103 |
| | | 0.1 | 18 | 0.096 | 0.087 | | 0.091 | 91 | 110 | 101 | 0.090 | 90 |
| | | 0.1 | 24 | 0.081 | 0.086 | | 0.084 | 84 | 101 | 90 | 0.093 | 93 |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.086 | 0.079 | 0.083 | 0.083 | 83 | 100 | 87 | 0.095 | 95 |
| | | 0.1 | 1 | 0.075 | 0.075 | NA | 0.075 | 75 | 91 | 81 | 0.093 | 93 |
| | | 0.1 | 3 | 0.090 | 0.092 | | 0.091 | 91 | 110 | 86 | 0.106 | 106 |
| | | 0.1 | 12 | 0.085 | 0.094 | | 0.090 | 90 | 108 | 89 | 0.101 | 101 |
| | | 0.1 | 18 | 0.088 | 0.087 | | 0.088 | 88 | 106 | 98 | 0.089 | 89 |
| | | 0.1 | 24 | 0.083 | 0.090 | | 0.086 | 86 | 104 | 88 | 0.098 | 98 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|--------------|--|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.086 | 0.079 | 0.082 | 0.082 | 82 | 100 | 82 | 0.100 | 100 |
| | | 0.1 | 3 | 0.081 | 0.079 | NA | 0.080 | 80 | 97 | 82 | 0.098 | 98 |
| | | 0.1 | 6 | 0.092 | 0.093 | | 0.092 | 92 | 112 | 87 | 0.106 | 106 |
| | | 0.1 | 12 | 0.086 | 0.094 | | 0.090 | 90 | 109 | 91 | 0.099 | 99 |
| | | 0.1 | 18 | 0.093 | 0.087 | | 0.090 | 90 | 109 | 101 | 0.089 | 89 |
| | | 0.1 | 24 | 0.090 | 0.096 | | 0.093 | 93 | 113 | 89 | 0.104 | 104 |
| | Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.086 | 0.080 | 0.083 | 0.083 | 83 | 100 | 85 | 0.098 | 98 |
| | | 0.1 | 3 | 0.084 | 0.083 | NA | 0.084 | 84 | 101 | 83 | 0.101 | 101 |
| | | 0.1 | 6 | 0.091 | 0.097 | | 0.094 | 94 | 113 | 85 | 0.111 | 111 |
| | | 0.1 | 12 | 0.083 | 0.088 | | 0.086 | 86 | 103 | 89 | 0.096 | 96 |
| | | 0.1 | 18 | 0.088 | 0.082 | | 0.085 | 85 | 102 | 100 | 0.085 | 85 |
| | | 0.1 | 24 | 0.090 | 0.096 | | 0.093 | 93 | 112 | 89 | 0.104 | 104 |
| | Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.090 | 0.084 | 0.085 | 0.086 | 86 | 100 | 88 | 0.098 | 98 |
| | | 0.1 | 3 | 0.089 | 0.089 | NA | 0.089 | 89 | 103 | 89 | 0.100 | 100 |
| | | 0.1 | 6 | 0.091 | 0.094 | | 0.093 | 93 | 107 | 85 | 0.109 | 109 |
| | | 0.1 | 12 | 0.088 | 0.094 | | 0.091 | 91 | 105 | 94 | 0.097 | 97 |
| | | 0.1 | 18 | 0.102 | 0.099 | | 0.101 | 101 | 116 | 106 | 0.095 | 95 |
| | | 0.1 | 24 | 0.102 | 0.109 | | 0.106 | 106 | 122 | 105 | 0.100 | 100 |
| | Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.088 | 0.082 | 0.083 | 0.085 | 85 | 100 | 86 | 0.099 | 99 |
| | | 0.1 | 3 | 0.083 | 0.083 | NA | 0.083 | 83 | 98 | 83 | 0.100 | 100 |
| | | 0.1 | 6 | 0.091 | 0.094 | | 0.093 | 93 | 109 | 85 | 0.109 | 109 |
| | | 0.1 | 12 | 0.087 | 0.093 | | 0.090 | 90 | 106 | 90 | 0.100 | 100 |
| | | 0.1 | 18 | 0.097 | 0.087 | | 0.092 | 92 | 108 | 97 | 0.095 | 95 |
| | | 0.1 | 24 | 0.091 | 0.099 | | 0.095 | 95 | 112 | 89 | 0.107 | 107 |
| Oilseed rape | Prothioconazole-desthio | 0.1 | 0 | 0.085 | 0.082 | 0.078 | 0.082 | 82 | 100 | 89 | 0.092 | 92 |
| | | 0.1 | 1 | 0.092 | 0.093 | NA | 0.092 | 92 | 113 | 83 | 0.111 | 111 |
| | | 0.1 | 3 | 0.074 | 0.079 | | 0.077 | 77 | 94 | 83 | 0.092 | 92 |
| | | 0.1 | 12 | 0.082 | 0.078 | | 0.080 | 80 | 98 | 82 | 0.098 | 98 |
| | | 0.1 | 18 | 0.074 | 0.073 | | 0.073 | 73 | 89 | 85 | 0.086 | 86 |
| | | 0.1 | 24 | 0.081 | 0.079 | | 0.080 | 80 | 98 | 90 | 0.089 | 89 |
| | | 0.1 | 0 | 0.090 | 0.090 | 0.080 | 0.087 | 87 | 100 | 93 | 0.093 | 93 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|-----------------|--|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 1 | 0.106 | 0.107 | NA | 0.106 | 106 | 122 | 94 | 0.113 | 113 |
| | | 0.1 | 3 | 0.084 | 0.090 | | 0.087 | 87 | 100 | 92 | 0.095 | 95 |
| | | 0.1 | 12 | 0.090 | 0.079 | | 0.084 | 84 | 97 | 85 | 0.099 | 99 |
| | | 0.1 | 18 | 0.081 | 0.078 | | 0.079 | 79 | 91 | 90 | 0.088 | 88 |
| | | 0.1 | 24 | 0.098 | 0.096 | | 0.097 | 97 | 112 | 98 | 0.099 | 99 |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.092 | 0.092 | 0.082 | 0.089 | 89 | 100 | 97 | 0.091 | 91 |
| | | 0.1 | 3 | 0.106 | 0.109 | NA | 0.107 | 107 | 121 | 93 | 0.115 | 115 |
| | | 0.1 | 6 | 0.080 | 0.086 | | 0.083 | 83 | 94 | 92 | 0.090 | 90 |
| | | 0.1 | 12 | 0.086 | 0.080 | | 0.083 | 83 | 94 | 86 | 0.097 | 97 |
| | | 0.1 | 18 | 0.079 | 0.079 | | 0.079 | 79 | 89 | 91 | 0.087 | 87 |
| | | 0.1 | 24 | 0.096 | 0.093 | | 0.095 | 95 | 107 | 100 | 0.095 | 95 |
| | Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.092 | 0.089 | 0.082 | 0.088 | 88 | 100 | 95 | 0.092 | 92 |
| | | 0.1 | 3 | 0.102 | 0.103 | NA | 0.102 | 102 | 116 | 94 | 0.109 | 109 |
| | | 0.1 | 6 | 0.075 | 0.081 | | 0.078 | 78 | 89 | 91 | 0.086 | 86 |
| | | 0.1 | 12 | 0.077 | 0.074 | | 0.075 | 75 | 86 | 89 | 0.084 | 84 |
| | | 0.1 | 18 | 0.076 | 0.073 | | 0.074 | 74 | 84 | 92 | 0.080 | 80 |
| | | 0.1 | 24 | 0.093 | 0.089 | | 0.091 | 91 | 104 | 96 | 0.095 | 95 |
| | Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.090 | 0.088 | 0.080 | 0.086 | 86 | 100 | 93 | 0.092 | 92 |
| | | 0.1 | 3 | 0.102 | 0.102 | NA | 0.102 | 102 | 119 | 90 | 0.113 | 113 |
| | | 0.1 | 6 | 0.077 | 0.082 | | 0.079 | 79 | 92 | 75 | 0.105 | 105 |
| | | 0.1 | 12 | 0.081 | 0.074 | | 0.078 | 78 | 90 | 86 | 0.090 | 90 |
| | | 0.1 | 18 | 0.079 | 0.077 | | 0.078 | 78 | 91 | 90 | 0.087 | 87 |
| | | 0.1 | 24 | 0.090 | 0.086 | | 0.088 | 88 | 102 | 95 | 0.093 | 93 |
| | Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.095 | 0.090 | 0.082 | 0.089 | 89 | 100 | 96 | 0.093 | 93 |
| | | 0.1 | 3 | 0.127 | 0.128 | NA | 0.127 | 127 | 143 | 106 | 0.120 | 120 |
| | | 0.1 | 6 | 0.098 | 0.107 | | 0.102 | 102 | 115 | 109 | 0.094 | 94 |
| | | 0.1 | 12 | 0.081 | 0.076 | | 0.079 | 79 | 88 | 87 | 0.090 | 90 |
| | | 0.1 | 18 | 0.081 | 0.083 | | 0.082 | 82 | 92 | 91 | 0.090 | 90 |
| | | 0.1 | 24 | 0.101 | 0.096 | | 0.098 | 98 | 110 | 95 | 0.103 | 103 |
| Straw- berry | Prothioconazole-desthio | 0.1 | 0 | 0.104 | 0.104 | 0.100 | 0.103 | 103 | 100 | 104 | 0.099 | 99 |
| | | 0.1 | 1 | 0.095 | 0.097 | NA | 0.096 | 96 | 94 | 93 | 0.103 | 103 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|---------|---|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| | | 0.1 | 3 | 0.093 | 0.093 | | 0.093 | 93 | 91 | 93 | 0.100 | 100 |
| | | 0.1 | 12 | 0.089 | 0.090 | | 0.090 | 90 | 87 | 91 | 0.098 | 98 |
| | | 0.1 | 18 | 0.091 | 0.087 | | 0.089 | 89 | 87 | 96 | 0.093 | 93 |
| | | 0.1 | 24 | 0.125 | 0.116 | | 0.121 | 121 | 117 | 104 | 0.116 | 116 |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.104 | 0.103 | 0.101 | 0.103 | 103 | 100 | 103 | 0.100 | 100 |
| | | 0.1 | 1 | 0.097 | 0.100 | NA | 0.099 | 99 | 96 | 96 | 0.103 | 103 |
| | | 0.1 | 3 | 0.100 | 0.099 | | 0.100 | 100 | 97 | 99 | 0.101 | 101 |
| | | 0.1 | 12 | 0.081 | 0.086 | | 0.083 | 83 | 81 | 87 | 0.095 | 95 |
| | | 0.1 | 18 | 0.084 | 0.082 | | 0.083 | 83 | 81 | 94 | 0.088 | 88 |
| | | 0.1 | 24 | 0.123 | 0.112 | | 0.117 | 117 | 114 | 104 | 0.113 | 113 |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.104 | 0.104 | 0.101 | 0.103 | 103 | 100 | 103 | 0.100 | 100 |
| | | 0.1 | 3 | 0.100 | 0.103 | NA | 0.102 | 102 | 99 | 95 | 0.107 | 107 |
| | | 0.1 | 6 | 0.100 | 0.101 | | 0.101 | 101 | 98 | 98 | 0.103 | 103 |
| | | 0.1 | 12 | 0.084 | 0.086 | | 0.085 | 85 | 83 | 89 | 0.096 | 96 |
| | | 0.1 | 18 | 0.089 | 0.086 | | 0.087 | 87 | 84 | 94 | 0.093 | 93 |
| | | 0.1 | 24 | 0.121 | 0.110 | | 0.116 | 116 | 112 | 102 | 0.113 | 113 |
| | Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.103 | 0.104 | 0.100 | 0.102 | 102 | 100 | 103 | 0.099 | 99 |
| | | 0.1 | 3 | 0.098 | 0.100 | NA | 0.099 | 99 | 97 | 93 | 0.106 | 106 |
| | | 0.1 | 6 | 0.097 | 0.097 | | 0.097 | 97 | 95 | 95 | 0.102 | 102 |
| | | 0.1 | 12 | 0.082 | 0.083 | | 0.083 | 83 | 81 | 88 | 0.094 | 94 |
| | | 0.1 | 18 | 0.086 | 0.084 | | 0.085 | 85 | 83 | 95 | 0.089 | 89 |
| | | 0.1 | 24 | 0.126 | 0.117 | | 0.122 | 122 | 119 | 104 | 0.117 | 117 |
| | Prothioconazole-6-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.105 | 0.106 | 0.101 | 0.104 | 104 | 100 | 102 | 0.102 | 102 |
| | | 0.1 | 3 | 0.102 | 0.104 | NA | 0.103 | 103 | 99 | 99 | 0.104 | 104 |
| | | 0.1 | 6 | 0.101 | 0.101 | | 0.101 | 101 | 97 | 99 | 0.102 | 102 |
| | | 0.1 | 12 | 0.086 | 0.086 | | 0.086 | 86 | 83 | 89 | 0.097 | 97 |
| | | 0.1 | 18 | 0.090 | 0.090 | | 0.090 | 90 | 87 | 97 | 0.093 | 93 |
| | | 0.1 | 24 | 0.135 | 0.126 | | 0.130 | 130 | 125 | 109 | 0.119 | 119 |
| | Prothioconazole- α -hydroxy-desthio, expressed as | 0.1 | 0 | 0.105 | 0.106 | 0.102 | 0.105 | 105 | 100 | 105 | 0.100 | 100 |
| | | 0.1 | 3 | 0.113 | 0.109 | NA | 0.111 | 111 | 106 | 95 | 0.117 | 117 |
| | | 0.1 | 6 | 0.102 | 0.102 | | 0.102 | 102 | 97 | 99 | 0.103 | 103 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|----------|---|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| | | | | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| Dry bean | prothioconazole-desthio | 0.1 | 12 | 0.084 | 0.088 | | 0.086 | 86 | 82 | 89 | 0.097 | 97 |
| | | 0.1 | 18 | 0.090 | 0.088 | | 0.089 | 89 | 85 | 95 | 0.094 | 94 |
| | | 0.1 | 24 | 0.133 | 0.122 | | 0.128 | 128 | 121 | 104 | 0.123 | 123 |
| | Prothioconazole-desthio | 0.1 | 0 | 0.086 | 0.088 | 0.091 | 0.088 | 88 | 100 | 89 | 0.099 | 99 |
| | | 0.1 | 1 | 0.101 | 0.111 | NA | 0.106 | 106 | 120 | 94 | 0.113 | 113 |
| | | 0.1 | 3 | 0.087 | 0.085 | | 0.086 | 86 | 97 | 91 | 0.095 | 95 |
| | | 0.1 | 12 | 0.083 | 0.092 | | 0.088 | 88 | 99 | 88 | 0.099 | 99 |
| | | 0.1 | 18 | 0.084 | 0.078 | | 0.081 | 81 | 92 | 96 | 0.084 | 84 |
| | | 0.1 | 24 | 0.092 | 0.091 | | 0.092 | 92 | 104 | 106 | 0.086 | 86 |
| | | 0.1 | 24 | 0.092 | 0.091 | | 0.092 | 92 | 104 | 106 | 0.086 | 86 |
| | Prothioconazole-3-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.084 | 0.087 | 0.089 | 0.087 | 87 | 100 | 90 | 0.097 | 97 |
| | | 0.1 | 1 | 0.109 | 0.119 | NA | 0.114 | 114 | 131 | 91 | 0.125 | 125 |
| | | 0.1 | 3 | 0.089 | 0.090 | | 0.090 | 90 | 103 | 93 | 0.096 | 96 |
| | | 0.1 | 12 | 0.088 | 0.094 | | 0.091 | 91 | 105 | 93 | 0.098 | 98 |
| | | 0.1 | 18 | 0.082 | 0.078 | | 0.080 | 80 | 92 | 97 | 0.082 | 82 |
| | Prothioconazole-4-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 24 | 0.103 | 0.103 | | 0.103 | 103 | 118 | 108 | 0.095 | 95 |
| | | 0.1 | 0 | 0.087 | 0.092 | 0.089 | 0.089 | 89 | 100 | 94 | 0.095 | 95 |
| | | 0.1 | 3 | 0.108 | 0.120 | NA | 0.114 | 114 | 128 | 92 | 0.124 | 124 |
| | | 0.1 | 6 | 0.087 | 0.087 | | 0.087 | 87 | 97 | 91 | 0.096 | 96 |
| | | 0.1 | 12 | 0.086 | 0.093 | | 0.090 | 90 | 100 | 91 | 0.098 | 98 |
| | | 0.1 | 18 | 0.084 | 0.079 | | 0.081 | 81 | 91 | 96 | 0.084 | 84 |
| | Prothioconazole-5-hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 24 | 0.102 | 0.101 | | 0.102 | 102 | 114 | 105 | 0.097 | 97 |
| | | 0.1 | 0 | 0.083 | 0.089 | 0.086 | 0.086 | 86 | 100 | 89 | 0.097 | 97 |
| | | 0.1 | 3 | 0.100 | 0.111 | NA | 0.105 | 105 | 122 | 91 | 0.115 | 115 |
| | | 0.1 | 6 | 0.084 | 0.084 | | 0.084 | 84 | 98 | 95 | 0.088 | 88 |
| | | 0.1 | 12 | 0.074 | 0.083 | | 0.079 | 79 | 91 | 90 | 0.087 | 87 |
| | | 0.1 | 18 | 0.076 | 0.073 | | 0.075 | 75 | 87 | 95 | 0.078 | 78 |
| | Prothioconazole-6-hydroxy-desthio, expressed as | 0.1 | 24 | 0.099 | 0.099 | | 0.099 | 99 | 115 | 106 | 0.093 | 93 |
| | | 0.1 | 0 | 0.088 | 0.094 | 0.093 | 0.092 | 92 | 100 | 91 | 0.101 | 101 |
| | | 0.1 | 3 | 0.106 | 0.115 | NA | 0.110 | 110 | 120 | 92 | 0.120 | 120 |
| | | 0.1 | 6 | 0.088 | 0.088 | | 0.088 | 88 | 96 | 93 | 0.095 | 95 |
| | | 0.1 | 12 | 0.082 | 0.090 | | 0.086 | 86 | 94 | 89 | 0.097 | 97 |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | | |
|---------|--|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|---|---|---|---|
| | | | | Uncorrected residue results (mg/kg) ¹ | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| | prothioconazole-desthio | 0.1 | 18 | 0.085 | 0.082 | | 0.083 | 83 | 91 | 97 | 0.086 | 86 |
| | | 0.1 | 24 | 0.096 | 0.101 | | 0.098 | 98 | 107 | 108 | 0.091 | 91 |
| | Prothioconazole- α -hydroxy-desthio, expressed as prothioconazole-desthio | 0.1 | 0 | 0.084 | 0.090 | 0.089 | 0.087 | 87 | 100 | 88 | 0.099 | 99 |
| | | 0.1 | 3 | 0.126 | 0.136 | NA | 0.131 | 131 | 151 | 100 | 0.131 | 131 |
| | | 0.1 | 6 | 0.107 | 0.109 | | 0.108 | 108 | 124 | 109 | 0.099 | 99 |
| | | 0.1 | 12 | 0.080 | 0.092 | | 0.086 | 86 | 99 | 92 | 0.093 | 93 |
| | | 0.1 | 18 | 0.088 | 0.081 | | 0.085 | 85 | 97 | 97 | 0.087 | 87 |
| | | 0.1 | 24 | 0.103 | 0.103 | | 0.103 | 103 | 118 | 109 | 0.094 | 94 |

¹ calculated as detailed in paragraph 8.8.1 of the study report.

² (mean at x months) / (mean at 0 month) * 100 (not included in the final report but calculated during dRR compilation)

³ (mean at x months) / (procedural recoveries at x months) * 100 (not included in the final report but calculated during dRR compilation)

⁴ (mean, corrected for procedural recovery) / (nominal fortification) * 100 (not included in the final report but calculated during dRR compilation)

⁵ After 18 and 21months of storage stability, loss higher than 30 % was not confirmed by another analysis at 24 months.

Conclusion

Storage stability is demonstrated for prothioconazole-desthio, prothioconazole-3-hydroxy-desthio, prothioconazole-4-hydroxy-desthio, prothioconazole-5-hydroxy-desthio, prothioconazole-6-hydroxy-desthio and prothioconazole- α -hydroxy-desthio in wheat (whole plant, grain and straw), in oilseed rape (grain), in strawberry and in dry bean when stored at $\leq -18^{\circ}\text{C}$ for a storage period up to 24 months.

A 2.1.1.1.1.3 Study 3

| | |
|-------------------|--|
| Comments of zRMS: | The storage stability was demonstrated in homogenates of oilseed rape (seeds) upon storage at $\leq -18^{\circ}\text{C}$ in the dark for 2 months for 1,2,4-triazole and for 9 months for triazole alanine. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte. The study is acceptable. |
|-------------------|--|

| | |
|----------------|---|
| Reference: | KCA 6.1/03 |
| Report | Final Report; Storage Stability of 1,2,4-Triazole (1,2,4-T) and Triazole alanine (TA) in Oilseed rape under Deep Frozen Conditions Yozgatli, H., 2022a Study no.: S20-08247, sponsor no.: 000107053 |
| Guideline(s): | Yes, EC Guideline 7032/VI/95, Appendix H; OECD Guideline 506 (2007) |
| Deviations: | None with impact on the study results |
| GLP: | Yes |
| Acceptability: | Yes |

Study objective

The study objective was to determine the freezing storage stability of triazole metabolites 1, 2, 4-triazole (1, 2, 4-T) and triazole alanine (TA) in oilseed rape (stored at $\leq -18^{\circ}\text{C}$ for 18 months).

Due to insufficient stability of 1, 2, 4-triazole in oilseed rape (seeds) under deep frozen conditions in the dark proven after 3 months of storage the analyses for the next storage periods were cancelled for 1, 2, 4-triazole.

The test of the storage stability for triazole alanine in oilseed rape (seeds) under deep frozen conditions in the dark was stopped after the storage interval of 9 months.

Materials and methods

Control (untreated) specimens of oilseed rape (seeds) originated from a local market. The sample material was thoroughly homogenised in a cutter with dry ice. Weighed sub-samples were stored at $\leq -18^{\circ}\text{C}$ in the dark until fortification and extraction. Aliquots of homogenised matrix material were transferred into a 50 mL centrifuge tube with cap and fortified with the test items. Storage and recovery samples were prepared by fortifying the analytes separately. Samples were fortified separately with 0.1 mg/kg 1, 2, 4-triazole (10 \times LOQ) and with 1.0 mg/kg (100 \times LOQ) triazole alanine. Fortification solutions of each test item were distributed dropwise to the thawed sample with a solvent volume not exceeding a total of 2% of the sample extraction volume per sample. The sample was mixed by brief swirling to ensure distribution of the test items in the respective matrix and the solvent was allowed to evaporate. After the procedure the samples were stored $\leq 18^{\circ}\text{C}$.

Samples were stored for a period of 0 days, 1, 2 and 3 months (1, 2, 4-triazole samples) and for 0 days, 1, 2, 3, 4, 5, 6, 7, 8 and 9 months (triazole alanine samples). Control samples used for procedural recoveries were handled and stored in the same way and for the same time period as the analytical sample extracts that were prepared within the same analytical set.

At each storage interval, two treated samples (three at day 0) were removed from the freezer and allowed to come to room temperature before being extracted and analysed. One control sample was freshly fortified and used for recovery experiment (procedural recovery). This freshly fortified control was analysed together with the aged, fortified samples.

Sample extraction and determination of residues were performed according to the analytical method GRM053.01A that was validated in the study S20-00406. For further details on method validations, please refer to dRR Part B.5, point KCP 5.1.2. For extraction 5.0 g of homogenised sample material plus 12 mL water and 48 mL methanol were added in a screw capped glass. The sample was blended using a high speed homogenizer at high speed for approx. 2 min. A filter with cotton was used to collect the filtrate. To 6 mL of the filtrate 0.50 mL of the 0.20 µg/mL Internal Standard (IS) solution was added. A nitrogen evaporator or vacuum concentrator were used to concentrate the solution to an aqueous remainder. The volume was adjusted to 5.0 mL by addition of water and swirled thoroughly. The final sample extract was analysed by LC-DMS-MS/MS.

The LOQ (Limit of quantification) of 1,2,4-triazole and triazole alanine was 0.01 mg/kg corresponding to a LOD (Limit of detection, defined as 30 % of the LOQ) of 0.003 mg/kg.

The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-DMS-MS/MS was 6 days. Any possible losses of the analyte(s) in the final extracts were compensated by usage of internal standard(S) for quantification. So the stability of the analyte(s) in the final extracts is not to be proven.

Results and discussions

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set, when analysing the storage samples.

For 1,2,4-triazole, the average amount of analyte recovered relative to the initial recovery at day 0 was $\geq 70\%$ at any testing interval up to 2 months and was $< 70\%$ after 3 months, which can be seen as criterion for sufficient storage stability up to 2 months and insufficient storage stability for storage periods ≥ 3 months. For triazole alanine the average amount of analyte recovered relative to the initial recovery at day 0 was $\geq 70\%$ at any testing interval up to 9 months, which can be seen as criterion for sufficient storage stability. Thus, stability was demonstrated in homogenates of oilseed rape (seeds) upon storage at ≤ -18 °C in the dark for 2 months for 1,2,4-triazole and for 9 months for triazole alanine.

Table A 3: Stability of 1,2,4-triazole (1,2,4-T) and triazole alanine (TA) in oilseed rape (seeds) following storage at ≤ -18°C

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|--------------------|-----------|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|---|
| | | | | Uncorrected residue results (mg/kg) | | | | | % corrected results with day 0 as 100 % ² | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | Residues after storage mean ³ (mg/kg) | Residues after storage mean ⁴ (% of nominal spiking level) |
| Oilseed rape seeds | 1, 2, 4-T | 0.1 | 0 | 0.106 | 0.100 | 0.110 | 0.105 | 106, 100, 110 (105) | - | NA | 0.105 | 105 |
| | | 0.1 | 1 | 0.087 | 0.077 | NA | 0.082 | 87, 77 (82) | 78 | 108 | 0.076 | 76 |
| | | 0.1 | 2 | 0.077 | 0.070 | | 0.074 | 77, 70 (74) | 70 | 105 | 0.070 | 70 |
| | | 0.1 | 3 | 0.036 | 0.062 | | 0.049 | 36, 62 (49) | 47 | 94 | 0.052 | 52 |
| | TA | 1.0 | 0 | 1.09 | 1.07 | 0.90 | 1.02 | 109, 107, 90 (102) | - | NA | 1.02 | 102 |
| | | 1.0 | 1 | 1.01 | 0.96 | NA | 0.99 | 101, 96 (99) | 97 | 91 | 1.09 | 109 |
| | | 1.0 | 2 | 0.77 | 0.88 | | 0.83 | 77, 88 (83) | 81 | 98 | 0.85 | 85 |
| | | 1.0 | 3 | 0.91 | 0.86 | | 0.89 | 91, 86 (89) | 87 | 88 | 1.01 | 101 |
| | | 1.0 | 4 | 0.81 | 0.87 | | 0.84 | 81, 87 (84) | 82 | 98 | 0.86 | 86 |
| | | 1.0 | 5 * (150 days) | 0.72 | 0.93 | | 0.87 | 72, 93, 95, 87 (87) | 85 | 107 | 0.81 | 81 |
| | | 1.0 | 5 (164 days) | 0.95 | 0.87 | | | | | 80 | 1.08 | 108 |
| | | 1.0 | 6* (182 days) | 0.84 | 1.12 | | 0.97 | 84, 112, 94, 98 (97) | 92 | 86 | 1.09 | 109 |
| | | 1.0 | 6 (193 days) | 0.94 | 0.98 | | | | | 104 | 0.90 | 90 |
| | | 1.0 | 7 (210 days) | 0.90 | 0.81 | | 0.86 | 90, 81 (86) | 84 | 91 | 0.95 | 95 |
| | | 1.0 | 8 (240 days) | 0.83 | 0.94 | | 0.89 | 83, 94 (89) | 87 | 101 | 0.88 | 88 |
| | | 1.0 | 9 (270 days) | 0.93 | 0.86 | | 0.85 | 93, 86 (85) | 83 | 99 | 0.86 | 86 |

² (mean at x months) / (mean at 0 month) * 100 (not included in the final report but calculated during dRR compilation)

³ (mean at x months) / (procedural recoveries at x months) * 100 (not included in the final report but calculated during dRR compilation)

⁴ (mean, corrected for procedural recovery) / (nominal fortification) * 100 (not included in the final report but calculated during dRR compilation)

⁵ After 18 and 21 months of storage stability, loss higher than 30 % was not confirmed by another analysis at 24 months.

*The difference between the highest and lowest recovery exceeded 20%. Therefore, the back-up samples for these storage intervals have additionally been analysed.

Conclusion

Stability was demonstrated for 1,2,4-triazole (1,2,4-T) in homogenates of oilseed rape (seeds) upon storage at ≤ -18 °C for 2 months.

Stability was demonstrated for triazole alanine (TA) in homogenates of oilseed rape (seeds) upon storage at ≤ -18 °C for 9 months.

A 2.1.1.1.1.4 Study 4

| | |
|-------------------|---|
| Comments of zRMS: | <p>The storage stability of prothioconazole-desthio was demonstrated in pollen, nectar surrogate, flowers and honey at $\leq -18\text{ }^{\circ}\text{C}$ in the dark over a storage period of up to 13 months. The storage stability of prothioconazole was demonstrated in honey at $\leq -18\text{ }^{\circ}\text{C}$ in the dark over a storage period of up to 13 months and in nectar surrogate up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage.</p> <p>Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for fluxapyroxad, prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey (KCP 5.1.2/23, Lindner, M., Grewe, D. 2020, report no.: S19-20860 (MAC-1940V)). The LOQ was set at 0.01 mg/kg for prothioconazole and prothioconazole-desthio. The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|---|
| Reference: | KCA 6.1/04 |
| Report: | Storage Stability of Prothioconazole, Prothioconazole-desthio and Azoxystrobin in Pollen, Nectar, Flowers and Honey under Deep Frozen Conditions Lindner, M., 2022 Study no.: S19-02145, sponsor no.: 000104133 |
| Guideline(s): | EC Guideline 7032/VI/95, Appendix H; OECD 506, 2007 |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes |

Study objective

The study objective was to obtain data about the storage stability of prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey at $\leq -18\text{ }^{\circ}\text{C}$ (target) in the dark over a storage period of up to 13 months. Results for azoxystrobin are not reported here, as not relevant for product ADM.03500.F.2.B.

Materials and methods

Matrix types, sample origin and preparation before extraction are summarised in the following:

| Matrix Types | Preparation | Origin |
|-----------------------------------|---|-------------------------------|
| <i>Phacelia</i> Pollen | The sample material was homogenised by use of an appropriate glass rod or spatula before taking subsamples. Further homogenisation was done upon sample extraction. | supplied by the Test Facility |
| Nectar Surrogate | Instead of nectar a 36 % sucrose solution in water was used as surrogate. The sample material was shaken/inverted before taking subsamples. | supplied by the Test Facility |
| <i>Phacelia</i> Flowers | The sample material was milled with dry ice using a laboratory mill (batch mill with disposable grinding chamber) before taking subsamples. | supplied by the Test Facility |
| Honey (Multi-flower, pH ~ 4.0) | None, the material was already in homogenised state. | supplied by the Test Facility |

The fortification level for storage samples was at ten times the limit of quantification (LOQ) of the method (i.e. 0.10 mg/kg) on aliquots of homogenised control sample material. For all samples used for assessment of storage stability (storage samples) prothioconazole, prothioconazole-desthio and azoxystrobin were fortified separately. Freshly prepared fortification samples for demonstrating the analytical performance of

the method (recovery samples) were prepared by fortifying prothioconazole and azoxystrobin jointly, while prothioconazole-desthio was fortified separately. Storage samples were kept at ≤ -18 °C and analysed after 0 days, 2, 6 and 13 months. Day 0 testing was accompanied by analysis of a control sample while the testing after each storage interval was accompanied by analysis of a control sample and procedural recovery samples.

Sample extraction and determination of residues was performed according to an analytical procedure that was previously validated for prothioconazole, prothioconazole-desthio and azoxystrobin in pollen, nectar surrogate, flowers and honey². For further details on method validation, please refer to dRR Part B.5, point KCP 5.1.2/23.

Samples of flowers, nectar surrogate and pollen were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). The extraction procedure is based on the QuPPE-PO-Method but with L-cystein added. After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturised cell disruption system (FastPrep) was included to the extraction procedure. Quantification was performed by use of LC-MS/MS detection.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

Results and discussions

The residues levels detected in the storage samples allow the monitoring of the stability of the analyte upon storage. The values were as given in the following table.

For prothioconazole the mean recovery for samples extracted without any storage (i.e. day 0 storage samples and procedural recoveries) was 95% for pollen, 91% for nectar surrogate, 93% for flowers and 96% for honey.

For prothioconazole-desthio the mean recovery for samples extracted without any storage (i.e. day 0 storage samples and procedural recoveries) was 100% for pollen, 97% for nectar surrogate, 102% for flowers and 98% for honey.

These values demonstrate satisfying analytical performance for all analytes and matrices while analysing the storage samples.

For prothioconazole in nectar surrogate, the recoveries relative to the initial mean recovery at day 0 were $\geq 70\%$ up to 6 months, while for prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. For honey, the average amount of prothioconazole recovered relative to the initial mean recovery at day 0 was $\geq 70\%$ after 13 months of storage.

For prothioconazole-desthio in pollen, nectar surrogate, flowers and honey, the average amount of analyte recovered relative to the initial mean recovery at day 0 was $\geq 70\%$ after 13 months of storage.

The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction to injection to LC-MS/MS was 3 days. The stability of the analyte in the final extracts of pollen, nectar surrogate, flowers and honey upon storage at typically 1 °C to 10 °C for at least 7 days was demonstrated in study S19-20860.

² Study No. S19-20860 “Validation of the Multi-Residue Method QuEChERS for the Determination of Prothioconazole, Prothioconazole-desthio and Azoxystrobin in Nectar, Pollen, Flower and Honey”, Eurofins Agrosience Services Chem GmbH, Hamburg, Germany (22 Oct 2020).

Table A 4: Stability of prothioconazole and prothioconazole-desthio in pollen, nectar surrogate, flowers and honey following storage at ≤ -18°C

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | | |
|------------------|-------------------------|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|-----|---|---|---|---|
| | | | | Uncorrected residue results (mg/kg) | | | | | | % corrected results with day 0 as 100 % ¹ | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| | | | | | | | | | | | | Residues after storage mean ² (mg/kg) | Residues after storage mean ³ (% of nominal spiking level) |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | | | | | |
| Pollen | Prothioconazole | 0.1 | 0 | 0.103 | 0.098 | 0.093 | 0.098 | 103, 98, 93 (98) | - | - | - | - | |
| | | 0.1 | 2 | 0.030 | 0.032 | NA | 0.031 | 30, 32 (31) | 32 | 100, 98 (99) | 0.031 | 31 | |
| | | 0.1 | 6 | 0.030 | 0.032 | | 0.031 | 30, 32 (31) | 32 | 97, 92 (95) | 0.033 | 33 | |
| | | 0.1 | 13 | 0.030 | 0.032 | | 0.031 | 30, 32 (31) | 32 | 94, 84 (89) | 0.035 | 35 | |
| | Prothioconazole-desthio | 0.1 | 0 | 0.100 | 0.099 | 0.102 | 0.100 | 100, 99, 102 (100) | - | - | - | - | |
| | | 0.1 | 2 | 0.106 | 0.108 | NA | 0.107 | 106, 108 (107) | 107 | 111, 106 (109) | 0.098 | 98 | |
| | | 0.1 | 6 | 0.097 | 0.097 | | 0.097 | 97, 97 (97) | 97 | 105, 104 (105) | 0.092 | 92 | |
| | | 0.1 | 13 | 0.076 | 0.073 | | 0.075 | 76, 73 (75) | 74 | 87, 87 (87) | 0.086 | 86 | |
| Nectar surrogate | Prothioconazole | 0.1 | 0 | 0.096 | 0.095 | 0.094 | 0.095 | 96, 95, 94 (95) | - | - | - | - | |
| | | 0.1 | 2 | 0.088 | 0.092 | NA | 0.090 | 88, 92 (90) | 95 | 83, 87 (85) | 0.105 | 105 | |
| | | 0.1 | 6 | 0.075 | 0.074 | | 0.075 | 75, 74 (75) | 78 | 93, 91 (92) | 0.082 | 82 | |
| | | 0.1 | 13 | 0.024 | 0.027 | | 0.026 | 24, 27 (26) | 27 | 94, 90 (92) | 0.028 | 28 | |
| | Prothioconazole-desthio | 0.1 | 0 | 0.102 | 0.101 | 0.100 | 0.101 | 102, 101, 100 (101) | - | - | - | - | |
| | | 0.1 | 2 | 0.082 | 0.080 | NA | 0.081 | 82, 80 (81) | 80 | 110, 106 (108) | 0.075 | 75 | |
| | | 0.1 | 6 | 0.074 | 0.075 | | 0.075 | 74, 75 (75) | 74 | 78, 80 (79) | 0.095 | 95 | |
| | | 0.1 | 13 | 0.092 | 0.094 | | 0.093 | 92, 94 (93) | 92 | 97, 99 (98) | 0.095 | 95 | |
| Flowers | Prothioconazole | 0.1 | 0 | 0.089 | 0.091 | 0.084 | 0.088 | 89, 91, 84 (88) | - | - | - | - | |
| | | 0.1 | 2 | 0.030 | 0.031 | NA | 0.031 | 30, 31 (31) | 35 | 94, 92 (93) | 0.033 | 33 | |
| | | 0.1 | 6 | 0.010 | 0.011 | | 0.011 | 10, 11 (11) | 12 | 100, 100 (100) | 0.011 | 11 | |
| | | 0.1 | 13 | 0.014 | 0.011 | | 0.013 | 14, 11 (14) | 14 | 99, 90 (95) | 0.015 | 15 | |
| | Prothioconazole-desthio | 0.1 | 0 | 0.102 | 0.105 | 0.102 | 0.103 | 102, 105, 102 (103) | - | - | - | - | |
| | | 0.1 | 2 | 0.089 | 0.087 | NA | 0.088 | 89, 87 (88) | 85 | 99, 97 (98) | 0.090 | 90 | |
| | | 0.1 | 6 | 0.088 | 0.089 | | 0.089 | 88, 89 (89) | 86 | 108, 104 (106) | 0.084 | 84 | |
| | | 0.1 | 13 | 0.084 | 0.086 | | 0.085 | 84, 86 (85) | 83 | 99, 98 (99) | 0.086 | 86 | |
| Honey | Prothioconazole | 0.1 | 0 | 0.104 | 0.106 | 0.087 | 0.099 | 104, 106, 87 (99) | - | - | - | - | |
| | | 0.1 | 2 | 0.110 | 0.108 | NA | 0.109 | 110, 108 (109) | 110 | 114, 99 (107) | 0.102 | 102 | |

| Storage | | | | Residues and recoveries in specimens stored frozen (not corrected for procedural recoveries) | | | | | | Residues and recoveries in specimens stored frozen (recovery corrected) | | |
|---------|-------------------------|---------------------------------------|-----------------------------------|--|----------|----------|-------|---|--|---|---|--|
| | | | | Uncorrected residue results (mg/kg) | | | | | | Procedural recovery of freshly spiked control sample (%) (mean) | Corrected results (corrected for procedural recovery) | |
| Matrix | Analyte | Level (nominal fortification) (mg/kg) | Nominal storage interval (months) | sample 1 | sample 2 | sample 3 | mean | Residues after storage (mean, % of nominal spiking level) | % corrected results with day 0 as 100 % ¹ | | | Residues after storage mean ² (mg/kg) |
| | Prothioconazole-desthio | 0.1 | 6 | 0.069 | 0.075 | | 0.072 | 69, 75 (72) | 73 | 79, 78 (79) | 0.091 | 91 |
| | | 0.1 | 13 | 0.081 | 0.068 | | 0.075 | 81, 68 (75) | 75 | 103, 96 (100) | 0.075 | 75 |
| | | 0.1 | 0 | 0.101 | 0.104 | 0.094 | 0.100 | 101, 104, 94 (100) | - | - | - | - |
| | | 0.1 | 2 | 0.087 | 0.087 | NA | 0.087 | 87, 87 (87) | 87 | 107, 104 (106) | 0.082 | 82 |
| | | 0.1 | 6 | 0.095 | 0.093 | | 0.094 | 95, 93 (94) | 94 | 90, 92 (91) | 0.103 | 103 |
| | | 0.1 | 13 | 0.098 | 0.103 | | 0.101 | 98, 103 (101) | 101 | 97, 96 (97) | 0.104 | 104 |

¹ (mean at x months) / (mean at 0 month) * 100 (not included in the final report but calculated during dRR compilation)

² (mean at x months) / (procedural recoveries at x months) * 100 (not included in the final report but calculated during dRR compilation)

³ (mean, corrected for procedural recovery) / (nominal fortification) * 100 (not included in the final report but calculated during dRR compilation)

Conclusion

With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the storage samples.

The study is deemed sufficient for assessing the stability of flowers, nectar surrogate and pollen upon storage at $\leq -18^{\circ}\text{C}$ for 13 months.

For prothioconazole in nectar surrogate, the recoveries relative to the initial mean recovery at day 0 were $\geq 70\%$ up to 6 months, while for prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. For honey, the average amount of prothioconazole recovered relative to the initial mean recovery at day 0 was $\geq 70\%$ even after 13 months of storage.

For prothioconazole-desthio in pollen, nectar surrogate, flowers and honey, the average amount of analyte recovered relative to the initial mean recovery at day 0 was $\geq 70\%$ after 13 months of storage.

A 2.1.1.1.1.5 Study 5

| | |
|-------------------|---|
| Comments of zRMS: | <p>A study was conducted to determine the stability of residues of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in 10xLOQ fortified samples of honey during deep-freeze storage for a period of ca. 5 months (150 days) at $\leq -18^{\circ}\text{C}$. Samples were analysed after nominal storage intervals of 0, 1, 3, and 5 months.</p> <p>After a deep-freezer storage ($\leq -18^{\circ}\text{C}$) period of about 5 months, the mean recovery rates were 109% for 1,2,4-triazole, 96% for triazole alanine, 95% for triazole acetic acid and 89% for triazole lactic acid in honey.</p> <p>Furthermore, the mean concurrent recoveries of all investigated days of storage determined from freshly fortified samples were in a range of 93-104% for 1,2,4-triazole, in a range of 89- 98% for triazole alanine, in a range of 95-100% for triazole acetic acid and in a range of 94- 105% for triazole lactic acid in honey.</p> <p>All method validation data are in compliance with the relevant guidelines.</p> <p>The study results demonstrate that the residues of the analytes are stable in honey for at least 5 months under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$).</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|---|
| Reference: | KCA 6.1/05 |
| Report | Residue analytical method 01602 and short term storage of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in/on honey HPLC DMS-MS/MS, Report Amendment No. 2 Kalathoor, R., 2021 Study no.: M-680825-03-1, sponsor no.: S19-01126 |
| Guideline(s): | Yes, EC Guideline 7032/VI/95, Appendix H; OECD Guideline 506 |
| Deviations: | n.a. |
| GLP: | Yes |
| Acceptability: | n.a. |

Study owner: Triazole Derivative Metabolite Group. Access via Letter of Access.

A 2.1.1.1.2 Storage stability of residues in animal products

No new study submitted.

A 2.1.2 Nature of residues in plants, livestock and processed commodities

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

No new study submitted.

A 2.1.2.1.2 Nature of residue in rotational crops

No new study submitted.

A 2.1.2.1.3 Nature of residues in processed commodities

A 2.1.2.1.3.1 Study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>In this study no significant hydrolysis or degradation products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.</p> <p>There was no change in sample weight and in radioactivity content after any processing.</p> <p>The test item ($[^{14}\text{C}]$prothioconazole-desthio) was stable:</p> <ul style="list-style-type: none"> - at pH 4 at 90°C for 20 minutes which simulates the pasteurisation process; - at pH 5 at 100°C for 60 minutes which simulates the baking/brewing/boiling process; - at pH 6 at 120°C for 20 minutes which simulates the sterilisation process. <p>The study is acceptable.</p> |
|-------------------|---|

Reference: KCA 6.5.1/01

Report Prothioconazole-desthio: Aqueous Hydrolysis of $[^{14}\text{C}]$ Prothioconazole-desthio at 90, 100 and 120 °C;
Bloß, K., 2019;
Report No.: S18-07655, Sponsor no.: 000101817

Guideline(s): Yes,
OECD Guideline No 507 “Nature of the pesticide residues in processed commodities - high temperature hydrolysis”, Adopted 16th October, 2007;
EC working document, 1607/VI/97, rev. 2, Appendix E, 7035/VI/95, rev.5;
Processing studies 22 July 1997

Deviations: None

GLP: Yes

Acceptability: Yes

Executive summary

The objective of this study was to establish whether or not breakdown or reaction products arise from prothioconazole-desthio residues in raw agricultural commodities when subjected to processing.

The following hydrolytic conditions, representative of processing procedures, were used:

Condition 1: 90°C x 20 min (pH 4), representative of pasteurisation

Condition 2: 100°C x 60 min (pH 5), representative of baking, brewing, and boiling

Condition 3: 120°C x 20 min (pH 6), representative of sterilisation (closed system under pressure)

This study was performed with $[1,2,4\text{-triazole-U-}^{14}\text{C}]$ -prothioconazole-desthio. The radiochemical purity was checked before application and confirmed to be > 95%. An initial amount of 4.15 MBq/L, corresponding to 1.76 mg/L (specific activity: 2.36 MBq/mg) was applied.

Analysis of the samples was performed using Liquid Scintillation Counting (LSC) for quantification and High-Performance Liquid Chromatography (radio-HPLC) for characterisation. HPLC results were confirmed by analysis with Thin Layer Chromatography (TLC).

The content of radioactivity labelled prothioconazole-desthio before processing was set to 100%. After simulated processing prothioconazole-desthio represented 98.9 - 102.8 % of the applied radioactivity. No cleavage of prothioconazole-desthio was observed.

The test item was stable during all processing conditions and no hydrolysis or degradation products were formed under conditions representative of simulating pasteurisation, baking/brewing/boiling and sterilisation.

Materials and methods

A. Materials

1. Test item (labelled): Prothioconazole-desthio, [1,2,4-triazole-U-¹⁴C]

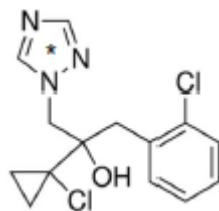


Figure A- 1: [1,2,4-triazole-U-¹⁴C]prothioconazole-desthio: Position of ¹⁴C- label is indicated by *

- | | |
|-----------------------|-------------|
| Batch no.: | XXIV/5/B/1 |
| Radiochemical purity: | 100 % |
| Specific activity: | 2.36 MBq/mg |
2. Reference item (unlabelled): Prothioconazole-desthio
- | | |
|------------|-------------------------|
| CAS no.: | 120983-64-4 |
| Batch no.: | 534-191-00 |
| Purity: | 98.7 % (w/w) |
| Stability: | Expiry date: 03.03.2021 |
3. Test conditions:
- | | |
|------------------------------|---|
| Pasteurisation: | 90 °C, at pH 4, for 20 min |
| Baking, brewing and boiling: | 100 °C, at pH 5, for 60 min |
| Sterilisation: | 120 °C, at pH 6, for 20 min, (closed system under pressure) |

B. Study design and methods

1. Buffer Solutions

The study was performed with buffer solutions at three different pH-values chosen to simulate normal processing practice.

pH 4 citrate buffer: 0.05 M citrate monohydrate was dissolved in demineralized water, adjusted to pH 4 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

pH 5 citrate buffer: 0.05 M acetic acid was dissolved in demineralized water, adjusted to pH 5 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

pH 6 citrate buffer: 0.05 M citrate monohydrate was dissolved in demineralized water, adjusted to pH 6 with 2 M sodium hydroxide and filled up to 1000 ml with demineralized water.

The buffer solutions were sterilised by autoclaving. After sterilisation the pH of the buffer solution was checked and confirmed to deviate less than 0.1 in regards of the nominal pH value.

2. Application Solution

A stock solution with the test item was prepared by diluting the test substance in 200 µL acetonitrile. The application solution was prepared by diluting 50 µL of the stock solution in 950 µL acetonitrile. The radioactivity was determined by LSC and a final volume of 23 µL application solution was used for application in 15 mL buffer. The concentration of the application solution was 3090 MBq/L.

The actual amount of applied radioactivity, based on the application control, was 4.15 MBq/L, corresponding to 1.76 mg test item assuming a specific activity of 2.36 MBq/mg.

3. Preparation of Test Solution

The samples were prepared as follows: 15 mL of buffer solution were added to the test vessel, followed by 23 µL of the application solution. All test vessels were covered with aluminium foil in order to shield it from light.

4. Test condition 1: Pasteurisation:

The stability of the test item was determined under conditions typical for pasteurisation (e.g. for making fruit juice). The processing temperature was 90° C in an oil bath. The incubation time at this temperature and pH for processing was 20 minutes. The test was performed in the dark with two independent (duplicate) samples.

5. Test condition 2: Baking, Brewing and Boiling:

The stability of the test item was determined under conditions typical for baking and boiling (e.g. for making bread and cooking vegetables). The processing temperature was 100° C in an oil bath. The incubation time at this temperature and pH for processing was 60 minutes. The test was performed in the dark with two independent (duplicate) samples.

6. Test condition 3: Sterilisation:

The stability of the test item was determined at conditions typical for sterilisation (e.g. for making canned vegetables). The processing temperature was 120° C (controlled by autoclave paper) in an autoclave. The incubation time at this temperature and pH for processing was 20 minutes. The test was performed in the dark with two independent (duplicate) samples.

7. Sampling:

The test vessels were weighed before undergoing processing conditions, and the weight of the sample in each vessel was calculated.

An aliquot of 2 mL was taken from the test vessel before and after processing and analysed by LSC (two times 100 µL). 500µL of the aliquot were analysed by HPLC and 50 µL by TLC.

The pH was measured in the test solution before and after processing.

8. Determination of radioactivity and of metabolite profiles:

For quantification, the radioactivity in solutions was determined by liquid scintillation counting (LSC). From every sample an aliquot was mixed with scintillation cocktail.

For characterisation, the radioactivity of the samples was determined with HPLC by a Mira Star (Raytest) radioactivity-HPLC flow detector. Quantification was done by integration.

TLC measurement was used as confirmation method.

9. Storage stability:

Regarding stability of the samples before analysis, all samples were analysed within 1 day after preparation and were kept refrigerated within this period. Therefore, according to OECD guideline 507 no storage stability data was required.

After analysis, samples were stored in a freezer at $\leq -18^{\circ}\text{C}$.

Results and discussion

Test condition 1: Pasteurisation

The conditions were citrate buffer pH 4 at a temperature of 90°C for 20 minutes. The test was performed in the dark with two independent (duplicate) samples.

The treatment had no impact on the pH value of the test solution (pH 4.02 before and pH 4.01 after processing).

There was no change in sample weight and in radioactivity content after processing (mass recovery: 100.1 %, recovery of radioactivity: 98.9 % AR).

The radio-HPLC results showed that no degradation products were formed during processing under pasteurisation conditions. TLC analysis confirmed HPLC results.
The test item was stable at pH 4 at 90°C for 20 minutes which simulates the pasteurisation process.
The results after processing are summarised in Table A 5 below.

Test condition 2: Baking, Brewing and Boiling

The conditions were acetic acid buffer pH 5 at a temperature of 100°C for 60 minutes. The test was performed in the dark with two independent (duplicate) samples.
The treatment had no impact on the pH value of the test solution (pH 5.01 before and pH 5.01 after processing).
There was no change in sample weight and in radioactivity content after processing (mass recovery: 100.2 %, recovery of radioactivity: 100.4 % AR).
The radio-HPLC results showed that no degradation products were formed during processing under baking/brewing/boiling conditions. TLC analysis confirmed HPLC results.
The test item was stable at pH 5 at 100°C for 60 minutes which simulates the baking/brewing/boiling process.
The results after processing are summarised in Table A 5 below.

Test condition 3: Sterilisation

The conditions were citrate buffer pH 6 at a temperature of 120°C for 20 minutes. The test was performed in the dark with two independent (duplicate) samples.
The treatment had no impact on the pH value of the test solution (pH 6.02 before and pH 6.02 after processing).
There was no change in sample weight and in radioactivity content after processing (mass recovery: 99.9 %, recovery of radioactivity: 102.8 % AR).
The radio-HPLC results showed that no degradation products were formed during processing under sterilisation conditions (selected chromatograms are shown in Figure 8 and Figure 9). TLC analysis confirmed HPLC results.
The test item was stable at pH 6 at 120°C for 20 minutes which simulates the sterilisation process.
The results after processing are summarised in Table A 5 below.

Table A 5: Standard hydrolysis study of [1,2,4-triazole-U-¹⁴C]prothioconazole-desthio (values are given in % of applied radioactivity) after processing

| Processes represented | T° (°C) | Time (min) | pH | Parent Initial conc. (mg/L) | Recoveries (% applied radioactivity)* |
|--------------------------|---------|------------|-----|-----------------------------|---------------------------------------|
| | | | | | Prothioconazole-desthio |
| Pasteurisation | 90 | 20 | 4.0 | 1.76 | 98.9 |
| Baking, brewing, boiling | 100 | 60 | 5.0 | 1.76 | 100.4 |
| Sterilisation | 120 | 20 | 6.0 | 1.76 | 102.8 |

* mean value of two determinations

Conclusions

The results of this study demonstrated that no significant hydrolysis or reaction products were formed under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.
There was no significant change in the radioactivity content following processing under the three different conditions. The recovery of the applied [1,2,4-triazole-U-¹⁴C]prothioconazole-desthio was in a range of 98.9% to 102.8%.
Therefore, [¹⁴C]prothioconazole-desthio can be considered stable during all processing conditions and no formation of any hydrolysis or degradation products is to be expected under conditions representative for simulating pasteurisation, baking/brewing/boiling and sterilisation.

A 2.1.2.2 Nature of residues in livestock

No new study submitted.

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat, rye, triticale (KCA 6.3.1)

Table A 6: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Wheat, rye, triticale | | | | | |
| cGAP EU (EFSA, 2007) | 3 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| cGAP EU (Art. 12, EFSA, 2014) | 3 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| Intended cGAP (1)* | 1 | 0.2 kg as/ha | - | 69 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Note: In 2019, 5 crop residue trials were conducted using the mixture product containing prothioconazole plus azoxystrobin and 4 crop residue trials were conducted using the solo product containing prothioconazole only. Due to the challenges in locating sites which had not previously used triazole compounds, 3 of the trial sites reported in Wheat Study 2 were also used to generate data in Wheat Study 3.

Similarly in 2021, 6 residue trials were conducted using the mixture product containing prothioconazole plus fluxapyroxad and 8 crop residue trials were conducted using the mixture product containing prothioconazole plus difenoconazole. In this case 5 of the trial sites reported in Wheat Study 4 were also used to generate data in Wheat Study 5. All data has been reported for each study and to assist the review trials performed at the same site within different studies have been annotated in Column 1 with capital letters A, B, C etc. to indicate a second set of data for the same site is reported.

A 2.1.3.1.1 Wheat study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe to gain the residue level of azoxystrobin, prothioconazole and its metabolites in specimens of wheat whole plant without roots and grain and straw following one foliar application of MCW-2073 (200 g a.s./L of azoxystrobin and 150 g a.s./ha of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 69.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>In seed specimens taken at normal commercial harvest (42-46 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method was fully validated for wheat whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4.</p> <p>All the analytes were determined by HPLC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) is comprised between 44 and 203 days for determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|--|

Reference: KCA 6.3.1/01

Report: Residue study of azoxystrobin, prothioconazole and its metabolites in wheat whole plants and Raw Agricultural Commodity after one foliar application of MCW-2073 - 1 harvest and 2 decline trials – Northern Europe (France and Poland) – 2018
Huaultmé, J.-M., 2019a
Report no.: BPL18/713/GC, sponsor no.: R-39643

Guideline(s): EC Guideline SANCO/7029/VI/95 rev. 5 (22/07/1997)
OECD 509, adopted 7 September 2009
Guidance document SANCO/3029/99 rev. 4 of 11/07/00
OECD guidance document on pesticide residue analytical methods.
Document ENV/JM/MONO(2007)17

Deviations: None with impact on study results.

GLP: Yes

Acceptability: Yes

and

| | |
|-------------------|---|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) following one foliar application of MCW 2073.</p> <p>The application had to be performed at crop growth stage BBCH 69.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.08 and 0.32 mg/kg.</p> <p>Residues of TAA in grain were between 0.02 and 0.05 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) according to SANCO/3029/99, rev. 4 within this study by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the recoveries. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120 % and the mean recoveries at each fortification level were in the range of 70 – 110 % with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 1056 days for wheat (whole plants without roots), 959 days for wheat (grain) and 965 for wheat (straw).</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw) as well as TA and TAA (grain).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|-------------------|---|

Reference: KCA 6.3.1/02

Report: Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plant without roots, grain and straw) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France and Poland) 2018

| | |
|----------------|---|
| | Yozgatli, H.P., 2021b |
| | Study No. S18-02654, sponsor no.: R-39643B |
| Guideline(s): | EC guidance working document SANCO/7029/VI/95 rev. 5 |
| | Guidance document SANCO/3029/99 rev. 4 |
| | OECD guidance document on pesticide residue analytical methods. |
| | Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 7: Summary of the wheat study 1 - 3 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Wheat / Cereals
Country: France, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/01

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|------------------------------|--|--------------------------------|--------------|-------------|---|--|--|---|---|---|---------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL18/713/GC-01-PL 88-300 Maslowice Poland N-EU 2017/18 | Winter wheat (TRZAW)/ Mema | 1. 21/09/17 2. 25/05/- 08/06/18 3. 21/07/18 | 0.146 | 295 | 0.050 | 08/06/18 | BBCH 69 | Grain Straw | <LOQ 0.14 | <LOQ 0.078 | 89 89 | 43 43 | Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites (g); |
| BPL18/713/GC-02-PL 55-110 Kroszczyna Mala Poland N-EU 2017/18 | Winter wheat (TRZAW)/ Hondia | 1. 23/10/17 2. 28/05/- 07/06/18 3. 23/07/18 | 0.149 | 301 | 0.050 | 07/06/18 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.25 0.12 0.11 0.10 <LOQ 0.082 | 0.25 0.072 0.05 0.038 <LOQ 0.039 | 69 73-75 75-77 85-87 89 89 | 0 10 20 35 46 46 | |

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Wheat / Cereals
Country: France, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/01

MCW-2073
SC
Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|------------------------------|--|--------------------------------|--------------|-------------|---|--|--|--|--|----------------------------------|--------------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL18/713/GC-03-FR 49610 St. Melaine sur Aubance France N-EU 2017/18 | Winter wheat (TRZAW)/ Apache | 1. 27/10/17 2. 15/05/- 31/05/18 3. 13/07/18 | 0.149 | 200 | 0.074 | 30/05/18 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.36 0.10 0.067* 0.064* <LOQ 0.15 | 0.36 0.067 0.030* 0.024* <LOQ 0.071 | 69 73 83 85 89 89 | 0 9 22 35 42 42 | LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 203 days (sampling to extraction), max. extract storage time (extraction to analysis) 10 days. Extract stability tested during the study. Results in all untreated specimens were below LOD. *Mean of two replicates |

(a) According to CODEX Classification / Guide

(b) Only if relevant

- (c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)
 - (d) Year must be indicated
 - (e) Days after last application not given in the study report. Calculated during dossier compilation.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- n.d. not detectable
LOQ Limit of quantification
LOD Limit of detection

Summary of the wheat study 1 - 3 trials (TDMs)

Crop residue data from supervised field trials

| | |
|--|-------------------------------------|
| Active ingredient (common name and content): | Prothioconazole, 148.7 g/L (actual) |
|--|-------------------------------------|

Crop/crop group: Winter Wheat / Cereals

Country: Poland, France (N-EU)

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agrosience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/02

MCW-2073

SC

Azoxystrobin, 206.6 g/L (actual)

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | |
|--|---------------------------------------|---|--------------------------------|-----------------|--------------------------|--|---|---------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|----|----|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatmen t or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | |
| BPL18/713/GC -01-PL 88-300 Maslowice Poland N-EU 2017/18 | Winter wheat (TRZAW)/ Mema | 1. 21/09/17 2. 25/05/ - 08/06/18 3. 21/07/18 | azy: 0.203 ptz: 0.146 | 295 | azy: 0.069 ptz: 0.050 | 08/06/18 | BBCH 69 | Grain | <LOQ | 0.29 | 0.05 | <LOQ (n.d.) | 89 | 43 | Analytical method: Syngenta GRM053.01A, LC- DMS-MS/MS detection. For method validation please refer to dRR Part B.5. point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | <LOQ | <LOQ (n.d.) | 89 | 43 | | | |
| | | | Untreated | | | | | | | Grain | <LOQ (n.d.) | 0.12 | 0.03 | <LOQ (n.d.) | | 89 | 43 |
| | | | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | <LOQ | <LOQ | | 89 | 43 |
| BPL18/713/GC -02-PL 55-110 Kroscina Mala Poland N-EU 2017/18 | Winter wheat (TRZAW)/ Hondia | 1. 23/10/17 2. 28/05/ - 07/06/18 3. 23/07/18 | azy: 0.207 ptz: 0.149 | 301 | azy: 0.059 ptz: 0.050 | 07/06/18 | BBCH 69 | Whole plants w/o roots | <LOQ | 0.02 | 0.01 | 0.02 | 69 | 0 | Max. sample storage time: 1056 days for whole plant w/o roots 959 days for grain and 965 days for straw (sampling to extraction), max extract storage time (extraction to | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.05 | 0.02 | 0.01 | 73-75 | 10 | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.06 | 0.02 | 0.01 | 75-77 | 20 | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 85-87 | 35 | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 46 | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.08 | 0.02 | <LOQ (n.d.) | 89 | 46 | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.01 | <LOQ | 89 | 46 | | | |
| | | | | | | | | | <LOQ (n.d.) | | | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|---------------------------------------|---|--------------------------------|-----------------|-------------|--|--|---------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL18/713/GC -03-FR 49610 St Melaine Sur Aubance France N-EU 2017/18 | Winter wheat (TRZAW)/ Apache | | Untreated | | | | | Whole plants w/o roots | <LOQ | 0.02 | 0.02 | 0.03 | 69 | 0 | analysis) 0 day for straw and grain and 1 day for whole plant w/o roots. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Whole plants w/o roots | <LOQ | 0.02 | 0.01 | <LOQ | 75-77 | 20 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.01 | <LOQ (n.d.) | 89 | 46 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 46 | |
| | | 1. 27/10/17 | azy: 0.207 | 200 | azy: 0.103 | 30/05/18 | BBCH | Whole plants | <LOQ | <LOQ | <LOQ | 0.01 | 69 | 0 | |
| | | 2. 15 - | ptz: 0.149 | | ptz: 0.074 | | 69 | w/o roots | <LOQ | 0.10 | 0.01 | 0.02 | 73 | 9 | |
| | | 31/06/18 | | | | | | Whole plants | <LOQ | 0.15 | 0.02 | 0.02 | 83 | 22 | |
| | | 3. 13/07/18 | | | | | | w/o roots | <LOQ (n.d.) | 0.06 | 0.02 | <LOQ | 85 | 35 | |
| | | (farmer) | | | | | | Whole plants | <LOQ (n.d.) | 0.32 | 0.04 | <LOQ (n.d.) | 89 | 42 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.01 | 0.02 | <LOQ (n.d.) | 89 | 42 | |
| | | | | | | | | Straw | <LOQ (n.d.) | | | | | | |
| | | | Untreated | | | | | Whole plants | <LOQ (n.d.) | <LOQ | <LOQ | 0.01 | 69 | 0 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.01 | <LOQ | <LOQ | 73 | 9 | |
| | | | | | | | | Whole plants | <LOQ (n.d.) | 0.02 | <LOQ | <LOQ (n.d.) | 89 | 42 | |
| | | | | | | | | Grain | <LOQ (n.d.) | | | | 89 | 42 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ (n.d.) | 89 | 42 | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha azoxystrobin, 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

- (d) Year must be indicated
 - (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application.
 - (g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
- azy: Azoxystrobin
ptz: Prothioconazole
w/o Without
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection
Data in *italics* reported but outside acceptable storage stability

A 2.1.3.1.2 Wheat study 2

| | |
|-------------------|---|
| Comments of zRMS: | <p>Five field trials were conducted in Northern Europe to determine the residue level of azoxystrobin, prothioconazole and its metabolites in specimens of wheat whole plant without roots, grain and straw following one foliar application of MCW-2073 (200 g a.s./L of azoxystrobin and 150 g a.s./ha of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 69.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>In seed specimens taken at normal commercial harvest (34-45 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method was fully validated for wheat whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 258 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.1/03 |
| Report: | Residue study of azoxystrobin, prothioconazole and its metabolites in wheat whole plant and Raw Agricultural Commodity after one foliar application of MCW-2073 - 3 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019 |
| | Amic, S., 2020a |
| | Report no.: BPL19/757/GC, Sponsor no.: 000102745 |
| Guideline(s): | EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) |
| | OECD 509, adopted 7 September 2009 |
| | Guidance document SANCO/3029/99 rev. 4 of 11/07/00 |
| | OECD guidance document on pesticide residue analytical methods. |
| | Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

And

| | |
|-------------------|--|
| Comments of zRMS: | <p>Five field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) following one foliar application of MCW 2073 (200 g/L of azoxystrobin and 150 g/L of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 69.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.14 and 0.31 mg/kg.</p> <p>Residues of TAA in grain were between 0.04 and 0.11 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) according to SANCO/3029/99, rev. 4.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte.</p> |
|-------------------|--|

| | |
|--|--|
| | <p>and each matrix.</p> <p>The coefficients of determination (R²) of linear regression of the calibration plots were ≥ 0.98 and thus demonstrated linearity of the detection system over the working range of no more than 30% of the LOQ to at least + 20% of the highest analyte concentration level in a sample.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 505 days (above 16 months) for wheat (whole plants without roots), 496 days (above 16 months) for wheat (grain) and 879 (above 29 months) for wheat (straw).</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|--|--|

| | |
|----------------|--|
| Reference: | KCA 6.3.1/04 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant, grain and straw) following one foliar application of MCW 2073 (200 g/L of Azoxystrobin and 150 g/L of Prothioconazole), in 5 trials (3 HS + 2 DCS) in Northern EU (France, Hungary and Poland) 2019 Yozgatli, H.P., 2022b |
| Guideline(s): | Study No. S19-00725, sponsor no.: 000102779 EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 9: Summary of the wheat study 2 – 5 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Wheat / Cereals
Country: France, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/03

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);

Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|--------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|-----------------------|-------------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/757/GC-01-FR 71640 Givry, France N-EU 2018/19 (A) | Winter wheat (TRZAW)/ Complice | 1. 25/10/18 2. 27/05/-11/06/19 3. 10-16/07/19 | 0.147 | 198 | 0.074 | 08/06/19 | BBCH 69 | Grain Straw | <LOQ 0.12 | <LOQ 0.062 | 89 89 | 34 34 | Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL19/757/GC-02-HU 2141 Csömör, Hungary N-EU 2018/19 (B) | Winter wheat (TRZAW)/ Astaro | 1. 01/10/18 2. 22/05/-03/06/19 3. 09-11/07/19 | 0.153 | 258 | 0.059 | 03/06/19 | BBCH 69 | Grain Straw | <LOQ 0.13 | <LOQ 0.064 | 89 89 | 36 36 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites (g); LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for |
| BPL19/757/GC-03-PL 98-300 Wilún, Poland N-EU 2018/19 | Winter wheat (TRZAW)/ Mewa | 1. 05/10/18 2. 31/05/-13/06/19 3. 19/07/19 | 0.153 | 308 | 0.050 | 12/06/19 | BBCH 69 | Grain Straw | <LOQ 0.70 | <LOQ 0.54 | 89 89 | 37 37 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|--------------------------------|---|-----------------------------------|-----------------|----------------|--|--|--|---|--|---|---------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/757/GC-04-FR 60490 Mareuil-la-Motte, France N-EU 2018/19 (C) | Spring wheat(TRZAS)/ Lennox | 1. 19/02/19 2. 18- 21/06/19 3. 01/08/19 | 0.145 | 195 | 0.074 | 21/06/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.19 0.095 0.11 0.27 <u><LOQ</u> 0.74 | 0.19 0.085 0.087 0.20 <u><LOQ</u> 0.43 | 69 75 83 89 89 89 | 0 10 20 35 45 45 | prothioconazole expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time (sampling to extraction): 258 days, max. extract storage time (extraction to analysis) 10 days. Extract stability tested during the study. Results in all untreated specimens were below LOD. |
| BPL19/757/GC-05-PL 55-110 Prusice, Poland N-EU 2018/19 (D) | Winter wheat (TRZAW)/ Linus | 1. 01/10/18 2. 01- 20/06/19 3. 26- 27/07/19 | 0.147 | 297 | 0.050 | 18/06/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.19 0.57 0.76 0.31 <u><LOQ</u> 0.31 | 0.19 0.47 0.60 0.18 <u><LOQ</u> 0.16 | 69 83-84 85-87 87-89 89 89 | 0 10 20 32 39 39 | |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.2, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. not detectable

LOQ Limit of quantification

LOD Limit of detection

Table A 10: Summary of the wheat study 2 – 5 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148.7 g/L (actual)

Crop/crop group: Winter Wheat / Cereals

Country: France (N-EU), Hungary, Poland

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agrosience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.1/04

MCW-2073

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Azoxystrobin, 206.6 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | |
|---|---|---|--------------------------------|-----------------|--------------------------|---|--|------------------|---------------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | |
| BPL19/757/GC -01-FR 71640 Givry France N-EU 2018/19 (A) | Winter wheat (TRZAW)/ Complice | 1. 25/10/18 2. 27/05/ - 11/06/19 3. 10 - 16/07/19 | azy: 0.204 ptz: 0.147 | 198 | azy: 0.103 ptz: 0.074 | 08/06/19 | BBCH 69 | Grain | <LOQ | 0.14 | 0.06 | <LOQ | 89 | 34 | Analytical method: GRM053.01A, LC- DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) | |
| | | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.05 | <LOQ (n.d.) | 89 | 34 | | |
| | | | | | | | | Straw | <LOQ (n.d.) n.a.*** | <LOQ (n.d.) | 0.02 | 0.01 | 89 | 34 | | |
| BPL19/757/GC -02-HU 2141 Csömör Hungary N-EU 2018/19 (B) | Winter wheat (TRZAW)/ Astarado | 1. 01/10/18 2. 22/05/- 03/06/19 3. 09 - 11/07/19 | azy: 0.123 ptz: 0.153 | 258 | azy: 0.083 ptz: 0.059 | 03/06/19 | BBCH 69 | Grain | <LOQ | 0.31 | 0.05 | <LOQ | 89 | 36 | Max. sample storage time: 505 days for whole plant w/o roots, 496 days for grain and 879 days for straw (sampling to extraction), max. extract storage time | |
| | | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | <LOQ | <LOQ (n.d.) | 89 | 36 | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 89 | 36 | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | |
|---|---------------------------------------|---|--------------------------------|-----------------|--------------------------|---|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|----|----|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | |
| BPL19/757/GC -03-PL 1998-300 Wielun Poland N-EU 2018/19 | Winter wheat (TRZAW)/ Mewa | 1. 05/10/18 2. 31/05/- 13/06/19 3. 19/07/19 | azy: 0.212 ptz: 0.153 | 308 | azy: 0.069 ptz: 0.050 | 12/06/19 | BBCH 69 | Grain | <LOQ (n.d.) | 0.29 | 0.09 | <LOQ | 89 | 37 | (extraction to analysis): 6 days for whole plant w/o roots, 3 days for grain and 1 day for straw. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. | | |
| | | | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | | | Grain | <LOQ (n.d.) | 0.12 | 0.10 | <LOQ (n.d.) | | 89 | 37 |
| | | | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.04 | | 89 | 37 |
| BPL19/757/GC -04-FR 60490 Mareuil- Lamotte France N-EU 2019 (C) | Spring wheat (TRZAS)/ Lennox | 1. 19/02/19 2. 18/06/ - 21/06/19 3. 01/08/19 | azy: 0.202 ptz: 0.145 | 195 | azy: 0.103 ptz: 0.074 | 21/06/19 | BBCH 69 | whole plant w/o roots | <LOQ (n.d.) | 0.02 | 0.01 | 0.01 | 69 | 0 | | | |
| | | | | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.08 | 0.02 | 0.03 | 75 | 10 | | | |
| | | | | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.09 | 0.02 | 0.02 | 83 | 20 | | | |
| | | | | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.13 | 0.04 | 0.04 | 89 | 35 | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.22 | 0.04 | <LOQ (n.d.) | 89 | 45 | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.04 | 89 | 45 | | | |
| | | | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | whole plant w/o roots | <LOQ | 0.01 | <LOQ | 0.01 | 69 | 0 | | | |
| | | | whole plant w/o roots | <LOQ | 0.02 | 0.01 | 0.01 | 83 | 20 | | | | | | | | |
| | | | Grain | <LOQ (n.d.) | 0.07 | 0.02 | <LOQ (n.d.) | 89 | 45 | | | | | | | | |
| | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.01 | 0.03 | 89 | 45 | | | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--------------------------------------|---|--------------------------------|-----------------|--------------------------|---|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL19/757/GC -05-PL 55110 Prusice Poland N-EU 2018/19 (D) | Winter wheat (TRZAW)/ Linus | 1. 01/10/18 2. 01/06/ - 20/06/19 3. 26- 27/07/19 | azy: 0.204 ptz: 0.147 | 297 | azy: 0.069 ptz: 0.050 | 18/06/19 | BBCH 69 | whole plant w/o roots | <LOQ | 0.05 | 0.07 | 0.05 | 69 | 0 | |
| | | | | | | | | whole plant w/o roots | <LOQ | 0.07 | 0.09 | 0.04 | 83 – 84 | 10 | |
| | | | | | | | | whole plant w/o roots | <LOQ | 0.08 | 0.11 | 0.04 | 85 - 87 | 20 | |
| | | | | | | | | whole plant w/o roots | <LOQ | 0.07 | 0.09 | 0.02 | 87 - 89 | 32 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.14 | 0.11 | <LOQ (n.d.) | 89 | 39 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.07 | 0.02 | 89 | 39 | |
| | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.02 | 0.03 | 0.02 | 69 | 0 | |
| | | | | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.01 | 0.03 | 0.02 | 85 - 87 | 20 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.10 | 0.08 | <LOQ (n.d.) | 89 | 39 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.01 | 89 | 39 | |
| | | | | | | | | | | | | | | | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance.

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

n.d. Not detectable

n.a. Not available. The initial analytical set was invalid for 1,2,4-T (mean recoveries were outside of the acceptance range), but was valid for TA, TAA and TLA. Due to a lack of sample material reanalysis for 1,2,4-Triazole was not possible.

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.1.3 Wheat study 3

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites in specimens of wheat whole plant without roots, grain and straw following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) at the dose rate 0.8 L/ha (200 g a.s./ha of prothioconazole). Application was performed at BBCH 69.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 DAA, 20 DAA and 35 (± 3) DAA for the two decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>In seed specimens taken at normal commercial harvest (34-45 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method was validated for wheat whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 149 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.1/05 |
| Report: | Residue study of prothioconazole and its metabolites in wheat whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (FR, HU, PL) – 2019 Amic, S., 2020b Report no.: BPL19/762/GC, Sponsor no.: 000102751 |
| Guideline(s): | EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

And

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 69.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 DAA, 20 DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.29 and 0.58 mg/kg.</p> <p>Residues of TAA in grain were between 0.09 and 0.21 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)</p> |
|-------------------|---|

| | |
|--|--|
| | <p>in wheat (whole plants without roots, grain and straw) according to SANCO/3029/99, rev.4. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.98.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 538 days (above 17 months) for wheat - whole plants without roots, 525 days (above 17 months) for wheat grain and 499 (above 16 months) for wheat straw.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|--|--|

| | |
|----------------|--|
| Reference: | KCA 6.3.1/06 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (RAC whole plant without roots , grain and straw) following one foliar application of ADM.3500.F.2.B (250g a.s./L of prothioconazole), in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland), 2019 |
| | Yozgatli, H.P., 2021d |
| | Study no: S19-00733, sponsor no.: 000102783 |
| Guideline(s): | EC Guideline SANCO/7029/VI/95 rev. 5 |
| | Guidance document SANCO/3029/99 rev. 4 |
| | OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 11: Summary of the wheat study 3 - 4 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 250 g/L (actual 248.2 g/L)
Crop/crop group: Wheat / Cereals
Country: FR, HU, PL
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/05

ADM.3500.F.2.B (MCW-2075)

EC

None

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);

Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|--------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------------|-------------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/762/GC-01-FR 71640 Givry, France N-EU 2018/19 (A) | Winter wheat (TRZAW)/ Complice | 1. 25/10/18 2. 27/05/- 11/06/19 3. 10- 16/07/19 | 0.201 | 198 | 0.099 | 08/06/19 | BBCH 69 | Grain Straw | <u><LOQ</u> 0.20 | <u><LOQ</u> 0.076 | 89 89 | 34 34 | Analytical methods: based on European Committee for Standardization (CEN): EN 15662:2009-02, quantification via LC-MS/MS |
| BPL19/762/GC-02-HU 2141 Csömör, Hungary N-EU 2018/19 (B) | Winter wheat (TRZAW)/ Astardo | 1. 01/10/18 2. 22/05/- 03/06/19 3. 09- 11/07/19 | 0.202 | 256 | 0.079 | 03/06/19 | BBCH 69 | Grain Straw | <u><LOQ</u> 0.30 | <u><LOQ</u> 0.13 | 89 89 | 36 36 | For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: Prothioconazole-desthio (g) 0.01 mg/kg, |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|------------------------------------|---|-----------------------------------|-----------------|----------------|--|--|--|--|--|---|---------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/762/GC-03-PL 55-110 Krościna Mała, Poland N-EU 2018/19 | Winter wheat (TRZAW)/ Linus | 1. 01/10/18 2. 01- 20/06/19 3. 26- 27/07/19 | 0.195 | 297 | 0.066 | 18/06/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.51* 1.1* 1.1 1.2 <u><LOQ*</u> 0.88 | 0.51* 0.905* 0.86 0.67 <u>0.013*</u> 0.49 | 69 83-84 85-87 87-89 89 89 | 0 10 20 32 39 39 | prothioconazole expressed as prothioconazole- desthio as a sum of the metabolites (h) = 0.06 mg/kg |
| BPL19/762/GC-04-FR 60490 Mareuil- Lamotte, France N-EU 2018/19 (C) | Spring wheat (TRZAW)/ Lennox | 1. 19/02/19 2. 18- 21/06/19 3. 01/08/19 | 0.192 | 195 | 0.099 | 21/06/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 1.2 0.30 0.21 0.35 <u><LOQ</u> 1.4 | 1.2 0.26 0.16 0.22 <u><LOQ</u> 0.53 | 69 75 83 87-89 89 89 | 0 10 20 35 45 45 | Max. sample storage time (sampling to extraction): 149 days, max. extract storage time, 15 days (extraction to analysis). Results in all untreated specimens were below LOD. *Mean of two extractions |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. not detectable

LOQ Limit of quantification

LOD Limit of detection

Table A 12: Summary of the wheat study 3 - 4 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 248.2 g/L (actual)

Crop/crop group: Winter Wheat / Cereals
Country: France (N-EU), Hungary, Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/06

ADM.3500.F.2.B

EC
None

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL19/762/GC-01-FR 71640 Givry France N-EU 2018/19 (A) | Winter wheat (TRZAW)/ Complice | 1. 25/10/18 2. 27/05/ - 11/06/19 3. 10/07/ - 16/07/19 | 0.201 | 202 | 0.099 | 08/06/19 | BBCH 69 | Grain | <LOQ (n.d.) | 0.29 | 0.13 | <LOQ | 89 | 34 | Analytical method: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 538 days for whole plant w/o roots, 525 days for grain and 499 days for straw (sampling to |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.04 | 0.05 | 89 | 34 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.06 | <LOQ (n.d.) | 89 | 34 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.02 | 89 | 34 | |
| BPL19/762/GC-02-HU 2141 Csömör Hungary N-EU 2018/19 (B) | Winter wheat (TRZAW)/ Astardo | 1. 01/10/18 2. 22/05/- 03/06/19 3. 09/07/- 11/07/19 | 0.202 | 256 | 0.079 | 03/06/19 | BBCH 69 | Grain | <LOQ (n.d.) | 0.58 | 0.12 | 0.01 | 89 | 36 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.08 | 0.06 | 0.16 | 89 | 36 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ (n.d.) | 89 | 36 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 0.01 | 89 | 36 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|---------------------------------------|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|-------------------------|--------------------------------|--------------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazol e alanine | Triazol e acetic acid | Triazol e lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL19/762/GC-03-PL 55-110 Krościna Mala Poland N-EU 2018/19 | Winter wheat (TRZAW)/ Linus | 1. 01/10/18 2. 01/06/- 20/06/19 3. 26/07/- 26/07/19 | 0.195 | 296 | 0.066 | 18/06/19 | BBCH 69 | whole plant | <LOQ (n.d.) | 0.05 | 0.10 | 0.08 | 69 | 0 | extraction), max. extract storage time (extraction to analysis) 0 day for straw and 1 day for whole plant w/o roots and grain. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.05 | 0.12 | 0.06 | 83-84 | 10 | |
| | | | | | | | | whole plant | <LOQ (n.d.) | 0.06 | 0.13 | 0.05 | 85-87 | 20 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.08 | 0.12 | 0.03 | 87-89 | 32 | |
| | | | | | | | | whole plant | <LOQ | 0.34 | 0.21 | <LOQ (n.d.) | 89 | 39 | |
| | | | | | | | | w/o roots | <LOQ | 0.02 | 0.13 | 0.05 | 89 | 39 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 0.05 | 0.02 | 89 | 45 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.06 | 89 | 45 | |
| | | | | | | | | whole plant | <LOQ (n.d.) | 0.01 | 0.02 | 0.01 | 69 | 0 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.02 | 0.04 | 0.02 | 85-87 | 20 | |
| BPL19/762/GC-04-FR 60490 Mareuil- Lamotte France N-EU 2019 (C) | Spring wheat (TRZAS)/ Lennox | 1. 19/02/19 2. 18/06/ - 21/06/19 3. 01/08/19 | 0.192 | 194 | 0.099 | 21/06/19 | BBCH 69 | whole plant | <LOQ (n.d.) | 0.01 | <LOQ | <LOQ | 69 | 0 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.13 | 0.02 | 0.04 | 75 | 10 | |
| | | | | | | | | whole plant | <LOQ (n.d.) | 0.16 | 0.02 | 0.04 | 83 | 20 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.14 | 0.04 | 0.06 | 87-89 | 35 | |
| | | | | | | | | whole plant | <LOQ (n.d.) | 0.54 | 0.09 | <LOQ | 89 | 45 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.06 | 89 | 45 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.06 | 89 | 45 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.06 | 89 | 45 | |
| | | | | | | | | whole plant | <LOQ (n.d.) | 0.01 | 0.02 | 0.01 | 69 | 0 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.02 | 0.04 | 0.02 | 85-87 | 20 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|------------------------|---|--------------------------------|-----------------|-------------|--|---|--------------------------|--------------------|-------------------------|-----------------------------|-----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatmen t or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazol e alanine | Triazol e acetic acid | Triazol e lactic acid | Timing (BBCH) | DALA (days) | |
| | | | | | | | | | | | | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.01 | 0.01 | 0.01 | 69 | 0 | |
| | | | | | | | | whole plant w/o roots | <LOQ (n.d.) | 0.01 | 0.01 | 0.01 | 83 | 20 | |
| | | | | | | | | Grain | <LOQ | 0.03 | 0.03 | <LOQ (n.d.) | 89 | 45 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.02 | 0.04 | 89 | 45 | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.1.4 Wheat study 4

| | |
|-------------------|---|
| Comments of zRMS: | <p>Six field trials were conducted in Northern Europe to determine the residue level of prothioconazole and fluxapyroxad and their respective metabolites in specimens of wheat grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad).</p> <p>Application was performed at BBCH 69.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Prothioconazole</u></p> <p>In seed specimens taken at normal commercial harvest (24-52 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method based on the method 00979/M001 was validated for wheat grain and straw according to guideline SANTE/2020/12830, Rev.1.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 125 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Triazole metabolites</u></p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat (whole plants without roots, grain and straw) according to SANTE/2020/12830, Rev.1.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>In the treated wheat specimens, the residue levels of the triazole metabolites ranged from: For 1,2,4-Triazole, all results were<LOQ (nd) to <LOQ in grain and <LOQ (nd) in straw specimens, For Triazole alanine: - 0.26 and 0.61 mg/kg in grain, - <LOQ and 0.04 mg/kg in straw, For Triazole acetic acid: - 0.06 and 0.39 mg/kg in grain, - 0.01 and 0.12 mg/kg in straw, For Triazole lactic acid: - All results were <LOQ in grain, - <LOQ and 0.25 mg/kg in straw.</p> <p>Analysis (extraction) of the specimens took place maximum 106 days after samples collection.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

Reference:
Report:

KCA 6.3.1/07
Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in wheat Raw Agricultural Commodities after foliar

| | |
|----------------|--|
| | application of ADM.03503.F.1.A under field conditions –Northern Europe – 2021 |
| | Le Mineur, A., 2022a |
| | Study no.: BPL21/954/GC, sponsor no.: 000107608 |
| Guideline(s): | OECD/OCDE 509 Adopted: 7 September 2009, OECD Guidelines for the testing of chemicals, Crop Field Trial. |
| | ENV/JM/MONO(2011)50/REV1 07-Sep-2016 OECD Guidance Document on crop field trials, second edition, Series on Pesticides - No. 66 Series on Testing & Assessment - No. 164 |
| | SANTE/2020/12830, Rev.1 24, February 2021, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00. |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 13: Summary of wheat study 4 – 6 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148 g/L)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/07

ADM.03503. F.1.A
EC
Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---------------------------------|---|--------------------------------|--------------|-------------|---|--|--------------------|-------------------------|--------------------------|---------------|--------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/954/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A) | Winter wheat (TRZAW) / Pastoral | 1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21 | 0.177 | 288 | 0.062 | 10/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.16* | <LOQ (n.d.) 0.052* | 89 89 | 50 50 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of |
| BPL21/954/GC-02-GE 74861 Krefsbach Germany N-EU 2020/21 (B) | Winter wheat (TRZAW) / Kometus | 1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21 | 0.188 | 356 | 0.053 | 15/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.095 | <LOQ (n.d.) 0.31 | 89 89 | 44 44 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---------------------------------------|---|-----------------------------------|-----------------|----------------|--|---|---------------------|-------------------------------|----------------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/954/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) | Spring wheat (TRZAS) / Pirkadat | 1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21 | 0.181 | 293 | 0.062 | 15/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.87 | <LOQ 0.73 | 89 89 | 28 28 | metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole- desthio as a sum of metabolites |
| BPL21/954/GC-04-PL 98 300 Masłowiec Poland N-EU 2021 | Spring wheat (TRZAS) / Nimfa C1 | 1/ 05/03/21 2/ 25/06 - 04/07/21 3/ 26/07/21 | 0.186 | 301 | 0.062 | 02/07/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 1.2 | <LOQ 0.51 | 89 89 | 24 24 | Max. sample storage time: 125 days (sampling to extraction), max. extract storage time (extraction to analysis) 17 days. |
| BPL21/954/GC-05-FR 37 210 Parçay Meslay France N-EU 2020/21 (D) | Winter wheat (TRZAW) / Unik | 1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21 | 0.182 | 197 | 0.093 | 05/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.53* | <LOQ (n.d.) 0.18* | 89 89 | 45 45 | Extract stability proven within the study. |
| BPL21/954/GC-06-FR 51 240 Marson France N-EU 2021 (E) | Winter wheat (TRZAW) / Syllon | 1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21 | 0.183 | 297 | 0.062 | 11/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.068 | <LOQ (n.d.) 0.021 | 89 89 | 52 52 | Results in all untreated specimens were below LOD. |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:

(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)

- (d) Year must be indicated
 - (e) Days after last application.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- * Mean of two extractions
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 14: Summary of wheat study 4 – 6 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148 g/L (actual)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:

Residues calculated as:

KCA 6.3.1/07

ADM.03503.F.1.A

EC

Fluxapyroxad Nominal 77.4 g/L (actual)

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|---------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL21/954/GC -01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A) | Winter wheat (TRZAW) / Pastoral | 1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21 | 0.177 | 288 | 0.062 | 10/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | 0.31 | 0.07 | <LOQ (n.d.) | 89 | 50 | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.01 | <LOQ | 89 | 50 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ (n.d.) | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ (n.d.) | 89 | 50 | |
| BPL21/954/GC -02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) | Winter wheat (TRZAW) / Kometus | 1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21 | 0.188 | 356 | 0.053 | 15/06/21 | BBCH 69 | Grain | <LOQ | 0.34 | 0.07 | <LOQ (n.d.) | 89 | 44 | Max. sample storage time: 106 days (sampling to extraction), max. extract storage time (extraction to analysis) 7 days for grain and 3 |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.01 | 89 | 44 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--|---|--------------------------------|-----------------|-------------|---|--|------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (hL) | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.06 | 0.03 | <LOQ (n.d.) | 89 | 44 | days for straw. |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.01 | <LOQ | 89 | 44 | Extract stability proven within the study. |
| BPL21/954/GC -03-HU 2340 Kiskunlacháza Hungary N-EU 2021(C) | Spring wheat (TRZAS) / Pirkadat | 1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21 | 0.181 | 293 | 0.062 | 15/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | 0.61 | 0.39 | <LOQ | 89 | 28 | Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.04 | 0.12 | 0.25 | 89 | 28 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.17 | 0.20 | <LOQ | 89 | 28 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.06 | 0.14 | 89 | 28 | |
| BPL21/954/GC -04-PL 98 300 Masłowice Poland N-EU 2021 | Spring wheat (TRZAS) / Nimfa C1 | 1/ 05/03/21 2/ 25/06 - 04/07/21 3/ 26/07/21 | 0.186 | 301 | 0.062 | 02/07/21 | BBCH 69 | Grain | <LOQ (n.d.) | 0.38 | 0.06 | <LOQ | 89 | 24 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.02 | 0.01 | 89 | 24 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.06 | 0.04 | <LOQ (n.d.) | 89 | 24 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | <LOQ | 89 | 24 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--|---|--------------------------------|-----------------|-------------|---|--|------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL21/954/GC -05-FR 37 210 Parçay Meslay France N-EU 2020/21 (D) | Winter wheat (TRZAW) / Unik | 1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21 | 0.182 | 197 | 0.093 | 05/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | 0.26 | 0.06 | <LOQ (n.d.) | 89 | 45 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.01 | 89 | 45 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.12 | 0.05 | <LOQ (n.d.) | 89 | 45 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.01 | 89 | 45 | |
| BPL21/954/GC -06-FR 51 240 Marson France N-EU 2021 (E) | Winter wheat (TRZAW) / Syllon | 1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21 | 0.183 | 297 | 0.062 | 11/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | 0.37 | 0.09 | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.01 | 89 | 52 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.04 | 0.02 | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 89 | 52 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503.F.1.A at 1.25 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

n.d. Not detectable

LOQ Limit of quantification, LOD Limit of detection

A 2.1.3.1.5 Wheat study 5

| | |
|-------------------|--|
| Comments of zRMS: | <p>Eight field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of difenoconazole in specimens of wheat whole plant without roots, grain and straw following one foliar application of ADM.03501.F.1.A (175 g a.s./L of prothioconazole and 125 g a.s./L of difenoconazole) at the dose rate 1 L/ha (175 g a.s./ha of prothioconazole and 125 g a.s./ha of difenoconazole).</p> <p>Application was performed at BBCH1 69.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>In seed specimens taken at normal commercial harvest (28 – 72 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>For prothioconazole and its metabolites, the principle of analytical method was based on the method 00979/M001. For prothioconazole and its metabolites, the analytical method was validated (reduced validations) on wheat (whole plant, grain and straw), following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. LOQ: 0.01 mg/kg for each analyte, LOQ: 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p> <p>The storage duration (interval between sampling and extraction date) was 109 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>Remark:</p> <p>Only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary without data of TDMs.</p> <p>The study is acceptable.</p> |
|-------------------|--|

| | |
|----------------|---|
| Reference: | KCA 6.3.1/08 |
| Report: | Residue study of prothioconazole, difenoconazole and their metabolites in wheat whole plant and Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe - 2021. Le Mineur, A., 2022b Report no.: BPL21/958/GC, sponsor no.: 000107612 |
| Guideline(s): | EC guidance working document 7029/VI/95 rev. 5 (22/07/1997) Appendix B OECD/OCDE 509 (2009) Crop field trial ENV/JM/MONO(2011)50 SANTE/2020/12830, Rev.1 of 24/02/21 ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Additional residue data of difenoconazole and triazole derivative metabolites (TDMs) have been determined in this study. However, difenoconazole residues are not relevant for ADM.03500.F.2.B (containing prothioconazole only) and TDMs are overestimated with regard to the product as they results from both active substances in the used formulation (prothioconazole and difenoconazole). Therefore, only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary. However, it is demonstrated in all trials that 1,2,4-T is below LOQ (<0.01 mg/kg) in all matrices.

Table A 15: Summary of the wheat study 5 - 8 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 172.8 g/L)
Crop/crop group: Wheat / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.1/08

ADM.03501.F.1.A
EC
Difenoconazole, nominal 125 g/L (actual 125.0 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------------|--------------------------|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/958/GC-01-FR 10 600 La Chapelle Saint-Luc France N-EU 2020/21 (A) | Winter wheat (TRZAW) / Pastoral | 1/ 20/10/20 2/ 28/05 - 12/06/21 3/ 24/07/21 | 0.173 | 300 | 0.058 | 10/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.16 | <LOQ (n.d.) 0.050* | 89 89 | 50 50 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL21/958/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) | Winter wheat (TRZAW) / Kometus | 1/ 20/10/20 2/ 07 - 14/06/21 3/ 29 - 30/07/21 | 0.175 | 354 | 0.049 | 15/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.26 | <LOQ (n.d.) 0.072* | 89 89 | 44 44 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---|---|-----------------------------------|-----------------|----------------|--|--|--|---|---|---|---|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/958/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) | Spring wheat (TRZAS) / Pirkadat | 1/ 16/03/21 2/ 09 - 15/06/21 3/ 12 - 15/07/21 | 0.170 | 295 | 0.058 | 15/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.45 | <LOQ 0.29 | 89 89 | 28 28 | metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole- desthio as a sum of metabolites |
| BPL21/958/GC-04-PL 57 200 Tarnów Poland N-EU 2020/21 | Winter wheat (TRZAW) / Euforia C1 | 1/ 15/11/20 2/ 23/06 - 02/07/21 3/ 14/08/21 | 0.170 | 296 | 0.058 | 01/07/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.15 | <LOQ (n.d.) 0.022 | 89 89 | 44 44 | Max. sample storage time: 109 days (sampling to extraction), max. |
| BPL21/958/GC-05-PL 55 010 Krościna Mała Poland N-EU 2020/21 | Winter wheat (TRZAW) / RGT Kilimanjaro | 1/ 30/10/20 2/ 13/06 - 01/07/21 3/ 16/08/21 | 0.169 | 294 | 0.058 | 01/07/21 | BBCH 69 | whole plant w/o roots whole plant w/o roots whole plant w/o roots whole plant w/o roots Grain Straw | 0.55 0.16 0.15 0.085 <LOQ (n.d.) 0.17 | 0.54 0.047 0.027 0.013 <LOQ (n.d.) 0.028* | 69 71 73 – 75 87 89 89 | 0 11 20 33 46 46 | extract storage time (extraction to analysis) 8 days. Extract stability proven within the study. Results in all untreated specimens were below LOD. |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|--|---|-----------------------------------|-----------------|----------------|--|--|-----------------------|-------------------------------|----------------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/958/GC-06-FR 80560 Arqueves France N-EU 2020/21 | Winter wheat (TRZAW) / Fructidor | 1/ 18/10/20 2/ 07 - 14/06/21 3/ 26/08/21 | 0.176 | 204 | 0.086 | 14/06/21 | BBCH 69 | whole plant w/o roots | 0.44 | 0.44 | 69 | 0 | |
| | | | | | | | | whole plant w/o roots | 0.17 | 0.081 | 83 | 10 | |
| | | | | | | | | whole plant w/o roots | 0.071 | 0.023 | 85 | 18 | |
| | | | | | | | | whole plant w/o roots | 0.088 | 0.016 | 85 | 35 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 72 | |
| | | | | | | | | Straw | 0.065 | 0.018 | 89 | 72 | |
| BPL21/958/GC-07-FR 37 210 Parçay Meslay France N-EU 2020/21 (D) | Winter wheat (TRZAW) / Unik | 1/ 18/10/20 2/ 25/05 - 08/06/21 3/ 20/07/21 | 0.171 | 199 | 0.086 | 05/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 45 | |
| | | | | | | | | Straw | 0.49 | 0.015* | 89 | 45 | |
| BPL21/958/GC-08-FR 51240 Marson France N-EU 2020/21 (E) | Winter wheat (TRZAW) / Syllon | 1/ 18/10/20 2/ 30/05 - 12/06/21 3/ 22/07/21 | 0.178 | 309 | 0.058 | 11/06/21 | BBCH 69 | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | 0.14 | 0.047* | 89 | 52 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 175 g a.s./ha of Prothioconazole and 125 g a.s./ha of Difenconazole (equivalent to ADM.03501.F.1.A at 1.0 L/ha)

- (d) Year must be indicated
 - (e) Days after last application.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- w/o Without
* Mean of two extractions
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.3.2 Barley, oat (KCA 6.3.2)

Table A 16: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Barley, oat | | | | | |
| cGAP EU (EFSA, 2007) | 2 | 0.2 kg as/ha | 14-21 days | 61 | 35 |
| cGAP EU (Art. 12, EFSA, 2014) | 2 | 0.2 kg as/ha | 14-21 days | 69 | 35 |
| Intended cGAP (2)* | 1 | 0.2 kg as/ha | - | 65 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

Note: In 2019, 5 crop residue trials were conducted using the mixture product containing prothioconazole plus azoxystrobin, 4 crop residue trials were conducted using the solo product containing prothioconazole only and 3 crop residue trials were conducted using the mixture product containing prothioconazole plus fenpropidin. Due to the challenges in locating sites which had not previously used triazole compounds, 4 of the trial sites reported in Barley Study 2 were also used to generate data in Barley Study 3. In addition, 3 of the trial sites reported in Barley Study 2 were also used to generate data in Barley Study 4. Similarly in 2021, 6 residue trials were conducted using the mixture product containing prothioconazole plus fluxapyroxad and 8 crop residue trials were conducted using the mixture product containing prothioconazole plus difenoconazole. In this case all 6 of the trial sites reported in Barley Study 6 were also used to generate data in Barley Study 7. All data has been reported for each study and to assist the review trials performed at the same site within different studies have been annotated in Column 1 with capital letters A, B, C etc. to indicate a second/third set of data for the same site is reported.

A 2.1.3.2.1 Barley study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe (France) to gain the residue level of azoxystrobin, prothioconazole and its metabolites in specimens of barley whole plant without roots and grain and straw following one foliar application of MCW-2073 (200 g a.s./L of azoxystrobin and 150 g a.s./ha of prothioconazole).</p> <p>One foliar application was performed at BBCH 65 under typical cultural practices. Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA and grain and straw at BBCH 89 (harvest).</p> <p>Results:</p> <p>In seed specimens taken at normal commercial harvest (36-51 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4.</p> <p>All the analytes were determined by HPLC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The limit of detection (LOD) was set at 0.003 mg/kg for each analyte and each matrix.</p> <p>Acceptance criteria for method and results validation were fully met with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.</p> <p>Analysis (extraction) of the specimens took place 45 - 151 days after sample collection. Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

Reference:
Report:

KCA 6.3.2/01
Residue study of azoxystrobin, prothioconazole and its metabolites in barley whole plants and Raw Agricultural Commodity after one foliar application of MCW-2073 - 1 harvest and 2 decline trials –

| | |
|----------------|---|
| Guideline(s): | Northern Europe (France) – 2018 Huaulmé, J.-M., 2019b Report no.: BPL18/715/GC, Sponsor no.: R-39645 EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted: 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | Actual amount of test item applied on the treated plot of trial 01-FR was + 17.9% of the targeted dose rate. Residue might be slightly overestimated, no impact on risk assessments. |
| GLP: | Yes |
| Acceptability: | Yes |

And

| | |
|-------------------|--|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of MCW 2073.</p> <p>The application had to be performed at crop growth stage BBCH 65.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.1 and 0.2 mg/kg.</p> <p>Residues of TAA in grain were between 0.05 and 0.11 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) according to SANCO/3029/99, rev. 4 within this study by fortification of control (untreated) test portions of the respective matrix and subsequent determination of the recoveries. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 1009 days for barley (whole plants without roots), 959 days for wheat (grain) and 1240 for wheat (straw).</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw), TAA (grain and straw) as well as TA (grain).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|-------------------|--|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/02 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plant without roots, grain and straw) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France) 2018 Yozgatli, H.P., 2021e |
| Guideline(s): | Study no.: S18-02656, sponsor no.: R-39645B EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results. |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 17: Summary of the barley study 1 - 3 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Spring barley / Cereal
Country: France
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.2/01

Active ingredient (common name and content):

SC
Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.2 | 8.3 | 9 | | 10 |
|---|-----------------------------------|---|--------------------------------|--------------|-------------|---|--|--|---|--|--|---|--|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL18/715/GC-01-FR 67270 Duntzenheim, France N-EU 2018 | Spring barley (HORVS)/ RGT Planet | 1. 09/04/18 2. 13/06/18 3. 19/07/18 | 0.175* | 236 | 0.074 | 13/06/18 | BBCH 65 | Grain Straw | <LOQ (n.d.) 0.58 | <LOQ (n.d.) 0.31 | 89 89 | 36 36 | Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS. Fully validated within the study. For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL18/715/GC-02-FR 49320 Vauchrétien, France N-EU 2017/18 | Winter barley (HORVW) / Etincel | 1. 31/10/17 2. 05/05/-10/05/18 3. 27/06/18 | 0.148 | 248 | 0.059 | 07/05/18 | BBCH 65 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.29 0.26 <LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.) 0.18 | 0.29 0.26 0.038 <LOQ <LOQ 0.068 | 65 71 75 83 89 89 | 0 10 21 36 51 51 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.2 | 8.3 | 9 | | 10 |
|---|--|--|-----------------------------------|-----------------|----------------|--|--|--|--|--|--------------------------------------|-------------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity / Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date (d) | Growth stage at last treatme nt or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) (f) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) (g) | Prothio- conazole- desthio (h) | Timing (BBCH) | DALA (days) (e) | |
| BPL18/715/GC- 03-FR 71640 Givry France N-EU 2018 | Spring barley (HORVS) / RGT Planet | 1. 09/04/18 2. 10/06/- 20/06/18 3. 27/07/18 | 0.143 | 241 | 0.059 | 15/06/18 | BBCH 65 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.29 0.42 0.26 0.28 <u><LOQ</u> (n.d.) 0.15 | 0.29 0.38 0.22 0.16 <u><LOQ</u> 0.24 | 65 71 73 87 89 89 | 0 10 18 32 42 42 | prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites Max. sample storage time: 151 days (sampling to analytical completion), max. extract storage time (extraction to analysis) 29 days, extract stability tested during the study. Results in all untreated specimens were below LOD. |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.2, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. not detectable

LOQ Limit of quantification

LOD Limit of detection

* Actual amount of test item applied on the treated plot of trial 01-FR was + 17.9% of the targeted dose rate.

Table A 18: Summary of the barley study 1 - 3 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148.7 g/L (actual)

Crop/crop group: Barley / Cereals

Country: France (N-EU)

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/02

MCW-2073

Formulation (e.g. SC):

SC

Other active substance in the formulation:

Azoxystrobin, 206.6 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|-----------------------------------|---|--------------------------------|--------------|--------------------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL18/715/GC-01-FR 67270 Duntzenheim France N-EU 2018 | Spring barley (HORVS)/ RGT Planet | 1. 09/04/18 2. 13/06/18 3. 19/07/18 | azy: 0.244 ptz: 0.175 | 236 | azy: 0.103 ptz: 0.074 | 13/06/18 | BBCH 65 | Grain | <LOQ (n.d.) | 0.10 | 0.05 | <LOQ | 89 | 36 | Analytical methods: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | 0.02 | 89 | 36 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ (n.d.) | 89 | 36 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 36 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|-------------------------------------|---|--------------------------------|-----------------|--------------------------------|--|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL18/715/GC-02-FR 49320 Vauchrétien France N-EU 2017/18 | Winter barley (HORVW)/Etincel | 1. 31/10/17 2. 05- 10/05/18 3. 27/06/18 | azy: 0.205 ptz: 0.148 | 248 | azy: 0.083 ptz: 0.059 | 07/05/18 | BBCH 65 | Whole plant w/o roots | <LOQ | 0.05 | 0.02 | 0.07 | 65 | 0 | LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 1009 days for whole plant w/o roots, 959 days for grain and 1240 days for straw (sampling to extraction), max. extract storage time (extraction to analysis) 8 days for whole plant w/o roots, 1 day for grain and 0 day for straw. |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.06 | 0.03 | 0.05 | 71 | 10 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.08 | 0.03 | 0.03 | 75 | 21 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.07 | 0.03 | 0.01 | 83 | 35 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.20 | 0.10 | <LOQ | 89 | 51 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.05 | 0.02 | 89 | 51 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | 0.05 | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.06 | 0.04 | 0.03 | 75 | 21 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.10 | 0.07 | <LOQ | 89 | 51 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | <LOQ | 89 | 51 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--|---|--------------------------------|-----------------|-----------------------------|--|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL18/715/GC-03-FR 71640 Givry France N-EU 2018 | Spring barley (HORVS)/ RGT Planet | 1. 09/04/18 2. 10 - 20/06/18 3. 27/07/18 | azy: 0.199 ptz: 0.143 | 241 | azy: 0.083 ptz: 0.059 | 15/06/18 | BBCH 65 | Whole plants | <LOQ | 0.02 | 0.01 | 0.03 | 65 | 0 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Whole plants | <LOQ | 0.05 | 0.02 | 0.04 | 71 | 10 | |
| | | | | | | | | Whole plants | <LOQ | 0.06 | 0.04 | 0.04 | 73 | 18 | |
| | | | | | | | | Whole plants | <LOQ | 0.05 | 0.07 | 0.03 | 87 | 32 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.17 | 0.11 | <LOQ | 89 | 42 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.05 | 0.02 | 89 | 42 | |
| | | | Untreated | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.03 | 0.02 | 0.04 | 65 | 0 | |
| | | | Whole plant w/o roots | <LOQ | 0.04 | 0.05 | 0.05 | 71 | 10 | | | | | | |
| | | | Grain | <LOQ | 0.08 | 0.09 | <LOQ | 89 | 42 | | | | | | |
| | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.03 | 0.01 | 89 | 42 | | | | | | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha azoxystrobin, 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

azy: Azoxystrobin

ptz: Prothioconazole

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.2.2 Barley study 2

| | |
|-------------------|---|
| Comments of zRMS: | <p>Five field trials were conducted in Northern Europe to determine the residue level of azoxystrobin, prothioconazole and its metabolites in specimens of barley whole plant without roots, grain and straw following one foliar application of MCW-2073 (200 g a.s./L of azoxystrobin and 150 g a.s./ha of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 65.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 DAA, 20 (± 2) DAA and 35 DAA for the two decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>Residues of prothioconazole-desthio in grain were between <LOQ and 0.026 mg/kg.</p> <p>In seed specimens taken at normal commercial harvest residues of prothioconazole (sum) were <LOQ.</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion.</p> <p>The LOQ of each analyte was at 0.01 mg/kg for each matrix.</p> <p>The mean recovery was between 70% and 110% with a RSD less than or equal to 20% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 217 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|---|
| Reference: | KCA 6.3.2/03 |
| Report: | Residue study of azoxystrobin, prothioconazole and its metabolites in barley whole plant and Raw Agricultural Commodity after one foliar application of MCW-2073 - 3 harvest and 2 decline trials – Northern Europe (France, Poland and Hungary) – 2019 Amic, S., 2020c |
| Guideline(s): | Report no.: BPL19/759/GC, sponsor no.: 000102749 EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted: 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

and

| | |
|-------------------|---|
| Comments of zRMS: | <p>Five field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of MCW 2073 (200 g/L of azoxystrobin and 150 g/L of prothioconazole).</p> <p>The application had to be performed at crop growth stage BBCH 65-69.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.06 and 0.14 mg/kg.</p> <p>Residues of TAA in grain were between 0.02 and 0.11 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)</p> |
|-------------------|---|

| | |
|--|---|
| | <p>in wheat (whole plants without roots, grain and straw) according to SANCO/3029/99, rev. 5. The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The coefficients of determination (R²) of linear regression of the calibration plots were ≥ 0.98 and thus demonstrated linearity of the detection system over the working range of no more than 30% of the LOQ to at least + 20% of the highest analyte concentration level in a sample.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 774 days (above 25 months) for barley whole plants without roots, 463 days (above 15 months) for grain and 463 (above 15 months) for straw.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|--|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/04 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of MCW 2073 (200 g/L of Azoxystrobin and 150 g/L of Prothioconazole), in 5 trials (3 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019 Yozgatli, H.P., 2021f |
| Guideline(s): | Study no.: S19-00727, sponsor no.: 000102781 EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 19: Summary of the barley study 2 - 5 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Spring barley / Cereal
Country: France, Poland, Hungary
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France
Indoor/outdoor: Outdoor

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.2/03

MCW-2073

SC
Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|----------------------------------|---|--------------------------------|--------------|-------------|---|--|--------------------|-----------------------|-------------------------|---------------|--------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/759/GC-01-FR 60490 Mareuil-la Motte France N-EU 2019 (A) | Spring barley (HORVS)/ Planet | 1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19 | 0.151 | 204 | 0.074 | 06/06/19 | BBCH 65 | Grain Straw | <LOQ (n.d.) 0.12 | <LOQ (n.d.) 0.056 | 89 89 | 53 53 | Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL19/759/GC-02-PL 98-300 Wieluń Poland N-EU 2019 (E) | Spring barley (HORVS) / Paustian | 1. 22/03/19 2. 09/06/- 15/06/19 3. 02/08/19 | 0.147 | 297 | 0.050 | 12/06/19 | BBCH 65 | Grain Straw | <LOQ 0.44 | 0.026 0.20 | 89 89 | 51 51 | LOQ: 0.01 mg/kg (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg) LOD: 0.003 mg/kg for each |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---|---|-----------------------------------|-----------------|----------------|--|--|--|--|---|---|---------------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/759/GC-03-HU 2141 Csömör, Hungary N-EU 2018/19 (B) | Spring barley (HORVS) / Monique | 1. 02/10/18 2. 09/05/- 20/05/19 3. 27/06/19- 03/09/19 | 0.144 | 242 | 0.059 | 11/05/19 | BBCH 65 | Grain Straw | <LOQ (n.d.) <LOQ | <LOQ (n.d.) 0.015 | 89 89 | 52 52 | analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites Max. sample storage time: 217 days (sampling to extraction); max. extract storage time (extraction to analysis) 8 days, extract stability tested during the study. |
| BPL19/759/GC-04-FR 49320 Vauchrétien, France N-EU 2018/19 (C) | Winter barley (HORVW) / Etincel | 1. 15/11/18 2. 06/05/- 15/05/19 3. 03/07/19 | 0.148 | 248 | 0.059 | 13/05/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.20 0.11 <LOQ <LOQ <LOQ (n.d.) 0.25 | 0.20 0.11 0.024 0.013 <LOQ 0.083 | 69 71 77 85 89 89 | 0 10 22 35 50 50 | Results in all untreated specimens were below LOD. |
| BPL19/759/GC-05-PL 48-320 Skoroszyce, Poland N-EU 2018/19 (D) | Spring barley (HORVS) / KWS Dante | 1. 23/03/19 2. 11/06/- 15/06/19 3. 29/07/19 | 0.147 | 296 | 0.050 | 13/06/19 | BBCH 65 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.18 0.19 0.19 0.30 <LOQ 0.27 | 0.18 0.15 0.13 0.20 0.015 0.14 | 65 73-75 83-85 87-89 89 89 | 0 10 20 35 46 46 | |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.2, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. not detectable

LOQ Limit of quantification, LOD Limit of detection

Table A 20: Summary of the barley study 2 - 5 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148.7 g/L (actual)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/04

MCW-2073

Formulation (e.g. SC):

SC

Other active substance in the formulation:

Azoxystrobin, 206.6 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | |
|--|--|---|--------------------------------|-----------------|--------------------------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|------|----|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | | |
| (a) | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | |
| BPL19/759/GC-01-FR 60490 Mareuil-la-Motte France N-EU 2019 (A) | Spring barley (HORVS)/ Planet | 1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19 | azy: 0.210 ptz: 0.151 | 204 | azy: 0.103 ptz: 0.074 | 06/06/19 | BBCH 65 | Grain | <LOQ (n.d.) | 0.07 | 0.05 | <LOQ (n.d.) | 89 | 53 | Analytical methods: Syngenta GRM053.01A, LC- DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) | | | |
| | | | | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.06 | <LOQ (n.d.) | 89 | 53 | | | | |
| | | | | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | | 0.03 | 89 | |
| BPL19/759/GC-02-PL 98-300Wieluń Poland N-EU 2019 (E) | Spring barley (HORVS)/ Paustian | 1. 22/03/19 2. 09/06/ - 15/06/19 3. 02/08/19 | azy: 0.204 ptz: 0.147 | 297 | azy: 0.069 ptz: 0.050 | 02/06/19 | BBCH 65 | Grain | <LOQ (n.d.) | 0.07 | 0.03 | <LOQ (n.d.) | 89 | 51 | Max. sample storage time: 774 days for whole plant w/o roots, 463 | | | |
| | | | | | | | | Straw | <LOQ | 0.05 | 0.04 | 0.08 | 89 | 51 | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|---|---|--------------------------------|-----------------|--------------------------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ (n.d.) | 89 | 51 | days for grain and straw (sampling to extraction), max. extract storage time (extraction to analysis) 22 days for grain and straw and 5 day for whole plant w/o roots. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 51 | |
| BPL19/759/GC-03-HU Csömör, 2141 Hungary N-EU 2018/19 (B) | Winter barley (HORVW)/ Monique | 1. 02/10/18 2. 09/05/ - 20/05/19 3. 27/06/ - 03/07/19 | azy: 0.200 ptz: 0.144 | 242 | azy: 0.083 ptz: 0.059 | 11/05/19 | BBCH 65 | Grain | <LOQ (n.d.) | 0.08 | 0.02 | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.04 | 89 | 52 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.09 | 0.09 | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.04 | 89 | 52 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | | | |
|---|-------------------------------------|---|--------------------------------|-----------------|--------------------------------|--|--|------------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------------------|----------------|---|------|------|------|----|----|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | | | |
| BPL19/759/GC-04-FR 49320 Vauchrétien France N-EU 2018/19 (C) | Winter barley (HORVW)/Etincel | 1. 15/11/18 2. 06/05/ - 15/05/19 3. 03/07/19 | azy: 0.205 ptz: 0.148 | 248 | azy: 0.083 ptz: 0.059 | 13/03/19 | BBCH 69 | Whole plants w/o roots | <LOQ (n.d.) | 0.01 | <LOQ | 0.02 | 69 | 0 | ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. | | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.02 | <LOQ | 0.01 | 71 | 10 | | | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.03 | <LOQ | <LOQ | 77 | 22 | | | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.04 | 0.01 | 0.01 | 85 | 35 | | | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.06 | 0.02 | <LOQ (n.d.) | 89 | 50 | | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.04 | 89 | 50 | | | | | | |
| | | | | | | | | Untreated | | | | | Whole plants w/o roots | <LOQ (n.d.) | | 0.03 | <LOQ | 0.03 | 69 | 0 |
| | | | | | | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | | 0.04 | 0.02 | 0.02 | 77 | 22 |
| | | | | | | | | | | | | | Grain | <LOQ (n.d.) | | 0.07 | 0.04 | <LOQ | 89 | 50 |
| | | | | | | | | | | | | | Straw | <LOQ | | <LOQ | 0.03 | 0.03 | 89 | 50 |
| | | | | | | | | | | | | | | | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | |
|--|---|---|--------------------------------|-----------------|--------------------------------|--|--|------------------------------|--------------------|---------------------|------------------------------|----------------------------|------------------|----------------|---------------------|------|----|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | |
| BPL19/759/GC-05-PL Skoroszyce, 48-320 Poland N-EU 2019 (D) | Spring Barley (HORVS)/ KWS Dante | 1. 23/03/19 2. 11/06/ - 15/06/19 3. 29/07/19 | azy: 0.204 ptz: 0.147 | 296 | azy: 0.069 ptz: 0.050 | 13/06/19 | BBCH 65 | Whole plants w/o roots | <LOQ | 0.04 | 0.02 | 0.07 | 65 | 0 | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.06 | 0.04 | 0.08 | 73-75 | 11 | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.06 | 0.07 | 0.09 | 83-85 | 20 | | | | |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.03 | 0.07 | 0.12 | 87-89 | 35 | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.14 | 0.11 | <LOQ | 89 | 46 | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.07 | 0.02 | 89 | 46 | | | | |
| | | | | | | | | Untreated | | | Whole plants w/o roots | <LOQ | 0.08 | 0.07 | | 0.19 | 65 | 0 |
| | | | | | | | | Whole plants w/o roots | <LOQ (n.d.) | 0.10 | 0.13 | 0.11 | 83-85 | 20 | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.08 | 0.06 | <LOQ (n.d.) | 89 | 46 | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.01 | 89 | 46 | | | | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha azoxystrobin, 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application.
 - (g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
- w/o Without
- azy: Azoxystrobin
- ptz: Prothioconazole
- n.d. Not detectable
- LOQ Limit of quantification
- LOD Limit of detection
- Data in *italics* reported but outside acceptable storage stability

A 2.1.3.2.3 Barley study 3

| | |
|-------------------|--|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) at the dose rate 0.8 L/ha (200 g a.s./ha of prothioconazole). Application was performed at BBCH 65 except for trial 03-FR (BBCH 69). Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 DAA for the two decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In seed specimens taken at normal commercial harvest (46-52 days) residues of prothioconazole (sum) and prothioconazole-desthio were <LOQ.</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 158 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.</p> |
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|----------------|--|
| Reference: | KCA 6.3.2/05 |
| Report: | Residue study of prothioconazole and its metabolites in barley whole plant and RAC after one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) - 2 harvest and 2 decline trials – Northern Europe (France, Hungary and Poland) – 2019 Amic, S., 2020d |
| Guideline(s): | Report no.: BPL19/764/GC, sponsor no.: 000102753 EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted: 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

and

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole). The application had to be performed at crop growth stage BBCH 65 or 69. Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T in grain were <LOQ. Residues of TLA in grain were <LOQ between and 0.01 mg/kg. Residues of TA in grain were between 0.12 and 0.29 mg/kg. Residues of TAA in grain were between 0.03 and 0.12 mg/kg.</p> <p>The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)</p> |
|-------------------|---|

| | |
|--|--|
| | <p>in barley (whole plants without roots, grain and straw) according to SANCO/3029/99, rev.4. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.98.</p> <p>The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>The maximum storage interval from sampling to extraction was 667 days (above 22 months) for barley - whole plants without roots, 700 days (above 23 months) for grain and 513 (above 17 months) for straw.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|--|--|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/06 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3500.F.2.B (250 g a.s./L of prothioconazole) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Hungary and Poland) 2019 |
| | Yozgatli, H.P., 2021g |
| | Study no.: S19-00735, sponsor no.: 000102785 |
| Guideline(s): | EC Guideline SANCO/7029/VI/95 rev. 5 |
| | Guidance document SANCO/3029/99 rev. 4 |
| | OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 21: Summary of barley study 3 - 4 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 250 g/L (actual 248.2 g/L)

Crop/crop group: Barley / Cereal

Country: France, Poland, Hungary

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/05

ADM.3500.F.2.B

EC

None

**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|--|--|--------------------------------|-----------------|----------------|--|---|------------------|--|---|------------------|---------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date (d) | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) (f) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) (g) | Prothio- conazole- desthio (h) | Timing (BBCH) | DALA (days) (e) | |
| BPL19/764/GC -01-FR 60490 Mareuil- Lamotte France N-EU 2019 (A) | Spring barley (HORVS)/ Planet | 1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19 | 0.193 | 195 | 0.099 | 06/06/19 | BBCH 65 | Grain Straw | <LOQ (n.d.) 0.24 | <LOQ 0.11 | 89 89 | 53 53 | Analytical methods: Analogous to QuEChERS method, HPLC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg) |
| BPL19/764/GC -02-HU 2141 Csömör Hungary N-EU 2019 (B) | Spring barley (HORVS) / Monique | 1. 28/09/18 2. 07/05/- 20/05/19 3. 27/06/19- 03/07/19 | 0.197 | 249 | 0.079 | 11/05/19 | BBCH 65 | Grain Straw | <LOQ (n.d.) 0.069 | <LOQ (n.d.) 0.21 | 89 89 | 52 52 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---|---|--------------------------------|-----------------|----------------|---|---|--|---|--|---|---------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/764/GC -03-FR 49320 Vauchrétien, France N-EU 2018/19 (C) | Winter barley (HORVW) / Etincel | 1. 15/11/18 2. 06/05/- 15/05/19 3. 03/07/19 | 0.196 | 247 | 0.079 | 13/05/19 | BBCH 69 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.63 0.31 0.087 0.062 <u><LOQ</u> (n.d.) 0.37 | 0.63 0.31 0.077 0.031 <u><LOQ</u> 0.15 | 69 71 77 85 89 89 | 0 10 22 35 50 50 | LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites |
| BPL19/764/GC -04-PL 48-320 Skoroszyce, Poland N-EU 2018/19 (D) | Spring barley (HORVS) / KWS Dante | 1. 23/03/19 2. 11/06/- 15/06/19 3. 29/07/19 | 0.203 | 296 | 0.066 | 13/06/19 | BBCH 65 | Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Whole plant w/o roots Grain Straw | 0.49 0.34 0.48 0.46 <u><LOQ</u> (n.d.) 0.84 | 0.49 0.29 0.37 0.32 <u><LOQ</u> 0.49 | 65 73-75 83-85 87-89 89 89 | 0 11 20 35 46 46 | Max. sample storage time: 158 days (sampling to analytical completion); max. extract storage time (extraction to analysis) 1 day. Results in all untreated specimens were below LOD (n.d.). |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. = not detectable

LOQ Limit of quantification, LOD Limit of detection

Table A 22: Summary of barley study 3 - 4 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 248.2 g/L (actual)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Hungary, Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code): KCA 6.3.2/06
ADM.3500.F.2.B

Formulation (e.g. SC): EC

Other active substance in the formulation: None

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL19/764/GC-01-FR 60490 Mareuil-la-Motte France N-EU 2019 (A) | Spring barley (HORVS)/ Planet | 1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19 | 0.193 | 195 | 0.099 | 06/06/19 | BBCH 65 | Grain | <LOQ | 0.12 | 0.07 | <LOQ | 89 | 53 | Analytical methods: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) |
| | | | | | | | | Straw | <LOQ | <LOQ (n.d.) | 0.02 | 0.05 | 89 | 53 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.05 | <LOQ (n.d.) | 89 | 53 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.03 | 89 | 53 | |
| BPL19/764/GC-02-HU 2141 Csömör Hungary N-EU 2018/19 (B) | Spring barley (HORVS)/ Monique | 1. 28/09/18 2. 07/05/ - 20/05/19 3. 27/06/ - 03/07/19 | 0.197 | 249 | 0.079 | 11/05/19 | BBCH 65 | Grain | <LOQ | 0.19 | 0.04 | <LOQ | 89 | 52 | Max. sample storage time: 667 days for whole plant w/o roots, 700 days for |
| | | | | | | | | Straw | <LOQ | 0.01 | 0.02 | 0.03 | 89 | 52 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|-------------|--|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.04 | 0.01 | <LOQ (n.d.) | 89 | 52 | grain and 513 days for straw (sampling to extraction), max. extract storage time (extraction to analysis) 1 day for whole plant w/o roots, 14 days for straw and 16 days for grain. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 52 | |
| BPL19/764/GC- 03-FR 49320 Vauchrétien France N-EU 2018/19 (C) | Winter barley (HORVW)/ Etincel | 1. 15/11/18 2. 06/05/ - 15/05/19 3. from 03/07/19 | 0.196 | 247 | 0.079 | 13/05/19 | BBCH 69 | Whole plant w/o roots | <LOQ | 0.01 | <LOQ | 0.02 | 69 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.01 | <LOQ | <LOQ | 71 | 10 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.02 | <LOQ | 0.01 | 77 | 22 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.03 | <LOQ | <LOQ | 85 | 35 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.13 | 0.03 | <LOQ | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.02 | 89 | 50 | |
| | | | | | | | | | | | | | | | |
| | | | Untreated | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.01 | <LOQ | 0.02 | 69 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.02 | <LOQ | 0.01 | 77 | 22 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.04 | 0.01 | <LOQ (n.d.) | 89 | 50 | |
| | | | | | | | | Straw | <LOQ | <LOQ (n.d.) | 0.01 | 0.01 | 89 | 50 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--|---|--------------------------------|-----------------|-------------|--|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL19/764/GC-04-PL 48-320 Skoroszyce Poland N-EU 2019 (D) | Spring barley (HORVS)/KWS Dante | 1. 23/03/19 2. 11/06/ - 15/06/19 3. 29/07/19 | 0.203 | 308 | 0.066 | 13/06/19 | BBCH 65 | Whole plant w/o roots | <LOQ (n.d.) | 0.03 | 0.02 | 0.07 | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.09 | 0.06 | 0.12 | 73-75 | 11 | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.11 | 0.10 | 0.14 | 83-85 | 20 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.09 | 0.11 | 0.12 | 87-89 | 35 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.09 | 0.11 | 0.12 | 87-89 | 35 | |
| | | | | | | | | Grain | <LOQ | 0.29 | 0.12 | <LOQ | 89 | 46 | |
| | | | | | | | | Straw | 0.02 | 0.02 | 0.12 | 0.26 | 89 | 46 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.04 | 0.04 | 0.14 | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.02 | 0.06 | 0.10 | 83-85 | 20 | |
| | | | | | | | | Grain | <LOQ | 0.22 | 0.21 | 0.01 | 89 | 46 | |
| | | | | | | | | Straw | <LOQ | <LOQ | 0.11 | 0.31 | 89 | 46 | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detectionData in *italics* reported but outside acceptable storage stability

A 2.1.3.2.4 Barley study 4

| | |
|-------------------|--|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of fenpropidin in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) at the dose rate 1 L/ha. Application was performed at BBCH 65 except for trial 04-FR (BBCH 69). Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 DAA for the two decline trials. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed. In seed specimens taken at normal commercial harvest residues of prothioconazole (sum) were <LOQ.</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4. All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. LOQ = 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix. The storage duration (interval between sampling and extraction date) was 114 days for the determination of prothioconazole and its metabolites. Sufficient stability data are available to support the residue data presented in this study. The study is acceptable.</p> |
|-------------------|--|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/07 |
| Report: | Residue study of prothioconazole and its metabolites, and fenpropidin in barley whole plant and RAC (grain and straw) after one foliar application of ADM.3502.F.1.A - 2 harvest and 2 decline trials - Northern Europe (France, Poland and Hungary) - 2019 Huauilmé, J.-M., 2020 |
| Guideline(s): | Report no.: BPL19/772/GC, sponsor no.: 000102761 EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted 7 September 2009 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

And

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin). The application had to be performed at crop growth stage BBCH 65 or 69. Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH). Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ. Residues of TA in grain were between 0.07 and 0.13 mg/kg. Residues of TAA in grain were between 0.02 and 0.07 mg/kg.</p> |
|-------------------|---|

The analytical method GRM053.01A was validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) according to SANCO/3029/99, rev.4. Three fortifications of untreated control samples at the level of LOQ (0.01 mg/kg) and three fortifications at the level of tenfold LOQ (0.1 mg/kg) were performed, representing a reduced validation data set.

The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.

The coefficients of determination (R^2) of linear regression of the calibration plots were ≥ 0.98 .

The accuracy and precision of the method during sample analysis were considered to be acceptable since single recoveries were in the range of 60 - 120% and the mean recoveries at each fortification level were in the range of 70 – 110% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.

The maximum storage intervals from sampling until extraction was as follows:

| Sample Type | Days of Storage from Sampling to last Extraction | | | |
|----------------------------|--|-----|-----|-----|
| | 1,2,4-T | TA | TAA | TLA |
| Whole plants without roots | 712 | 751 | 712 | 712 |
| Grain | 664 | 699 | 664 | 664 |
| Straw | 660 | 660 | 660 | 660 |

It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, grain and straw).

For this reason, the obtained results cannot be used for evaluation and risk assessment.

Reference:

KCA 6.3.2/08

Report:

Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2019
Mahlow, S., 2021

Guideline(s):

Study no.: S19-00752, sponsor no.: 000102794
EC Guideline SANCO/7029/VI/95 rev. 5
Guidance document SANCO/3029/99 rev. 4
OECD ENV/JM/MONO(2007)17

Deviations:

None with impact on study results

GLP:

Yes

Acceptability:

Yes

Table A 23: Summary of the barley study 4 - 4 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 173.5 g/L)

Crop/crop group: Barley / Cereals

Country: France, Poland, Hungary

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/07

ADM.3502.F.1.A

EC

Fenpropidin, nominal 250 g/L (actual 250 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazoledesthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);

Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|-----------------------------------|--|--------------------------------|--------------|-------------|---|--|--------------------|-----------------------|-------------------------|---------------|--------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/772/GC-01-FR 60490 Mareuil-Lamotte France N-EU 2019 (A) | Spring barley (HORVS)/ RGT Planet | 1. 19/02/19 2. 06/06/- 21/06/19 3. 01/08/19 | 0.181 | 209 | 0.087 | 06/06/19 | BBCH 65 | Grain Straw | <LOQ (nd) 0.17 | <LOQ (nd) 0.083 | 89 89 | 53 53 | Analytical methods: Study code: S13-05182, QuEChERS method, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites; LOD: 0.003 mg/kg for |
| BPL19/772/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019 (E) | Spring barley (HORVS)/ Paustian | 1. 22/03/19 2. 09/06/- 15/06/19 3. 02/08/19 | 0.169 | 294 | 0.058 | 11/06/19 | BBCH 65 | Grain Straw | <LOQ (nd) 0.61 | 0.027 0.28 | 89 89 | 52 52 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|-------------|--|--|-----------------------|-------------------------------|----------------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL19/772/GC-03-HU 2141 Csömör Hungary N-EU 2018/19 (B) | Winter barley (HORVW)/ Monique | 1. 29/09/18 2. 07/05/- 02/05/19 3. 27/06/- 03/07/19 | 0.170 | 247 | 0.069 | 11/05/19 | BBCH 65 | Whole plant w/o roots | 0.87 | 0.87 | 65 | 0 | each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. Max. sample storage time: 114 days (sampling to extraction), max. extract storage time (extraction to analysis) 13 days. Extract stability tested during the study. |
| | | | | | | | | Whole plant w/o roots | 0.28 | 0.24 | 71 | 11 | |
| | | | | | | | | Whole plant w/o roots | 0.11 | 0.089 | 75 | 20 | |
| | | | | | | | | Whole plant w/o roots | 0.13 | 0.042 | 85 | 37 | |
| | | | | | | | | Grain | <LOQ (nd) | <LOQ (nd) | 89 | 52 | |
| | | | | | | | | Straw | 0.16 | 0.063 | 89 | 52 | |
| BPL19/772/GC-04-FR 49320 Vauchrétien France N-EU 2018/19 (C) | Winter barley (HORVW)/ Etincel | 1. 15/11/18 2. 06/05/- 15/05/19 3. 03/07/19 | 0.174 | 250 | 0.069 | 13/05/19 | BBCH 69 | Whole plant w/o roots | 1.1 | 1.1 | 69 | 0 | Results in all untreated specimens were below LOD. |
| | | | | | | | | Whole plant w/o roots | 0.54 | 0.51 | 71 | 10 | |
| | | | | | | | | Whole plant w/o roots | 0.15 | 0.12 | 77 | 22 | |
| | | | | | | | | Whole plant w/o roots | 0.088 | 0.046 | 85 | 35 | |
| | | | | | | | | Grain | <LOQ (nd) | 0.010 | 89 | 50 | |
| | | | | | | | | Straw | 0.49 | 0.25 | 89 | 50 | |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance(s) as they were calculated with the actual concentration of the active substance(s).

(d) Year must be indicated

- (e) Days after last application not given in the study report. Calculated during dossier compilation.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- nd not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 24: Summary of the barley study 4 - 4 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 173.5 g/L (actual)

Crop/crop group: Barley / Cereals

Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agrosience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/08

ADM.3501.F.1.B

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Fenpropidin, 250 g/L

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | |
|--|--|---|--------------------------------|-----------------|--------------------------|---|--|------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | |
| BPL19/772/GC -01-FR 1960490 Mareuil- Lamotte France N-EU 2019 (A) | Spring barley (HORVS)/ RGT Planet | 1. 19/02/19 2. 06/06/ - 21/06/19 3. 01/08/19 | ptz: 0.181 fnp: 0.244 | 209 | ptz: 0.087 fnp: 0.083 | 06/06/19 | BBCH 65 | Grain | <LOQ (n.d.) | 0.11 | 0.07 | <LOQ | 89 | 53 | Analytical methods: GRM053.01A, LC- DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.06 | 89 | 53 | | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.06 | 0.06 | <LOQ (n.d.) | 89 | 53 | | LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) |
| | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.04 | 89 | 53 | | | | | |
| BPL19/772/GC -02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019 (E) | Spring barley (HORVS)/ Paustian | 1. 22/03/19 2. 09/06/ - 15/06/19 3. 02/08/19 | ptz: 0.169 fnp: 0.244 | 294 | ptz: 0.058 fnp: 0.083 | 11/06/19 | BBCH 65 | Grain | <LOQ | 0.09 | 0.06 | <LOQ | 89 | 52 | Max. sample storage time: for whole plant w/o roots (712 days for 1,2,4-T, 751 days for TA, 712 days for TAA and TLA; for grain (699 days for TA and 664 days for 1,2,4-T, | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.02 | 89 | 52 | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|--------------------------|---|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (g) | (d) | (e) | (a) | (g) | (g) | (g) | (g) | (f) | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ (n.d.) | 89 | 52 | TAA and TLA); for straw (660 days for all metabolites) (sampling to extraction), max. extract storage time (extraction to analysis) 6 days for 1,2,4-T, 3 days for TAA and TLA and 1 day for TA. |
| | | | | | | | | Straw | <LOQ | <LOQ | 0.01 | <LOQ | 89 | 52 | |
| BPL19/772/GC -03-HU 2141 Csömör Hungary N-EU 2018/19 (B) | Winter barley (HORVW)/ Monique | 1. 28/09/18 2. 07/05/ - 20/05/19 3. 27/06/ - 03/07/19 | ptz: 0.170 fnp: 0.246 | 247 | ptz: 0.069 fnp: 0.100 | 11/05/19 | BBCH 65 | Whole plant w/o roots | <LOQ | 0.01 | <LOQ | 0.02 | 65 | 0 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.08 | 0.01 | 0.02 | 71 | 11 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.08 | 0.01 | 0.02 | 75 | 20 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.11 | 0.04 | 0.03 | 85 | 37 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.11 | 0.02 | <LOQ | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.04 | 0.05 | 89 | 52 | |
| | | | | | | | | Untreated | | | | | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.01 | <LOQ | 0.02 | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.02 | <LOQ | <LOQ | 75 | 20 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.03 | <LOQ | <LOQ (n.d.) | 89 | 52 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 52 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | |
|---|---|---|--------------------------------|-----------------|--------------------------|---|--|--------------------------|--------------------|--------------------------|----------------------------|----------------------------|------------------|----------------|---------------------|----|----|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | |
| BPL19/772/GC -04-FR 49320 Vauchrétien France N-EU 2018/19 (C) | Winter barley (HORVW)/ Etincel | 1. 15/11/18 2. 06/05/ - 15/05/19 3. 03/07/19 | ptz: 0.174 fnp: 0.250 | 250 | ptz: 0.069 fnp: 0.100 | 13/05/19 | BBCH 69 | Whole plant w/o roots | <LOQ | 0.02 | <LOQ | 0.02 | 69 | 0 | | | |
| | | | | | | | | Whole plant w/o roots | <LOQ | 0.03 | <LOQ | 0.02 | 71 | 10 | | | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.05 | 0.01 | 0.02 | 77 | 22 | | | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.08 | 0.02 | <LOQ | 85 | 35 | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.13 | 0.05 | <LOQ | 89 | 50 | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.03 | 89 | 50 | | | |
| | | | Untreated | | | | | | | Whole plant w/o roots | <LOQ | 0.02 | <LOQ | 0.02 | | 69 | 0 |
| | | | | | | | | | | Whole plant w/o roots | <LOQ | 0.02 | <LOQ | 0.01 | | 77 | 22 |
| | | | | | | | | | | Grain | <LOQ (n.d.) | 0.07 | 0.03 | <LOQ | | 89 | 50 |
| | | | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.01 | 0.02 | | 89 | 50 |

(a) According to Codex classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

ptz: Prothioconazole

fnp: Fenpropidin

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.2.5 Barley study 5

| | |
|-------------------|--|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of fenpropidin in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) at the dose rate 1 L/ha. Application was performed at BBCH 65.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 9 DAA, 20 DAA and 33 to 35 DAA for the two decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazoledesthio) ranged from:</p> <ul style="list-style-type: none"> - 0.069 and 0.43 mg/kg in whole plant, - <LOQ (nd) and 0.062 mg/kg in grain, - 0.11 and 1.3 mg/kg in straw. <p>Analytical method: Study code: S13-05182, QuEChERS method, LC-MS/MS</p> <p>The analytical method was validated for barley whole plant without roots, grain and straw according to guideline SANCO/3029/99 rev. 4 (reduced validation).</p> <p>LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 70 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
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| Reference: | KCA 6.3.2/09 |
| Report: | Residue study of Prothioconazole and its metabolites, and Fenpropidin in barley whole plant and Raw Agricultural Commodity after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) - 2 harvest and 2 decline trials – Northern Europe (FR, PL, HU) - 2020 Huaultmé, J.-M., 2021a Report no.: BPL20/844/GC, sponsor no.: 000105350 |
| Guideline(s): | EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997) OECD 509, adopted 7 September 2009 ENV-JM-MONO(2011)50-REV1., 07-Sep-2016 Guidance document SANCO/3029/99 rev. 4 of 11/07/00 OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

And

| | |
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| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) following one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin).</p> <p>The application had to be performed at crop growth stage BBCH 65.</p> <p>Grain and straw specimens were taken at BBCH growth stage 89, normal commercial harvest (NCH).</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the two decline trials.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TLA in grain were <LOQ.</p> <p>Residues of TA in grain were between 0.05 and 0.15 mg/kg.</p> <p>Residues of TAA in grain were between 0.02 and 0.04 mg/kg.</p> <p>The analytical method GRM053.01A was successfully validated for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (whole plants without roots, grain and straw) with an LOQ of 0.01 mg/kg and up to 0.1 mg/kg according to SANCO/3029/99, rev.4.</p> <p>With regard to selectivity, accuracy and precision, the analytical method was applied successfully for each analytical set when analysing the samples of the study.</p> <p>The maximum storage interval from sampling to extraction was 153 days (above 5 months) for barley - whole plants without roots, 103 days (above 3 months) for grain and for straw. Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
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| Reference: | KCA 6.3.2/10 |
| Report: | Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in barley (RAC whole plant, grain and straw) following one foliar application of ADM.3502.F.1.A (175g a.s./L of prothioconazole and 250 g/L fenpropidin) in 4 trials (2 HS + 2 DCS) in Northern Europe (France, Poland and Hungary), 2020 Yozgatli, H.P., 2021h Study no.: S20-01302, sponsor no.: 000105545 |
| Guideline(s): | EC Guideline SANCO/7029/VI/95 rev. 5 Guidance document SANCO/3029/99 rev. 4 OECD ENV/JM/MONO(2007)17 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

| | |
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| Comments of zRMS: | <p>The objective of this study was to determine residues of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazoledesthio (sum of isomers)) residues in barley (grain, straw) after one foliar application of ADM.3502.F.1.A (175 g a.s./L of prothioconazole and 250 g a.s./L of fenpropidin) in 2 harvest and 2 decline trials in Northern Europe obtained during the study referenced BPL20/844/GC – ADAMA Sponsor code 000105350 (see KCA 6.3.2/09).</p> <p>The analytical method has been demonstrated to be a reliable and accurate procedure for the determination of prothioconazole (sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)) in barley (grain, straw). The method complies with the Guideline SANTE/2020/12830, Rev.1 of 24/02/2021. LOQ (Limit of quantification): 0.060 mg/kg expressed as prothioconazole-desthio.</p> |
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|--|---|
| | <p>In the barley specimens, the residue level of prothioconazole (expressed as sum of prothioconazoledesthio) ranged from:</p> <ul style="list-style-type: none"> - <LOQ in grain, - 0.14 and 1.3 mg/kg in straw. <p>In the barley specimens, the residue level of prothioconazole-desthio ranged from:</p> <ul style="list-style-type: none"> - <LOQ and 0.026 mg/kg in grain, - 0.056 and 0.91 mg/kg in straw. <p>The storage duration (interval between sampling and extraction date) was 504 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|--|---|

Reference: KCA 6.3.2/13

Report: Analysis of prothioconazole and its metabolites in barley after application of ADM.3502.F.1.A (prothioconazole and fenpropidin) in trial in Northern - 2020
Barbier, G., 2022

Guideline(s): Study no.: B21G-A4-P-05, sponsor no.: 000108763
SANTE/2020/12830, Rev.1 of 24/02/2021
OECD ENV/JM/MONO(2007)17

Deviations: None with impact on study results

GLP: Yes

Acceptability: Yes

Table A 25: Summary of the barley study 5 - 4 trials (including second analysis using another method to account for potential conjugated metabolites)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 175.9 g/L)
Crop/crop group: Barley / Cereals
Country: France, Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/09 & /13

ADM.3502.F.1.A

EC

Fenpropidin, nominal 250 g/L (actual 253.7 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);

Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | | | | | 8.2 | 9 | | 10 |
|--|-----------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------------------------|------|-------|-------|------|------|--|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) ¹ | | | | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) ² | 3-OH | 4-OH | 5-OH | 6-OH | α-OH | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | | | (d) | | | (g) | | | | | | (h) | | (e) | (f) |
| BPL20/844/GC-01-FR 71 570 La Chapelle de Guinchay, France N-EU 2020 | Spring barley (HORVS)/ RGT Planet | 1. 23/03/20 2. 22/-29/06/20 3. 15/-31/07/20 | 0.174 | 199 | 0.087 | 25/06/20 | BBCH 65 | Grain | <LOQ | <LOQ | <LOD | <LOD | <LOD | <LOD | 0.033** 0.026 Mean: 0.030 | 89 | 29 | Analytical methods: Study code: S13-05182, QuEChERS method, LC-MS/MS and for study 6.2.3/13 method 00979/M001, LC-MS/MS. For method |
| | | | | | | | | Straw | 1.3 | 0.15 | 0.061 | 0.036 | <LOQ | 0.14 | 0.93** 0.91 Mean: 0.092 | 89 | 29 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | | | | | 8.2 | 9 | | 10 |
|--|----------------------------------|--|--------------------------------|--------------|------------|---|--|------------------|------------------------------------|-------|-------|-------|------|------|--|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) ¹ | | | | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ha | Water (L/ha) | kg a.s./hL | | | | Prothioconazole (sum) ² | 3-OH | 4-OH | 5-OH | 6-OH | α-OH | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | | | | | | (h) | | (e) | (f) |
| BPL20/844/GC-02-PL 98-300 Masłowice, Wieluń Poland N-EU 2019 | Spring barley (HORVS)/ KWS Dante | 1. 30/03/20 | 0.170 | 290 | 0.059 | 13/06/20 | BBCH 65 | Grain | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOQ (nd) <LOD Mean: <LOQ | 89 | 58 | validation please refer to dRR Part B.5, point KCP 5.1.2. |
| | | 2. 08/-18/06/20 3. 10/08/20 | | | | | | Straw | 0.14 | 0.034 | 0.021 | 0.014 | <LOD | <LOQ | 0.041 0.056 Mean: 0.049 | 89 | 58 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | | | | | 8.2 | 9 | | 10 |
|--|--------------------------------|--|--------------------------------|--------------|------------|---|--|-----------------------|------------------------------------|-------|-------|-------|------|--------------|----------------------------|---------------|------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) ¹ | | | | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ha | Water (L/ha) | kg a.s./hL | | | | Prothioconazole (sum) ² | 3-OH | 4-OH | 5-OH | 6-OH | α -OH | Prothioconazole-desthio | Timing (BBCH) | DAL (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | | | | | | (h) | | (e) | (f) |
| BPL20/844/GC-03-HU 2141 Csömör Hungary N-EU 2019/20 | Winter barley (HORVW)/ Monique | 1. 28/09/19 | 0.175 | 248 | 0.070 | 13/05/20 | BBCH 65 | Whole plant w/o roots | 0.43 | | | | | | 0.43 | 65 | 0 | expressed as prothioconazole-desthio as a sum of metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites. |
| | | 2. 03/13/05/20 | | | | | | Whole plant w/o roots | 0.43 | | | | | | 0.42 | 71 | 9 | |
| | | 3. 02/06/07/20 | | | | | | Whole plant w/o roots | 0.30 | | | | | | 0.27 | 75 | 20 | |
| | | | | | | | | Whole plant w/o roots | 0.11 | | | | | | 0.048 | 83 | 35 | |
| | | | | | | | | Grain | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOQ (nd) | 89 | 50 | |
| | | | | | | | | Straw | 0.33 | 0.077 | 0.071 | 0.042 | <LOQ | 0.014 | 0.12 0.12 Mean: 0.12 | 89 | 50 | Max. sample storage time: 70 days and 504 days for study KCA 6.2.3/13 (sampling to extraction), max. extract |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | | | | | 8.2 | 9 | | 10 |
|---|--|--|-----------------------------------|---------------------|-------------------|---|--|-----------------------------|--|-------|-------|-------|------|--------------|---------------------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) ¹ | | | | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) ² | 3-OH | 4-OH | 5-OH | 6-OH | α -OH | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | | | | | | (h) | | (e) | (f) |
| BPL20/844/GC-04-PL 55-110 Krościna Mała Poland N-EU 2020 | Spring barley (HORVS)/ Harris | 1. 23/03/20 | 0.179 | 305 | 0.059 | 10/06/20 | BBCH 65 | Whole plant w/o roots | 0.37 | | | | | | 0.37 | 65 | 0 | storage time (extraction to analysis) 2 days. Extract stability tested during the studies. Results in all untreated specimens were below LOD. **Mean of two extractions. |
| | | 2. 07/- 18/06/20 | | | | | | Whole plant w/o roots | 0.42 | | | | | | 0.39 | 69 | 9 | |
| | | 3. 11/08/20 | | | | | | Whole plant w/o roots | 0.11 | | | | | | 0.076 | 71 | 20 | |
| | | | | | | | | Whole plant w/o roots | 0.069 | | | | | | 0.027 | 83 | 33 | |
| | | | | | | | | Grain | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOQ (nd) <LOQ Mean: <LOQ | 89 | 62 | |
| | | | | | | | | Straw | 0.19 | 0.036 | 0.021 | 0.018 | <LOD | 0.013 | 0.084 0.10 Mean: 0.092 | 89 | 62 | |

¹ Results in italics originate from second analysis (study KCA 6.3.2/13) including a deconjugation step to account for potential conjugated metabolites.

² Sum calculated during dossier compilation to include new results from study KCA 6.3.2/13 as well as mean of results for PTZ-Desthio from both studies. For PTZ-Desthio analysis in the new study is technically a replicate analysis even though 2 different methods have been used, as in both only free PTZ-desthio is measured. Therefore, the results for PTZ-Desthio from both methods are considered equivalent and the mean is presented.

(a) According to CODEX Classification / Guide

(b) Only if relevant

- (c) These values are actual rate of active substance(s) as they were calculated with the actual concentration of the active substance(s).
 - (d) Year must be indicated
 - (e) Days after last application not given in the study report. Calculated during dossier compilation.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- nd not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 26: Summary of the barley study 5 - 4 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 175.9 g/L (actual)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Poland, Hungary

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.2/10

ADM.03502.F.1.B

Formulation (e.g. SC):

EC

Other active substance in the formulation:

Fenpropidin, 253.7 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | |
|---|-----------------------------------|---|--------------------------------|--------------|--------------------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|--|--|--|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | |
| BPL20/844/GC-01-FR 71570 La Chapelle de Guinchay France N-EU 2020 | Spring barley (HORVS)/ RGT Planet | 1. 23/03/20 2. 22 - 29/06/20 3. 15-31/07/20 | ptz: 0.174 fnp: 0.251 | 199 | ptz: 0.087 fnp: 0.126 | 25/06/20 | BBCH 65 | Grain | <LOQ (n.d.) | 0.13 | 0.04 | <LOQ (n.d.) | 89 | 29 | Analytical methods: Syngenta GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 153 days for whole plant w/o roots, | | | |
| | | | | | | | | Straw | <LOQ | 0.01 | 0.02 | 0.03 | 89 | 29 | | | | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.18 | 0.10 | <LOQ (n.d.) | 89 | 29 | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.04 | 89 | 29 | | | | |
| BPL20/844/GC-02-PL 98-300 Maslowice Poland N-EU 2020 | Spring barley (HORVS)/KWS Dante | 1. 20/03/20 2. 08 - 18/06/20 3. 10/08/20 | ptz: 0.170 fnp: 0.245 | 290 | ptz: 0.059 fnp: 0.085 | 13/06/20 | BBCH 65 | Grain | <LOQ (n.d.) | 0.15 | 0.04 | <LOQ (n.d.) | 89 | 58 | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 58 | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|-------------------------------------|---|--------------------------------|-----------------|-----------------------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.06 | 0.02 | <LOQ (n.d.) | 89 | 58 | 103 days for grain and straw (sampling to extraction), max. extract storage time (extraction to analysis) 0 days for whole plant w/o roots and grain and 23 days for straw. |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 58 | |
| BPL20/844/GC- 03-HU 202141 Csömör Hungary N-EU 2019/20 | Winter barley (HORVW)/Monique | 1. 28/09/19 2. 03 - 13/05/20 3. 02 - 06/07/20 | ptz: 0.175 fnp: 0.252 | 248 | ptz: 0.070 fnp: 0.101 | 13/05/20 | BBCH 65 | Whole plant | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ | 65 | 0 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ | 71 | 9 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.02 | <LOQ | <LOQ | 73 | 20 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ | 83 | 35 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ | 89 | 50 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | 0.02 | 0.01 | <LOQ | 89 | 50 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.02 | <LOQ | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.02 | 0.03 | 89 | 50 | |
| | | | | | | | | Untreated | | | | | 65 | 0 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 73 | 20 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 50 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 50 | |
| | | | | | | | | w/o roots | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 50 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|------------------------------------|---|--------------------------------|-----------------|-----------------------------|--|--|--------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL20/844/GC-04-PL 55-110 Krościna Mała Poland N-EU 2020 | Spring barley (HORVS) Harris | 1. 23/03/20 2. 07 - 18/06/20 3. 11/08/20 | ptz: 0.179 fnp: 0.258 | 305 | ptz: 0.059 fnp: 0.085 | 10/06/20 | BBCH 65 | Whole plant w/o roots | <LOQ (n.d.) | 0.01 | <LOQ | 0.02 | 65 | 0 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.02 | <LOQ | 0.01 | 69 | 9 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.04 | 0.02 | 0.02 | 71 | 20 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.04 | 0.03 | 0.04 | 83 | 33 | |
| | | | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.12 | 0.04 | <LOQ (n.d.) | 89 | 62 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.01 | 0.01 | 89 | 62 | |
| | | | Untreated | | | Whole plant w/o roots | <LOQ (n.d.) | <LOQ | <LOQ | 0.01 | 65 | 0 | | | |
| | | | | | | Whole plant w/o roots | <LOQ (n.d.) | 0.01 | 0.02 | 0.01 | 71 | 20 | | | |
| | | | | | | Grain | <LOQ (n.d.) | 0.05 | 0.04 | <LOQ (n.d.) | 89 | 62 | | | |
| | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 62 | | | |

(a) According to Codex classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

w/o Without

ptz: Prothioconazole

fnp: Fenpropidin

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

A 2.1.3.2.6 Barley study 6

| | |
|-------------------|---|
| Comments of zRMS: | <p>Six field trials were conducted in Northern Europe to determine the residue level of prothioconazole and fluxapyroxad and their respective metabolites in specimens of barley grain and straw following one foliar application of ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad). The target dose rate of test item ADM.03503.F.1.A was 1.25 L/ha (187.5 g/ha of Prothioconazole and 93.75 g/ha of Fluxapyroxad).</p> <p>Application was performed at BBCH 65.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>The analytical method for determination of prothioconazole and metabolites based on the method 00979/M001 was validated for barley grain and straw according to guideline SANTE/2020/12830, Rev.1.</p> <p>For the triazole metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid, sample extraction and determination of residues were performed according to the analytical method GRM053.01A.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. The LOQ of each analyte was at 0.01 mg/kg for each matrix, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recovery was between 70% and 110% at each level of fortification, for each reference item and for each matrix.</p> <p>The storage duration (interval between sampling and extraction date) was 115 days for the determination of prothioconazole and its metabolites and 114 days for TDMs.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>In the treated barley specimens, the residue levels of prothioconazole-desthio and its metabolites ranged from:</p> <p>For prothioconazole-desthio:</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.061 mg/kg in grain, - 0.041 and 1.7 mg/kg in straw. <p>For 3-hydroxy-prothioconazole-desthio,</p> <ul style="list-style-type: none"> - LOQ (nd) and 0.014 in grain, - <LOQ and 0.25 mg/kg in straw. <p>For 4-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.21 mg/kg in straw. <p>For 5-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.089 mg/kg in straw. <p>For 6-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ (nd) and 0.012 mg/kg in straw. <p>For Alpha-hydroxy-prothioconazole-desthio:</p> <ul style="list-style-type: none"> - All results are <LOQ in grain, - <LOQ and 0.17 mg/kg in straw. <p>For 1,2,4-Triazole, all results were <LOQ in grain and straw specimens,</p> <p>For Triazole alanine:</p> <ul style="list-style-type: none"> - 0.04 and 0.14 mg/kg in grain, - <LOQ (nd) and 0.02 mg/kg in straw, <p>For Triazole acetic acid:</p> <ul style="list-style-type: none"> - 0.02 and 0.13 mg/kg in grain, - <LOQ and 0.04 mg/kg in straw, <p>For Triazole lactic acid:</p> <ul style="list-style-type: none"> - <LOQ (nd) and 0.02 mg/kg in grain, - <LOQ and 0.19 mg/kg in straw. <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/11 |
| Report: | Residue study of fluxapyroxad and prothioconazole and their metabolites in barley Raw Agricultural Commodities after application of ADM.03503.F.1.A under field conditions –Northern Europe - 2021 Hualmé, J.-M., 2022a Study no.: BPL21/962/GC, sponsor no.: 000107616 |
| Guideline(s): | OECD/OCDE 509 Adopted: 7 September 2009, OECD Guidelines for the testing of chemicals, Crop Field Trial. ENV/JM/MONO(2011)50/REV1 07-Sep-2016 OECD Guidance Document on crop field trials, second edition, Series on Pesticides - No. 66 Series on Testing & Assessment - No. 164 SANTE/2020/12830, Rev.1 24, February 2021, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00. |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 27: Summary of the barley study 6 - 6 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148 g/L)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.2/11

ADM.03503. F.1.A
EC
Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|-----------------------------------|---|--------------------------------|--------------|-------------|---|--|--------------------|-----------------------|-------------------------|---------------|--------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (hL) | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/962/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A) | Spring barley (HORVS) / Planet | 1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21 | 0.187 | 303 | 0.062 | 21/06/21 | BBCH 65 | Grain Straw | <LOQ 0.14 | 0.013 0.085* | 89 89 | 39 39 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL21/962/GC-02-GE 74861 Krefßbach Germany N-EU 2020/21 (B) | Winter barley (HORVW) / Su Vireni | 1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21 | 0.172 | 326 | 0.053 | 28/05/21 | BBCH 65 | Grain Straw | <LOQ 0.20 | <LOQ 0.055 | 89 89 | 62 62 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole- |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|--|---|-----------------------------------|-----------------|----------------|--|---|--------------------|--|---|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) | Spring barley (HORVS) / Conchita | 1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21 | 0.177 | 287 | 0.062 | 15/06/21 | BBCH 65 | Grain Straw | <u>0.087</u> 2.2 | <u>0.054</u> 1.7 | 89 89 | 28 28 | desthio as a sum of metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole- desthio as a sum of metabolites |
| BPL21/962/GC-04-PL 55 110 Krościna Mała, Poland N-EU 2021(D) | Spring barley (HORVS) / KWS Harris | 1/ 08/03/20 2/ 15 - 23/06/21 3/ 31/07/21 | 0.186 | 302 | 0.062 | 18/06/21 | BBCH 65 | Grain Straw | <u><LOQ</u> 1.0 | <u>0.010</u> 0.34 | 89 89 | 43 43 | Max. sample storage time: 115 days (sampling to extraction), max. extract storage time (extraction to analysis) 4 days. |
| BPL21/960/GC-05-GE 85368 Moosburg an der Isar Germany N-EU 2021 (E) | Spring barley (HORVS) / Marthe | 1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21 | 0.182 | 345 | 0.053 | 12/07/21 | BBCH 65 | Grain Straw | <u><LOQ</u> <u>(n.d.)</u> 0.061 | <u><LOQ</u> <u>(n.d.)</u> 0.041* | 89 89 | 44 44 | Extract stability proven within the study. |
| BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 (F) | Spring barley (HORVS) / Conchita | 1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21 | 0.180 | 291 | 0.062 | 21/06/21 | BBCH 65 | Grain Straw | <u>0.095</u> 0.93 | <u>0.061</u> 0.49 | 89 89 | 29 29 | Results in all untreated specimens were below LOD. |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:

(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)

- (d) Year must be indicated
 - (e) Days after last application.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
 - * Mean of two extractions
- n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

Table A 28: Summary of the barley study 6 - 6 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148 g/L (actual)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.2/11

ADM.03503. F.1.A

EC

Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|-----------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL21/962/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A) | Spring barley (HORVS) / Planet | 1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21 | 0.187 | 303 | 0.062 | 21/06/21 | BBCH 65 | Grain | <LOQ | 0.08 | 0.03 | <LOQ (n.d.) | 89 | 39 | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 114 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day for |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 39 | |
| | | | Untreated | | | | | Grain | <LOQ | 0.01 | <LOQ | <LOQ (n.d.) | 89 | 39 | |
| | | | | | | | | Straw | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 39 | |
| BPL21/962/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) | Winter barley (HORVW) / Su Vireni | 1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21 | | | | 28/05/21 | BBCH 65 | Grain | <LOQ (n.d.) | 0.10 | 0.09 | <LOQ (n.d.) | 89 | 62 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ | 89 | 62 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (hL) | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.04 | 0.05 | <LOQ (n.d.) | 89 | 62 | grain and straw. |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.01 | <LOQ | 89 | 62 | Extract stability proven within the study. |
| BPL21/962/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) | Spring barley (HORVS) / Conchita | 1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21 | 0.177 | 287 | 0.062 | 15/06/21 | BBCH 65 | Grain | <LOQ (n.d.) | 0.14 | 0.13 | 0.02 | 89 | 28 | Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | Untreated | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.04 | 0.19 | 89 | 28 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ (n.d.) | 89 | 35 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 0.02 | 89 | 35 | |
| BPL21/962/GC-04-PL Krościna Mała, 55-110 Poland N-EU 2021 (D) | Spring barley (HORVS) / KWS Harris | 1/ 08/03/21 2/ 15 - 23/06/21 3/ 31/07/21 | 0.186 | 302 | 0.062 | 18/06/21 | BBCH 65 | Grain | <LOQ (n.d.) | 0.07 | 0.04 | <LOQ | 89 | 43 | |
| | | | Untreated | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.01 | 0.01 | 89 | 43 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ (n.d.) | 89 | 43 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 43 | |
| BPL21/962/GC-05-GE 85368 Moosburg an der Isar Germany N-EU 2021 (E) | Spring barley (HORVS) / Marthe | 1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21 | 0.182 | 345 | 0.053 | 12/07/21 | BBCH 65 | Grain | <LOQ (n.d.) | 0.04 | 0.02 | <LOQ (n.d.) | 89 | 44 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | 0.02 | 89 | 44 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ (n.d.) | 89 | 44 | |
| | | | | | | | | Strain | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 44 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|---|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL21/962/GC-06-HU 5126 Jászfényszaru Hungary N-EU 2021 (F) | Spring barley (HORVS) / Conchita | 1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21 | 0.180 | 291 | 0.062 | 21/06/21 | BBCH 65 | Grain | <LOQ | 0.04 | 0.02 | <LOQ | 89 | 29 | |
| | | | | | | | | Straw | <LOQ | <LOQ (n.d.) | <LOQ | 0.01 | 89 | 29 | |
| | | | Untreated | | | | | Grain | <LOQ (n.d.) | 0.01 | 0.01 | <LOQ (n.d.) | 89 | 29 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | <LOQ | 89 | 29 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 187.5 g a.s./ha of Prothioconazole and 93.75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503. F.1.A at 1.25 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

A 2.1.3.2.7 Barley study 7

| | |
|-------------------|---|
| Comments of zRMS: | <p>Eight field trials were conducted in Northern Europe to determine the residue level of prothioconazole and its metabolites, and of difenoconazole in specimens of barley whole plant without roots, grain and straw following one foliar application of ADM.03501.F.1.A (175 g a.s./L of prothioconazole and 125 g a.s./L of difenoconazole) at the dose rate 1 L/ha (175 g a.s./ha of prothioconazole and 125 g a.s./ha of difenoconazole).</p> <p>Application was performed at BBCH 59 or 61.</p> <p>Specimens of whole plant without roots were generated at ± 0 DAA, 10 (± 1) DAA, 20 (± 2) DAA and 35 (± 3) DAA for the decline trials.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p>Results:</p> <p>For prothioconazole-desthio:</p> <ul style="list-style-type: none"> - 0.049 and 0.69 mg/kg in whole plant, - <LOQ (nd) and 0.027 mg/kg in grain, - 0.015 and 1.1 mg/kg in straw. <p>For prothioconazole (sum): <LOQ.</p> <p>For prothioconazole and its metabolites, the principle of analytical method was based on the method 00979/M001. For prothioconazole and its metabolites, the analytical method was validated on barley (whole plant, grain and straw), following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021.</p> <p>All the analytes were determined by LC-MS/MS using a quantitation and confirmation ion. LOQ: 0.01 mg/kg for each analyte, LOQ: 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of metabolites.</p> <p>The mean recoveries at each fortification level comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev. 1.</p> <p>The storage duration (interval between sampling and extraction date) was 166 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>Remark:</p> <p>Only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary without data of TDMs.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.2/12 |
| Report: | Residue study of prothioconazole, difenoconazole and their metabolites in barley Raw Agricultural Commodities after foliar application of ADM.03501.F.1.A under field conditions – Northern Europe – 2021. Huauilmé, J.-M., 2022b, Report no.: BPL21/960/GC, sponsor no.: 000107614 |
| Guideline(s): | EC guidance working document 7029/VI/95 rev. 5 (22/07/1997) Appendix B OECD/OCDE 509 (2009) Crop field trial ENV/JM/MONO(2011)50/REV1 07-Sep-2016 Crop Field Trials, - Series on Testing & Assessment - No. 164 SANTE/2020/12830, Rev.1 of 24/02/21 ENV/JM/MONO(2007)17 OECD Series on Testing and Assessment, Number 72 |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Additional residue data of difenoconazole and triazole derivative metabolites (TDMs) have been determined in this study. However, difenoconazole residues are not relevant for ADM.03500.F.2.B

(containing prothioconazole only) and TDMs are overestimated with regard to the product as they results from both active substances in the used formulation (prothioconazole and difenoconazole). Therefore, only residues of prothioconazole expressed as prothioconazole-desthio are reported in the following summary.

Table A 29: Summary of the barley study 7 - 8 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 175 g/L (actual 172.8 g/L)
Crop/crop group: Barley / Cereals
Country: France (N-EU), Germany, Hungary, Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.2/12

ADM.03501. F.1.A
EC
Difenoconazole, nominal 125 g/L (actual 125 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|-----------------------------------|---|--------------------------------|--------------|-------------|---|--|--------------------|------------------------|-------------------------|---------------|--------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (hL) | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/960/GC-01-FR 10600 La Chapelle Saint-Luc France N-EU 2021 (A) | Spring barley (HORVS) / Planet | 1/ 27/03/21 2/ 16 - 25/06/21 3/ 30/07/21 | 0.173 | 300 | 0.058 | 14/06/21 | BBCH 69 | Grain Straw | <LOQ (n.d.) 0.17 | <LOQ (n.d.) 0.083 | 89 89 | 46 46 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL21/960/GC-02-GE 74861 Kreßbach Germany N-EU 2020/21 (B) | Winter barley (HORVW) / Su Vireni | 1/ 22/10/20 2/ 23 - 31/05/21 3/ 29 - 30/07/21 | 0.165 | 334 | 0.049 | 22/05/21 | BBCH 59 | Grain Straw | <LOQ (n.d.) <LOQ | <LOQ 0.015 | 89 89 | 68 68 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---|---|-----------------------------------|-----------------|----------------|--|---|-----------------------|----------------------------|----------------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/960/GC-03-HU 2340 Kiskunlacháza Hungary N-EU 2021 (C) | Spring barley (HORVS) / Conchita | 1/ 16/03/21 2/ 11 - 17/06/21 3/ 12 - 15/07/21 | 0.172 | 298 | 0.058 | 08/06/21 | BBCH 59 | Grain | <LOQ | 0.027 | 89 | 35 | desthio as a sum of metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole- desthio as a sum of metabolites Max. sample storage time: 185 days (sampling to extraction), max. extract storage time (extraction to analysis) 2 days. Extract stability proven within the study. Results in all untreated specimens were below LOD. |
| | | | | | | | | Straw | 1.6 | 1.1 | 89 | 35 | |
| BPL21/960/GC-04-PL 98 300 Masłowice Poland N-EU 2021 | Spring barley (HORVS) / KWS Dante | 1/ 04/03/20 2/ 14 - 22/06/21 3/ 20 - 25/07/21 | 0.177 | 308 | 0.058 | 14/06/21 | BBCH 59/61 | Grain | <LOQ | <LOQ | 89 | 36 | |
| | | | | | | | | Straw | 0.53 | 0.21 | 89 | 36 | |
| BPL21/960/GC-05-FR 71570 La Chapelle de Guinchay France N-EU 2020/21 | Winter barley (HORVW) / Amistar | 1/ 20/10/20 2/ 07 - 21/05/21 3/ 15 - 30/07/21 | 0.174 | 203 | 0.086 | 07/05/21 | BBCH 59/61 | whole plant w/o | 0.69 | 0.69 | 59/61 | +0 | |
| | | | | | | | | roots plant w/o | 0.39 | 0.31 | 65 – 69 | 11 | |
| | | | | | | | | whole roots plant w/o | 0.23 | 0.11* | 71 | 20 | |
| | | | | | | | | whole roots plant w/o | 0.18 | 0.049 | 85 | 38 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ | 89 | 83 | |
| | | | | | | | | Straw | 0.11 | 0.052 | 89 | 83 | |
| | | | | | | | | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | | | 8.1 | 8.2 | 9 | | 10 |
|---|--|---|-----------------------------------|-----------------|----------------|--|---|-----------------------|--|--|----------------------------|----------------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | | | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | | | (g) | (h) | | (e) | (f) |
| BPL21/960/GC-06-PL Krościna Mała, 55-110 Poland N-EU 2021 (D) | Spring barley (HORVS) / KWS Harris | 1/ 08/03/21 2/ 15 - 23/06/21 3/ 31/07/21 | 0.169 | 294 | 0.058 | 15/06/21 | BBCH 59/61 | whole plant w/o | | | 0.62 | 0.62 | 59/61 | +0 | |
| | | | | | | | | roots whole plant w/o | | | 0.50 | 0.36 | 69 – 71 | 10 | |
| | | | | | | | | roots whole plant w/o | | | 0.96 | 0.54 | 75 – 77 | 20 | |
| | | | | | | | | roots whole plant w/o | | | 0.52 | 0.18 | 83 – 85 | 36 | |
| | | | | | | | | Grain | | | <LOQ | 0.014 | 89 | 46 | |
| | | | | | | | | Straw | | | 0.77 | 0.27 | 89 | 46 | |
| | | | | | | | | | | | | | | | |
| BPL21/960/GC-07-GE 85368 Moosburg an der Isar Germany N-EU 2021 (E) | Spring barley (HORVS) / Marthe | 1/ 23/04/21 2/ 08 - 15/07/21 3/ 25/08/21 | 0.166 | 337 | 0.049 | 15/06/21 | BBCH 59 | Grain | | | <LOQ (n.d.) | <LOQ | 89 | 51 | |
| | | | | | | | | Straw | | | 0.11 | 0.070 | 89 | 51 | |
| BPL21/960/GC-08-HU 5126 Jászfényszaru Hungary N-EU 2021 (F) | Spring barley (HORVS) / Conchita | 1/ 29/03/21 2/ 19 - 23/06/21 3/ 16 - 22/07/21 | 0.175 | 304 | 0.058 | 16/06/21 | BBCH 59 | Grain | | | <LOQ | <LOQ | 89 | 34 | |
| | | | | | | | | Straw | | | 0.48 | 0.13* | 89 | 34 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 175 g a.s./ha of Prothioconazole and 125 g a.s./ha of difenoconazole (equivalent to ADM.03501. F.1.A at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

* Mean of two extractions

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

A 2.1.3.3 Oilseed rape (KCA 6.3.3)

Table A 30: Comparison of intended and critical EU GAPs

| Type of GAP | Number of applications | Application rate per treatment (precise unit) | Interval between application | Growth stage at last application | PHI (days) |
|-------------------------------|------------------------|---|------------------------------|----------------------------------|------------|
| Oilseed rape | | | | | |
| cGAP EU (EFSA, 2007) | 2 | 0.175 kg as/ha | 14-28 days | Not stated, start at BBCH 53 | 56 |
| cGAP EU (Art. 12, EFSA, 2014) | 2 | 0.12 kg as/ha | 14 days | Not stated | 28 |
| Intended cGAP (3)* | 1 | 0.175 kg as/ha | - | 73 | n/a |

* Critical GAP number(s) in accordance with column 0 of Table 7.1- 1.

n/a Not applicable. The pre-harvest interval for the envisaged area of application is covered by the growing period remaining between the envisaged application and harvest; it is not necessary to indicate a pre-harvest interval in days.

A 2.1.3.3.1 Oilseed rape study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe to determine the residue level of azoxystrobin, prothioconazole and metabolites in whole plant, straw and seeds of oilseed rape after one application of MCW-2073 at the rate of 1 L/ha (200 g/ha of azoxystrobin and 150 g/ha of prothioconazole).</p> <p>Application was performed at BBCH 73.</p> <p>Whole plant specimens were taken at respectively 0, 7 ±1, 14 ±1 DAA and 28 DAA.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Results:</u></p> <p>At harvest, the residues prothioconazole (sum of all metabolites, expressed as prothioconazole-desthio) were not detectable (<LOQ (nd)) in seeds for two trials PL02 and FR03 while they were in average and 0.103 mg/kg for trial FR01. The results of trial FR01 should be considered with caution because suspected to be non-representative in comparison with all other results found in this study.</p> <p>The analytical method for prothioconazole and its metabolites was validated within this study, according to SANCO/3029/99 rev.4.</p> <p>The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg, for each matrix (0.01 mg/kg per analyte).</p> <p>The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). (QuEChERS)</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The storage duration (interval between sampling and extraction date) was 525 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

Reference:

KCA 6.3.3/01

Report:

Magnitude of the residues of azoxystrobin + prothioconazole and metabolites in oilseed rape (RAC whole plant and seeds), following one application of MCW-2073 in 3 trials (2 DCS and 1 HS), Northern Europe (Northern France and Poland) – 2018

Roussel, Ch. H., 2020

Report no.: ChR-18-33731, sponsor no.: R-39647

Guideline(s):

EU guidance SANCO 7029/VI/95 rev. 5 (22/07/1997);

OECD 509, adopted 7 September 2009;

Guidance document SANCO/3029/99 rev. 4 of 11/07/00
OECD guidance document on pesticide residue analytical methods.
Document ENV/JM/MONO(2007)17

Deviations: None with impact on study results, but the following was noted in the study report: “Trial FR01 was clearly having higher residues than other trials, particularly in seeds, both for azoxystrobin and prothioconazole. Although the inversion between seeds and straw was not proven but suspected, the results of trial FR01 should be considered with caution because suspected to be non-representative in comparison with all other results found in this study.”

GLP: Yes

Acceptability/Reliability: Yes

and

| | |
|-------------------|---|
| Comments of zRMS: | <p>Three field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape whole plants, grain and straw (originating from field study ChR-18-33731) following one foliar application of MCW-2073 (200 g/L of azoxystrobin and 150 g/L of prothioconazole).</p> <p>Application was performed at BBCH 73.</p> <p>Whole plant specimens were taken at respectively 0, 7 ±1, 14 ±2 DAA and 28 ±3 DAA.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T and TAA in seeds were <LOQ.</p> <p>Residues of TLA in seeds were between <LOQ and 0.06 mg/kg.</p> <p>Residues of TA in grain were between 0.08 and 1.2 mg/kg.</p> <p>The analytical method GRM053.01A was validated in reduced validation sets for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape (whole plant, seeds and straw) according to SANCO/3029/99, rev. 4.</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The maximum storage intervals from sampling until extraction was 1002 days.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, seed and straw) and for TA (seed).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|-------------------|---|

Reference: KCA 6.3.3/02

Report: Determination of the residue of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in OSR (RAC whole plant and seed) following one application of MCW 2073 in 3 trials (2 DCS + 1 HS) in northern EU (North France and Poland) 2018 Gustloff, C., 2021

Guideline(s): Study no.: S18-02650, sponsor no.: R-39647B
EC Guideline SANCO/7029/VI/95 rev. 5
Guidance document SANCO/3029/99 rev. 4
OECD ENV/JM/MONO(2007)17

Deviations: None with impact on study results.

GLP: Yes

Acceptability: Yes

Table A 31: Summary of the oilseed study 1 - 3 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Oilseed rape / Oilseeds
Country: France, Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): STAPHYT, Inchy en Artois, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.3/01

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|-------------------------------|--|--------------------------------|--------------|-------------|---|--|--|--|---|--------------------------------------|------------------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (d) | (e) | (f) | (g) | (h) | (i) | (j) | (k) | (l) | (m) | (n) |
| ChR-18-33731 FR01 62860 Inchy en Artois France N-EU 2017/18 | Oilseed rape (BRSNN)/ Grizzly | 1. 07/09/17 2. 01/04/- 01/05/18 3. 11/07/18 | 0.156 | 317 | 0.049 | 22/05/18 | BBCH 73 | Whole plant Whole plant Whole plant Whole plant Seeds Straw | 0.53 0.21 0.074 <LOQ <u>0.103*</u> <LOQ* | 0.53 0.20 0.054 0.22 <u>0.072*</u> 0.011* | 73 77 79 81 89 89 | 0 6 15 28 50 50 | Analytical methods: The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). (QuEChERS). For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg) |
| ChR-18-33731 PL02 14106 Grabinek Poland N-EU 2019 | Oilseed rape (BRSNN) / Pamela | 1. 24/08/17 2. 26/04/- 10/05/18 3. 20/07/18 | 0.149 | 302 | 0.049 | 15/06/18 | BBCH 73 | Whole plant Whole plant Whole plant Whole plant Seeds Straw | 0.30 0.36 0.12 <LOQ <u><LOQ</u> (n.d.) <LOQ | 0.30 0.34 0.094 0.020 <u><LOQ</u> 0.013 | 73 75 81 87 89 89 | 0 7 14 28 35 35 | |

| | | | | | | | | | | | | | |
|---|---|--|-------|-----|-------|----------|---------|-------|----------------|----------------|----|----|---|
| ChR-18-33731 FR03 49320 Les Alleuds France N-EU 2017/18 | Oilseed rape (BRSNN) / DK Explicit | 1. 01/09/17 2. 02/04/- 27/04/18 3. 28/06/18 | 0.156 | 262 | 0.060 | 09/05/18 | BBCH 73 | Seeds | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | <p>LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites</p> <p>Max. sample storage time (sampling to analytical completion): 525 days *. Max. extract storage time (extraction to analysis) up to 64 days for prothioconazole-desthio and metabolites, extract stability tested during the study. Results in all untreated specimens were below LOQ (n.d.).</p> <p>*: Mean of ship and retain specimen, each being a mean value of one or two injections</p> |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | |

- (a) According to CODEX Classification / Guide
 - (b) Only if relevant
 - (c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)
 - (d) Year must be indicated
 - (e) Days after last application not given in the study report. Calculated during dossier compilation.
 - (f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
 - (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
 - (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- n.d. not detectable
LOQ Limit of quantification
LOD Limit of detection
- # Max. sample storage time (sampling to analytical completion): 525 days in trial FR01, max. 120 days in the other trials.

Crop residue data from supervised field trials

Reference no.:

KCA 6.3.3/02

Commercial product (name/code):

MCW-2073

Formulation (e.g. SC):
Other active substance in the
formulation:

SC
Azoxystrobin, 206.6 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|-------------------------------------|---|--------------------------------|-----------------|--------------------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|---|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| ChR-18-33731 FR01 62860 Inchy en Artois France N-EU 2017/18 | Oilseed rape (BRSNN)/ Grizzly | 1. 07/09/17 2. 01/04/ - 01/05/18 3. 11/07/18 | azy: 0.217 ptz: 0.156 | 317 | azy: 0.069 ptz: 0.049 | 22/05/18 | BBCH 73 | Whole plant | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 73 | 0 | Analytical methods: SyngentaGRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| | | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 77 | 6 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 15 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.01 | <LOQ (n.d.) | <LOQ (n.d.) | 81 | 28 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.08 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | |
| | | | Untreated | | | Whole Plant | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 73 | 0 | Max. sample storage time: 1002 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day. | | |
| | | | | | | Whole Plant | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 15 | | | |
| | | | | | | Seeds | <LOQ (n.d.) | 0.05 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | | | |
| | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|--------------------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| ChR-18- 33731 PL02 14106 Grabinek Poland N-EU 2017/18 | Oilseed rape (BRSNN)/ Pamela | 1. 24/08/17 2. 26/04/ - 10/05/18 3. 20/07/18 | azy: 0.207 ptz: 0.149 | 302 | azy: 0.069 ptz: 0.049 | 15/06/18 | BBCH 73 | Whole plant | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | <LOQ (n.d.) | 73 | 0 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.03 | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 7 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.03 | <LOQ (n.d.) | <LOQ (n.d.) | 81 | 14 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.03 | <LOQ (n.d.) | <LOQ (n.d.) | 87 | 28 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.10 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 35 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 35 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Whole Plant | <LOQ (n.d.) | 0.03 | <LOQ (n.d.) | <LOQ (n.d.) | 73 | 0 | |
| | | | | | | | | Whole Plant | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | <LOQ (n.d.) | 81 | 14 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.09 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 35 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 35 | |
| ChR-18- 33731 FR03 49320 Les Alleuds France N-EU 2017/18 | Oilseed rape (BRSNN)/ DK Explicit | 1. 01/09/17 2. 04/04/ - 27/04/18 3. 28/06/18 | azy: 0.217 ptz: 0.156 | 262 | azy: 0.83 ptz: 0.60 | 09/05/18 | BBCH 73 | Seeds | <LOQ (n.d.) | 1.2** | <LOQ | 0.06 | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.01 | <LOQ | 89 | 50 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.27** | 0.01 | <LOQ (n.d.) | 89 | 50 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | |

- (a) According to Codex Classification / Guide
 - (b) Only if relevant
 - (c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha azoxystrobin, 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)
 - (d) Year must be indicated
 - (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application.
 - (g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
- azy: Azoxystrobin
ptz: Prothioconazole
** Average value from 3 analyses
n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection
Data in *italics* reported but outside acceptable storage stability

A 2.1.3.3.2 Oilseed rape study 2

A 2.1.3.3.3

| | |
|-------------------|---|
| Comments of zRMS: | <p>Six field trials were conducted in Northern Europe to determine the residue level of azoxystrobin, prothioconazole and metabolites in whole plant, straw and seeds of oilseed rape after one application of MCW-2073 at the rate of 1 L/ha (200 g/ha of azoxystrobin and 150 g/ha of prothioconazole).</p> <p>Application was performed at BBCH 73 except trial FR02 which was applied at BBCH 75. Five samplings were taken in the decline trials (PL01 and FR02): at 0 days after application, 7 (+/-1) DALA, 14 (± 2) DALA, 28 (± 3) DALA and at commercial harvest.</p> <p>One sampling at commercial harvest was done in the harvest trials (DE03, DE04, PL05 and PL06).</p> <p><u>Results:</u></p> <p>Residues of prothioconazole (sum of all metabolites, expressed as prothioconazole-desthio) were <LOQ in seeds and <LOQ to 0.13 mg/kg in straw.</p> <p>The residues in whole plant immediately after application were between 0.13 and 0.15 mg/kg for prothioconazole (sum of all metabolites, expressed as prothioconazole-desthio).</p> <p>The analytical method for prothioconazole and its metabolites was validated within this study, according to SANCO/3029/99 rev.4.</p> <p>The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg, for each matrix (0.01 mg/kg per analyte).</p> <p>The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). (QuEChERS)</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The storage duration (interval between sampling and extraction date) was 248 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|----------------|---|
| Reference: | KCA 6.3.3/03 |
| Report: | <p>Magnitude of the residues of azoxystrobin + prothioconazole and metabolites in oilseed rape (RAC whole plant, seeds and straw), following one application of MCW-2073 in 6 trials (2 DCS, 3 HS and 1 backup HS), Northern Europe (Poland, Northern France and Germany) – 2019</p> <p>Peterek, S., 2020</p> <p>Report no.: SPK-19-38368, sponsor no.: 000102602</p> |
| Guideline(s): | <p>EU guidance SANCO 7029/VI/95 rev. 5 (22/07/1997);</p> <p>OECD 509, adopted 7 September 2009;</p> <p>Guidance Document SANCO/3029/99 rev. 4 of 11/07/00;</p> <p>Guidance Document SANCO/825/00 rev.8.1 of 16 Nov. 2010;</p> <p>OECD guidance document on pesticide residue analytical methods. Document ENV/JM/MONO(2007)17</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

and

| | |
|-------------------|--|
| Comments of zRMS: | <p>Six field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape whole plants, grain and straw (originating from field study SPK-19-38368) following one foliar application of MCW-2073 (200 g/L of azoxystrobin and 150 g/L of prothioconazole).</p> <p>Application was performed at BBCH 73.</p> <p>Whole plant specimens were taken at respectively 0, 7 ±1, 14 ±2 DAA and 28 ±3 DAA. Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T in seeds were <LOQ.</p> <p>Residues of TA in grain were between 0.23 and 2.8 mg/kg.</p> <p>Residues of TAA in seeds were between <LOQ and 0.039 mg/kg.</p> <p>Residues of TLA in seeds were between 0.014 mg/kg and 0.12 mg/kg.</p> <p>The analytical method GRM053.01A was validated in reduced validation sets for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape (whole plant, seeds and straw) according to SANCO/3029/99, rev. 4 and ANTE/2020/12830, rev. 1 (2021).</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The maximum storage intervals from sampling until extraction was 771 days.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, seed and straw) and for TA (seed).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|-------------------|--|

| | |
|----------------|---|
| Reference: | KCA 6.3.3/04 |
| Report: | <p>Determination of the residue of 1, 2, 4-Triazole (1, 2, 4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in Oilseed rape (RAC whole plant, seeds and straw) following one application of MCW-2073 in Northern Europe (Poland, Northern France and Germany) - 2019</p> <p>Ivanov, E., 2021a</p> <p>Study no.: S19-01822, sponsor no.: 000102627</p> |
| Guideline(s): | <p>EC Guideline SANCO/7029/VI/95 rev. 5</p> <p>SANTE/2020/12830, Rev.1 (2021)</p> <p>OECD ENV/JM/MONO(2007)17</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 33: Summary of the oilseed study 2 - 6 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Oilseed rape / Oilseeds
Country: France (N-EU), Poland, Germany

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): STAPHYT, Inchy en Artois, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.3/03

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|-------------------------------------|---|--------------------------------|--------------|-------------|---|--|--|---|---|----------------------------------|--------------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| SPK-19-38368 PL01 21-211 Uhnin Poland N-EU 2018/19 | Oilseed rape (BRSNN) / DK Expansion | 1. 20/08/18 2. 01/05/ - 28/05/19 3. 09/07/19 | 0.145 | 292 | 0.050 | 30/05/19 | BBCH 73 | Whole plant Whole plant Whole plant Whole plant Seeds Straw | 0.13 0.13 0.059* <LOQ (n.d.) <LOQ (n.d.) 0.032 | 0.13 0.12 0.049* <LOQ <LOQ 0.012 | 73 74 77 85 89 89 | 0 8 14 28 40 40 | Analytical methods: QuEChERS method, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg) LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for |
| SPK-19-38368 FR02 49260 Montreuil Bellay France N-EU 2018/19 | Oilseed rape (BRSNN) / DK Exlibris | 1. 01/09/18 2. 15/04/- 05/05/19 3. 06/07/19 | 0.153 | 257 | 0.060 | 17/05/19 | BBCH 75 | Whole plant Whole plant Whole plant Whole plant Seeds Straw | 0.15 0.23 0.078* 0.028 <LOQ (n.d.) <LOQ | 0.15 0.21 0.068* 0.018 <LOQ <LOQ | 75 79 79 81 89 89 | 0 7 12 28 47 47 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|----------------|--|--|---------------------|----------------------------|----------------------------------|------------------|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| SPK-19- 38368 DE03 91611 Lindach Germany N-EU 2018/19 | Winter oilseed rape (BRSNN) / DK Expansion | 1. 02/09/18 2. 22/04/- 16/05/19 3. 01/08/19 | 0.150 | 302 | 0.050 | 05/06/19 | BBCH 73 | Seeds Straw | <LOQ (n.d.) 0.059 | <LOQ 0.012 | 89 89 | 60 60 | prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites Max. sample storage time: 248 days (sampling to analytical completion). Max. extract storage time (extraction to analysis) 6 days, extract stability tested during the study. |
| SPK-19- 38368 DE04 79618 Minseln Germany N-EU 2018/19 | Winter oilseed rape (BRSNN) / PX 128 | 1. 20/09/18 2. 14/05/- 31/05/19 3. 24/07/19 | 0.150 | 302 | 0.050 | 30/05/19 | BBCH 73 | Seeds Straw | <LOQ (n.d.) 0.13 | <LOQ 0.048 | 89 89 | 54 54 | Results in all untreated specimens were below LOQ (n.d.). |
| SPK-19- 38368 PL05 21-036 Woryty Poland N-EU 2019 | Spring oilseed rape (BRSNN) / Markus | 1. 27/04/19 2. 13/06/- 16/07/19 3. 30/08/19 | 0.147 | 295 | 0.050 | 11/07/19 | BBCH 73 | Seeds Straw | <LOQ 0.072 | <LOQ 0.023 | 89 89 | 50 50 | *Mean of two injections |
| SPK-19- 38368 PL06 63-220 Racendów Poland | Winter oilseed rape (BRSNN) / ES Valegro | 1. 30/08/18 2. 23/04/- 15/05/19 3. 11/07/19 | 0.153 | 309 | 0.050 | 31/05/19 | BBCH 73 | Seeds Straw | <LOQ (n.d.) 0.13 | <LOQ 0.038 | 89 89 | 41 41 | |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

- (g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).
- (h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)
- n.d. not detectable
- LOQ Limit of quantification
- LOD Limit of detection

Table A 34: Summary of the oilseed study 2 - 6 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148.7 g/L (actual)

Crop/crop group: Oilseed rape/ Oilseeds

Country: Poland, France (N-EU), Germany

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): Eurofins Agroscience Services Chem GmbH, Hamburg, Germany

Reference no.:

Commercial product (name/code):

KCA 6.3.3/04

MCW-2073

Formulation (e.g. SC):

SC

Other active substance in the formulation:

Azoxystrobin, 206.6 g/L (actual)

Residues calculated as:

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|------------------------------------|---|--------------------------------|--------------|-----------------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DAL (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| SPK-19-38368 PL01 Lubelskie 21-211 Uhnin Poland N-EU 2018/19 | Oilseed rape (BRSNN)/ DK Expansion | 1. 20/08/18 2. 01/05/ - 28/05/19 3. 09/07/19 | azy: 0.201 ptz: 0.145 | 292 | azy: 0.069 ptz: 0.050 | 30/05/19 | BBCH 73 | Whole plant | <LOQ (n.d.) | 0.12 | <LOQ (n.d.) | <LOQ (n.d.) | 73 | 0 | Analytical methods: SyngentaGRM053.0 1A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.12 | <LOQ (n.d.) | <LOQ (n.d.) | 74 | 8 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.15 | <LOQ (n.d.) | <LOQ (n.d.) | 77 | 14 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.17 | <LOQ (n.d.) | 0.017 | 85 | 28 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.83 | <LOQ (n.d.) | 0.048 | 89 | 40 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.064 | 0.010 | 0.013 | 89 | 40 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Whole Plant | <LOQ (n.d.) | 0.14 | <LOQ (n.d.) | 0.011 | 73 | 0 | |
| | | | | | | | | Whole Plant | <LOQ (n.d.) | 0.25 | <LOQ (n.d.) | 0.016 | 77 | 14 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 1.9 | 0.018 | 0.10 | 89 | 40 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.022 | 0.026 | 0.046 | 89 | 40 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | | | |
|--|--|---|--------------------------------|-----------------|--------------------------|--|--|---------------------|--------------------|-------------------------|-----------------------------|-----------------------------|------------------|----------------|---|---|--|--|--|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazol e alanine | Triazol e acetic acid | Triazol e lactic acid | Timing (BBCH) | DALA (days) | | | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | | | |
| SPK-19- 38368 FR02 49260 Montreuil Bellay France N-EU 2018/19 | Oilseed rape (BRSNN)/ DK Exlibris | 1. 01/09/18 2. 15/04/- 05/05/19 3. 06/07/19 | azy: 0.212 ptz: 0.153 | 257 | azy: 0.082 ptz: 0.060 | 17/05/19 | BBCH 75 | Whole plant | <LOQ (n.d.) | 0.046 | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 0 | analysis) 4 days. Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. | | | | | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.061 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 7 | | | | | | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.065 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 12 | | | | | | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.036 | <LOQ (n.d.) | <LOQ (n.d.) | 81 | 28 | | | | | | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.23 | <LOQ (n.d.) | 0.014 | 89 | 47 | | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.014 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 47 | | | | | | |
| | | | Untreated | | | | | Whole plant | <LOQ (n.d.) | 0.036 | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 0 | | Residues in untreated samples (background levels) were found in a part of samples, and results are given. | | | | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.035 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 12 | | | | | | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.23 | <LOQ (n.d.) | 0.012 | 89 | 47 | | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.014 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 47 | | | | | | |
| SPK-19- 38368 DE03 91611 Lindach Germany N-EU 2018/19 | Oilseed rape (BRSNN)/ DK Expansion | 1. 02/09/18 2. 22/04/- 16/05/19 3. 01/08/19 | azy: 0.208 ptz: 0.150 | 302 | azy: 0.069 ptz: 0.050 | 05/06/19 | BBCH 73 | Seeds | <LOQ (n.d.) | 2.8 | 0.039 | 0.12 | 89 | 60 | | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.22 | 0.030 | 0.019 | 89 | 60 | | | | | | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 2.5 | 0.040 | 0.15 | 89 | 60 | | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.043 | 0.020 | <LOQ | 89 | 60 | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | | |
|--|--|---|---|-----------------|--------------------------------|--|---|---------------------|--------------------------|-------------------------|--------------------------------|--------------------------------|------------------|----------------|---------------------|------|----------------|----|----|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatmen t or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazol e alanine | Triazol e acetic acid | Triazol e lactic acid | Timing (BBCH) | DALA (days) | | | | | |
| (a) | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | | |
| SPK-19- 38368 DE04 79618 Minseln Germany N-EU 2018/19 | Oilseed rape (BRSNN)/ PX 128 | 1. 20/09/18 2. 14/05/- 31/05/19 3. 24/07/19 | azy: 0.208 ptz: 0.150 | 302 | azy: 0.069 ptz: 0.050 | 30/05/13 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.39 | <LOQ | 0.015 | 89 | 54 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 0.012 | 89 | 54 | | | | | |
| | | | Untreated | | | | | | | Seeds | <LOQ (n.d.) | 0.22 | <LOQ | 0.012 | | 89 | 54 | | |
| | | | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | | 54 | | | |
| | | | SPK-19- 38368 PL05 11-036 Woryty Warminsko- Poland N-EU 2019 | | Oilseed rape (BRSNN)/Markus | 1. 27/04/19 2. 13/06/- 16/07/19 3. 30/08/19 | azy: 0.203 ptz: 0.146 | 295 | azy: 0.069 ptz: 0.049 | 11/07/19 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.35 | | <LOQ | 0.023 | 89 | 50 |
| | | | | | | | | | | | | Straw | <LOQ (n.d.) | 0.011 | | <LOQ | <LOQ (n.d.) | 89 | 50 |
| Untreated | | | | | | | Seeds | <LOQ (n.d.) | 0.40 | <LOQ | 0:024 | 89 | 50 | | | | | | |
| | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 50 | | | | | | |
| SPK-19- 38368 PL06 63-220 Racendov Poland N-EU 2018/19 | Oilseed rape (BRSNN)/ ES Valegro | 1. 30/08/18 2. 23/04/- 15/05/19 3. 11/07/19 | azy: 0.213 ptz: 0.153 | 309 | azy: 0.069 ptz: 0.050 | 31/05/19 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.60 | 0.018 | 0.029 | 89 | 41 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.069 | 0.017 | <LOQ | 89 | 41 | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|-----------------------|---|--------------------------------|-----------------|--------------|--|---|---------------------|--------------------|-------------------------|-----------------------------|-----------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatmen t or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazol e alanine | Triazol e acetic acid | Triazol e lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (g a.s./ hL) | (d) | (e) | (a) | | | | | | (f) | (g) |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.79 | 0.037 | 0.046 | 89 | 41 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.047 | 0.021 | 0.012 | 89 | 41 | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha azoxystrobin, 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

azy: Azoxystrobin

ptz: Prothioconazole

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.3.4 Oilseed rape study 3

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residue level of prothioconazole and metabolites in whole plant, seeds and straw of oilseed rape after one application of ADM.3500.F.2.B at the rate of 0.8 L/ha representing 200 g/ha prothioconazole.</p> <p>Application was performed at BBCH 73 and 75 (FR02).</p> <p>Five samplings were taken in the decline trials (PL01 and FR02): at 0 days after application, 7 (+/-1) DALA, 14 (± 2) DALA, 28 (± 3) DALA and at commercial harvest.</p> <p>One sampling at commercial harvest was done in the harvest trials (DE03, DE04).</p> <p>Results:</p> <p>The residues in whole plant immediately after application were between 0.69 and 1.0 mg/kg for prothioconazole (sum of all metabolites, expressed as prothioconazole-desthio).</p> <p>At harvest, residues of prothioconazole (sum of all metabolites, expressed as prothioconazoledesthio) were <LOQ in seeds, and were between <LOQ and 0.65 mg/kg in straw.</p> <p>The analytical method for analysis of residues of prothioconazole and its metabolites was fully validated for the matrices whole plant seed and straw according to SANCO/3029/99 rev.4 in previous studies in 2018 and in 2019. Therefore, only daily recoveries were performed during this study.</p> <p>The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg, for each matrix (0.01 mg/kg per analyte).</p> <p>The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). (QuEChERS)</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The storage duration (interval between sampling and extraction date) was 252 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
|-------------------|---|

Reference: KCA 6.3.3/05

Report: Magnitude of the residues of prothioconazole and metabolites in oilseed rape (RAC whole plant, seeds and straw), following one application of ADM.3500.F.2.B in 4 trials (2 DCS and 2 HS), Northern Europe (Poland, Northern France and Germany) – 2019/2020
Grall, E., 2021
Report no.: SPK-19-38370, sponsor no.: 000102604

Guideline(s): EU guidance SANCO 7029/VI/95 rev. 5 (22/07/1997);
OECD 509, adopted 7 September 2009;
Guidance Document SANCO/3029/99 rev. 4 of 11/07/00;
OECD guidance document on pesticide residue analytical methods.
Document ENV/JM/MONO(2007)17

Deviations: None with impact on study results

GLP: Yes

Acceptability: Yes

And

| | |
|-------------------|---|
| Comments of zRMS: | <p>Four field trials were conducted in Northern Europe to determine the residues of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape whole plants, grain and straw (originating from field study SPK-19-38370) following one foliar application of ADM.3500.F.2.B (250 g/L of prothioconazole).</p> <p>Application was performed at BBCH 73 and 75.</p> <p>Whole plant specimens were taken at respectively 0, 7 ±1, 14 ±2 DAA and 28 ±3 DAA.</p> <p>Specimens of grain and straw were generated at harvest stage BBCH 89 from all the field trials performed.</p> <p><u>Results:</u></p> <p>Residues of 1,2,4-T in seeds were <LOQ.</p> <p>Residues of TA in grain were between 0.22 and 1.5 mg/kg.</p> <p>Residues of TAA in seeds were between <LOQ and 0.02 mg/kg.</p> <p>Residues of TLA in seeds were between <LOQ and 0.1 mg/kg.</p> <p>The analytical method GRM053.01A was validated in reduced validation sets for the determination of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in oilseed rape (whole plant, seeds and straw) according to SANCO/3029/99, rev. 4 and ANTE/2020/12830, rev. 1 (2021).</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte and each matrix.</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations ≤20%.</p> <p>The maximum storage intervals from sampling until extraction was 791 days.</p> <p>It should be noted that the storage period exceeded the maximum storage stability for 1,2,4-T (whole plant, seed and straw) and for TA (seed).</p> <p>For this reason, the obtained results cannot be used for evaluation and risk assessment.</p> |
|-------------------|---|

| | |
|----------------|--|
| Reference: | KCA 6.3.3/06 |
| Report: | <p>Determination of residue of 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in Oilseed rape (RAC whole plant, seeds and straw) following one application of ADM.3500.F.2.B in 4 trials (2 DCS and 2 HS) in Northern Europe (Poland, Northern France and Germany) - 2019</p> <p>Ivanov, E., 2021b</p> <p>Study no.: S19-01824, sponsor no.: 000102629</p> |
| Guideline(s): | <p>EC Guideline SANCO/7029/VI/95 rev. 5</p> <p>SANTE/2020/12830, Rev.1 (2021)</p> <p>OECD ENV/JM/MONO(2007)17</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 35: Summary of the oilseed rape study 3 - 4 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 250 g/L (actual 248.2 g/L)

Crop/crop group: Oilseed rape / Oilseeds

Country: France (N-EU), Poland, Germany

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): STAPHYT, Gines, Spain

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.3/05

ADM.3500.F.2.B

EC

none

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|-------------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|-----------------------|-------------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| SPK-19-38370 PL01 21-211 Uhnin Poland N-EU 2018/19 | Oilseed rape (BRSNN) / DK Expansion | 1. 20/08/18 2. 01/05/ - 28/05/19 3. 09/07/19 | 0.199 | 300 | 0.066 | 30/05/19 | BBCH 73 | Whole plant | 0.69 | 0.69 | 73 | 0 | Analytical methods: QuEChERS method, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte (except prothioconazole expressed as prothioconazole-desthio as a sum of the metabolites = 0.06 mg/kg) LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed |
| | | | | | | | | Whole plant | 0.26 | 0.25 | 74 | 8 | |
| | | | | | | | | Whole plant | 0.14 | 0.11 | 77 | 14 | |
| | | | | | | | | Whole plant | 0.11 | 0.062 | 85 | 28 | |
| | | | | | | | | Seeds | <LOQ | 0.028 | 89 | 40 | |
| | | | | | | | | Straw | 0.41 | 0.24 | 89 | 40 | |
| SPK-19-38370 FR02 49260 Montreuil Bellay France N-EU 2018/19 | Oilseed rape (BRSNN) / DK Exlibris | 1. 01/09/18 2. 15/04/- 05/05/19 3. 06/07/19 | 0.208 | 262 | 0.079 | 17/05/19 | BBCH 75 | Whole plant | 1.0 | 1.0 | 75 | 0 | |
| | | | | | | | | Whole plant | 0.44 | 0.40 | 79 | 7 | |
| | | | | | | | | Whole plant | 0.33 | 0.29 | 79 | 12 | |
| | | | | | | | | Whole plant | 0.13 | 0.09 | 81 | 28 | |
| | | | | | | | | Seeds | <LOQ | 0.037 | 89 | 47 | |
| | | | | | | | | Straw | <LOQ | 0.032 | 89 | 47 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---|---|--------------------------------|-----------------|----------------|--|--|--------------------|----------------------------------|----------------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| SPK-19- 38370 DE03 91611 Lindach Germany N-EU 2018/19 | Winter oilseed rape (BRSNN) / DK Expansion | 1. 16/08/19 2. 25/04/- 11/05/20 3. 25/07/20 | 0.205 | 207 | 0.099 | 20/05/20 | BBCH 73 | Seeds Straw | <u><LOQ</u> (n.d.) 0.65 | <u><LOQ</u> 0.30 | 89 89 | 63 63 | as prothioconazole-desthio as a sum of the metabolites Max. sample storage time: 252 days (sampling to analytical completion). Max. extract storage time (extraction to analysis) 5 days, extract stability tested during the study. |
| SPK-19- 38370 DE04 79618 Minseln Germany N-EU 2018/19 | Winter oilseed rape (BRSNN) / PX 128 | 1. 20/09/18 2. 14/05/- 31/05/19 3. 24/07/19 | 0.202 | 305 | 0.066 | 30/05/19 | BBCH 73 | Seeds Straw | <u><LOQ</u> 0.24 | <u>0.019</u> 0.10 | 89 89 | 54 54 | Results in all untreated specimens were below LOQ (n.d.). |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2.B at 0.8 L/ha)

(d) Year must be indicated

(e) Days after last application not given in the study report. Calculated during dossier compilation.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. not detectable

LOQ Limit of quantification

LOD Limit of detection

Crop residue data from supervised field trials

| | |
|--|---|
| Indoor/outdoor: | Outdoor |
| Responsible body for reporting (name, address): | Eurofins Agrosience Services Chem GmbH, Hamburg, Germany |

Residues calculated as:

EC
None

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|---|----------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| SPK-19- 38370 PL01 Lubelskie 21- 211 Uhnin Poland N-EU 2018/19 | Oilseed rape (BRSNN)/ DK Expansion | 1. 20/08/18 2. 01/05/ - 28/05/19 3. 09/07/19 | 0.199 | 300 | 0.066 | 30/05/19 | BBCH 73 | Whole plant | <LOQ (n.d.) | 0.17 | <LOQ | <LOQ | 73 | 0 | Analytical methods: SyngentaGRM053.01A LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.29 | <LOQ | 0.02 | 74 | 8 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.24 | <LOQ | 0.03 | 77 | 14 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.25 | 0.02 | 0.05 | 85 | 28 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 1.5 | 0.02 | 0.10 | 89 | 40 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.04 | 0.10 | 89 | 40 | |
| | | | Untreated | | | Whole plant | <LOQ (n.d.) | 0.16 | <LOQ | 0.01 | 73 | 0 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal | | |
| | | | Whole plant | <LOQ (n.d.) | 0.25 | <LOQ | 0.03 | 77 | 14 | | | | | | |
| | | | Seeds | <LOQ (n.d.) | 1.6 | 0.02 | 0.10 | 89 | 40 | | | | | | |
| | | | Straw | <LOQ (n.d.) | 0.02 | 0.02 | 0.05 | 89 | 40 | | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|--|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| SPK-19- 38370 FR02 49260- Montreuil Bellay France N-EU 2018/19 | Oilseed rape (BRSNN)/ DK Exlibris | 1. 01/09/18 2. 15/04/ - 05/05/19 3. 06/07/19 | 0.208 | 262 | 0.079 | 17/05/19 | BBCH 75 | Whole plant | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 0 | standard for quantification. Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.06 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 7 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.06 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 12 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.06 | <LOQ (n.d.) | <LOQ (n.d.) | 81 | 28 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.26 | <LOQ (n.d.) | 0.01 | 89 | 47 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 47 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 0 | |
| | | | | | | | | Whole plant | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | <LOQ (n.d.) | 79 | 12 | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.21 | <LOQ (n.d.) | 0.01 | 89 | 47 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | <LOQ | 89 | 47 | |
| SPK-19- 38370 DE03 91622 Lindach Germany N-EU 2019/20 | Oilseed rape (BRSNN)/ DK Expansion | 1. 16/08/19 2. 25/04/ - 11/05/20 3. 25/07/19 | 0.205 | 207 | 0.099 | 20/05/20 | BBCH 75 | Seeds | <LOQ (n.d.) | 0.22 | <LOQ (n.d.) | <LOQ | 89 | 63 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.01 | <LOQ | 89 | 63 | |
| | | | | | | | | Untreated | | | | | | | |
| | | | | | | | | Seeds | <LOQ (n.d.) | 0.23 | <LOQ (n.d.) | <LOQ | 89 | 63 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | <LOQ | <LOQ | 89 | 63 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 | | | | |
|---|--------------------------------------|---|--------------------------------|-----------------|-------------|--|--|---------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|----------------|---------------------|--|--|--|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) | | | | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | | | | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) | | | | |
| SPK-19- 38370 DE04 79618 Minseln Germany N-EU 2018/19 | Oilseed rape (BRSNN)/ PX128 | 1. 20/09/18 2. 14/05/ - 31/05/19 3. 24/07/19 | 0.202 | 305 | 0.066 | 30/05/19 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.33 | <LOQ | 0.01 | 89 | 54 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.01 | 89 | 54 | | | | | | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.22 | <LOQ (n.d.) | <LOQ | 89 | 54 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 54 | | | | | | |

(a) According to Codex Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate target 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2B at 0.8 L/ha)

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.

(f) Minimum number of days after last application.

(g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

n.d. Not detectable

LOQ Limit of quantification, LOD Limit of detection

Data in *italics* reported but outside acceptable storage stability

A 2.1.3.3.5 Oilseed rape study 4

| | |
|-------------------|---|
| Comments of zRMS: | <p>Ten field trials (eight main trials + two back-up trials) were conducted in North of France, Germany and Poland on oilseed rape. Three trials (01-FR, 02-GE and 03-HU) were cancelled due to insects' attacks which destroyed the crops (for trials 01-FR and 02-GE) and due to development issue (for trial 03-HU). Therefore the back-up trials BPL21/964/GC-09-PL and BPL21/964/GC-10-PL became main trials.</p> <p>One application with ADM.3500.F.2.B (250 g a.s./L of prothioconazole) was performed at BBCH 73-75 at dose rate between 0.73 and 0.81 L/ha of test item corresponding to a total dose of prothioconazole between 182.03 and 200.54 g/ha.</p> <p>For all the trials, one sampling event was carried out: oilseed rape seeds were harvested at crop stage (BBCH 89).</p> <p>The analytical method for analysis of residues of prothioconazole and its metabolites was fully validated for the matrice oilseed rape (seeds) according to SANTE/2020/12830, Rev.1 of 24/02/2021 during another study performed at GIRPA in 2021.</p> <p>The analytical method was validated for the determination of 1,2,4-T, TA, TAA and TLA according to SANTE/2020/12830, Rev.1 in study S21-02262 and S12-00072 performed by Eurofins Agroscience Services Chem GmbH.</p> <p>Therefore, only daily recovery was performed during this study.</p> <p>The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg (0.01 mg/kg per analyte).</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte of TDMs.</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.</p> <p>The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS).</p> <p>The storage duration (interval between sampling and extraction date) was 86 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p>Results:</p> <p>At harvest, residues of prothioconazole (sum of all metabolites, expressed as prothioconazoledesthio) were between <LOQ and 0.073 mg/kg in seeds.</p> <p>At harvest, residues of prothioconazole-desthio were between <LOQ and 0.021 mg/kg in seeds.</p> <p>Residues of 1,2,4-T in seeds were <LOQ.</p> <p>Residues of TA in seeds were between 0.08 and 2.42 mg/kg.</p> <p>Residues of TAA in seeds were between <LOQ and 0.02 mg/kg.</p> <p>Residues of TLA in seeds were between <LOQ and 0.14 mg/kg.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|---------------|---|
| Reference: | KCA 6.3.3/07 |
| Report: | Residue study of Prothioconazole and its metabolites in oilseed rape Raw Agricultural Commodities (seeds) after foliar application of ADM.3500.F.2.B (Prothioconazole) under field conditions – harvest trials - Northern Europe - 2021 Amic, S., 2021 |
| Guideline(s): | Study no.: BPL21/964/GC, sponsor no.: 000107621 EC guidance working document 7029/VI/95 rev. 5 (22/07/1997) Appendix B |

OECD/OCDE 509 Adopted: 7 September 2009, OECD Guidelines for the testing of chemicals, Crop Field Trial.
ENV/JM/MONO(2011)50/REV1 07-Sep-2016 OECD Guidance Document on crop field trials, second edition, Series on Pesticides - No. 66 Series on Testing & Assessment - No. 164
SANTE/2020/12830, Rev.1 24, February 2021, Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes - Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00.
ENV/JM/MONO(2007)17, 2007: OECD Guidance document on pesticide residue analytical methods, Series on Pesticides, Number 39.
None with impact on study results (one trial was cancelled)

Deviations:

GLP:

Acceptability:

Yes

Yes

Table A 37: Summary of the oilseed rape study 4 – 7 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 250 g/L (actual 252.8 g/L)
Crop/crop group: Oilseed rape / Oilseeds
Country: GE, FR, PL
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.3/07

ADM.03500.F.2.B (MCW-2075)

EC

None

**Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)**

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|-------------------------------|--|-----------------------------------|-----------------|----------------|---|--|------------------|---------------------------------------|---|------------------|---------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) (f) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) (g) | Prothio- conazole-desthio (h) | Timing (BBCH) | DALA (days) (e) | |
| BPL21/964/GC-04-GE 85368 Moosburg an der Isar Germany N-EU 2021 | Oilseed rape (BRSNN)/ Mirakel | 1. 27/04/21 2. 21-30/06/21 3. Not recorded | 0.193 | 292 | 0.066 | 10/07/21 | BBCH 73 | Seeds | <LOQ | <LOQ | 89 | 46 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL21/964/GC-05-FR 71570 La Chapelle de Guinchay France N-EU 2020/21 | Oilseed rape (BRSNN)/ PT 242 | 1. 18/09/20 2. 28/03/-03/05/21 3. 27/07/21 | 0.182 | 228 | 0.080 | 18/05/21 | BBCH 73 | Seeds | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 70 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole expressed as prothioconazole-desthio as a sum of |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|--|---|-----------------------------------|-----------------|----------------|--|--|------------------|----------------------------|------------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/964/GC-06-PL 55-110 Krościna Mała Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ SY Alibaba | 1. 21/08/20 2. 04 - 28/05/21 3. 24/07/21 | 0.201 | 303 | 0.066 | 07/06/21 | BBCH 73 | Seeds | <LOQ | <LOQ | 89 | 53 | metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole expressed as prothioconazole- desthio as a sum of metabolites Max. sample storage time: 86 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day. Results in all untreated specimens were below LOD. |
| BPL21/964/GC-07-PL 98-300 Masłowice Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ ROHAN F1 | 1. 04/09/20 2. 02 - 31/05/21 3. 20/07/21 | 0.197 | 298 | 0.066 | 07/06/21 | BBCH 73 | Seeds | 0.073 | 0.021 | 89 | 43 | |
| BPL21/964/GC-08-PL 99-311 Wola Kalkowa Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Medal | 1. 26/08/20 2. 20/05 - 07/06/21 3. 02/08/21 | 0.195 | 296 | 0.066 | 14/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | <LOQ | 89 | 49 | |
| BPL21/964/GC-09-PL 05-815 Kampinos Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Monocit | 1. 31/08/20 2. 18/05 - 07/06/21 3. 02/08/21 | 0.192 | 290 | 0.066 | 14/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | <LOQ | 89 | 49 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|---|---|-----------------------------------|-----------------|----------------|--|--|------------------|----------------------------|------------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole-desthio | Timing (BBCH) | DALA (days) | |
| (a) | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/964/GC- 10-PL 88-400 Murczyn Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 22/05 - 06/06/21 3. 02/08/21 | 0.191 | 193 | 0.099 | 11/06/21 | BBCH 73 - 75 | Seeds | <LOQ (n.d.) | <LOQ | 89 | 52 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance

(d) Year must be indicated

(e) Days after last application.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Table A 38: Summary of the oilseed rape study 4 – 7 trials (TDMs)

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 252.8 g/L (actual)

Crop/crop group: Oilseed rape / Oilseeds

Country: Germany, France (N-EU), Poland

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.3.3/07

ADM.03500.F.2.B

EC

None

1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|----------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | | | | | (f) | (g) |
| BPL21/964/GC-04-GE 85368 Moosburg an der Isar Germany N-EU 2021 | Oilseed rape (BRSNN)/ Mirakel | 1. 27/04/21 2. 21-30/06/21 3. Not recorded | 0.193 | 292 | 0.066 | 10/07/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.30 | <LOQ | 0.01 | 89 | 46 | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 20 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day for. |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.08 | <LOQ (n.d.) | <LOQ | 89 | 46 | |
| BPL21/964/GC-05-FR 71570 La Chapelle de Guinchay France N-EU 2020/21 | Oilseed rape (BRSNN)/ PT 242 | 1. 18/09/20 2. 28/03/-03/05/21 3. 27/07/21 | 0.182 | 228 | 0.080 | 18/05/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 2.42 | 0.02 | 0.14 | 89 | 70 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 1.17 | 0.02 | 0.11 | 89 | 70 | |
| BPL21/964/GC-06-PL 55-110 Krościna Mała | Oilseed rape (BRSNN)/ SY Alibaba | 1. 21/08/20 2. 04 - 28/05/21 3. 24/07/21 | 0.201 | 303 | 0.066 | 07/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.21 | <LOQ (n.d.) | 0.01 | 89 | 53 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|-------------------------------------|---|--------------------------------|--------------|-------------|---|--|------------------|------------------|------------------|----------------------|----------------------|---------------|-------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (c) | (c) | (L/ha) | (hL) | (d) | (e) | (a) | | | | | | (f) | (g) |
| Poland N-EU 2020/21 | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.47 | <LOQ | 0.04 | 89 | 53 | Extract stability Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| BPL21/964/GC-07-PL 98-300 Masłowice Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ ROHAN F1 | 1. 04/09/20 2. 02 - 31/05/21 3. 20/07/21 | 0.197 | 298 | 0.066 | 07/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.33 | <LOQ | 0.01 | 89 | 43 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.39 | <LOQ | 0.02 | 89 | 43 | |
| BPL21/964/GC-08-PL 99-311 Wola Kalkowa Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Medal | 1. 26/08/20 2. 20/05 - 07/06/21 3. 02/08/21 | 0.195 | 296 | 0.066 | 14/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.09 | <LOQ (n.d.) | <LOQ | 89 | 49 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.11 | <LOQ (n.d.) | <LOQ | 89 | 49 | |
| BPL21/964/GC-09-PL 05-815 Kampinos Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Monocit | 1. 31/08/20 2. 18/05 - 07/06/21 3. 02/08/21 | 0.192 | 290 | 0.066 | 14/06/21 | BBCH 73 | Seeds | <LOQ (n.d.) | 0.08 | <LOQ (n.d.) | <LOQ | 89 | 49 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.15 | <LOQ (n.d.) | <LOQ | 89 | 49 | |
| BPL21/964/GC-10-PL 88-400 Murczyn Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 22/05 - 06/06/21 3. 02/08/21 | 0.191 | 193 | 0.099 | 11/06/21 | BBCH 73 - 75 | Seeds | <LOQ (n.d.) | 0.08 | <LOQ (n.d.) | <LOQ | 89 | 52 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.16 | <LOQ (n.d.) | <LOQ | 89 | 52 | |

- (a) According to Codex Classification /Guide
 - (b) Only if relevant
 - (c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance.
 - (d) Year must be indicated
 - (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application.
 - (g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
- n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.3.3.6 Oilseed Rape study 5

| | |
|-------------------|--|
| Comments of zRMS: | <p>Ten field trials (eight main trials + two back-up trials) were conducted in Germany, Hungary and Poland on oilseed rape. Two main field trials were (01-FR and 02-GE) were cancelled due to insects' attacks which destroyed the crops so the back-up trials BPL21/966/GC-09-PL and BPL21/966/GC-10-PL became main trials.</p> <p>One application with ADM.03503.F.1.A (150 g/L of Prothioconazole and 75 g/L of Fluxapyroxad) was performed at BBCH 69-71 at dose rate between 0.96 and 1.02 L/ha of test item corresponding to a total dose of prothioconazole between 142.36 and 151.70 g/ha and of fluxapyroxad between 74.45 and 79.33 g/ha.</p> <p>For all the trials, one sampling event was carried out: oilseed rape seeds were harvested at crop stage (BBCH 89).</p> <p>The analytical method based on the method 00979/M001 for analysis of residues of prothioconazole and its metabolites was fully validated for the matrix oilseed rape (seeds) according to SANTE/2020/12830, Rev.1 of 24/02/2021 during another study performed at GIRPA SAS in 2021.</p> <p>The analytical method GRM053.01A1 was validated for the determination of 1,2,4-T, TA, TAA and TLA according to SANTE/2020/12830, Rev.1 in study S21-02262 and S12-00072 performed by Eurofins Agrosience Services Chem GmbH.</p> <p>Therefore, only procedural recoveries were performed during this study.</p> <p>The LOQ (Limit of quantification) of prothioconazole (sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio) was 0.060 mg/kg (0.01 mg/kg per analyte).</p> <p>The limit of quantification (LOQ) of the analytical method was 0.01 mg/kg for each analyte of TDMs.</p> <p>Acceptance criteria for method validations were met, with average recoveries ranging from 70% to 110% and relative standard deviations $\leq 20\%$.</p> <p>The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS).</p> <p>The storage duration (interval between sampling and extraction date) was 83 days for the determination of prothioconazole and its metabolites.</p> <p>Sufficient stability data are available to support the residue data presented in this study.</p> <p><u>Results:</u></p> <p>At harvest, residues of prothioconazole-desthio were between <LOQ and 0.018 mg/kg in seeds.</p> <p>At harvest, residues of prothioconazole (sum of all metabolites, expressed as prothioconazoledesthio) were between <LOQ and 0.064 mg/kg in seeds.</p> <p>Residues of 1,2,4-T in seeds were <LOQ.</p> <p>Residues of TA in seeds were between 0.13 and 2.2 mg/kg.</p> <p>Residues of TAA in seeds were between <LOQ and 0.03 mg/kg.</p> <p>Residues of TLA in seeds were between <LOQ and 0.17 mg/kg.</p> <p>The study is acceptable.</p> |
|-------------------|--|

Reference:

KCA 6.3.3/08

Report:

Residue study of Prothioconazole and Fluxapyroxad and their respective metabolites in oilseed rape Raw Agricultural Commodities (seeds) after foliar application of ADM.03503.F.1.A (Prothioconazole and Fluxapyroxad) under field conditions – harvest trials - Northern Europe - 2021. Amic, S., 2022,

Report no.: BPL21/966/GC, sponsor no.: 000107619

Guideline(s):

EC guidance working document 7029/VI/95 rev. 5 (22/07/1997)

Appendix B

OECD/OCDE 509 (2021) Crop field trial

ENV/JM/MONO(2011)50/REV1 07-Sep-2016 Crop Field Trials, -
Series on Testing & Assessment - No. 164
SANTE/2020/12830, Rev.1 of 24/02/21
ENV/JM/MONO(2007)17 OECD Series on Testing and Assessment,
Number 72

| | |
|----------------|-----------------------------------|
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Table A 1: Summary of the Oilseed Rape study 5 – 8 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 148 g/L)
Crop/crop group: Oilseed rape / Oilseeds
Country: Hungary, Germany, France (N-EU), Poland
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):
Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.3/08

ADM.03503.F.1.A
EC
Fluxapyroxad, nominal 75 g/L (actual 77.4 g/L)
Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.1, risk assessment residue definition);
Prothioconazole-desthio (mg/kg) (8.2, enforcement residue definition)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---------------------------------|--|--------------------------------|--------------|-------------|---|--|------------------|-----------------------|-------------------------|---------------|-------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothioconazole (sum) | Prothioconazole-desthio | Timing (BBCH) | DALA (days) | |
| | (a) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/966/GC-03-HU Csömör 2141 Hungary N-EU 2020/21 | Oilseed rape (BRSNN)/ Hybrirock | 1. 08/09/20 2. 26/04-11/05/21 3. 01 - 08/07/21 | 0.146 | 295 | 0.049 | 11/05/21 | BBCH 69 | Seeds | <LOQ | <LOQ | 89 | 56 | Analytical methods: RAR method 00979/M001, LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. |
| BPL21/966/GC-04-GE Moosburg an der Isar 85368 Germany N-EU 2021 | Oilseed rape (BRSNN)/ Mirakel | 1. 27/04/21 2. 21 - 30/06/21 3. NA | 0.142 | 241 | 0.059 | 01/07/21 | BBCH 69 - 71 | Seeds | <LOQ | <LOQ | 89 | 55 | LOQ: 0.01 mg/kg for each analyte, 0.06 mg/kg for prothioconazole |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|--|-------------------------------------|---|-----------------------------------|-----------------|----------------|--|---|------------------|----------------------------|----------------------------------|------------------|----------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/966/GC-05-FR La Chapelle de Guinchay France N-EU 2020/21 | Oilseed rape (BRSNN)/ PT242 | 1. 18/09/20 2. 28/03/- 03/05/21 3. 27/07/21 | 0.149 | 253 | 0.059 | 03/05/21 | BBCH 69 | Seeds | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 85 | expressed as prothioconazole-desthio as a sum of metabolites; LOD: 0.003 mg/kg for each analyte, 0.018 mg/kg for prothioconazole |
| BPL21/966/GC-06-PL Krościna Mała 55-110 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ SY Alibaba | 1. 21/08/20 2. 04 - 28/05/21 3. 24/07/21 | 0.152 | 308 | 0.049 | 26/05/21 | BBCH 69 | Seeds | <LOQ | <LOQ | 89 | 59 | expressed as prothioconazole-desthio as a sum of metabolites Max. sample storage time: 83 days (sampling to extraction), max. extract storage time (extraction to analysis) 24 h. |
| BPL21/966/GC-07-PL Masłowiec 98-300 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Rohan F1 | 1. 04/09/20 2. 02 - 31/05/21 3. 20/07/21 | 0.150 | 305 | 0.049 | 31/05/21 | BBCH 69 | Seeds | 0.064 | 0.018 | 89 | 50 | Results in all untreated specimens were below LOD. |
| BPL21/966/GC-08-PL Wegorzewo 62-280 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 21/05 - 06/06/21 3. 02/08/21 | 0.150 | 204 | 0.074 | 06/06/21 | BBCH 69 - 71 | Seeds | <LOQ | <LOQ | 89 | 57 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 9 | | 10 |
|---|---|---|-----------------------------------|-----------------|----------------|--|---|------------------|----------------------------|----------------------------------|------------------|----------------|---------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | Assessment | | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | Prothio- conazole (sum) | Prothio- conazole- desthio | Timing (BBCH) | DALA (days) | |
| (a) | (b) | (b) | (c) | | | (d) | | | (g) | (h) | | (e) | (f) |
| BPL21/966/GC-09-PL Murczyn 88-400 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 21/05 - 06/06/21 3. 02/08/21 | 0.151 | 205 | 0.074 | 06/06/21 | BBCH 69 - 71 | Seeds | <LOQ | <LOQ | 89 | 57 | |
| BPL21/966/GC-10-PL Wola Kalkowa 99-311 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Medal | 1. 26/08/20 2. 20/05 - 07/06/21 3. 02/08/21 | 0.142 | 290 | 0.049 | 07/06/21 | BBCH 69 | Seeds | <LOQ | <LOQ | 89 | 56 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 150 g a.s./ha of Prothioconazole and 75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503.F.1.A at 1.0 L/ha)

(d) Year must be indicated

(e) Days after last application.

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.1, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(h) Prothioconazole-desthio (sum of isomers) (8.2, enforcement residue definition)

NA Not available

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detectio

Table A 2: Summary of Oilseed Rape study 5 – 8 trials

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, 148 g/L (actual)
Crop/crop group: Oilseed rape / Oilseeds
Country: Hungary, Germany, France (N-EU), Poland

Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): SynTech Research France, La Chapelle de Guinchay, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):
Other active substance in the formulation:
Residues calculated as:

KCA 6.3.3/08

ADM.03503.F.1.A

EC

Fluxapyroxad, 77.4 g/L (actual)

1,2,4-Triazole, Triazolalanin, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|--|---------------------------------|---|--------------------------------|--------------|-------------|--|---|-----------------------------|------------------|------------------|----------------------|----------------------|---------------|------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date (e) | Portion analysed (a) | Residues (mg/kg) | | | | Assessment | | Details on trial(s) (g) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) (f) | |
| BPL21/966/GC -03-HU Csömör 2141 Hungary N-EU 2020/21 | Oilseed rape (BRSNN)/ Hybrirock | 1. 08/09/20 2. 26/04-11/05/21 3. 01 - 08/07/21 | 0.146 | 295 | 0.049 | 11/05/21 | BBCH 69 | Seeds | <LOQ (n.d.) | 0.49 | <LOQ | 0.03 | 89 | 56 | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time: 20 days (sampling to extraction), max. extract storage time (extraction to analysis) |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.50 | <LOQ | 0.03 | 89 | 56 | |
| BPL21/966/GC -04-GE Moosburg an der Isar 85368 Germany N-EU 2021 | Oilseed rape (BRSNN)/ Mirakel | 1. 27/04/21 2. 21 - 30/06/21 3. NA | 0.142 | 241 | 0.059 | 01/07/21 | BBCH 69 - 71 | Seeds | <LOQ (n.d.) | 0.20 | <LOQ | 0.01 | 89 | 55 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.06 | <LOQ (n.d.) | <LOQ | 89 | 55 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--|--|--------------------------------|-----------------|-------------|--|--|--------------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|---------------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date (e) | Portion analysed (a) | Residues (mg/kg) | | | | Assessment | | Details on trial(s) (g) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) (f) | |
| BPL21/966/GC -05-FR La Chapelle de Guinchay France N-EU 2020/21 | Oilseed rape (BRSNN)/ PT242 | 1. 18/09/20 2. 28/03/- 03/05/21 3. 27/07/21 | 0.149 | 253 | 0.059 | 03/05/21 | BBCH 69 | Seeds | <LOQ (n.d.) | 2.2 | 0.03 | 0.17 | 89 | 85 | 2 days for. |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 1.3 | 0.02 | 0.11 | 89 | 85 | Possible instability of the analytes in final sample extracts was automatically levelled out when using the response ratio of analyte to internal standard for quantification. |
| BPL21/966/GC -06-PL Krościna Mała 55-110 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ SY Alibaba | 1. 21/08/20 2. 04 - 28/05/21 3. 24/07/21 | 0.152 | 308 | 0.049 | 26/05/21 | BBCH 69 | Seeds | <LOQ (n.d.) | 0.27 | <LOQ | 0.01 | 89 | 59 | Residues in untreated samples (background levels) were found in a part of samples, and results are given. |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.53 | <LOQ | 0.04 | 89 | 59 | |
| BPL21/966/GC -07-PL Masłowice 98- 300 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Rohan F1 | 1. 04/09/20 2. 02 - 31/05/21 3. 20/07/21 | 0.150 | 305 | 0.049 | 31/05/21 | BBCH 69 | Seeds | <LOQ (n.d.) | 0.49 | <LOQ | 0.02 | 89 | 50 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.39 | <LOQ | 0.02 | 89 | 50 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | 8.2 | 8.3 | 8.4 | 9 | | 10 |
|---|--|--|--------------------------------|-----------------|-------------|--|--|----------------------------|--------------------|---------------------|----------------------------|----------------------------|------------------|-----------------------|--------------------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date (e) | Portion analysed (a) | Residues (mg/kg) | | | | Assessment | | Details on trial(s) (g) |
| | | | kg a.s./ ha (c) | Water (L/ha) | kg a.s./ hL | | | | 1,2,4- triazole | Triazole alanine | Triazole acetic acid | Triazole lactic acid | Timing (BBCH) | DALA (days) (f) | |
| BPL21/966/GC -08-PL Wegorzewo 62-280 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 21/05 - 06/06/21 3. 02/08/21 | 0.150 | 204 | 0.074 | 06/06/21 | BBCH 69 - 71 | Seeds | <LOQ (n.d.) | 0.13 | <LOQ (n.d.) | <LOQ | 89 | 57 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.13 | <LOQ (n.d.) | <LOQ | 89 | 57 | |
| BPL21/966/GC -09-PL Murczyn 88- 400 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ DK Expression | 1. 25/08/20 2. 21/05 - 06/06/21 3. 02/08/21 | 0.151 | 205 | 0.074 | 06/06/21 | BBCH 69 - 71 | Seeds | <LOQ (n.d.) | 0.17 | <LOQ (n.d.) | <LOQ | 89 | 57 | |
| | | | Untreated | | | | | | <LOQ (n.d.) | 0.12 | <LOQ (n.d.) | <LOQ | 89 | 57 | |
| BPL21/966/GC -10-PL Wola Kalkowa 99-311 Poland N-EU 2020/21 | Oilseed rape (BRSNN)/ Medal | 1. 26/08/20 2. 20/05 - 07/06/21 3. 02/08/21 | 0.142 | 290 | 0.049 | 07/06/21 | BBCH 69 | Seeds | <LOQ (n.d.) | 0.16 | <LOQ (n.d.) | <LOQ | 89 | 56 | |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | 0.13 | <LOQ (n.d.) | <LOQ | 89 | 56 | |

(a) According to Codex Classification /Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 150 g a.s./ha of Prothioconazole and 75 g a.s./ha of Fluxapyroxad (equivalent to ADM.03503.F.1.A at 1.0 L/ha)

(d) Year must be indicated

- (e) BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application.
 - (g) Remarks may include: climatic conditions ; reference to analytical method ; information concerning the metabolites included, the method of storage, storage, stability, analysis date.
- n.d. Not detectable
LOQ Limit of quantification
LOD Limit of detection

A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

No new study submitted.

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.1.5.1 Distribution of the residue in peel/pulp

No new study submitted.

A 2.1.5.2 Processing studies on a core set of representative processes

A 2.1.5.2.1 Magnitude of residues in processed commodities study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>For the common triazole derived metabolites resulting from oilseed rape treated with prothioconazole, in both trials no processing factors could be derived for 1,2,4-Triazole as all residues were below the LOQ in the RAC and in the processed fractions and for TA, TAA and TLA in refined oil and crude oil since all residues were below the LOQ in the processed fraction.</p> <p>Processing factors could be derived for TA, TAA and TLA for pressed cake.</p> <p>It should be noted that residues of TDMs were found in control samples. Therefore, for untreated samples of pressed cake and crude oil processing factors could be derived additionally. As processing factors from treated samples of pressed cake exceed those from untreated pressed cake, processing factors from treated pressed cake are considered relevant.</p> <p>Remark:</p> <p>For oilseed rape (seeds, refined oil and crude oil) the maximum storage interval from sampling until extraction was 40 days, for oilseed rape (pressed cake) the maximum storage interval from sampling until extraction was 62 days.</p> <p>It should be noted that the TDMs storage stability for processing commodities has been not demonstrated.</p> |
|-------------------|--|

Reference: KCA 6.5.2/01

Report Residue study of Triazole metabolites in oilseed rape seeds processed fractions after foliar application on the crop of ADM.03503.F.1.A (Prothioconazole and Fluxapyroxad) under field conditions -field trials for processing- Northern and Southern Europe - 2021
Amic, S., 2021
Report no.: BPL21/968/GC, sponsor no.: 000107694

Guideline(s): EC guidance working document SANCO/7029/VI/95 rev. 5 (22/07/1997)
OECD 509, adopted 14 June 2021
OECD 508, adopted 03 October 2008
EC working document, 1607/VI/97, rev. 2, Appendix E, 7035/VI/95, rev.5; Processing studies 22 July 1997
SANTE/2020/12830, Rev.1, 24 February 2021
OECD Series on Testing and Assessment, Number 72, Series on Pesticides, Number 39: Guidance document on pesticide residue analytical methods, OECD Document ENV/JM/MONO(2007)17, Paris, France, 2007

Deviations: None with impact to the study.

GLP: Yes

Acceptability: Yes

Materials and methods

Two field trials located in Northern and Southern Europe (France) were performed to determine residue

levels of triazole metabolites in processed fractions of oilseed rape seeds following one application of ADM.03503.F.1.A (150 g/L prothioconazole and 75 g/L fluxapyroxad) at crop stage BBCH 69 (end of flowering) at the target dose of 2.5 L/ha.

Each trial was comprised of one untreated control plot and one plot treated with ADM.03503.F.1.A. One application was performed at dose rate between 2.31 and 2.49 L/ha of the test item corresponding to a total dose of prothioconazole between 342.54 and 368.78 g/ha. Applications were performed at BBCH 69 (end of flowering).

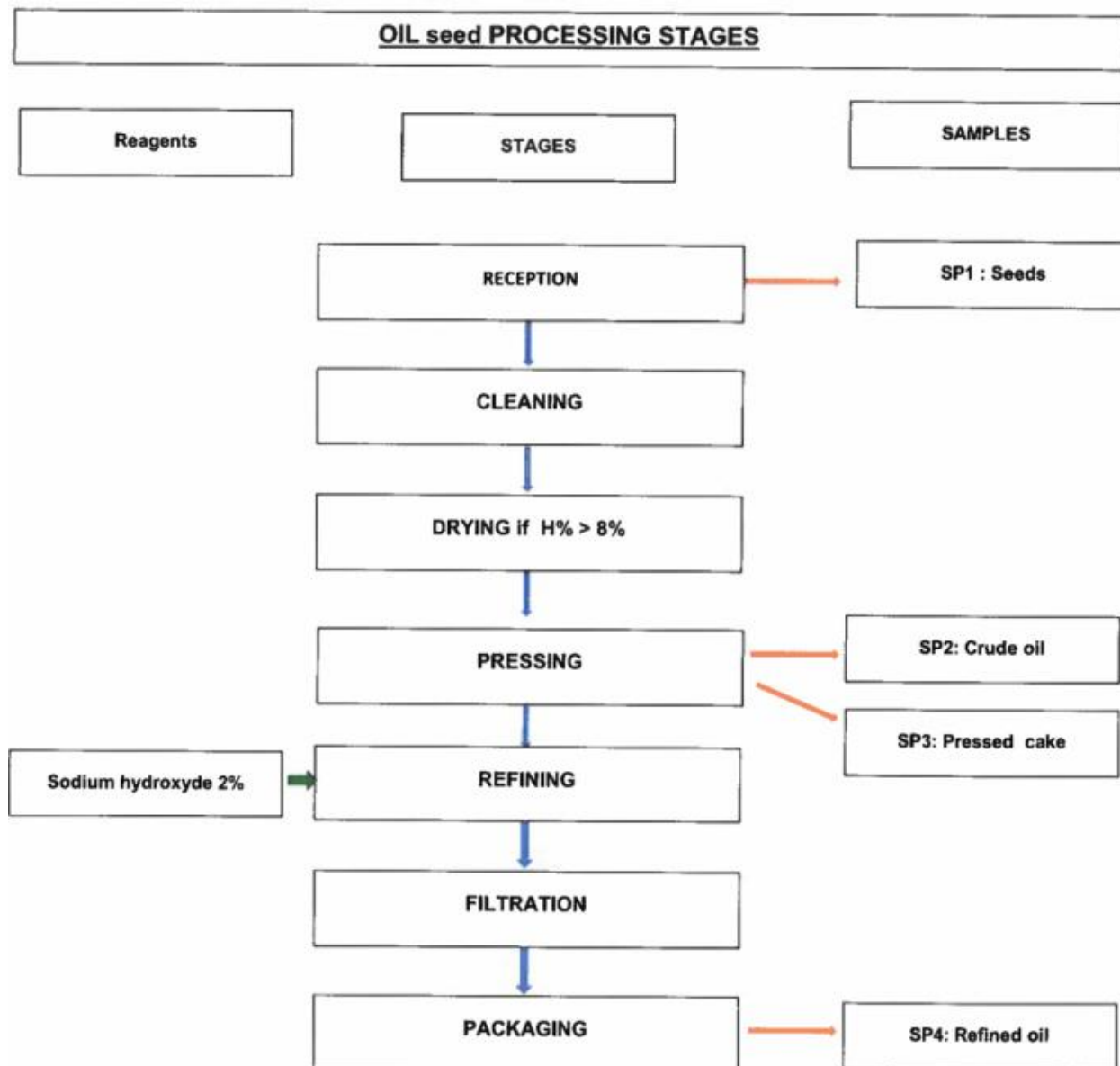
Oilseed rape seeds were collected at harvest (BBCH 89) from the two field trials in order to be processed to crude oil, pressed cake and refined oil.

Two processing procedures were conducted to simulate household and industrial practice at a laboratory scale. The following processed samples were generated:

-Processing of oilseed rape seeds to crude oil and pressed cake: The oil extraction press was preheated at 70 °C (\pm 2°C), when the temperature is reached, the crude oil extraction was started. The seeds were introduced into the container above the oil machine press and the press were rotated at a low speed adapted to the seeds and according to the meal quality at exit. After pressing of the seeds, the oil obtained was the crude oil. This crude oil was let for decantation for 30 min at ambient temperature. After this time, the oil was slowly poured in a fine sieve of 0.5 mm in order to remove large impurities. The pressed cake or meal was collected at exit of the press in an identified bucket and then homogenized manually. The crude oil and the pressed cake were sampled.

-Processing of oilseed rape seeds to refined oil: To neutralise the acid, 2 % of sodium hydroxide of oil was added into the crude oil. After shaking the jar manually to homogenize, the jar was heated in a steam room, at 75°C (\pm 5°C) during 30 min. (saponification). Then, oil was let cool down at ambient temperature until around 30 °C in order to perform the separation by filtration.

Figure A 1: Processing flowchart for RAC



Processed and unprocessed oilseed rape samples were analysed for 1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid according to the analytical method GRM053.01A. The method was validated in studies 000107909³ and R30330⁴. A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2. The LOQ was 0.01 mg/kg for each analyte and each matrix. were extracted from laboratory samples by high speed homogenisation with water and methanol. After filtration, internal standards are added and the extract is concentrated and then diluted in water.

The quantification was performed by addition of internal standard(s) and by use of liquid chromatography with tandem mass spectrometry coupled to differential mobility spectroscopy (LC-DMS-MS/MS) detection.

³ Gustloff, C.: Validation of an Analytical Method for the Determination of Triazole Metabolites (TDMs) in Crop Matrices of Season 2021, study code S21-02262 (MAC-2135V), Sponsor reference: 000107909

⁴ Klimmek S.: Freezing storage stability & validation of residues of 1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid and Triazole Lactic Acid in water, acid and dry matrix: cucumber, grapes and dry bean at 0,3,6,12,18, 24 and 36 months, EAS study code S12-00072, Sponsor reference R30330

Recovery determinations were conducted concurrently in parallel to the analyses of control and treated samples, before and after processing. Residue values were not corrected for the apparent residues in the control samples and the concurrent recoveries.

For oilseed rape (seeds, refined oil and crude oil) the maximum interval from sampling until extraction was 40 days, for oilseed rape (pressed cake) the maximum storage interval from sampling until extraction was 62 days. The storage temperature at the analytical test site was ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction to analysis

Results and discussions

All mean recovery values at fortification levels of 0.01 mg/kg and 0.1 mg/kg and 3.2 mg/kg comply with the standard acceptance criteria of the guidance document SANTE/2020/12830, rev.1. The following table gives an overview of the procedural recoveries for the determination of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in oilseed rape seeds and processed fractions.

The results of 1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid in oilseed rape seeds and in the processed fractions are summarised thereafter.

Table A 39: Procedural recoveries for the determination of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in oilseed rape seeds and processed fractions

| Matrix/Analyte | Fortification level (mg/kg) | No. of replicates | Recovery | | SD |
|-----------------------------------|-----------------------------|-------------------|-------------------------|----------|-----|
| | | | Recovery (%) | Mean (%) | |
| Oilseed rape seeds | | | | | |
| 1,2,4-triazole (m/z 70/43) | 0.01 | 4 | 92, 112, 114, 85 | 101 | 15 |
| | 0.1 | 4 | 88, 87, 82, 97 | 88 | 7.1 |
| Triazole alanine (m/z 157/70) | 0.01 | 5 | 92, 82, 101, 121, 100 | 99 | 15 |
| | 0.1 | 4 | 90, 87, 94, 105 | 94 | 8.4 |
| | 3.2 | 1 | 95 | - | - |
| Triazole acetic acid (m/z 128/70) | 0.01 | 4 | 102, 107, 119, 115 | 111 | 7.2 |
| | 0.1 | 4 | 98, 101, 98, 100 | 99 | 1.2 |
| Triazole lactic acid (m/z 158/70) | 0.1 | 5 | 91, 93, 98, 88, 110 | 96 | 9.3 |
| | 0.1 | 4 | 85, 79, 90, 110 | 91 | 15 |
| | 3.2 | 1 | 99 | - | - |
| Oilseed rape crude oil | | | | | |
| 1,2,4-triazole (m/z 70/43) | 0.01 | 4 | 115, 115, 86, 84 | 100 | 18 |
| | 0.1 | 4 | 109, 105, 98, 101 | 103 | 4.8 |
| Triazole alanine (m/z 157/70) | 0.01 | 5 | 115, 109, 123, 110, 114 | 114 | 4.8 |
| | 0.1 | 4 | 113, 103, 100, 105 | 105 | 5.4 |
| | 3.2 | 1 | 108 | - | - |
| Triazole acetic acid (m/z 128/70) | 0.01 | 4 | 108, 109, 119, 110 | 111 | 4.3 |
| | 0.1 | 4 | 102, 105, 106, 112 | 106 | 4.1 |
| Triazole lactic acid (m/z 158/70) | 0.1 | 5 | 115, 111, 118, 118, 117 | 116 | 2.7 |
| | 0.1 | 4 | 103, 102, 111, 111 | 107 | 4.6 |
| | 3.2 | 1 | 104 | - | - |
| Oilseed rape refined oil | | | | | |
| 1,2,4-triazole (m/z 70/43) | 0.01 | 4 | 108, 119, 86, 105 | 105 | 13 |
| | 0.1 | 4 | 113, 107, 118, 98 | 109 | 7.8 |
| Triazole alanine (m/z 157/70) | 0.01 | 4 | 104, 113, 115, 110 | 111 | 4.3 |
| | 0.1 | 4 | 111, 112, 108, 107 | 109 | 2.4 |
| Triazole acetic acid (m/z 128/70) | 0.01 | 4 | 111, 117, 119, 118 | 116 | 3.1 |
| | 0.1 | 4 | 106, 105, 109, 109 | 107 | 1.9 |
| Triazole lactic acid (m/z 158/70) | 0.1 | 4 | 110, 113, 105, 120 | 112 | 5.4 |
| | 0.1 | 4 | 104, 110, 101, 109 | 106 | 3.9 |
| Oilseed rape pressed cake | | | | | |
| 1,2,4-triazole (m/z 70/43) | 0.01 | 4 | 99, 111, 115, 121 | 111 | 8.6 |
| | 0.1 | 4 | 93, 95, 100, 114 | 101 | 9.3 |
| Triazole alanine (m/z 157/70) | 0.01 | 5 | 104, 92, 98, 104, 99 | 99 | 5.0 |
| | 0.1 | 4 | 76, 89, 85, 95 | 86 | 8.9 |
| | 3.2 | 1 | 80 | - | - |
| Triazole acetic acid (m/z 128/70) | 0.01 | 4 | 111, 113, 125, 110 | 114 | 6.0 |
| | 0.1 | 4 | 103, 99, 107, 105 | 104 | 3.3 |
| Triazole lactic acid (m/z 158/70) | 0.1 | 5 | 107, 79, 96, 100, 117 | 100 | 14 |
| | 0.1 | 4 | 77, 91, 115, 111 | 98 | 18 |
| | 3.2 | 1 | 95 | - | - |

SD = Standard deviation

Table A 40: Summary of magnitude of residues in processed commodities study 1

Crop residue data from supervised field trials

| | |
|--|-------------------------------------|
| Active ingredient (common name and content): | Prothioconazole, 148.2 g/L (actual) |
|--|-------------------------------------|

Crop/crop group: Oilseed rape / Oilseeds

Country: France (S-EU, N-EU)

Indoor/outdoor: Outdoor

Responsible body for reporting (name, address): BIOTEK Agriculture, Saint-Pouange, France

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.5.2/01

ADM.3503.F.1.A

EC

Fluxapyroxad (77.4 g/L actual)

1,2,4-Triazole, Triazolalanin, Triazole acetic acid, Triazole lactic acid (mg/kg)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | 8.2 | | 8.3 | | 8.4 | | 9 | 10 |
|---|--------------------------------------|--|-----------------------------------|-----------------|----------------|---|--|---|--|------------------|--|---------------------|--|---------------------|--|---------------------|---------------------------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodi ty/ Variety | Date of 1.Sowing or planting 2.Floweri ng 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | | | | | Assess ment | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | | Triazole alanine | | Triazole acetic acid | | Triazole lactic acid | | DAL A (days) | |
| | | | | | | | | | | PF | | PF | | PF | | PF | | (f) |
| BPL21/96 6/GC-01- FR 71570 La Chapelle de Guinvhay France N-EU 2020/21 | Oilseed rape (BRSNN)/ PT242 | 1. 18/09/20 2. 28/03/ - 03/05/21 3. 27/07/21 | 0.369 | 252 | 0.147 | 03/05/21 | BBCH 69 | Seeds Crude oil Pressed cake Refined oil | <LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.) <LOQ (n.d.) | # # # # | 1.4 <LOQ 1.9 <LOQ | - # 1.36 # | 0.01 <LOQ (n.d.) 0.02 <LOQ (n.d.) | - # 2.00 # | 0.06 <LOQ (n.d.) 0.09 <LOQ (n.d.) | - # 1.50 # | 85** 88* 88* 88* | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte. LOD: 0.003 mg/kg for each analyte Max. sample storage time: 62 days (sampling to extraction), max. extract storage time |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | 8.2 | | 8.3 | | 8.4 | | 9 | 10 |
|---|---------------------------|--|-----------------------------------|-----------------|----------------|---|--|---------------------|------------------|----|---------------------|------|-------------------------|------|-------------------------|------|--------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodi ty/ Variety | Date of 1.Sowing or planting 2.Floweri ng 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | | | | | Assess ment | Details on trial(s) |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | | Triazole alanine | | Triazole acetic acid | | Triazole lactic acid | | DAL A (days) | |
| | | | | | | | | | | PF | | PF | | PF | | PF | | |
| | (a) | (b) | (c) | | | (d) | (e) | (a) | | PF | | PF | | PF | | PF | (f) | (g) |
| | | | Untreated | | | | | Seeds | <LOQ (n.d.) | # | 1.1 | - | 0.02 | - | 0.11 | - | 85** | (extraction to analysis) 1 day. |
| | | | | | | | | Crude oil | <LOQ (n.d.) | # | <LOQ | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | 87* | Residues in untreated samples were determined (present). |
| | | | | | | | | Pressed cake | <LOQ (n.d.) | # | 1.73 | 1.00 | 0.02 | 1.00 | 0.15 | 1.36 | 87* | *interval between last application and specimen sampling after processing |
| | | | | | | | | Refined oil | <LOQ (n.d.) | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | 87* | **interval between last application and sampling of the field specimens |

(a) According to Codex classification / Guide should be used

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 375 g a.s./ha prothioconazole, 187.5 g a.s./ha fluxapyroxad equivalent to ADM.03503.F.1.A at 2.5 L/ha)

(d) Year must be indicated

(e) Growth stages of mono- and dicotyledonous plants – BBCH Monograph – 2. Edition, 2001 – Edited by Uwe Meier

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

* Interval between last application and specimen sampling after processing

** Interval between last application and sampling of the field specimens

No processing factor can be calculated as the residue in processed fraction was <LOQ

PF Processing factor (PF=Residue level in processed commodity/ Residue level in the seeds specimen before processing)

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8.1 | | 8.2 | | 8.3 | | 8.4 | | 9 | 10 | |
|---|--|--|-----------------------------------|-----------------|----------------|---|--|---------------------|------------------|----------------|---------------------|----------------|-------------------------|----------------|-------------------------|----------------|--------------------|---|------|
| Trial No./ Location/ EU zone/ Year | Commodi ty/ Variety | Date of 1.Sowing or planting 2.Floweri ng 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatment s and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | | | | | | | Assess ment | Details on trial(s) | |
| | | | kg a.s./ ha | Water (L/ha) | kg a.s./ hL | | | | 1,2,4-triazole | | Triazole alanine | | Triazole acetic acid | | Triazole lactic acid | | DAL A (days) | | |
| | | | | | | | | | | PF | | PF | | PF | | PF | | | (f) |
| BPL21/96 6/GC-02- FR 447370 St. Georges France S-EU 2021 | Oilseed rape (BRSNN)/ ES Saoker CL | 1. 03/03/21 2. 14/05/ - 08/06/21 3. 18/08/21 | 0.343 | 185 | 0.185 | 08/06/19 | BBCH 69 | Seeds | <LOQ (n.d.) | # | 0.52 | - | <LOQ (n.d.) | - | 0.04 | - | 71** | Analytical methods: GRM053.01A, LC-DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte. LOD: 0.003 mg/kg for each analyte Max. sample storage time: 62 days (sampling to extraction), max. extract storage time (extraction to analysis) 1 day. Residues in untreated samples were determined (present). *interval between last application and specimen sampling after processing **interval between last application and sampling of the field specimens | |
| | | | | | | | | | Crude oil | <LOQ (n.d.) | # | <LOQ | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | | 92* |
| | | | | | | | | | Pressed cake | <LOQ (n.d.) | # | 0.62 | 1.19 | <LOQ (n.d.) | # | <LOQ (n.d.) | # | | 92* |
| | | | | | | | | | Refined oil | <LOQ (n.d.) | # | <LOQ | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | | 92* |
| | | | Untreated | | | | | | Seeds | <LOQ (n.d.) | # | 0.19 | - | <LOQ | - | 0.02 | - | | 71** |
| | | | | | | | | | Crude oil | <LOQ (n.d.) | # | 0.21 | 1.11 | <LOQ | # | 0.02 | 1.00 | | 91* |
| | | | | | | | | | Pressed cake | <LOQ (n.d.) | # | 0.18 | 0.95 | <LOQ | # | 0.01 | 0.05 | | 91* |
| | | | | | | | | | Refined oil | <LOQ (n.d.) | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | <LOQ (n.d.) | # | | 91* |

(a) According to Codex classification / Guide should be used

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Dose rate targeted was 375 g a.s./ha prothioconazole, 187.5 g a.s./ha fluxapyroxad equivalent to ADM.03503.F.1.A at 2.5 L/ha)

(d) Year must be indicated

(e) Growth stages of mono- and dicotyledonous plants – BBCH Monograph – 2. Edition, 2001 – Edited by Uwe Meier

(f) Minimum number of days after last application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: climatic conditions; reference to analytical method; information concerning the metabolites included, the method of storage, storage, stability, analysis date.

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

- * Interval between last application and specimen sampling after processing
- ** Interval between last application and sampling of the field specimens
- # No processing factor can be calculated as the residue in processed fraction was <LOQ
- PF Processing factor ($PF = \text{Residue level in processed commodity} / \text{Residue level in the seeds specimen before processing}$)

Table A 41: Processing factors per trial

| Sample type | Plot | Processing factors | | | | | | | | | |
|--------------|---------|--------------------------|-------------|-----------------------|-------------|---------|----------------------------|-------------|----------------------------|-------------|---------|
| | | 1,2,4-triazole (1,2,4-T) | | Triazole alanine (TA) | | | Triazole acetic acid (TAA) | | Triazole lactic acid (TLA) | | |
| | | Trial 01-FR | Trial 02-FR | Trial 01-FR | Trial 02-FR | Mean PF | Trial 01-FR | Trial 02-FR | Trial 01-FR | Trial 02-FR | Mean PF |
| Crude oil | Treated | -* | -* | -* | -* | - | -* | -* | -* | -* | - |
| | Control | -* | -* | 1.11 | -* | - | -* | -* | -* | 1.00 | - |
| Pressed cake | Treated | -* | -* | 1.36 | 1.19 | 1.3 | 2.00 | -* | 1.50 | -* | - |
| | Control | -* | -* | 1.73 | 0.95 | 1.3 | 1.00 | -* | 1.36 | 0.50 | 0.9 |
| Refined oil | Treated | -* | -* | -* | -* | - | -* | -* | -* | -* | - |
| | Control | -* | -* | -* | -* | - | -* | -* | -* | -* | - |

* No processing factor can be calculated as the residue in process fraction was <LOQ. The processing factors are calculated using rounded values

No processing factors could be calculated at all for 1,2,4-Triazole as no residues were detected in the seeds and processing fractions.

In both trials processing factors could be derived for TA, TAA and TLA for pressed cake. In refined oil and crude oil no processing factor could be derived from treated samples since all residues were below the limit of quantification in the processed fraction. However, in control samples for crude oil residues of TA and TLA were found and thus, a processing factor could be additionally obtained from untreated samples for these metabolites. Due to the widespread occurrence of the analytes in matrices of plant origin, residues are often found in control samples. The background level of the analytes in the chosen control material were considered to be unavoidable.

Conclusion

In order to determine processing factors for triazole metabolites (1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid) from oilseed rape seeds, crude oil, pressed cake and refined oil, two processing studies have been conducted.

In both trials, except for pressed cake, no processing factors could be derived from treated samples since all residues were below the limit of quantification in the processed fractions.

However, due to the widespread occurrence of the analytes in matrices of plant origin, residues were found in control samples. The background levels of the analytes in the chosen control material were considered to be unavoidable. Therefore, for untreated samples of pressed cake and crude oil processing factors could be derived additionally. As processing factors from treated samples of pressed cake exceed those from untreated pressed cake, processing factors from treated pressed cake are considered relevant.

A 2.1.6 Magnitude of residues in representative succeeding crops

A 2.1.6.1 Magnitude of residues in representative succeeding crops 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>The study (contained four rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L) with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) on bare soil.</p> <p>Methods were validated according to SANCO/3029/99, rev. 4. Quantification was performed by use of LC-MS/MS detection for all analytes and matrices. The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg for each analyte and each matrix The mean recoveries at each fortification level were in the range of 70 – 120% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p><u>Results:</u> <u>Prothioconazole</u> At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.</p> <p><u>TDMs</u> Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.</p> <p><u>Remark:</u> It should be noted that the sample storage period for 1,2,4-T (444-539 days) exceeded the maximum storage stability demonstrated for 1,2,4-T in high water commodities (6 months) and cereal grains and straws (12 months). To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study (Semrau, 2022; Report No. S21-00408, ADAMA No. 000107470) was conducted to verify the no residue situation observed for 1,2,4-T (see below, point A 2.1.6.2)</p> <p>The study is acceptable.</p> |
|-------------------|--|

| | |
|---------------|--|
| Reference: | KCA 6.6.2/01 |
| Report: | Determination of Residues of Prothioconazole and its Metabolites after One Application of MCW-2073 on Bare Soil in Rotational Crops (Radish, Leaf lettuce and Barley) at 2 Sites in Northern Europe and 2 Sites in Southern Europe 2018/2019 Semrau, J., 2021 Study no.: S18-02513, sponsor no.: R-39638 |
| Guideline(s): | OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32); OECD Test Guideline 509: Crop field trials; |

OECD (2016) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66);
EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials;
OECD Test Guideline 504: Residues in rotational crops (limited field studies);
EU Guidance Document SANCO/3029/99 rev. 4 for generating and reporting methods of analysis in support of pre-registration data requirements

| | |
|----------------|---------------------------------------|
| Deviations: | None with impact on the study results |
| GLP: | Yes |
| Acceptability: | Yes |

Executive summary

The aim of the study was to determine residues of prothioconazole (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio (sum of isomers)), as well as of triazole derivative metabolites (TDMs) (1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of MCW-2073 on bare soil at three plant back intervals of nominal 30-3, 120±5 and 270±10 days. In addition, samples of soil were analysed for residues of prothioconazole-desthio. Four trials were carried out in Poland (2x, N-EU residue zone), Southern France and Italy (S-EU residue zone) in 2018-2019.

Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 75 and at normal commercial harvest. Samples of barley taken at BBCH 75 were sampled manually while barley grain and straw samples were obtained by mechanical threshing. Samples of soil cores were taken directly after application (except trial -03 where control samples of sampling 2 were taken before application) and directly before planting for each plant back interval from the untreated and respective treated plots.

Residues of prothioconazole except TDMs

No residues of analytes at or above the LOD were detected in any of the untreated samples of soil. The following residues were detected in the treated soil samples:

Table A 42: Residues of prothioconazole-desthio in soil

| Sampling Point | Timing (nominal) | Plot No. | PBI (days) | Sample Code | EAS (Chem) Internal code | Sample Type | Residue of PTZ-desthio (mg/kg) |
|--------------------------------------|------------------|----------|------------|-------------|--------------------------|-------------|--------------------------------|
| Trial S18-02513-01 (Poland) | | | | | | | |
| S1 | 0 DAA1 | 4 | 272 | -036A | 2 | soil | <0.01 |
| S2 | 0 DAA2 | 3 | 117 | -004A | 4 | soil | 0.022 |
| S3 | 0 DAA3 | 2 | 28 | -006A | 6 | soil | <0.01 |
| S4 | 0(-1) DBP | 2 | 28 | -008A | 8 | soil | 0.016 |
| | | 3 | 117 | -009A | 9 | soil | <0.01 |
| | | 4 | 272 | -010A | 10 | soil | <0.01 |
| Trial S18-02513-02 (Poland) | | | | | | | |
| S1 | 0 DAA1 | 4 | 273 | -036A | 102 | soil | <0.01 |
| S2 | 0 DAA2 | 3 | 119 | -004A | 104 | soil | 0.015 |
| S3 | 0 DAA3 | 2 | 28 | -006A | 106 | soil | <0.01 |
| S4 | 0(-1) DBP | 2 | 28 | -008A | 108 | soil | <0.01 |
| | | 3 | 119 | -009A | 109 | soil | <0.01 |
| | | 4 | 273 | -010A | 110 | soil | <0.01 |
| Trial S18-02513-03 (Southern France) | | | | | | | |
| S1 | 0 DAA1 | 4 | 266 | -036A | 202 | soil | 0.015 |
| S2 | 0 DAA2 | 3 | 125 | -004A | 204 | soil | 0.011 |
| S3 | 0 DAA3 | 2 | 34 | -006A | 206 | soil | 0.013 |
| S4 | 0(-1) DBP | 2 | 34 | -008A | 208 | soil | 0.019 |
| | | 3 | 125 | -009A | 209 | soil | <0.01 |
| | | 4 | 266 | -010A | 210 | soil | <0.01 |
| Trial S18-02513-04 (Italy) | | | | | | | |
| S1 | 0 DAA1 | 5 | 274 | -002A | 302 | soil | <0.01 |
| S2 | 0 DAA2 | 4 | 120 | -004A | 304 | soil | 0.010 |
| S3 | 0 DAA3 | 3 | 30 | -006A | 306 | soil | 0.016 |
| S4 | 0(-1) DBP | 3 | 30 | -008A | 308 | soil | 0.049 |
| | | 4 | 120 | -009A | 309 | soil | <0.01 |
| | | 5 | 274 | -010A | 310 | soil | 0.013 |

DAA = days after last application; DBP = days before planting; 2, 3, 4, 5 = treated; U1= untreated

Residues are not corrected for procedural recoveries. Residues are given as “dry matter”, i.e. corrected for their moisture content

No residues of analytes at or above the LOD were detected in any of the untreated samples of plant matrices. The following residues were detected in the treated samples of plant matrices:

Residues of prothioconazole (except TDMs) in plant matrices

[illegible]

| Sampling Point | Timing (nominal) | Plot No. | Sample Code | Nominal PBI (days) | EAS (Chem) Internal code | Sample Type | Residue of PTZ-desthio (mg/kg) | Residue of 3-OH-PTZ-desthio* (mg/kg) | Residue of 4-OH-PTZ-desthio* (mg/kg) | Residue of 5-OH-PTZ-desthio* (mg/kg) | Residue of 6-OH-PTZ-desthio* (mg/kg) | Residue of alpha-OH-PTZ-desthio* (mg/kg) | Sum of residues of PTZ-desthio isomers** (mg/kg) |
|-----------------------------|------------------|----------|-------------|--------------------|--------------------------|--------------------|--------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|--|
| Trial S18-02513-02 (Poland) | | | | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | 2 | -013A | 28 | 113 | radish leaves | 0.015 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 2 | -014A | 28 | 114 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -015A | 119 | 115 | radish leaves | 0.018 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.06 |
| | | 3 | -016A | 119 | 116 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -017A | 273 | 117 | radish leaves | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -018A | 273 | 118 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S6 | BBCH 49 (NCH) | 2 | -020A | 28 | 120 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -021A | 119 | 121 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -022A | 273 | 122 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S7 | BBCH 75 (NCH) | 2 | -024A | 28 | 124 | barley whole plant | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -025A | 119 | 125 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -026A | 273 | 126 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S8 | BBCH 89 (NCH) | 2 | -029A | 28 | 129 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 2 | -030A | 28 | 130 | barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -031A | 119 | 131 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -032A | 119 | 132 | barley straw | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -033A | 273 | 133 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -034A | 273 | 134 | barley straw | <0.01 | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |

[illegible]

| Sampling Point | Timing (nominal) | Plot No. | Sample Code | Nominal PBI (days) | EAS (Chem) Internal code | Sample Type | Residue of PTZ-desthio (mg/kg) | Residue of 3-OH-PTZ-desthio* (mg/kg) | Residue of 4-OH-PTZ-desthio* (mg/kg) | Residue of 5-OH-PTZ-desthio* (mg/kg) | Residue of 6-OH-PTZ-desthio* (mg/kg) | Residue of alpha-OH-PTZ-desthio* (mg/kg) | Sum of residues of PTZ-desthio isomers** (mg/kg) |
|----------------------------|------------------|----------|-------------|--------------------|--------------------------|--------------------|--------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--------------------------------------|--|--|
| Trial S18-02513-04 (Italy) | | | | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | 6 | -013A | 30 | 313 | radish leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 6 | -014A | 30 | 314 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 7 | -015A | 120 | 315 | radish leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 7 | -016A | 120 | 316 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 8 | -017A | 272 | 317 | radish leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 8 | -018A | 272 | 318 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S6 | BBCH 49 (NCH) | 6 | -020A | 30 | 320 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 7 | -021A | 120 | 321 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 8 | -022A | 272 | 322 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S7 | BBCH 75 (NCH) | 3 | -024A | 30 | 324 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -025A | 120 | 325 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 5 | -026A | 274 | 326 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| S8 | BBCH 89 (NCH) | 3 | -029A | 30 | 329 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 3 | -030A | 30 | 330 | barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -031A | 120 | 331 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 4 | -032A | 120 | 332 | barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 5 | -033A | 274 | 333 | barley grain | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |
| | | 5 | -034A | 274 | 334 | barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.018 n.d. |

NCH = normal commercial harvest; 3, 4, 5, 6, 7, 8 = treated; U1= untreated; n.d. not detected (below LOD, set at 30 % of LOQ)

Residues are not corrected for procedural recoveries

* expressed as prothioconazole-desthio

** Sum of isomers: PTZ-desthio; 3-hydroxy-PTZ-desthio; 4-hydroxy-PTZ-desthio; 5-hydroxy-PTZ-desthio; 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio; with an LOQ of 0.06 mg/kg and an LOD of 0.018 mg/kg.

Residues of TDMs

The following residues were detected in the untreated and treated samples:

Table A 44: Residues of TDMs in plant matrices

| Residues of FENs in plant matrices | | | | | | | | | | |
|------------------------------------|------------------|----------|------------|-------------|------------------------|--------------------|------------------------|--------------------------|------------------------------|------------------------------|
| Sampling Point | Timing (nominal) | Plot No. | PBI (days) | Sample Code | EAS Chem Internal code | Sample Type | 1,2,4-Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
| Trial S18-02513-01 (Poland) | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | U1 | -- | -011A | 11 | radish leaves | < 0.01 | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | U1 | -- | -012A | 12 | radish roots | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | 2 | 28 | -013A | 13 | radish leaves | < 0.01 | 0.05 | < 0.003 n.d. | < 0.01 |
| | | 2 | 28 | -014A | 14 | radish roots | < 0.003 n.d. | 0.04 | < 0.003 n.d. | < 0.003 n.d. |
| | | 3 | 117 | -015A | 15 | radish leaves | < 0.01 | 0.06 | < 0.003 n.d. | < 0.01 |
| | | 3 | 117 | -016A | 16 | radish roots | < 0.003 n.d. | 0.04 | < 0.003 n.d. | < 0.003 n.d. |
| | | 4 | 272 | -017A | 17 | radish leaves | < 0.003 n.d. | 0.07 | < 0.003 n.d. | 0.02 |
| | | 4 | 272 | -018A | 18 | radish roots | < 0.003 n.d. | 0.05 | < 0.003 n.d. | < 0.003 n.d. |
| S6 | BBCH 49 (NCH) | U1 | -- | -019A | 19 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.01 |
| | | 2 | 28 | -020A | 20 | lettuce leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.04 |
| | | 3 | 117 | -021A | 21 | lettuce leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.04 |
| | | 4 | 272 | -022A | 22 | lettuce leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.04 |
| S7 | BBCH 75 (NCH) | U1 | -- | -023A | 23 | barley whole plant | < 0.003 n.d. | 0.01 | < 0.01 | <0.01 |
| | | 2 | 28 | -024A | 24 | barley whole plant | < 0.003 n.d. | 0.04 | 0.04 | 0.06 |
| | | 3 | 117 | -025A | 25 | barley whole plant | < 0.003 n.d. | 0.04 | 0.03 | 0.07 |
| | | 4 | 272 | -026A | 26 | barley whole plant | < 0.01 | 0.04 | 0.04 | 0.08 |
| S8 | BBCH 89 (NCH) | U1 | -- | -027A | 27 | barley grain | < 0.003 n.d. | 0.13 | 0.02 | < 0.003 n.d. |
| | | U1 | -- | -028A | 28 | barley straw | < 0.003 n.d. | < 0.01 | < 0.01 | 0.01 |
| | | 2 | 28 | -029A | 29 | barley grain | < 0.003 n.d. | 0.17 | 0.10 | < 0.003 n.d. |
| | | 2 | 28 | -030A | 30 | barley straw | < 0.003 n.d. | 0.03 | 0.05 | 0.06 |
| | | 3 | 117 | -031A | 31 | barley grain | < 0.003 n.d. | 0.18 | 0.10 | < 0.01 |
| | | 3 | 117 | -032A | 32 | barley straw | < 0.003 n.d. | 0.03 | 0.04 | 0.06 |
| | | 4 | 272 | -033A | 33 | barley grain | < 0.003 n.d. | 0.15 | 0.09 | < 0.01 |
| | | 4 | 272 | -034A | 34 | barley straw | < 0.003 n.d. | 0.03 | 0.04 | 0.05 |
| Trial S18-02513-02 (Poland) | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | U1 | -- | -011A | 11 | radish leaves | < 0.003 n.d. | 0.05 | < 0.003 n.d. | 0.01 |

| Sampling Point | Timing (nominal) | Plot No. | PBI (days) | Sample Code | EAS Chem Internal code | Sample Type | 1,2,4-Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
|--------------------------------------|------------------|----------|------------|-------------|------------------------|--------------------|------------------------|--------------------------|------------------------------|------------------------------|
| | | U1 | -- | -012A | 12 | radish roots | < 0.003 n.d. | 0.02 | < 0.003 n.d. | < 0.003 n.d. |
| | | 2 | 28 | -013A | 13 | radish leaves | < 0.01 | 0.27 | < 0.01 | 0.13 |
| | | 2 | 28 | -014A | 14 | radish roots | < 0.003 n.d. | 0.12 | < 0.003 n.d. | 0.02 |
| | | 3 | 119 | -015A | 15 | radish leaves | < 0.003 n.d. | 0.10 | < 0.003 n.d. | 0.05 |
| | | 3 | 119 | -016A | 16 | radish roots | < 0.003 n.d. | 0.04 | < 0.003 n.d. | < 0.01 |
| | | 4 | 273 | -017A | 17 | radish leaves | < 0.01 | 0.12 | < 0.003 n.d. | 0.05 |
| | | 4 | 273 | -018A | 18 | radish roots | < 0.003 n.d. | 0.07 | < 0.003 n.d. | < 0.01 |
| S6 | BBCH 49 (NCH) | U1 | -- | -019A | 19 | lettuce leaves | < 0.01 n.d. | < 0.01 | < 0.003 n.d. | 0.03 |
| | | 2 | 28 | -020A | 20 | lettuce leaves | < 0.003 n.d. | 0.03 | < 0.01 | 0.19 |
| | | 3 | 119 | -021A | 21 | lettuce leaves | < 0.01 n.d. | 0.01 | < 0.003 n.d. | 0.12 |
| | | 4 | 273 | -022A | 22 | lettuce leaves | < 0.003 n.d. | 0.01 | < 0.003 n.d. | 0.09 |
| S7 | BBCH 75 (NCH) | U1 | -- | -023A | 23 | barley whole plant | < 0.003 n.d. | 0.04 | 0.03 | 0.04 |
| | | 2 | 28 | -024A | 24 | barley whole plant | < 0.003 n.d. | 0.11 | 0.19 | 0.25 |
| | | 3 | 119 | -025A | 25 | barley whole plant | < 0.003 n.d. | 0.07 | 0.15 | 0.27 |
| | | 4 | 273 | -026A | 26 | barley whole plant | < 0.01 | 0.06 | 0.08 | 0.11 |
| S8 | BBCH 89 (NCH) | U1 | -- | -027A | 27 | barley grain | < 0.003 n.d. | 0.11 | 0.07 | < 0.003 n.d. |
| | | U1 | -- | -028A | 28 | barley straw | < 0.003 n.d. | 0.02 | 0.08 | 0.08 |
| | | 2 | 28 | -029A | 29 | barley grain | < 0.003 n.d. | 0.41 | 0.55 | 0.01 |
| | | 2 | 28 | -030A | 30 | barley straw | < 0.01 | 0.04 | 0.40 | 0.45 |
| | | 3 | 119 | -031A | 31 | barley grain | <0.01 | 0.28 | 0.29 | 0.01 |
| | | 3 | 119 | -032A | 32 | barley straw | < 0.01 | 0.05 | 0.24 | 0.20 |
| | | 4 | 273 | -033A | 33 | barley grain | < 0.003 n.d. | 0.16 | 0.20 | < 0.01 |
| | | 4 | 273 | -034A | 34 | barley straw | < 0.003 n.d. | 0.04 | 0.20 | 0.15 |
| Trial S18-02513-03 (Southern France) | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | U1 | -- | -011A | 11 | radish leaves | < 0.01 | < 0.01 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | U1 | -- | -012A | 12 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | 2 | 34 | -013A | 13 | radish leaves | < 0.01 | 0.18 | < 0.003 n.d. | 0.01 |
| | | 2 | 34 | -014A | 14 | radish roots | < 0.003 n.d. | 0.04 | < 0.003 n.d. | 0.02 |
| | | 3 | 125 | -015A | 15 | radish leaves | < 0.01 | 0.14 | < 0.003 n.d. | 0.02 |
| | | 3 | 125 | -016A | 16 | radish roots | < 0.003 n.d. | 0.05 | < 0.003 n.d. | 0.02 |

| Sampling Point | Timing (nominal) | Plot No. | PBI (days) | Sample Code | EAS Chem Internal code | Sample Type | 1,2,4-Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
|----------------------------|------------------|----------|------------|-------------|------------------------|--------------------|------------------------|--------------------------|------------------------------|------------------------------|
| | | 4 | 266 | -017A | 17 | radish leaves | < 0.01 | 0.22 | < 0.003 n.d. | 0.02 |
| | | 4 | 266 | -018A | 18 | radish roots | < 0.003 n.d. | 0.07 | < 0.01 | 0.02 |
| S6 | BBCH 49 (NCH) | U1 | -- | -019A | 19 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.01 |
| | | 2 | 34 | -020A | 20 | lettuce leaves | < 0.003 n.d. | 0.02 | < 0.003 n.d. | 0.10 |
| | | 3 | 125 | -021A | 21 | lettuce leaves | < 0.003 n.d. | 0.02 | < 0.003 n.d. | 0.10 |
| | | 4 | 266 | -022A | 22 | lettuce leaves | < 0.003 n.d. | 0.02 | < 0.003 n.d. | 0.10 |
| S7 | BBCH 75 (NCH) | U1 | -- | -023A | 23 | barley whole plant | < 0.003 n.d. | < 0.01 | < 0.01 | 0.01 |
| | | 2 | 34 | -024A | 24 | barley whole plant | < 0.003 n.d. | 0.10 | 0.15 | 0.17 |
| | | 3 | 125 | -025A | 25 | barley whole plant | < 0.003 n.d. | 0.05 | 0.08 | 0.10 |
| | | 4 | 266 | -026A | 26 | barley whole plant | < 0.003 n.d. | 0.11 | 0.15 | 0.16 |
| S8 | BBCH 89 (NCH) | U1 | -- | -027A | 27 | barley grain | < 0.003 n.d. | 0.02 | 0.02 | < 0.003 n.d. |
| | | U1 | -- | -028A | 28 | barley straw | < 0.003 n.d. | < 0.003 n.d. | 0.02 | 0.02 |
| | | 2 | 34 | -029A | 29 | barley grain | < 0.003 n.d. | 0.28 | 0.33 | 0.01 |
| | | 2 | 34 | -030A | 30 | barley straw | < 0.003 n.d. | 0.03 | 0.22 | 0.28 |
| | | 3 | 125 | -031A | 31 | barley grain | < 0.003 n.d. | 0.21 | 0.28 | 0.01 |
| | | 3 | 125 | -032A | 32 | barley straw | < 0.003 n.d. | 0.01 | 0.14 | 0.21 |
| | | 4 | 266 | -033A | 33 | barley grain | < 0.003 n.d. | 0.28 | 0.32 | 0.02 |
| | | 4 | 266 | -034A | 34 | barley straw | < 0.003 n.d. | 0.02 | 0.17 | 0.27 |
| Trial S18-02513-04 (Italy) | | | | | | | | | | |
| S5 | BBCH 49 (NCH) | U2 | -- | -011A | 11 | radish leaves | < 0.01 | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | U2 | -- | -012A | 12 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | 6 | 30 | -013A | 13 | radish leaves | < 0.01 | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | 6 | 30 | -014A | 14 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | 7 | 120 | -015A | 15 | radish leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | 7 | 120 | -016A | 16 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | 8 | 272 | -017A | 17 | radish leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | 8 | 272 | -018A | 18 | radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| S6 | BBCH 49 (NCH) | U2 | -- | -019A | 19 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |

| Sampling Point | Timing (nominal) | Plot No. | PBI (days) | Sample Code | EAS Chem Internal code | Sample Type | 1,2,4-Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
|----------------|------------------|----------|------------|-------------|------------------------|--------------------|------------------------|--------------------------|------------------------------|------------------------------|
| | | 6 | 30 | -020A | 20 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.01 |
| | | 7 | 120 | -021A | 21 | lettuce leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | < 0.01 |
| | | 8 | 272 | -022A | 22 | lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.01 |
| S7 | BBCH 75 (NCH) | U1 | -- | -023A | 23 | barley whole plant | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.01 |
| | | 3 | 30 | -024A | 24 | barley whole plant | < 0.01 | 0.03 | 0.02 | 0.04 |
| | | 4 | 120 | -025A | 25 | barley whole plant | < 0.01 | 0.02 | 0.01 | 0.02 |
| | | 5 | 274 | -026A | 26 | barley whole plant | < 0.003 n.d. | 0.01 | < 0.01 | 0.01 |
| S8 | BBCH 89 (NCH) | U1 | -- | -027A | 27 | barley grain | < 0.003 n.d. | 0.13 | 0.08 | < 0.01 |
| | | U1 | -- | -028A | 28 | barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | 0.01 |
| | | 3 | 30 | -029A | 29 | barley grain | < 0.003 n.d. | 0.14 | 0.11 | < 0.01 |
| | | 3 | 30 | -030A | 30 | barley straw | < 0.003 n.d. | < 0.01 | 0.03 | 0.06 |
| | | 4 | 120 | -031A | 31 | barley grain | < 0.003 n.d. | 0.11 | 0.08 | < 0.01 |
| | | 4 | 120 | -032A | 32 | barley straw | < 0.003 n.d. | < 0.01 | 0.02 | 0.04 |
| | | 5 | 274 | -033A | 33 | barley grain | < 0.003 n.d. | 0.14 | 0.09 | < 0.01 |
| | | 5 | 274 | -034A | 34 | barley straw | < 0.01 | < 0.01 | 0.02 | 0.02 |

NCH = normal commercial harvest; 2, 3, 4, 5, 6, 7, 8 = treated; U1, U2= untreated

n.d. not detected (below LOD, set at 30 % of LOQ)

Residues are not corrected for procedural recoveries, but corrected for background level of reagent blank sample

Materials and methods

A. Materials

| | |
|--------------------------------------|---|
| Test item: | MCW-2073 (Azoxystrobin Prothioconazole 200 150 SC) |
| Active ingredient (a.s.): | Azoxystrobin (a.s 1) Prothioconazole (a.s 2) |
| CAS no.: | a.s 1: 131860-33-8, a.s 2: 178928-70-6 |
| Lot/Batch no.: | 1032-040218-01 |
| Expiry date: | February 2020 |
| Application rate (nominal): | 300 g prothioconazole/ha |
| No. and growth stage at application: | One application, (application on bare soil) |
| Application time points: | Trial S18-02513-01, Trial S18-02513-02, Trial S18-02513-03 270±10: 07-08.2018 (A1) 120±5: 12.2018 (A2) 30-3: 03.2019 (A3) Trial S18-02513-04: 270±10: 05.2018 (A1), 07.2018 (A2) 120±5: 10.2018 (A3), 01.2019 (A5) 0-3: 12.2018 (A4), 03.2019 (A6) |
| Trial locations: | Trial S18-02513-01: 64-520 Gaj Mały, Wielkopolska, Poland Trial S18-02513-02: 88- 400 Podgórzyn, Kujawskopomorskie, Poland Trial S18-02513-03: 82290 Barry d'Islemade, Tarn et Garonne, Southern France Trial S18-02513-04: 40016 San Giorgio di Piano, Bologna, Italy |
| Sampled commodities: | Radish (leaves and roots): BBCH 49 (NCH) Leaf lettuce (leaves): BBCH 49 (NCH) Barley (whole plant, grain and straw): BBCH 75 and BBCH 89 (NCH) |

B. Study design and method

1. Field part:

The four residue trials were conducted in open field at four locations in Poland, Southern France and Italy. Regions, varieties and cultivation were typical for the rotational crops radish, leaf lettuce and barley. Each trial comprised three plant back intervals of nominal 30-3, 120±5 and 270±10 days. Trials -01 to -03 were consisted of four plots, one untreated and three treated with MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L, nominal content), the plots U1, 2, 3 and 4 plots were splitted into three equal sub-plots on which radish, leaf lettuce and barley were planted in 2019 after the dedicated plant back interval (PBI). Trial -04 comprised eight plots: two untreated and six treated with MCW-2073 (SC formulation containing 150 g prothioconazole/L and 200 g azoxystrobin/L, nominal content), the plots U2, 6, 7 and 8 were divided into two equal sub-plots on which radish and leaf lettuce were planted in 2019 after the dedicated PBI while plots U1, 3, 4 and 5 remained undivided only planted with barley after the dedicated PBI. In each trail one application of MCW-2073 per treated plot and plant back interval was performed to bare soil with a target rate of 2000 mL product/ha (300 g prothioconazole /ha) using boom sprayer equipment. The test item was diluted with water immediately prior to application to a spray volume of 300 L/ha (nominal).

For Radish samples, plants were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Tops (foliage) and roots were separated, and both were sampled by hand. If necessary, adhering soil from roots was removed. Leaf lettuce samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Any decayed leaves, roots and soil were removed and discarded before deep freezing. Leaf lettuce samples were sampled by hand. Whole plant barley samples comprised at least 12 short lengths from rows over the entire plot. Culms were cut approx. 15 cm above the ground. Grain and straw samples were threshed

mechanically. Control samples were taken before treated samples, they were kept later on separated by an adequate space at all times. All samples were immediately deep frozen (-18 °C or below) after arrival at the test facility.

2. Stability of Prothioconazole and Triazole metabolites in final sample extracts

Extract stability is not considered to be an issue since matrix-matched standards that were used for quantification were always prepared on the same day as the work up of the sample for residue analysis took place and stability was confirmed from the acceptable procedural recovery samples analysed with each analytical batch (70-110% range).

3. Analytical part

This study comprised two analytical phases.

Prothioconazole metabolites (except TDMs):

In the analytical phase S18-02513-L2 of this study samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole-desthio (sum of isomers of PTZ-desthio, PTZ-3-; -4-; -5-; and -6-hydroxy desthio and alpha-hydroxy-PTZ-desthio, each expressed as PTZ-desthio). In addition, samples of soil were analysed for residues of prothioconazole-desthio.

Sample extraction and determination of residues in the matrices radish (leaves and roots), barley (grain, straw and whole plant) and lettuce (leaves) were performed according to the GIRPA Method R-39651 based on the multi-residue method QuEChERS that was validated within this analytical phase for the matrices radish (roots), barley (grain and straw) and lettuce (leaves) according to SANCO/3029/99, rev. 4. For the analysis of soil, sample extraction and determination of residues were performed according to the multi-residue method QuEChERS that was also validated within this analytical phase according to SANCO/3029/99, rev. 4. Quantification was performed by use of LC-MS/MS detection for all analytes and matrices.

The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg (expressed as prothioconazole-desthio) for each analyte and each matrix with a limit of detection (LOD) set at 0.003 mg/kg (30 % of the LOQ).

For prothioconazole-desthio (sum of isomers of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio) the LOQ was 0.06 mg/kg for all matrices with a limit of detection (LOD) set at 0.018 mg/kg (30 % of the LOQ). A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

TDMs:

In the analytical phase S18-02513-L3 of this study, samples of radish (leaves and roots), lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) with a limit of quantification of 0.01 mg/kg for each analyte and matrix type. Analyses were performed according to method GRM053.01A that was provided by Sponsor. For method transfer and applicability this method was reduced validated within this analytical phase according to SANCO/3029/99, rev.4 on all matrices of radish (leaves and roots), leaf lettuce and barley (whole plant, grain and straw) at the LOQ level (0.01 mg/kg) and 10xLOQ level (0.1 mg/kg). Quantification was performed by addition of internal standard(s) and use of LC-DMS-MS/MS detection for all analytes and matrices. A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

Results and discussion

During analysis of the field specimen mean recoveries values obtained by LC-MS/MS for Prothioconazole and Triazole metabolites in radish (leaves, roots), leaf lettuce (leaves) and barley (whole plant, grain, straw) were in the range of 70-110% with relative standard deviation below 20%.

Prothioconazole metabolites (except TDMs):

No residues of analytes at or above the LOD were detected in any of the untreated samples of plant matrices.

Residues of prothioconazole-desthio in treated samples were below the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, except for one trial (PL02) where radish leaves had a residue of 0.015 and 0.018 mg/kg at PBI 28 days and 119 days respectively. Since application rate to bare soil was at an exaggerated rate (1.5N) and proposed application to cereals would be BBCH 59-69 when 90% interception to soil would be expected, it is concluded that these residues found at a single site are more reflective of the worst case conditions used in the study. Under proposed use conditions a no residue situation would be expected following the use of prothioconazole as shown in the confined rotational crop metabolism study.

Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals.

TDMs:

In untreated samples residues of triazole alanine (TA) and triazole lactic acid (TLA) were above the LOQ (0.01 mg/kg) in several samples across all crops whereas residues of triazole acetic acid (TAA) were registered over the LOQ (0.01 mg/kg) only in cereals. Residues of 1,2,4-triazole were below the LOQ (0.01 mg/kg) in all samples and all crops.

Regarding the treated samples, residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOQ in all samples and all crops.

- Highest residues found at 30-3 days PBI in radish (roots) were found at 0.02 mg/kg (TLA) and 0.12 mg/kg (TA), those at 120±5 days PBI were found at 0.02 mg/kg (TLA) and 0.05 mg/kg (TA), whereas at 270±10 days, highest residues varied between 0.02 mg/kg (TLA) and 0.07 mg/kg (TA).
- Highest residues found at 30-3 days PBI in leaf lettuce were found at 0.03 mg/kg TA and 0.19 mg/kg TLA, those at 120±5 days PBI were found at 0.01 mg/kg TA and 0.12 mg/kg TLA, whereas at 270±10 days, highest residues were found to be 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 30-3 days PBI in barley (grain) were found to be 0.01 mg/kg TLA, 0.41 mg/kg TA and 0.55 mg/kg TAA, those at 120±5 days PBI were 0.01 mg/kg TLA, 0.28 mg/kg TA and 0.29 mg/kg TAA, whereas at 270±10 days, highest residues were found at 0.02 mg/kg TLA, 0.28 mg/kg TA and 0.32 mg/kg TAA.
- Highest residues found at 30-3 days PBI in barley (straw) were in 0.04 mg/kg TA, 0.40 TAA and 0.45 mg/kg TLA, those at 120±5 days PBI were 0.05 mg/kg TA, 0.24 mg/kg TAA and 0.21 mg/kg TLA, whereas at 270±10 days, highest residues were found at 0.27 mg/kg TLA, 0.04 mg/kg TA and 0.20 mg/kg TAA.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study.

Detailed results can be found in the following tables:

Table A 45: Summary of the rotational crop field study 1 - 4 trials (Prothioconazole residues except TDMs)

| | | | |
|---|--|---|---|
| Reference no.: | KCA 6.6.2/01 | | |
| Report | Determination of residues of prothioconazole and its metabolites after one application of MCW-2073 on bare soil in rotational crops (radish, leaf lettuce and barley) at 2 sites in Northern Europe and 2 sites in Southern Europe 2018/2019 Semrau, J., 2021 Report No.: S18-02513, R-39638 | | |
| GLP: | Yes | Sample storage conditions: | below -18 °C |
| Preceding crop: | Bare soil | Analytical method: | For plant matrices: Prothioconazole metabolites: GIRPA Method R-39651, based on DIN EN 15662:2018-07, QuEChERS-method, validated within the analytical phase; TDMs: GRM053.01A validated within the analytical phase For soil: multi-residue method,– QuEChERS, validated within the analytical phase |
| Succeeding crop: | Radish, Leaf lettuce, spring barley | Limit of Quantification (mg/kg): | 0.01 mg/kg for each analyte and matrix; 0.06 mg/kg for prothioconazole as sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio (mg/kg) |
| Indoor/Outdoor: | outdoor | Limit of Detection (mg/kg): | 0.003 mg/kg for each analyte and matrix; 0.018 mg/kg for prothioconazole as sum of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio and alpha-hydroxy-prothioconazole-desthio expressed as prothioconazole-desthio (mg/kg) |
| Formulation: | MCW-2073 SC | Residues calculated as: | 1. Prothioconazole-desthio (sum of isomers) (acc. to enforcement residue definition) 2. Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio alpha-hydroxy-prothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (acc. to risk assessment residue definition) 3. 1,2,4-Triazole, Triazole alanine, Triazole acetic acid, Triazole lactic acid (mg/kg) |
| Content of active substance (g/kg or g/L): | Prothioconazole, nominal 150 g/L (actual 145 g/L), Azoxystrobin, nominal 200 g/L (actual 201.6 g/L) | | |

Crop residue data from supervised field trials

Active ingredient (common name and content): Prothioconazole, nominal 150 g/L (actual 145.0 g/L)
Crop/crop group: Radish / root vegetables, Leaf lettuce / leaf vegetables, Barley / cereals
Country: Poland, France (S-EU), Italy
Indoor/outdoor: Outdoor
Responsible body for reporting (name, address): ADAMA Makhteshim Ltd, Beer Sheva, Israel

Reference no.:

Commercial product (name/code):

Formulation (e.g. SC):

Other active substance in the formulation:

Residues calculated as:

KCA 6.6.2/01

MCW-2073

SC

Azoxystrobin, nominal 200 g/L (actual 201.6 g/L)

Prothioconazole as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (mg/kg) (8.2, risk assessment residue definition); Prothioconazole-desthio (mg/kg) (8.1, enforcement residue definition)

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH | 7 Portion analysed | 8.1 Residues (mg/kg) | | 8.2 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) |
|--|------------------------------------|--|--|-----------------|----------------|--|--|-----------------------|-------------------------|------------------|-------------------------|-----------------------|---|--|---------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | | | |
| (a) | (b) | (b) | (c) | (L/ha) | (ha) | (d) | (e) | | (g) | (h) | | (i) | (f) | | |
| S18-02513-01 64-520 Gaj Mały, Wielkopolska, Poland N-EU 2019 | Radish (RAPSR) / Escala | 1-24/04/19 2- n.a 3-05/06/19 | 0.1 | 304 | 0.305 | 27/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 70 | LC-MS/MS detection for all analytes and matrices. For method validation please refer to dRR Part B.5, point KCP 5.1.2. Max. sample storage time in all four trials: 488 days (sampling to extraction), max. extract storage time (extraction to analysis) 7 days. Extract stability verified during the study. Results in all untreated specimens were below LOD. | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | | | |
| | | | 0.1 | 304 | 0.305 | 28/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 159 | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 159 | | | |
| | | | 0.1 | 308 | 0.308 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 314 | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 314 | | | |
| | Leaf lettuce (LACSP) / Fynly | 1-24/04/19 2- n.a 3-07/06/19 | 0.1 | 306 | 0.306 | 27/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 72 | | | |
| | | | 0.1 | 309 | 0.309 | 28/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 161 | | | |
| | | | 0.1 | 313 | 0.313 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 316 | | | |

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH (e) | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) (f) |
|--|-------------------------------------|--|--|-----------------|----------------|--|---|-----------------------|-------------------------|------------------|------------------|-----------------------|--------------------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| | Spring Barley (HORVS)/ Airway | 1-24/04/19 2- n.a 3-13/08/19 | 0.1 | 300 | 0.300 | 27/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 100 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 139 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 139 | |
| | | | 0.1 | 299 | 0.299 | 28/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 189 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 228 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 228 | |
| | | | 0.1 | 306 | 0.306 | 26/07/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 344 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 383 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 383 | |

Table continued

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH | 7 Portion analysed | 8.1 Residues (mg/kg) | | 8.2 PTZ (sum) | | 10 Assessment | | 11 Details on trial(s) |
|---|-------------------------------------|--|--|-----------------|----------------|--|--|-----------------------|-------------------------|------------------|------------------|-----------------------|------------------|--|---------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | | | |
| S18-02513-02 88-400 Podgórzyn, Kujawskopomor skie Poland N-EU 2019 | Radish (RAPSR) / Escala | 1-25/04/19 2- n.a 3-06/06/19 | 0.1 | 304 | 0.303 | 28/03/19 (PBI 30-3) | Bare soil | Leaves | 0.015 | <LOQ (n.d.) | 49 | 70 | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | | | |
| | | | 0.1 | 303 | 0.303 | 27/12/18 (PBI 120±5) | Bare soil | Leaves | 0.018 | <LOQ | 49 | 161 | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 161 | | | |
| | | | 0.1 | 306 | 0.306 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ | <LOQ (n.d.) | 49 | 315 | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 315 | | | |
| | Leaf lettuce (LACSP) / Fynly | 1-25/04/19 2- n.a 3-06/06/19 | 0.1 | 305 | 0.305 | 28/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | | | |
| | | | 0.1 | 309 | 0.310 | 27/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 161 | | | |
| | | | 0.1 | 286 | 0.286 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 315 | | | |
| | Spring Barley (HORVS)/ Airway | 1-25/04/19 2- n.a 3-06/08/19 | 0.1 | 298 | 0.298 | 28/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ | <LOQ (n.d.) | 75 | 102 | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 131 | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 131 | | | |
| | | | 0.1 | 299 | 0.299 | 27/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 193 | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 222 | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 222 | | | |

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) (d) | 6 Growth stage at last treatment or date (e) BBCH (e) | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) (f) |
|--|---------------------------------------|---|--|-----------------|----------------|---|---|-----------------------|-------------------------|------------------|------------------|-----------------------|--------------------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| | | | 0.1 | 296 | 0.296 | 26/07/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 347 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 376 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 376 | |

Table continued

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) |
|---|---|--|--|-----------------|----------------|--|--|-----------------------|-------------------------|------------------|------------------|-----------------------|---------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| S18-02513-03 82290 Barry d'Islemade, Tarn et Garonne France S-EU 2019 | Radish (RAPSR) / Radis de 18 jours | 1-24/04/19 2- n.a 3-31/05/19 | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 71 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 71 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 162 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 162 | |
| | | | 0.1 | 312 | 0.292 | 01/08/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 303 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 303 | |
| | Leaf lettuce (LACSP) / Grafitti | 1-24/04/19 2- n.a 3-11/06/19 | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 82 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 173 | |
| | | | 0.1 | 312 | 0.312 | 01/08/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 314 | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| | Spring Barley (HORVS)/ Planet | 1-24/04/19 2- n.a 3-29/07/19 | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 110 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 130 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 130 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 201 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 221 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 221 | |

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) (d) | 6 Growth stage at last treatment or date (e) BBCH (e) | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) (f) |
|--|---------------------------------------|---|--|-----------------|----------------|---|---|-----------------------|-------------------------|------------------|------------------|-----------------------|--------------------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| | | | 0.1 | 312 | 0.312 | 01/08/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 342 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 362 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 362 | |

Table continued

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH (e) | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) (f) |
|--|--|--|--|-----------------|----------------|--|---|-----------------------|-------------------------|------------------|------------------|-----------------------|--------------------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| S18-02513-04 40016 San Giorgio di Piano, Bologna Italy S-EU 2019 | Radish (RAPSR) / Saxa 2 | 1-18/04/19 2- n.a 3-11/07/19 | 0.1 | 288 | 0.288 | 19/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 114 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 114 | |
| | | | 0.1 | 317 | 0.317 | 19/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 204 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 204 | |
| | | | 0.1 | 277 | 0.277 | 20/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 356 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 356 | |
| | Leaf lettuce (LACSP) / Gentilina | 1-18/04/19 2- n.a 3-02/07/19 | 0.1 | 288 | 0.288 | 19/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 105 | |
| | | | 0.1 | 317 | 0.317 | 19/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 195 | |
| | | | 0.1 | 277 | 0.277 | 20/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 347 | |
| | Spring Barley (HORVS)/ Campagne | 1-13/02/19 2- n.a 3-03/07/19 | 0.1 | 323 | 0.323 | 14/01/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 161 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 170 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 170 | |
| | | | 0.1 | 287 | 0.287 | 16/10/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 251 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 260 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 260 | |

| 1 Trial No./ Location/ EU zone/ Year | 2 Commodity/ Variety | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest | 4 Application rate per treatment | | | 5 Dates of treatment(s) or no. of treatment(s) and last date (d) | 6 Growth stage at last treatment or date (e) BBCH (e) | 7 Portion analysed | 8.1 Residues (mg/kg) | | 10 Assessment | | 11 Details on trial(s) |
|--|----------------------------|--|--|-----------------|----------------|--|---|-----------------------|-------------------------|------------------|------------------|-----------------------|---------------------------|
| | | | kg a.s./ hL (c) | Water (L/ha) | kg a.s./ ha | | | | PTZ- desthio (g) | PTZ (sum) (h) | Timing (BBCH) | DALA (days) (i) | |
| | (a) | (b) | 0.1 | 290 | 0.145 | 15/05/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | 75 | 405 | |
| | | | | | | | | Grain | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 414 | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 89 | 414 | |

(a) According to EPPO codes

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance: (Nominal rate: 150 g a.s./ha prothioconazole equivalent to MCW-2073 at 1.0 L/ha)

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

(g) Prothioconazole-desthio (sum of isomers) (8.1, enforcement residue definition)

(h) Prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio (8.2, acc. to risk assessment residue definition). For the sum of prothioconazole-desthio, the calculations were performed with value of 0.01 mg/kg for results <LOQ and as zero for results <LOQ (nd).

(i) Minimum number of days after last application

n.d. Not detectable

LOQ Limit of quantification

LOD Limit of detection

Table A 46: Summary of the rotational crop field study 1 - 4 trials (TDMs)

| 1 Trial No./ Location/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment g a.s./ hL Water (l/ha) kg a.s./ha | | | 5 Dates of treatment or no. of treatments and last date (d) | 6 Growth stage at last treatment or date BBCH (e) | 7 Portion analyzed | 8 Residues (mg/kg) 1,2,4-T TA TAA TLA | | | | 9 Timing (BBCH) | 10 PHI (days) (f) | 11 Remarks (g) |
|--|---------------------------------------|---|---|-----|-------|---|---|--------------------------|--|----------------|----------------|----------------|-----------------------|--------------------------------|---|
| | | | | | | | | | | | | | | | |
| S18-02513-01 64-520 Gaj Mały, Wielkopolska Poland N-EU 2018/19 | Radish (RAPSR) / Escala | 1-24/04/19 2- n.a 3-05/06/19 | 0.1 | 304 | 0.305 | 27/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ | 0.05 | <LOQ (n.d.) | <LOQ | 49 | 70 | Analytical methods: GRM053.01A, LC- DMS-MS/MS detection. For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg with LOD: 0.003 mg/kg (for each analyte and each matrix) Max. sample storage time in all four trials: 539 days (sampling to extraction), max. extract storage time (extraction to analysis) 9 days. Extract stability verified during the study. Residues in untreated samples (background levels) were found in a part of samples, and |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | |
| | | | 0.1 | 304 | 0.305 | 28/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ | 0.06 | <LOQ (n.d.) | <LOQ | 49 | 159 | |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 159 | |
| | | | 0.1 | 308 | 0.308 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | 0.07 | <LOQ (n.d.) | 0.02 | 49 | 314 | |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.05 | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 314 | |
| | | | Untreated | | | | | Leaves | <LOQ | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | |
| | Leaf lettuce (LACSP) / Fynly | 1-24/04/19 2- n.a 3-07/06/19 | 0.1 | 306 | 0.306 | 27/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 0.04 | 49 | 72 | |
| | | | 0.1 | 309 | 0.309 | 28/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 0.04 | 49 | 161 | |
| | | | 0.1 | 313 | 0.313 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 0.04 | 49 | 316 | |
| | | | Untreated | | | | | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 49 | - | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | | | | 9 | 10 | 11 | | | | |
|---------------------------------|--|---|-----------------------------------|-----------------|---------------|---|---|---------------------|------------------|------|------|----------------|------------------|---------------|--------------------|--|--|--|--|
| Trial No./ Location/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date BBCH | Portion analyzed | Residues (mg/kg) | | | | Timing (BBCH) | PHI (days) | Remarks | | | | |
| | | | g a.s./ hL | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | | | | | |
| (a) | (b) | (c) | | | | (d) | (e) | | | | | | (f) | (g) | | | | | |
| | Spring Barley (HORVS)/ Airway | 1-24/04/19 2- n.a 3-13/08/19 | 0.1 | 300 | 0.300 | 27/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | 0.04 | 0.04 | 0.06 | 75 | 100 | results are given. | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.17 | 0.10 | <LOQ (n.d.) | 89 | 139 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.05 | 0.06 | 89 | 139 | | | | | |
| | | | 0.1 | 299 | 0.299 | 28/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | 0.04 | 0.03 | 0.07 | 75 | 189 | | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.18 | 0.10 | <LOQ | 89 | 228 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.04 | 0.06 | 89 | 139 | | | | | |
| | | | 0.1 | 306 | 0.306 | 26/07/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ | 0.04 | 0.04 | 0.08 | 75 | 344 | | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.15 | 0.09 | <LOQ | 89 | 383 | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.04 | 0.05 | 89 | 383 | | | | | |
| | | | Untreated | | | | | Whole plant | <LOQ (n.d.) | 0.01 | <LOQ | <LOQ | 75 | - | | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.13 | 0.02 | <LOQ (n.d.) | 89 | - | | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | <LOQ | <LOQ | 0.01 | 89 | - | | | | | |

Table continued

| 1 Trial No./ Location/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment | | | 5 Dates of treatment or no. of treatments and last date (d) | 6 Growth stage at last treatment or date BBCH (e) | 7 Portion analyzed | 8 Residues (mg/kg) | | | | 9 Timing (BBCH) | 10 PHI (days) (f) | 11 Remarks (g) |
|--|---------------------------------------|---|--|-----------------|---------------|---|---|--------------------------|-----------------------|----------------|----------------|----------------|-----------------------|--------------------------------|--------------------------|
| | | | g a.s./ hL (c) | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | |
| S18-02513-02 88-400 Podgórzyn, Kujawskopo morskie Poland N-EU 2018/19 | Radish (RAPSR) / Escala | 1-25/04/19 2- n.a 3-06/06/19 | 0.1 | 304 | 0.304 | 28/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 70 | |
| | | | 0.1 | 303 | 0.303 | 27/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 161 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 161 | |
| | | | 0.1 | 306 | 0.306 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 315 | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 315 | |
| | Leaf lettuce (LACSP) / Fynly | 1-24/04/19 2- n.a 3-07/06/19 | Untreated | | | | | Leaves | <LOQ (n.d.) | 0.05 | <LOQ (n.d.) | 0.01 | 49 | - | |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | |
| | | | 0.1 | 305 | 0.305 | 28/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | 0.03 | <LOQ | 0.19 | 49 | 70 | |
| | | | 0.1 | 309 | 0.310 | 27/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ | 0.01 | <LOQ (n.d.) | 0.12 | 49 | 161 | |
| | | | 0.1 | 286 | 0.286 | 26/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | 0.01 | <LOQ (n.d.) | 0.09 | 49 | 315 | |
| | | | Untreated | | | | | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | 0.03 | 49 | - | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | | | | 9 | 10 | 11 | | | |
|---------------------------------|--|--|-----------------------------------|-----------------|---------------|--|--|---------------------|------------------|------|------|----------------|------------------|--------------------------|--------------------|--|--|--|
| Trial No./ Location/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date BBCH (e) | Portion analyzed | Residues (mg/kg) | | | | Timing (BBCH) | PHI (days) (f) | Remarks (g) | | | |
| | | | g a.s./ hL (c) | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | | | | |
| | Spring Barley (HORVS)/ Airway | 1-25/04/19 2- n.a 3-06/08/19 | 0.1 | 298 | 0.298 | 28/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | 0.11 | 0.19 | 0.25 | 75 | 102 | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.41 | 0.55 | 0.01 | 89 | 131 | | | | |
| | | | | | | | | Straw | <LOQ | 0.04 | 0.40 | 0.45 | 89 | 131 | | | | |
| | | | 0.1 | 299 | 0.299 | 27/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | 0.07 | 0.15 | 0.27 | 75 | 193 | | | | |
| | | | | | | | | Grain | <LOQ | 0.28 | 0.29 | <LOQ | 89 | 222 | | | | |
| | | | | | | | | Straw | <LOQ | 0.05 | 0.24 | 0.20 | 89 | 222 | | | | |
| | | | 0.1 | 296 | 0.296 | 26/07/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ | 0.06 | 0.08 | 0.11 | 75 | 347 | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.16 | 0.20 | <LOQ | 89 | 376 | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.04 | 0.20 | 0.15 | 89 | 376 | | | | |
| | | Untreated | | | | | | Whole plant | <LOQ (n.d.) | 0.04 | 0.03 | 0.04 | 75 | - | | | | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.11 | 0.07 | <LOQ (n.d.) | 89 | - | | | | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.08 | 0.08 | 89 | - | | | | |

Table continued

| 1 Trial No./ Location/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment | | | 5 Dates of treatment or no. of treatments and last date (d) | 6 Growth stage at last treatment or date BBCH (e) | 7 Portion analyzed | 8 Residues (mg/kg) | | | | 9 Timing (BBCH) | 10 PHI (days) (f) | 11 Remarks (g) |
|---|---|---|--|-----------------|---------------|---|---|--------------------------|-----------------------|----------------|----------------|----------------|-----------------------|--------------------------------|--------------------------|
| | | | g a.s./ hL (c) | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | |
| S18-02513-03 82290 Barry d'Islemade, Tarn et Garonne France S-EU 2018/19 | Radish (RAPSR) / Radis de 18 jours | 1-24/04/19 2- n.a 3-31/05/19 | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ | 0.18 | <LOQ (n.d.) | 0.01 | 49 | 71 | |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.04 | <LOQ (n.d.) | 0.02 | 49 | 71 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ | 0.14 | <LOQ (n.d.) | 0.02 | 49 | 162 | |
| | | | | | | | | Roots | n.d. | 0.05 | <LOQ (n.d.) | 0.02 | 49 | 162 | |
| | | | 0.1 | 312 | 0.312 | 01/08/18 (PBI 270±10) | Bare soil | Leaves | <LOQ | 0.22 | <LOQ (n.d.) | 0.02 | 49 | 315 | |
| | | | | | | | | Roots | <LOQ (n.d.) | 0.07 | <LOQ | 0.02 | 49 | 315 | |
| | Leaf lettuce (LACSP) / Grafitti | 1-24/04/19 2- n.a 3-11/06/19 | Untreated | | | | | Leaves | <LOQ | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | |
| | | | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | 0.10 | 49 | 82 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | 0.10 | 49 | 173 | |

| 1 Trial No./ Location/ Year | 2 Commodity/ Variety (a) | 3 Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | 4 Application rate per treatment | | | 5 Dates of treatment or no. of treatments and last date (d) | 6 Growth stage at last treatment or date BBCH (e) | 7 Portion analyzed | 8 Residues (mg/kg) | | | | 9 Timing (BBCH) | 10 PHI (days) (f) | 11 Remarks (g) |
|--------------------------------------|--|---|--|-----------------|---------------|---|---|--------------------------|-----------------------|----------------|----------------|------|-----------------------|--------------------------------|--------------------------|
| | | | g a.s./ hL | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | |
| | | | (c) | | | | | | | | | | | | |
| | | | 0.1 | 312 | 0.312 | 01/08/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | 0.02 | <LOQ (n.d.) | 0.10 | 49 | 314 | |
| | | | Untreated | | | | | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 49 | - | |
| | | | | | | | | | | | | | | | |
| | Spring Barley (HORVS)/ Planet | 1-24/04/19 2- n.a 3-29/07/19 | 0.1 | 293 | 0.293 | 21/03/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ (n.d.) | 0.10 | 0.15 | 0.17 | 75 | 110 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.28 | 0.33 | 0.01 | 89 | 130 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.03 | 0.22 | 0.28 | 89 | 130 | |
| | | | 0.1 | 292 | 0.292 | 20/12/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ (n.d.) | 0.05 | 0.08 | 0.10 | 75 | 201 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.21 | 0.28 | 0.01 | 89 | 221 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.01 | 0.14 | 0.21 | 89 | 221 | |
| | | | 0.1 | 312 | 0.312 | 01/08/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | 0.11 | 0.15 | 0.16 | 75 | 342 | |
| | | | | | | | | Grain | <LOQ (n.d.) | 0.28 | 0.32 | 0.02 | 89 | 362 | |
| | | | | | | | | Straw | <LOQ (n.d.) | 0.02 | 0.17 | 0.27 | 89 | 362 | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | | | | 9 | 10 | 11 |
|---------------------------------|----------------------------------|--|-----------------------------------|-----------------|---------------|--|--|---------------------|------------------|----------------|----------------|------|------------------|--------------------------|--------------------|
| Trial No./ Location/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date BBCH (e) | Portion analyzed | Residues (mg/kg) | | | | Timing (BBCH) | PHI (days) (f) | Remarks (g) |
| | | | g a.s./ hL | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | |
| | | | (c) | | | | | | | | | | | | |
| | | | Untreated | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ | | | |
| | | | | | | | Grain | <LOQ (n.d.) | 0.02 | 0.02 | <LOQ (n.d.) | 89 | - | | |
| | | | | | | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | 0.02 | 0.02 | 89 | - | | |

Table continued

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | | | | 9 | 10 | 11 | | | | |
|--|--|--|-----------------------------------|-----------------|---------------|--|--|---------------------|------------------|----------------|----------------|----------------|------------------|--------------------------|--------------------|--|--|--|--|
| Trial No./ Location/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date BBCH (e) | Portion analyzed | Residues (mg/kg) | | | | Timing (BBCH) | PHI (days) (f) | Remarks (g) | | | | |
| | | | g a.s./ hL (c) | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | | | | | |
| S18-02513-04 40016 San Giorgio di Piano, Bologna Italy S-EU 2018/19 | Radish (RAPSR) / Saxa 2 | 1-18/04/19 2- n.a 3-11/07/19 | 0.1 | 288 | 0.288 | 19/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 114 | | | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 114 | | | | | |
| | | | 0.1 | 317 | 0.317 | 19/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 204 | | | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 204 | | | | | |
| | | | 0.1 | 277 | 0.277 | 20/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 356 | | | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | 356 | | | | | |
| | | | Untreated | | | | | Leaves | <LOQ | <LOQ | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | | | | | |
| | | | | | | | | Roots | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 49 | - | | | | | |
| | Leaf lettuce (LACSP) / Gentilina | 1-18/04/19 2- n.a 3-02/07/19 | 0.1 | 288 | 0.288 | 19/03/19 (PBI 30-3) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 49 | 105 | | | | | |
| | | | 0.1 | 317 | 0.317 | 19/12/18 (PBI 120±5) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ | <LOQ (n.d.) | <LOQ | 49 | 195 | | | | | |
| | | | 0.1 | 277 | 0.277 | 20/07/18 (PBI 270±10) | Bare soil | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 49 | 347 | | | | | |

| 1 | 2 | 3 | 4 | | | 5 | 6 | 7 | 8 | | | | 9 | 10 | 11 | |
|--|------------------------------------|--|-----------------------------------|-----------------|--------------------------|--|--|---------------------|------------------|----------------|----------------|----------------|------------------|--------------------------|--------------------|----------------|
| Trial No./ Location/ Year | Commodity/ Variety (a) | Date of 1.Sowing or planting 2.Flowering 3. Harvest (b) | Application rate per treatment | | | Dates of treatment or no. of treatments and last date (d) | Growth stage at last treatment or date BBCH (e) | Portion analyzed | Residues (mg/kg) | | | | Timing (BBCH) | PHI (days) (f) | Remarks (g) | |
| | | | g a.s./ hL | Water (l/ha) | kg a.s./ha | | | | 1,2,4-T | TA | TAA | TLA | | | | |
| | | | (c) | | | | | | | | | | | | | |
| | | | Untreated | | | | | | | Leaves | <LOQ (n.d.) | <LOQ (n.d.) | | | | <LOQ (n.d.) |
| Spring Barley (HORVS)/ Campagne | 1-13/02/19 2- n.a 3-03/07/19 | 0.1 | 323 | 0.323 | 14/01/19 (PBI 30-3) | Bare soil | Whole plant | <LOQ | 0.03 | 0.02 | 0.04 | 75 | 161 | | | |
| | | | | | | | Grain | <LOQ (n.d.) | 0.14 | 0.11 | <LOQ | 89 | 170 | | | |
| | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.03 | 0.06 | 89 | 170 | | | |
| | | 0.1 | 287 | 0.287 | 16/10/18 (PBI 120±5) | Bare soil | Whole plant | <LOQ | 0.02 | 0.01 | 0.02 | 75 | 251 | | | |
| | | | | | | | Grain | <LOQ (n.d.) | 0.11 | 0.08 | <LOQ | 89 | 260 | | | |
| | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.04 | 89 | 260 | | | |
| | | 0.1 | 290 | 0.145 | 15/05/18 (PBI 270±10) | Bare soil | Whole plant | <LOQ (n.d.) | 0.01 | <LOQ | 0.01 | 75 | 405 | | | |
| | | | | | | | Grain | <LOQ (n.d.) | 0.14 | 0.09 | <LOQ | 89 | 414 | | | |
| | | | | | | | Straw | <LOQ (n.d.) | <LOQ | 0.02 | 0.02 | 89 | 414 | | | |
| | | Untreated | | | | | | | Whole plant | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ | 75 | - | |
| | | Grain | <LOQ (n.d.) | 0.13 | 0.08 | <LOQ | 89 | - | | | | | | | | |
| | | Straw | <LOQ (n.d.) | <LOQ (n.d.) | <LOQ (n.d.) | 0.01 | 89 | - | | | | | | | | |

(a) According to EPPO codes

(b) Only if relevant

(c) High or low volume spraying, , spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

* One application to each subplot

- (e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4.
 - (f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA =days before last application; DAA1= days after application A1
 - (g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date
 - n.a. Not applicable
 - n.d. Not detected
 - LOQ Limit of quantification
 - LOD Limit of detection
- Data in *italics* reported but outside acceptable storage stability.

Conclusion

Four rotational crop field trials were performed in the Northern (two) and Southern (two) residue zone.

At all three plant back intervals of 30-3, 120±5 and 270±10 days, prothioconazole metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

Concerning TDMs, residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals. However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

For TA, TAA and TLA all samples were analysed within the demonstrated stability period and showed residues of <0.01-0.41 mg/kg, <0.01-0.55 mg/kg and <0.01-0.45 mg/kg respectively. Control samples also contain residues of these metabolites although generally at lower levels compared to treated samples. Stability of 1,2,4-T was only confirmed for 6 months in high water crops and 12 months in cereal grain and straw, but analysis was performed outside of this period (444-539 days). Nevertheless, residues were <0.01 mg/kg in both treated and control cereal samples, in line with the findings of the confined rotational crop study.

A 2.1.6.2 Magnitude of residues in representative succeeding crops 2

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| Comments of zRMS: | <p>To address the insufficient stability period for 1,2,4-T, a second reduced GLP field rotational crop study (Semrau, 2022; Report No. S21-00408, ADAMA No. 000107470) was conducted to verify the no residue situation observed for 1,2,4-T.</p> <p>The study (contained two rotational crop field trials) was conducted to determine residue levels of prothioconazole-desthio and prothioconazole (PTZ) hydroxy metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), and TDMs (1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)) in the raw agricultural commodities radish, leaf lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B; EC formulation containing 250 g prothioconazole/L) with a target rate of 1.2 L product/ha (300 g prothioconazole /ha) on bare soil. Each trial comprised one plant back interval of 28±2 days.</p> <p>Methods were validated according to SANCO/3029/99, rev. 4 and SANTE/2020/12830, Rev.1 of 24/02/2021.</p> <p>Quantification was performed by use of LC-MS/MS detection for all analytes and matrices. The limit of quantification (LOQ) of both analytical methods was 0.01 mg/kg for each analyte and each matrix.</p> <p>The mean recoveries at each fortification level were in the range of 70 – 120% with relative standard deviation(s) below 20% for all combinations of matrices and analytes.</p> <p>Results:</p> <p><u>Prothioconazole</u></p> <p>At plant back interval of 28±2 days, prothioconazole metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ-desthio, 4-hydroxy-PTZ-desthio, 5-hydroxy-PTZ-desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.</p> <p><u>TDMs</u></p> <p>Residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops.</p> <p>Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in</p> |
|-------------------|---|

| | |
|--|--|
| | <p>cereals.</p> <p>Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops at 28±2 days PBI. Highest residues in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA), in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA, in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA and in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.</p> <p>However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.</p> <p>The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites and prothioconazole triazole derivative metabolites was 182 days and 92 days, respectively. Sufficient stability data are available to support the residue data presented in this study.</p> <p>The study is acceptable.</p> |
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| Reference: | KCA 6.6.2/02 |
| Report: | Determination of residues of prothioconazole metabolites in rotational crops (radish, lettuce, barley) after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil at 1 site in Northern Europe and 1 site in Southern Europe 2021 Semrau, J., 2022 |
| Guideline(s): | Study no.: S21-00408, sponsor no.: 000107470 OECD (2009) Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment No. 64 and Series on Pesticides No. 32); OECD Test Guideline 509: Crop field trials; OECD (2016) Guidance Document ENV/JM/MONO(2011)50/REV1 , Second Edition, on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66); EC (1997) Guidance Document 7029/VI/95 rev. 5 general recommendations for the design, preparation and realization of residue trials; SANTE/2019/12752 Technical Guidelines on Data Requirements for Setting Maximum Residue Levels, Comparability of Residue Trial and Extrapolation of Residue Data on Products from Plant and Animal Origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3) OECD Test Guideline 504: Residues in rotational crops (limited field studies); SANTE/2020/12830, Rev.1 Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00); |
| Deviations: | None with impact on the study results |
| GLP: | Yes |
| Acceptability: | Yes |

Executive summary

The objective of the study was to determine the residue levels and behaviour of prothioconazole (PTZ) metabolites (sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio), as well as of 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in the raw agricultural commodities radish, lettuce and barley grown as rotational crops after one application of Prothioconazole 250 EC (ADM.03500.F.2.B) on bare soil. In addition, samples of soil were analysed for residues of

prothioconazole-desthio. Two rotational crop field trials were conducted in radish, leaf lettuce and barley during 2021, one in Germany (S21-00408-01), and one in Southern France (S21-00408-02).

Samples of radish (leaves and roots) and leaf lettuce (leaves) were taken by hand at normal commercial harvest (NCH). Samples of barley (whole plant) were taken at growth stage BBCH 51-55 and at normal commercial harvest. Samples of barley taken at BBCH 51-55 were sampled manually while barley grain and straw samples were obtained by mechanical threshing. Samples of soil cores (0-20 cm) were taken directly after application and directly before planting from the untreated and treated plot.

Prothioconazole metabolites (except TDMs):

Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

TDMs:

In untreated samples, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).
- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.
- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

Materials and methods

A. Materials

| | |
|--------------------------------------|---|
| Test item: | Prothioconazole 250 EC/ ADM.03500.F.2.B (Prothioconazole 250 g/L EC) |
| Active ingredient (a.s.): | Prothioconazole |
| CAS no.: | 178928-70-6 |
| Lot/Batch no.: | 3178-010519-01 |
| Expiry date: | April 2021 |
| Application rate (nominal): | 300 g prothioconazole/ha |
| No. and growth stage at application: | One application, (application on bare soil) |
| Application time points: | Trial S21-00408-01 (PBI 29d): 24.03.2021 Trial S21-00408-02 (PBI 30d): 23.03.2021 |
| Trial locations: | Trial S21-00408-01: 21709 Burgweg, Lower Saxony, Germany Trial S21-00408-02: 82290 Barry d'Islemade, Tarn-et-Garonne, France |
| Sampled commodities: | Radish (leaves and roots): BBCH 49 (NCH) Leaf lettuce (leaves): BBCH 49 (NCH) |

Barley (whole plant, grain and straw): BBCH 51-55 and BBCH 89 (NCH)

B. Study design and method

1. Field part:

The residue field rotational crop trials were carried out at two locations in Germany and Southern France. Regions, varieties and cultivation were typical for the rotational crops radish, leaf lettuce and barley. The trials comprised two plots (one untreated and one treated with Prothioconazole 250 EC) which were protected against wild life and livestock damage as appropriate.

In both trials the untreated and treated plots were divided into three equal sub-plots on which radish, leaf lettuce and barley were planted in 2021 after a plant back interval (PBI) of 28±2 days.

Treated plots were applied once to bare soil with a target rate of 1.2 L product/ha (300 g a.s./ha).

Radish samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Tops (foliage) and roots were separated and both were sampled by hand. If necessary, adhering soil from roots was removed. Leaf lettuce samples were taken from the entire subplot, with the exception of a 0.5 m wide strip round the edge of the subplot and at the ends of rows. Any decayed leaves, roots and soil were removed and discarded before deep freezing. Leaf lettuce samples were sampled by hand. Whole plant barley samples comprised at least 12 short lengths from rows over the entire plot. Culms were cut approx. 15 cm above the ground. Grain and straw samples were threshed mechanically (cut height 15 cm above ground level). At least 12 grab samples of grain and straw per sample were taken. Control samples were taken before treated samples. Sampling equipment was cleaned before usage. No diseased or damaged crop was collected. Duplicate samples were taken as cover. After sampling, the control samples and treated samples were kept separated by an adequate space at all times. Samples were deep frozen immediately after arrival at the test sites / test facility.

Soil samples (5 cores of 0-20 cm per sample) were taken at application (0 DAA) and planting (0 DBP) from the untreated and treated plots using manual stainless steel corers containing 20 cm plastic liners and capped with different colours marking top and bottom of each core. The cores were taken randomly across each plot, holes back-filled with soil and compacted. Samples were deep frozen immediately after arrival at the test sites / test facility.

Treated and untreated field samples were maintained in a deep frozen condition (typically -18 °C or less) and adequately separated during storage and shipment.

The maximum frozen storage period of soil samples from sampling until extraction was 153 days. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days. The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites was 182 days.

2. Stability of Prothioconazole and Triazole metabolites in final sample extracts

The interval from preparation of the final extracts to injection for PTZ-desthio did not exceed 24 hours. Due to the shortness of the interval any effects on the results due to a possible instability of the analyte in final sample extracts are considered to be insignificant.

The interval from preparation of the final extracts to injection for triazole metabolites in radish (leaves and roots), lettuce leaves and barley (whole plant, grain) did not exceed 24 hours. Due to the shortness of the interval any effect on the results due to a possible instability of the analyte(s) in final sample extracts are considered to be insignificant. An exception was made for barley straw, where the interval from preparation of the final extracts to injection was within 6 days. The stability of the analyte(s) in the final extracts of barley straw was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the extracts of the barley straw samples for residue analysis. The mean recovery value(s) were in the range of 70% – 120%. In addition, isotopically labelled internal standard was used for quantification and was added directly at the end of the sample extraction procedure. The internal standard is considered to show the same degradation behaviour as the analyte itself so that the stability of the analyte(s) in sample extracts was not investigated.

3. Analytical part

This study comprised two analytical phases.

S21-00408-L2: Analysis of prothioconazole metabolites in plants (except TDMs):

The analytical method for analysis of PTZ-desthio followed the principles of the multi-residue method QuEChERS. In the analytical phase S21-00408-L2 of this study, samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxyprothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, all expressed as prothioconazole-desthio (sum of isomers).

For barley (whole plants, grain, straw) and sugar beet (roots), the analytical method was validated (full validation) following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021 (section relevant to validation requirements for quantitative methods for risk assessment), during another study performed at GIRPA in 2021.

For radish (leaves, roots) and lettuce (leaves) (commodities with high water content as sugar beet roots), the analytical method was validated (reduced validation) following the guideline SANTE/2020/12830, Rev.1 of 24/02/2021 (section relevant to validation requirements for quantitative methods for risk assessment), within the analytical phase S21-00408-L2. The quantification of each analyte was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS). A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

S21-00408-L1: Analysis of TDMs in plants and of prothioconazole-desthio in soil:

In the analytical phase S21-00408-L1 of this study, samples of radish (leaves and roots), leaf lettuce (leaves) and barley (whole plant, grain and straw) were analysed for residues of prothioconazole (PTZ) metabolites, namely 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA). In addition, samples of soil were analysed for residues of prothioconazole-desthio (PTZ-desthio).

Sample extraction and determination of residues were performed according to the analytical method GRM053.01A for analytes 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) and the multi-residue method QuEChERS (for prothioconazole-desthio in soil) that was previously validated at Eurofins Agroscience Services Chem GmbH according to SANCO/3029/99, rev. 4 for matrices soil, radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw). The applicability and suitability of the methods for matrices soil, radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw) were demonstrated by concurrent recoveries within the analytical phase S21-00408-L1. For analytes 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) in samples of matrix radish (leaves and roots), lettuce leaves and barley (whole plant, grain and straw) quantification was performed by use of liquid chromatography-differential mobility spectrometry-tandem mass spectrometry (LC-DMS-MS/MS) detection with isotopically labelled internal standard(s). A description and validation of the analytical method is provided in dRR Part B.5, point KCP 5.1.2.

Results and discussion

Prothioconazole metabolites (except TDMs):

Residues of prothioconazole-desthio in treated samples were below the LOQ (0.01 mg/kg) in all crops and at all plant back intervals, except for one trial (S21-00408-02) where radish leaves had a residue of 0.021 mg/kg at PBI 30 days. Since application rate to bare soil was at an exaggerated rate (1.5N) and proposed application to cereals would be BBCH 59-69 when 90% interception to soil would be expected, it is concluded that these residues found are more reflective of the worst case conditions used in the study. Under proposed use conditions a no residue situation (<0.01 mg/kg) would be expected following the use of prothioconazole as shown in the confined rotational crop metabolism study.

Residues of prothioconazole (mg/kg) as sum of prothioconazole-desthio, 3-hydroxyprothioconazole-desthio, 4-hydroxyprothioconazole-desthio, 5-hydroxyprothioconazole-desthio, 6-hydroxyprothioconazole-desthio and alpha-hydroxyprothioconazole-desthio, expressed as prothioconazole-desthio were below the LOQ (0.06 mg/kg) in all crops and at all plant back intervals in treated and in untreated samples.

| Sampling Code | Target Timing | Treatment | Sample Code | Sample Type | Sum of prothioconazole-desthio and metabolites (sum of isomers) (mg/kg) |
|--|---------------------|-----------|-------------------|--------------------|---|
| Trial S21-00408-01 (Germany) | | | | | |
| S3 | BBCH 49 (NCH) | U1 | S21-00408-01-005A | Radish leaves | <LOD |
| | | U1 | S21-00408-01-006A | Radish roots | <LOD |
| | | T1 | S21-00408-01-007A | Radish leaves | <LOD |
| | | T1 | S21-00408-01-008A | Radish roots | <LOD |
| S4 | BBCH 49 (NCH) | U1 | S21-00408-01-009A | Lettuce leaves | <LOD |
| | | T1 | S21-00408-01-010A | Lettuce leaves | <LOD |
| S5 | BBCH 51-55 (Forage) | U1 | S21-00408-01-011A | Barley whole plant | <LOD |
| | | T1 | S21-00408-01-012A | Barley whole plant | <LOD |
| S6 | BBCH 89 (NCH) | U1 | S21-00408-01-013A | Barley grain | <LOD |
| | | U1 | S21-00408-01-014A | Barley straw | <LOD |
| | | T1 | S21-00408-01-015A | Barley grain | <LOD |
| | | T1 | S21-00408-01-016A | Barley straw | <LOD |
| Trial S21-00408-02 (South France) | | | | | |
| S3 | BBCH 49 (NCH) | U1 | S21-00408-02-005A | Radish leaves | <LOD |
| | | U1 | S21-00408-02-006A | Radish roots | <LOD |
| | | T1 | S21-00408-02-007A | Radish leaves | <LOQ |
| | | T1 | S21-00408-02-008A | Radish roots | <LOD |
| S4 | BBCH 49 (NCH) | U1 | S21-00408-02-009A | Lettuce leaves | <LOD |
| | | T1 | S21-00408-02-010A | Lettuce leaves | <LOD |
| S5 | BBCH 51-55 (Forage) | U1 | S21-00408-02-011A | Barley whole plant | <LOD |
| | | T1 | S21-00408-02-012A | Barley whole plant | <LOD |
| S6 | BBCH 89 (NCH) | U1 | S21-00408-02-013A | Barley grain | <LOD |
| | | U1 | S21-00408-02-014A | Barley straw | <LOD |
| | | T1 | S21-00408-02-015A | Barley grain | <LOD |
| | | T1 | S21-00408-02-016A | Barley straw | <LOD |

LOQ (Limit of quantification): 0.060 mg/kg expressed as prothioconazole-desthio

LOD (Limit of detection, defined as 30 % of the LOQ): 0.018 mg/kg expressed as prothioconazole-desthio

All residue results between LOD and LOQ are noted <LOQ

In untreated samples, residues of triazole alanine (TA), triazole lactic acid (TLA) and triazole acetic acid (TAA) were registered above the LOQ (0.01 mg/kg) in cereals but not in other crops. Residues of 1,2,4-triazole were below the LOD (0.003 mg/kg) in all samples of all crops.

Residues of triazole alanine (TA) and triazole lactic acid (TLA) in treated samples were found above the LOQ (0.01 mg/kg) in all crops, residues of triazole acetic acid (TAA) were found above the LOQ in cereals only, whereas residues of 1,2,4-triazole were below the LOD in all samples and all crops.

| Sampling Code | Target Timing | Treatment | Sample Code | Sample Type | 1,2,4-Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
|------------------------------|---------------|-----------|-------------|-------------|------------------------|--------------------------|------------------------------|------------------------------|
| Trial S21-00408-01 (Germany) | | | | | | | | |

| Samplin g Code | Target Timing | Treatme nt | Sample Code | Sample Type | 1,2,4- Triazole (mg/kg) | Triazole alanine (mg/kg) | Triazole acetic acid (mg/kg) | Triazole lactic acid (mg/kg) |
|-----------------------------------|-------------------------------|---------------|-------------------|--------------------|-------------------------------|--------------------------------|------------------------------------|------------------------------------|
| S3 | BBCH 49 (NCH) | U1 | S21-00408-01-005A | Radish leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | U1 | S21-00408-01-006A | Radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-01-007A | Radish leaves | < 0.003 n.d. | 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-01-008A | Radish roots | < 0.003 n.d. | 0.01 | < 0.003 n.d. | < 0.003 n.d. |
| S4 | BBCH 49 (NCH) | U1 | S21-00408-01-009A | Lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-01-010A | Lettuce leaves | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.01 |
| S5 | BBCH 51-55 (Forage) | U1 | S21-00408-01-011A | Barley whole plant | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.02 |
| | | T1 | S21-00408-01-012A | Barley whole plant | < 0.003 n.d. | 0.02 | 0.01 | 0.08 |
| S6 | BBCH 89 (NCH) | U1 | S21-00408-01-013A | Barley grain | < 0.003 n.d. | 0.03 | 0.03 | < 0.003 n.d. |
| | | U1 | S21-00408-01-014A | Barley straw | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-01-015A | Barley grain | < 0.003 n.d. | 0.15 | 0.14 | < 0.01 |
| | | T1 | S21-00408-01-016A | Barley straw | < 0.003 n.d. | < 0.01 | < 0.01 | 0.01 |
| Trial S21-00408-02 (South France) | | | | | | | | |
| S3 | BBCH 49 (NCH) | U1 | S21-00408-02-005A | Radish leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | U1 | S21-00408-02-006A | Radish roots | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-02-007A | Radish leaves | < 0.003 n.d. | 0.17 | < 0.003 n.d. | 0.03 |
| | | T1 | S21-00408-02-008A | Radish roots | < 0.003 n.d. | 0.10 | < 0.003 n.d. | 0.01 |
| S4 | BBCH 49 (NCH) | U1 | S21-00408-02-009A | Lettuce leaves | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. | < 0.003 n.d. |
| | | T1 | S21-00408-02-010A | Lettuce leaves | < 0.003 n.d. | 0.02 | < 0.003 n.d. | 0.10 |
| S5 | BBCH 51-55 (Forage) | U1 | S21-00408-02-011A | Barley whole plant | < 0.003 n.d. | < 0.01 | < 0.003 n.d. | 0.01 |
| | | T1 | S21-00408-02-012A | Barley whole plant | < 0.003 n.d. | 0.16 | 0.08 | 0.46 |
| S6 | BBCH 89 (NCH) | U1 | S21-00408-02-013A | Barley grain | < 0.003 n.d. | 0.04 | 0.04 | < 0.003 n.d. |
| | | U1 | S21-00408-02-014A | Barley straw | < 0.003 n.d. | < 0.01 | < 0.01 | < 0.01 |
| | | T1 | S21-00408-02-015A | Barley grain | < 0.003 n.d. | 0.82 | 0.57 | 0.04 |
| | | T1 | S21-00408-02-016A | Barley straw | < 0.003 n.d. | 0.04 | 0.13 | 0.12 |

NCH = normal commercial harvest; T1 = treated; U1= untreated; n.d. = not detected (below LOD set at 30 % of the LOQ)

Residues are not corrected for procedural recoveries; LOQ =
limit of quantification of 0.01 mg/kg

Table A 49: Summary of the rotational crop field study 2 - 2 trials
RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

| | | | |
|--|---|--|-------------------------------|
| Active substance (common name): | Prothioconazole | Commercial Product (name): | Prothioconazole 250 EC |
| Crop/crop group: | Soil | Producer of commercial product: | ADAMA Makhteshim Ltd. |
| Responsible body for reporting (name, address) | ADAMA Makhteshim Ltd. PO Box 60, Industrial Zone 8410001 Beer Sheva Israel | | |
| Country (of trial sites): | Germany | Indoor/Glasshouse/Outdoor: | outdoor |
| Content of active substance nominal (g/kg or g/L): | 250 g/L | Other active substance in the formulation (common name and content): | none |
| Formulation (e.g. WP): | EC | Residues calculated as: | mg/kg prothioconazole-desthio |

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-----------------------------------|---|---|--|-----------------|----------|--|--|-------------------------------------|----------------------------------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ-desthio | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Soil | 1) n/a 2) n/a 3) n/a | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | n/a | Soil Soil | 0.02 0.02 | 0 DAA 29 DAA | 29 (plot T1) Residues in mg/kg dry soil weight |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel**
Country (of trial sites): **Germany**
Content of active substance nominal (g/kg or g/L): **250 g/L**
Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|---------------------------------|---|---|--|-----------------|----------|--|--|---------------------------------|------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|----------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Radish / RAPSR / Lucia F1 | 1) 22 Apr 2021 2) n/a 3) 07 Jun 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Leaves Roots | <0.01 n.d. | n.d. n.d. | n.d. n.d. | n.d. n.d. | n.d. n.d. | n.d. n.d. | 75 DAA 75 DAA | 29 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.**
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): **Germany**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|--|---|---|--|-----------------|----------|--|--|-------------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Leaf lettuce / LACSP / Finity red | 1) 22 Apr 2021 2) n/a 3) 07 Jun 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Leaves | < 0.01 | n.d. | n.d. | n.d. | n.d. | n.d. | 75 DAA | 29 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Barley / cereals**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel**

Country (of trial sites): **Germany**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|---|--|-----------------|----------|--|--|---------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Barley / HORVS / Avalon | 1) 22 Apr 2021 2) n/a 3) 12 Aug 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Whole plan Grain Straw | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | 90 DAA 141 DAA 141 DAA | 29 days (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting
(name, address) ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the formulation (common name and content): none

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|---------------------------------|---|---|--|-----------------|----------|--|--|---------------------------------|----------------------------------|--------------|--------------|--------------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Radish / RAPSR / Lucia F1 | 1) 22 Apr 2021 2) n/a 3) 07 Jun 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Leaves Roots | n.d. n.d. | 0.01 0.01 | n.d. n.d. | n.d. n.d. | 75 DAA 75 DAA | 29 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting
(name, address) ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the formulation (common name and content): none

Formulation (e.g. WP): EC

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|--|---|---|--|-----------------|----------|--|--|-------------------------------------|----------------------------------|--------|------|------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| | | | | Phazic acetic acid (TAA), Phazic acetic acid (TLA) | | | | | | | | | | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Leaf lettuce / LACSP / Finity red | 1) 22 Apr 2021 2) n/a 3) 07 Jun 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Leaves | n.d. | < 0.01 | n.d. | 0.01 | 75 DAA | 29 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Barley / cereals**
Responsible body for reporting
(name, address) ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): Germany
Content of active substance nominal (g/kg or g/L): 250 g/L

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the formulation (common name and content): none

Formulation (e.g. WP): EC

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|---|--|-----------------|----------|--|--|---------------------------------|----------------------------------|------------------------|------------------------|------------------------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| S21-00408-01: 21709 Burweg, Lower Saxony, Germany | Barley / HORVS / Avalon | 1) 22 Apr 2021 2) n/a 3) 12 Aug 2021 | Bare soil with boom sprayer (Lechler, ID 120-02 reduced drift fan nozzles) | 0.10 | 297 | 0.2971 | 24 Mar 2021 | Bare soil | Whole plant Grain Straw | n.d. n.d. n.d. | 0.02 0.15 < 0.01 | 0.01 0.14 < 0.01 | 0.08 < 0.01 0.01 | 90 DAA 141 DAA 141 DAA | 29 days (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Soil**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.**
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): **France (South)**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio (PTZ-desthio)**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|--|--|-----------------|----------|--|--|---------------------------------|------------------------------|----------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ-desthio | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Soil | 1) n/a 2) n/a 3) n/a | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | n/a | Soil Soil | 0.05 0.06 | 0 DAA 30 DAA | 30 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.**
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): **France (South)**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|--|--|-----------------|----------|--|--|---------------------------------|------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|----------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Radish / RAPSR / Kiva | 1) 22 Apr 2021 2) n/a 3) 25 May 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Leaves Roots | 0.021 < 0.01 | 0.012 n.d. | n.d. n.d. | n.d. n.d. | n.d. n.d. | n.d. n.d. | 63 DAA 63 DAA | 30 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.**
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): **France (South)**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|--|---|--|--|-----------------|----------|--|--|---------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Leaf lettuce / LACSP / Avenir | 1) 22 Apr 2021 2) n/a 3) 14 Jun 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Leaves | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. | 83 DAA | 30 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Barley / cereals**
Responsible body for reporting (name, address): **ADAMA Makhteshim Ltd.**
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): **France (South)**
Content of active substance nominal (g/kg or g/L): **250 g/L**

Formulation (e.g. WP): **EC**

Commercial Product (name): **Prothioconazole 250 EC**
Producer of commercial product: **ADAMA Makhteshim Ltd.**

Indoor/Glasshouse/Outdoor: **outdoor**
Other active substance in the formulation (common name and content): **none**

Residues calculated as: **mg/kg prothioconazole-desthio, PTZ-3-hydroxy-desthio, PTZ-4-hydroxy-desthio, PTZ-5-hydroxy-desthio, PTZ-6-hydroxy-desthio, PTZ-alpha-hydroxy-desthio**

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|--|--|-----------------|----------|--|--|---------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|--|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | PTZ- desthio | PTZ-3- hydrox y desthio | PTZ-4- hydrox y desthio | PTZ-5- hydrox y desthio | PTZ-6- hydrox y desthio | PTZ- alpha- hydrox y desthio | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Barley / HORVS / Etoile | 1) 22 Apr 2021 2) 25 Jun - 05 Jul 2021 3) 03 Aug 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Whole plant Grain Straw | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | n.d. n.d. n.d. | 87 DAA 133 DAA 133 DAA | 30 days (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Radish / root vegetables**
Responsible body for reporting
(name, address) ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the formulation (common name and content): none

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodity/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|-------------------------------|---|--|--|-----------------|----------|--|--|---------------------------------|----------------------------------|--------------|--------------|--------------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Radish / RAPSR / Kiva | 1) 22 Apr 2021 2) n/a 3) 25 May 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Leaves Roots | n.d. n.d. | 0.17 0.10 | n.d. n.d. | 0.03 0.01 | 63 DAA 63 DAA | 30 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name): **Prothioconazole**
Crop/crop group: **Leaf lettuce / leaf vegetables**
Responsible body for reporting
(name, address) ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Country (of trial sites): France (South)
Content of active substance nominal (g/kg or g/L): 250 g/L

Formulation (e.g. WP): EC

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the formulation (common name and content): none

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodit y/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks: Actual Plant Back Interval (g) |
|--|--|---|--|--|-----------------|----------|--|--|-------------------------------------|----------------------------------|------|------|------|--------------------------------|--|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| | | | | Phazic acetic acid (TA), Phazic acetic acid (TA) | | | | | | | | | | | |
| S21-00408-02: 82290 Barry d'Islemade, Tarn-et- Garonne, France (South) | Leaf lettuce / LACSP / Avenir | 1) 22 Apr 2021 2) n/a 3) 14 Jun 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Leaves | n.d. | 0.02 | n.d. | 0.10 | 83 DAA | 30 (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/a = not applicable

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

RESIDUES DATA FROM SUPERVISED TRIALS (SUMMARY)

Active substance (common name):
Crop/crop group:
Responsible body for reporting
(name, address)

Prothioconazole
Barley / cereals
ADAMA Makhteshim Ltd.
PO Box 60, Industrial Zone
8410001 Beer Sheva
Israel

Commercial Product (name): Prothioconazole 250 EC
Producer of commercial product: ADAMA Makhteshim Ltd.

Country (of trial sites):
Content of active substance nominal (g/kg or
g/L):

France (South)
250 g/L

Indoor/Glasshouse/Outdoor: outdoor
Other active substance in the
formulation (common name and
content): none

Formulation (e.g. WP):

EC

Residues calculated as: mg/kg 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA),
Triazole acetic acid (TAA), Triazole lactic acid (TLA)

| 1 Report No. Location (region) | 2 Commodit y/Variety (a) | 3 Date of 1) Sowing or Planting 2) Flowering 3) Harvest (b) | 4 Method of Treatment (c) | 5 Application rate per treatment | | | 6 Dates of treatment(s) or no. of treatment(s) and last date (d) | 7 Growth stage at last treatment or date (e) BBCH | 8 Portion analysed (a) | 9 Residues (mg/kg) (*) | | | | 10 PHI (days) (f) | 11 Remarks Actual Plant Back Interval (g) |
|--|---------------------------------------|---|--|--|-----------------|----------|--|--|-------------------------------------|----------------------------------|----------------------|----------------------|----------------------|--------------------------------|---|
| | | | | kg as/hL | Water (L/ha) | kg as/ha | | | | 1,2,4-T | TA | TAA | TLA | | |
| | | | | | | | | | | | | | | | |
| S21-00408-02: 82290 Barry d’Islemade, Tarn-et- Garonne, France (South) | Barley / HORVS / Etoile | 1) 22 Apr 2021 2) 25 Jun – 05 Jul 2021 3) 03 Aug 2021 | Bare soil with boom sprayer (Teejet TT110015 flat fan nozzles) | 0.1202 | 250 | 0.3005 | 23 Mar 2021 | Bare soil | Whole plant Grain Straw | n.d. n.d. n.d. | 0.16 0.82 0.04 | 0.08 0.57 0.13 | 0.46 0.04 0.12 | 87 DAA 133 DAA 133 DAA | 30 days (plot T1) |

(a) According to EPPO codes

(b) Only if relevant, n/r = not recorded

(c) High or low volume spraying, spreading, dusting etc., overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph. Growth Stages of Plants. 1997. Blackwell. ISBN 3-8263-3152-4

(f) Minimum number of days after last application (Label pre-harvest interval. PHI. underline); DBLA = days before last application; DAA1= days after application A1

(g) Remarks may include: climatic conditions; reference to analytical method; Information concerning the metabolites included, the method of storage, storage stability, analysis date

(*) Limit of quantification = 0.01 mg/kg; limit of detection = 0.003 mg/kg for each analyte, n.d. = not detected (<LOD)

Conclusion

Two rotational crop field trials were performed in the Northern (one) and Southern (one) EU residue zone. At the tested plant back interval of 28±2 days, prothioconazole metabolites (sum of PTZ-desthio, 3-hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio, expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole metabolites was 182 days.

Concerning TDMs, residues of 1,2,4-triazole were below the LOQ of 0.01 mg/kg in all crops. Residues of triazole acetic acid (TAA) were found above the LOQ of 0.01 mg/kg solely in cereals. Residues of triazole alanine (TA) and triazole lactic acid (TLA) were found above the LOQ (0.01 mg/kg) in part of the samples across all crops and all plant back intervals:

- Highest residues found at 28±2 days PBI in treated radish (roots) were found at 0.01 mg/kg (TLA) and 0.10 mg/kg (TA).
- Highest residues found at 28±2 days PBI in treated leaf lettuce were found at 0.02 mg/kg TA and 0.10 mg/kg TLA.
- Highest residues at 28±2 days PBI in treated barley (grain) were found to be 0.04 mg/kg TLA, 0.82 mg/kg TA and 0.57 mg/kg TAA.
- Highest residues found at 28±2 days PBI in treated barley (straw) were in 0.04 mg/kg TA, 0.13 TAA and 0.12 mg/kg TLA.

However, it has to be stated that also in some of the untreated samples background levels of TA, TLA and TAA exceeding the LOQ (0.01 mg/kg) were found.

The maximum frozen storage period of crop samples from sampling until extraction for analysis of prothioconazole triazole derivative metabolites was 92 days.

Overall conclusion on the magnitude of residues in representative succeeding crops

In both studies, residues of prothioconazole as sum of PTZ-desthio, 3- hydroxy-PTZ desthio, 4-hydroxy-PTZ desthio, 5-hydroxy-PTZ -desthio, 6-hydroxy-PTZ-desthio and alpha-hydroxy-PTZ-desthio (expressed as prothioconazole-desthio) were below the LOQ (0.06 mg/kg) in all treated and untreated crop commodities and at all plant back intervals.

The second reduced rotational crop field study (KCA 6.6.2/02) was conducted to address the insufficient stability period for 1,2,4-T in the first study (KCA 6.6.2/01). The rationale for design of this second study is provided in a position paper (KCA 6.6.2/03) submitted with this application.

Results from the second study confirmed the findings of the first study (KCA 6.6.2/01); all residues of 1,2,4-T were <0.01 mg/kg in treated and control samples. Other TDMs were also in a similar range, being <0.01 - 0.82 mg/kg for TA, <0.01 - 0.14 mg/kg for TAA and <0.01 - 0.46 mg/kg for TLA. Again, some control samples also contained residues of TA, TAA and TLA but generally at lower levels than in treated samples.

In conclusion, all samples were analysed for 1,2,4-T within 182 days, complying with the demonstrated freezer storage period of 6 months for high water content crops and 12 months for cereal grain and straw. The new data confirm the findings of both the confined rotational crop study and the first rotational crop field trials; residues of 1,2,4-T would not be expected above the LOQ (0.01 mg/kg) in rotational crops, even when applied at exaggerated dose rates.

The following STMRs/HRs can be derived from the two studies:

Table A 50: Overview of the STMRs/HRs of 1,2,4-T in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) | | | PBI 120 (KCA 6.6.2/01) | | | PBI 270 (KCA 6.6.2/01) | | |
|----------------|--|------|------|-----------------------------------|------|------|-----------------------------------|------|------|
| Commodity | Residues | STMR | HR | Residues | STMR | HR | Residues | STMR | HR |
| Radish leaves | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Radish roots | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Lettuce leaves | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Barley grain | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Barley straw | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |

Table A 51: Overview of the STMRs/HRs of TA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) | | | PBI 120 (KCA 6.6.2/01) | | | PBI 270 (KCA 6.6.2/01) | | |
|----------------|---------------------------------------|-------|------|--------------------------|-------|------|--------------------------|-------|------|
| Commodity | Residues | STMR | HR | Residues | STMR | HR | Residues | STMR | HR |
| Radish leaves | 0.05, 0.27, 0.18, <0.01, 0.01, 0.17 | 0.11 | 0.27 | 0.06, 0.10, 0.14, <0.01 | 0.08 | 0.14 | 0.07, 0.12, 0.22, <0.01 | 0.095 | 0.22 |
| Radish roots | 0.04, 0.12, 0.04, <0.01, 0.01, 0.10 | 0.04 | 0.12 | 0.04, 0.04, 0.05, <0.01 | 0.04 | 0.05 | 0.05, 0.07, 0.07, <0.01 | 0.06 | 0.07 |
| Lettuce leaves | <0.01, 0.03, 0.02, <0.01, <0.01, 0.02 | 0.015 | 0.03 | <0.01, 0.01, 0.02, <0.01 | 0.01 | 0.02 | <0.01, 0.01, 0.02, <0.01 | 0.01 | 0.02 |
| Barley grain | 0.17, 0.41, 0.28, 0.14, 0.15, 0.82 | 0.225 | 0.82 | 0.18, 0.28, 0.21, 0.11 | 0.195 | 0.28 | 0.15, 0.16, 0.28, 0.14 | 0.155 | 0.28 |
| Barley straw | 0.03, 0.04, 0.03, <0.01, <0.01, 0.04 | 0.03 | 0.04 | 0.03, 0.05, 0.01, <0.01 | 0.02 | 0.05 | 0.03, 0.04, 0.02, <0.01 | 0.025 | 0.04 |

Table A 52: Overview of the STMRs/HRs of TAA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) | | | PBI 120 (KCA 6.6.2/01) | | | PBI 270 (KCA 6.6.2/01) | | |
|----------------|--|-------|------|-----------------------------------|------|------|-----------------------------------|-------|------|
| Commodity | Residues | STMR | HR | Residues | STMR | HR | Residues | STMR | HR |
| Radish leaves | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Radish roots | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Lettuce leaves | <0.01, <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, <0.01, <0.01, <0.01 | 0.01 | 0.01 |
| Barley grain | 0.10, 0.55, 0.33, 0.11, 0.14, 0.57 | 0.235 | 0.57 | 0.10, 0.29, 0.28, 0.08 | 0.19 | 0.29 | 0.09, 0.20, 0.32, 0.09 | 0.145 | 0.32 |
| Barley straw | 0.05, 0.40, 0.22, 0.03, <0.01, 0.13 | 0.09 | 0.40 | 0.04, 0.24, 0.14, 0.02 | 0.09 | 0.24 | 0.04, 0.20, 0.17, 0.02 | 0.105 | 0.20 |

Table A 53: Overview of the STMRs/HRs of TLA in treated rotational crop samples at normal commercial harvest

| | PBI 30 (KCA 6.6.2/01 & /02) | | | PBI 120 (KCA 6.6.2/01) | | | PBI 270 (KCA 6.6.2/01) | | |
|---------------|---------------------------------------|------|------|---------------------------|-------|------|---------------------------|------|------|
| Commodity | Residues | STMR | HR | Residues | STMR | HR | Residues | STMR | HR |
| Radish leaves | <0.01, 0.13, 0.01, <0.01, <0.01, 0.03 | 0.01 | 0.13 | <0.01, 0.05, 0.02, <0.01 | 0.015 | 0.05 | 0.02, 0.05, 0.02, <0.01 | 0.02 | 0.05 |
| Radish roots | <0.01, 0.02, 0.02, <0.01, <0.01, 0.01 | 0.01 | 0.02 | <0.01, <0.01, 0.02, <0.01 | 0.01 | 0.02 | <0.01, <0.01, 0.02, <0.01 | 0.01 | 0.02 |

| | PBI 30 (KCA 6.6.2/01 & /02) | | | PBI 120 (KCA 6.6.2/01) | | | PBI 270 (KCA 6.6.2/01) | | |
|------------------|---|-------------|-----------|-------------------------------|-------------|-----------|-------------------------------|-------------|-----------|
| Commodity | Residues | STMR | HR | Residues | STMR | HR | Residues | STMR | HR |
| Lettuce leaves | 0.04, 0.19, 0.10, <0.01, 0.01, 0.10 | 0.07 | 0.19 | 0.04, 0.12, 0.10, <0.01 | 0.07 | 0.12 | 0.04, 0.09, 0.10, <0.01 | 0.065 | 0.1 |
| Barley grain | <0.01, 0.01, 0.01, <0.01, <0.01, 0.04 | 0.01 | 0.04 | <0.01, 0.01, 0.01, <0.01 | 0.01 | 0.01 | <0.01, <0.01, 0.02, <0.01 | 0.01 | 0.02 |
| Barley straw | 0.06, 0.45, 0.28, 0.06, 0.01, 0.12 | 0.09 | 0.45 | 0.06, 0.20, 0.21, 0.04 | 0.13 | 0.21 | 0.05, 0.15, 0.27, 0.02 | 0.10 | 0.27 |

A 2.1.7 Other/Special Studies

A 2.1.7.1 Residues in pollen and nectar study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>In this study residues of prothioconazole and prothioconazole-desthio were measured in flower, pollen and nectar.</p> <p>The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers. The LOQ value was 0.01 mg/kg in flowers, pollen and nectar.</p> <p>Results: The levels of residues in nectar were below the LOQ after 7 and 10 days of application in all trials.</p> <p><u>Remark:</u> The maximum storage interval from sampling until extraction was 124 days at $\leq -18^{\circ}\text{C}$. According to the results of Study no.: S19-02145 (KCA 6.1/04) the storage stability of prothioconazole was demonstrated in nectar surrogate at $\leq -18^{\circ}\text{C}$ in the dark over a storage period of up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. So storage stability of prothioconazole was not demonstrated in pollen and flower. However, prothioconazole-desthio, which is a more representative compound, is stable up to 13 months. The study is acceptable for residue data in nectar.</p> |
|-------------------|---|

| | |
|----------------|---|
| Reference: | KCA 6.10.1/01 |
| Report | <p>Study on the Effect of ADM.3500.F.2.B on Honey Bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Germany Persigehl, M. et al., 2021 Study no.: P19010-3, sponsor no.: 000102470</p> |
| Guideline(s): | <p>OEPP/EPPO No. 170(4) (2010) OECD ENV/JM/MONO(2007)17 EC Guidance document on residue analytical methods, SANCO/3029/99 rev.4</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Objective of the study

The aim of the study was to determine possible side effects of ADM.3500.F.2.B (prothioconazole 250g/L) after spray application on honey bees (*Apis mellifera* L.) in tunnel tents under confined semi-field conditions. In addition, Phacelia flowers, pollen and nectar foraging bees (for nectar preparation) were collected for residue analysis. As only the results of the residue analyses are relevant for this Part B Section 7, only the study part and corresponding results connected to the residue determination are summarised in the following.

Materials and methods

- Crop/variety: Phacelia, surrogate crop
Test system: Three tunnels planted with Phacelia were set up for the collection of residue samples (sampling tunnels) and treated with the test item at BBCH 65.

| | |
|-----------------------------------|---|
| Location: | 40764 Reusrath, Germany |
| No of plots.: | Three tunnels for residue sampling (treated plots), four untreated control tunnels (only sampling of flowers at DAT -1 and 0). |
| Bee colonies, breed: | <i>Apis mellifera</i> L. |
| No. of colonies: | Three for the sampling of residues in pollen and nectar, one for each tunnel. |
| Acclimatisation: | Honey bee colonies were placed in the tunnels three days before application. |
| Applied product: | ADM.3500.F.2.B |
| Batch number | 3178-010519-01 |
| Actual content | 252.8 g/L |
| Expiry date | 30/04/2021 |
| Active substance: | Prothioconazole |
| No. of application: | 1x |
| Application rate: | 200 g a.s./ha, 0.8 L product/ha |
| Application: | Crop directed with boom sprayer |
| Date of application: | 02.06.2020 |
| Stage of crop development: | BBCH 65 |
| Date of sowing: | 27.03.2020 |
| Sampling of flowers: | Phacelia flowers were sampled before the application (DAT -1,) and on DAT 0 after the application (in control and sampling tunnels) and on DAT 2, 7 and 10 (only in sampling tunnels). Flowers were cut at the base of each inflorescence from different plants randomly chosen. |
| Sampling of pollen: | The 3 sampling colonies in the sampling tunnels were fitted with pollen-traps in front of the bee hive entrance for the duration of the sampling period. Pollen was sampled on DAT 0 (after application), DAT 4, DAT 7 and DAT 10. On the sampling days, a pollen-grid was inserted into the pollen-traps for the duration of pollen sampling. |
| Sampling of nectar foraging bees: | Honey bee foragers were sampled from the 3 sampling tunnels after test item application at 0 days after application (DAT), at DAT 4, DAT 7 and DAT 10. On each sampling day, the hive entrance was sealed before sampling and the forager bees returned to the bee hives were collected by using a modified portable vacuum collector with a container filled with dry ice. Nectar was sampled from captured honey bee nectar foragers whose honey stomachs were dissected in the laboratories of the test facility for extraction of nectar. |
| Sample storage: | Flowers, pollen, honey bees and nectar samples were stored deep-frozen at the test facility. |
| Analytical method validation: | S19-20860 (MAC-1940V), Eurofins Agrosience Services Chem GmbH, Hamburg, Germany (2020). The limit of quantification was 0.01 mg/kg. |

Three tunnels treated with the test item were set up for the collection of residue samples (sampling tunnels). Three days before application (DAT -3), honey bee colonies were placed in the tunnels when Phacelia was in full flowering (BBCH 65). Honey bee colonies were small, containing approximately 5.000 adult bees each and 4 to 8 brood combs with brood in all stages out of 10 combs in total. The pre-exposure and exposure phase was conducted on a study field located in Reusrath, North Rhine-Westphalia, Germany. The postexposure phase was conducted at the test facility in Leverkusen, Germany.

Applications of the test item (ADM.3500.F.2.B) were conducted by spraying the whole area of plants within the tunnels during full bee flight and at full flowering of the crop (BBCH 65).

Treated flowers were sampled on DAT 0, 2, 7 and 10. Untreated flowers were sampled at DAT -1 from sampling tunnels and at DAT -1 and 0 from control tunnels. Pollen as well as nectar foraging bees (for nectar preparation) were collected on DAT 0 (after application), 4, 7 and 10. All samples were stored deep-frozen. Samples of flowers, pollen and nectar were analysed for their content of prothioconazole and its metabolite prothioconazole-desthio after extraction via LC-MS/MS. Residues are reported in terms of mg active substance/kg for flowers, pollen or nectar.

The analytical procedure for residue determination was the following: Samples of nectar, pollen and flowers were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). This extraction procedure is based on the QuPpe-PO-Method⁵ but with L-cystein added to increase analyte stability. After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturized cell disruption system (FastPrep) was included to the extraction procedure.

The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers.

The maximum storage interval from sampling until extraction was 124 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 5 days. The stability of the analytes in the final extracts of flowers, pollen and nectar upon storage at typically 1 °C to 10 °C for 7 days was demonstrated in the method validation study.

Results and discussions

Residues of prothioconazole in nectar were low and the mean residue was 0.09 mg/kg at the day of application. At 4, 7 and 10 DAT residues in nectar were below the LOD (<0.003 mg/kg). Mean residues of prothioconazole-desthio were found to be at 0.03 mg/kg at 0 DAT and decreased to $< LOQ$ (<0.01 mg/kg) at 7 DAT and $< LOD$ at 10 DAT.

Table A 54: Overview of the mean residues in Phacelia flowers, nectar and pollen

| Sampling time | Mean residues [mg/kg] (3 tunnels) | | | | | |
|---------------|-----------------------------------|-------------------------|-----------------|-------------------------|-----------------|-------------------------|
| | Flowers | | Pollen | | Nectar | |
| | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio |
| DAT 0 | 6.87 | 4.83 | 10.03 | 1.77 | 0.09 | 0.03 |
| DAT 2 | 0.71 | 4.27 | - | - | - | - |
| DAT 4 | - | - | $< 0.01 - 0.01$ | 0.29 | < 0.003 | 0.02 |
| DAT 7 | 0.02 | 0.64 | $< 0.01 - 0.01$ | 0.16 | < 0.003 | < 0.01 |
| DAT 10 | $< 0.01 - 0.01$ | 0.44 | 0.01 | 0.22 | < 0.003 | < 0.003 |

Detailed residues found in each sample are given in the table below.

⁵ QuPpe-PO-Method: "Quick Method for the Analysis of Numerous Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC-MS/MS Measurement", Version 10.1; EU Reference Laboratory for pesticides requiring Single Residue Methods (EURL-SRM)

Table A 55: Detailed summary of the residue in nectar and pollen study 1

Crop residue data from supervised field trials

Active substance (common name and content): Prothioconazole, nominal 250 g/L (actual 252.8 g/L)
Crop/crop group: Phacelia (melliferous crop)
Country: Germany
Indoor/outdoor: Tunnel
Responsible body for reporting (name, address): tier3 solutions GmbH
51381 Leverkusen, Germany

Reference no.:

Commercial product (name):

KCA 6.10.1/01

ADM.3500.F.2.B

Formulation (e.g. SC):

EC

Other active substance in the formulation (common name and content):

None

Residues calculated as:

Prothioconazole, prothioconazole desthio (mg/kg)

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|---|-----------------------------------|---------------------------|---|--|---------------------|------------------------------|---|-------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-3 40764 Reusrath, Germany N-EU 2020 | Phacelia (PHCTA) | 1) 27/03/2020 2) 19/05 (BBCH 60); 31/05/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: 203.3 | 400 | 02/06/2020 | BBCH 65 | Flowers | 7.1 0.82 0.03 <0.01 | 4.7 4.8 0.61 0.34 | 0 2 7 10 | Analytical method & validation: S19-20860 (MAC-1940V), LC- MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, LOD: 0.003 mg/kg for each analyte, Max. sample storage time: 124 days (sampling to extraction), max. extract storage time (extraction to analysis) 5 days. Extract stability tested during the method validation study. Results in all untreated specimens were below LOQ. |
| | | | Tunnel 2: 201.7 | 400 | 02/06/2020 | BBCH 65 | Flowers | 7.0 0.21 0.02 <0.01 | 5.2 1.4 0.70 0.33 | 0 2 7 10 | |
| | | | Tunnel 3: 202.2 | 400 | 02/06/2020 | BBCH 65 | Flowers | 6.5 1.1 0.02 0.01 | 4.6 6.6 0.62 0.66 | 0 2 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|---|-----------------------------------|---------------------------|---|--|---------------------|--------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-3 40764 Reusrath, Germany N-EU 2020 | Phacelia (PHCTA) | 1) 27/03/2020 2) 19/05 (BBCH 60); 31/05/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: 203.3 | 400 | 02/06/2020 | BBCH 65 | Pollen | 8.5 <0.01 <0.01 <0.01 | 1.5 0.19 0.14 0.19 | 0 4 7 10 | |
| | | | Tunnel 2: 201.7 | 400 | 02/06/2020 | BBCH 65 | Pollen | 12 <0.01 <0.01 0.01 | 2.1 0.28 0.17 0.25 | 0 4 7 10 | |
| | | | Tunnel 3: 202.2 | 400 | 02/06/2020 | BBCH 65 | Pollen | 9.6 0.01 0.01 0.01 | 1.7 0.39 0.16 0.23 | 0 4 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|---|-----------------------------------|---------------------------|---|--|---------------------|-------------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| (a) | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-3 40764 Reusrath, Germany N-EU 2020 | Phacelia (PHCTA) | 1) 27/03/2020 2) 19/05 (BBCH 60); 31/05/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: 203.3 | 400 | 02/06/2020 | BBCH 65 | Nectar | 0.11 n.d. n.d. <u>n.d.</u> | 0.03 0.03 <0.01 <u>n.d.</u> | 0 4 7 10 | |
| | | | Tunnel 2: 201.7 | 400 | 02/06/2020 | BBCH 65 | Nectar | 0.10 n.d. n.d. <u>n.d.</u> | 0.03 0.02 <0.01 <u>n.d.</u> | 0 4 7 10 | |
| | | | Tunnel 3: 202.2 | 400 | 02/06/2020 | BBCH 65 | Nectar | 0.05 n.d. n.d. <u>n.d.</u> | 0.02 0.02 <0.01 <u>n.d.</u> | 0 4 7 10 | |

(a) According to CODEX Classification / Guide

(b) Only if relevant

(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2.B at 0.8 L/ha)

(d) Year must be indicated

(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.7.2 Residues in pollen and nectar study 2

| | |
|-------------------|--|
| Comments of zRMS: | <p>In this study residues of prothioconazole and prothioconazole-desthio were measured in flower, pollen and nectar.</p> <p>The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers.</p> <p>The LOQ value was 0.01 mg/kg in flowers, pollen and nectar.</p> <p>Results: The levels of <u>residues in nectar were below the LOQ</u> after 3, 7 and 10 days of application in all trials.</p> <p><u>Remark:</u> The maximum storage interval from sampling until extraction was 143 days at $\leq -18^{\circ}\text{C}$.</p> <p>According to the results of Study no.: S19-02145 (KCA 6.1/04) the storage stability of prothioconazole was demonstrated in nectar surrogate at $\leq -18^{\circ}\text{C}$ in the dark over a storage period of up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. So storage stability of prothioconazole was not demonstrated in pollen and flower.</p> <p>However, prothioconazole-desthio, which is a more representative compound, is stable up to 13 months.</p> <p>The study is acceptable for residue data in nectar.</p> |
|-------------------|--|

| | |
|----------------|---|
| Reference: | KCA 6.10.1/02 |
| Report | <p>Study on the Effect of ADM.3500.F.2.B on Honey Bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Spain</p> <p>Persigehl, M. et al., 2021</p> <p>Study no.: P19010-4, sponsor no.: 000102471</p> |
| Guideline(s): | <p>OEPP/EPPO No. 170(4) (2010)</p> <p>OECD ENV/JM/MONO(2007)17</p> <p>EC Guidance document on residue analytical methods, SANCO/3029/99 rev.4</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Objective of the study

The aim of the study was to determine possible side effects of ADM.3500.F.2.B (prothioconazole 250g/L) after spray application on honey bees (*Apis mellifera* L.) in tunnel tents under confined semi-field conditions. In addition, Phacelia flowers, pollen and nectar foraging bees (for nectar preparation) were collected for residue analysis. As only the results of the residue analyses are relevant for this Part B Section 7, only the study part and corresponding results connected to the residue determination are summarised in the following.

Materials and methods

| | |
|------------------|--|
| 1. Crop/variety: | Phacelia, surrogate crop |
| Test system: | Three tunnels planted with Phacelia were set up for the collection of residue samples (sampling tunnels) and treated with the test item at BBCH 65-67. |
| Location: | 46160 Liria, Valencia, Spain |

| | |
|-----------------------------------|---|
| No of plots.: | Three tunnels for residue sampling. |
| Bee colonies, breed: | <i>Apis mellifera</i> L. |
| No. of colonies: | Three tunnels for residue sampling (treated plots), four untreated control tunnels (only sampling of flowers at DAT -1 and 0). |
| Acclimatisation: | Honey bee colonies were placed in the tunnels three days before application. |
| Applied product: | ADM.3500.F.2.B |
| Batch number | 3178-010519-01 |
| Actual content | 252.8 g/L |
| Expiry date | 30/04/2021 |
| Active substance: | Prothioconazole |
| No. of application: | 1x |
| Application rate: | 200 g a.s./ha, 0.8 L product/ha |
| Application: | Crop directed with boom sprayer |
| Date of application: | 18.05.2020 |
| Stage of crop development: | BBCH 65-67 |
| Date of sowing: | 26.02.2020 |
| Sampling of flowers: | Phacelia flowers were sampled before the application (DAT -1) and on DAT 0 after the application (in control and sampling tunnels) and on DAT 3, 7 and 10 (only in sampling tunnels). Flowers were cut at the base of each inflorescence from different plants randomly chosen. |
| Sampling of pollen: | The 3 sampling colonies in the sampling tunnels were fitted with pollen-traps in front of the bee hive entrance for the duration of the sampling period. Pollen was sampled on DAT 0 (after application), DAT 3, DAT 7 and DAT 10. On the sampling days, a pollen-grid was inserted into the pollen-traps for the duration of pollen sampling. |
| Sampling of nectar foraging bees: | Honey bee foragers were sampled from the 3 sampling tunnels after test item application at 0 days after application (DAT), at DAT 3, DAT 7 and DAT 10. On each sampling day, the hive entrance was sealed before sampling and the forager bees returned to the bee hives were collected by using a modified portable vacuum collector with a container filled with dry ice. Nectar was sampled from captured honey bee nectar foragers whose honey stomachs were dissected in the laboratories of the test facility for extraction of nectar. |
| Sample storage: | Flowers, pollen, honey bees and nectar samples were stored deep-frozen ($\leq -18^{\circ}\text{C}$) at the test facility. |
| Analytical method validation: | S19-20860 (MAC-1940V), Eurofins Agroscience Services Chem GmbH, Hamburg, Germany (2020). The limit of quantification was 0.01 mg/kg. |

Three tunnels treated with the test item were set up for the collection of residue samples (sampling tunnels). Three days before application (DAT -3), honey bee colonies were placed in the tunnels when Phacelia was in full flowering (BBCH 65). Honey bee colonies were containing approximately 7.500 adult bees each and 2 to 3 brood combs with brood in all stages out of 6 combs in total. The pre-exposure and exposure phase was conducted on a study field located in Liria, Valencia, Spain. The postexposure phase was conducted at a remote location nearby Montroy (Valencia), Spain, approximately 34.5 km distant from the study field. Applications of the test item (ADM.3500.F.2.B) were conducted by spraying the whole area of plants within the tunnels during full bee flight and at full flowering of the crop (BBCH 65-67).

Treated flowers were sampled on DAT 0, 3, 7 and 10. Untreated flowers were sampled at DAT -1 from sampling tunnels and at DAT -1 and 0 from control tunnels. Pollen as well as nectar foraging bees (for nectar preparation) were also collected on DAT 0 (after application), 3, 7 and 10. All samples were stored deep-frozen. Samples of flowers, pollen and nectar were analysed for their content of prothioconazole and its metabolite prothioconazole-desthio after extraction via LC-MS/MS. Residues are reported in terms of mg active substance/kg for flowers, pollen or nectar.

The analytical procedure for residue determination was the following: Samples of nectar, pollen and flowers were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). This extraction procedure is based on the QuPpe-PO-Method⁶ but with L-cystein added to increase analyte stability. After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturized cell disruption system (FastPrep) was included to the extraction procedure.

The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole and prothioconazole-desthio in nectar, pollen and flowers.

The maximum storage interval from sampling until extraction was 143 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 6 days. The stability of the analytes in the final extracts of flowers, pollen and nectar upon storage at typically 1 °C to 10 °C for 7 days was demonstrated in the method validation study.

Results and discussions

Residues of prothioconazole in nectar were low and the mean residue was 0.15 mg/kg at the day of application. At 3, 7 and 10 DAT residues in nectar were below the LOD (<0.003 mg/kg). Mean residues of prothioconazole-desthio were found to be at 0.15 mg/kg at 0 DAT and decreased to <LOQ (<0.01 mg/kg) at 3 DAT and < LOD at 10 DAT.

Table A 56: Overview of the mean residues in Phacelia flowers, nectar and pollen

| Sampling time | Mean residues [mg/kg] (3 tunnels) | | | | | |
|---------------|-----------------------------------|-------------------------|-----------------|-------------------------|-----------------|--------------------------------|
| | Flowers | | Pollen | | Nectar | |
| | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio |
| DAT 0 | 3.9 | 7.5 | 34.33 | 6.17 | 0.15 | 0.06 |
| DAT 3 | 0.17 | 3.53 | 0.19 | 1.77 | < 0.003 | < 0.01 |
| DAT 7 | 0.01 | 0.92 | < 0.01 - 0.03 | 0.96 | < 0.003 | < 0.003 - < 0.01 |
| DAT 10 | < 0.003 | 0.31 | < 0.01 - 0.02 | 0.57 | < 0.003 | < 0.003 |

Detailed residues found in each sample are given in the table below.

⁶ QuPpe-PO-Method: "Quick Method for the Analysis of Numerous Highly Polar Pesticides in Food Involving Extraction with Acidified Methanol and LC-MS/MS Measurement", Version 10.1; EU Reference Laboratory for pesticides requiring Single Residue Methods (EURL-SRM)

Table A 57: Detailed summary of the residue in nectar and pollen study 2

Crop residue data from supervised field trials

Active substance (common name and content): Prothioconazole, nominal 250 g/L (actual 252.8 g/L)
Crop/crop group: Phacelia (melliferous crop)
Country: Spain
Indoor/outdoor: Tunnel
Responsible body for reporting (name, address): tier3 solutions GmbH
51381 Leverkusen, Germany

Reference no.:

Commercial product (name):

KCA 6.10.1/02

ADM.3500.F.2.B

Formulation (e.g. SC):

EC

Other active substance in the formulation (common name and content):

None

Residues calculated as:

Prothioconazole, prothioconazole desthio (mg/kg)

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|---|-----------------------|--|-----------------------------------|---------------------------|---|--|---------------------|-----------------------------|---|-------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-4 46160 Llíria, Valencia, Spain S-EU 2020 | Phacelia | 1) 26/02/2020 2) 11/05 - 31/05/2020 3) n/a | Tunnel 1: 203.04 | 400 | 18/05/2020 | BBCH 65- 67 | Flowers | 3.9 0.25 0.01 n.d. | 7.5 5.1 0.77 0.35 | 0 3 7 10 | Analytical method & validation: S19-20860 (MAC-1940V), LC- MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, LOD: 0.003 mg/kg for each analyte, Max. sample storage time: 143 days (sampling to extraction), max. extract storage time (extraction to analysis) 6 days. Extract stability tested during the method validation study. Results in all untreated specimens were below LOD. |
| | | | Tunnel 2: 204.76 | 400 | 18/05/2020 | BBCH 65- 67 | Flowers | 3.5 0.14 0.01 n.d. | 6.5 3.4 0.78 0.24 | 0 3 7 10 | |
| | | | Tunnel 3: 203.58 | 400 | 18/05/2020 | BBCH 65- 67 | Flowers | 4.3 0.11 0.01 n.d. | 8.5 2.1 1.2 0.35 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|---|-----------------------|--|-----------------------------------|---------------------------|---|--|---------------------|------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-4 46160 Lliria, Valencia, Spain S-EU 2020 | Phacelia | 1) 26/02/2020 2) 11/05 - 31/05/2020 3) n/a | Tunnel 1: 203.04 | 400 | 18/05/2020 | BBCH 65- 67 | Pollen | 41 0.24 0.03 0.01 | 6.9 1.8 1.3 0.69 | 0 3 7 10 | |
| | | | Tunnel 2: 204.76 | 400 | 18/05/2020 | BBCH 65- 67 | Pollen | 42 0.16 0.02 0.02 | 6.2 1.7 0.85 0.57 | 0 3 7 10 | |
| | | | Tunnel 3: 203.58 | 400 | 18/05/2020 | BBCH 65- 67 | Pollen | 20 0.17 <0.01 <0.01 | 5.4 1.8 0.73 0.44 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|---|-----------------------|--|-----------------------------------|---------------------------|---|--|---------------------|-------------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | g a.s./ha | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| (a) | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-4 46160 Llíria, Valencia, Spain S-EU 2020 | Phacelia | 1) 26/02/2020 2) 11/05 - 31/05/2020 3) n/a | Tunnel 1: 203.04 | 400 | 18/05/2020 | BBCH 65- 67 | Nectar | 0.19 n.d. n.d. <u>n.d.</u> | 0.07 <0.01 n.d. <u>n.d.</u> | 0 3 7 10 | |
| | | | Tunnel 2: 204.76 | 400 | 18/05/2020 | BBCH 65- 67 | Nectar | 0.12 n.d. n.d. <u>n.d.</u> | 0.04 <0.01 n.d. <u>n.d.</u> | 0 3 7 10 | |
| | | | Tunnel 3: 203.58 | 400 | 18/05/2020 | BBCH 65- 67 | Nectar | 0.14 n.d. n.d. <u>n.d.</u> | 0.06 <0.01 <0.01 <u>n.d.</u> | 0 3 7 10 | |

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are actual rate of active substance as they were calculated with the actual concentration of the active substance:
(Nominal rate: 200 g a.s./ha prothioconazole equivalent to ADM.3500.F.2.B at 0.8 L/ha)
(d) Year must be indicated
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.7.3 Residues in pollen and nectar study 3

| | |
|-------------------|--|
| Comments of zRMS: | <p>In this study residues of prothioconazole and prothioconazole-desthio were measured in flower, pollen and nectar.</p> <p>The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers. The LOQ value was 0.01 mg/kg in flowers, pollen and nectar.</p> <p>Results: The levels of <u>residues in nectar were below the LOQ</u> after 7 and 10 days of application in all trials.</p> <p>Remark: The maximum storage interval from sampling until extraction was 348 days (more than 11 months) at $\leq -18^{\circ}\text{C}$. According to the results of Study no.: S19-02145 (KCA 6.1/04) the storage stability of prothioconazole was demonstrated in nectar surrogate at $\leq -18^{\circ}\text{C}$ in the dark over a storage period of up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. So storage stability of prothioconazole was not demonstrated in nectar, pollen and flower. However, prothioconazole-desthio which is a more representative compound, is stable up to 13 months. The study is acceptable.</p> |
|-------------------|--|

KCA 6.10.1/03

| | |
|----------------|--|
| Report | <p>Study on the Effect of MCW-2073 on Honey bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Germany Persigehl, M. et al., 2020 Report no.: P19010-1, Sponsor no.: 000102468</p> |
| Guideline(s): | <p>OEPP/EPPO No. 170(4) (2010) OECD ENV/JM/MONO(2007)17 EC Guidance document on residue analytical methods, SANCO/3029/99 rev.4</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Objective of the study

The aim of the study was to determine possible side effects of MCW-2073 SC (azoxystrobin + prothioconazole 200 + 150 g/L) after spray application on honey bees (*Apis mellifera* L.) in tunnel tents under confined semi-field conditions. In addition, Phacelia flowers, pollen and nectar foraging bees (for nectar preparation) were collected for residue analysis. As only the results of the residue analyses are relevant for this Part B Section 7, only the study part and corresponding results connected to the residue determination are summarised in the following.

Materials and methods

| | |
|------------------|---|
| 1. Crop/variety: | Phacelia, surrogate crop |
| Test system: | Three tunnels planted with Phacelia were set up for the collection of residue samples (sampling tunnels) and treated with the test item at BBCH 65. |
| Location: | 40764 Reusrath, Germany |
| No of plots.: | Three tunnels for residue sampling (treated plots), four untreated control tunnels (only sampling of flowers at DAT -1 and 0). |

| | |
|------------------------------------|---|
| Bee colonies, breed: | <i>Apis mellifera</i> L. |
| No. of colonies: | Three for the sampling of residues in pollen and nectar, one for each tunnel. |
| Acclimatisation: | Honey bee colonies were placed in the tunnels three days before application. |
| Applied product: | MCW-2073 SC |
| Batch number: | 1032-040218-01; |
| Active substances, actual content: | azoxystrobin: 206.6 (± 2.1) g/L, prothioconazole: 148.7 (± 2.6) g/L |
| Expiry date: | 01/02/2020 |
| No. of application: | 1x |
| Application rate: | 200 g azoxystrobin/ha, 150 g prothioconazole/ha (1.0 L product/ha) |
| Application: | Crop directed with hand-held boom sprayer |
| Date of application: | 27.06.2019 |
| Stage of crop development: | BBCH 65 |
| Date of sowing: | 17.04.2019 |
| Sampling of flowers: | Phacelia flowers were sampled before the application (DAT -1,) and on DAT 0 after the application (in control and sampling tunnels) and on DAT 3, 7 and 10 (only in sampling tunnels). Flowers were cut at the base of each inflorescence from different plants randomly chosen. |
| Sampling of pollen: | The 3 sampling colonies in the sampling tunnels were fitted with pollen-traps in front of the bee hive entrance for the duration of the sampling period. Pollen was sampled on DAT 0 (after application), DAT 3/4, DAT 7 and DAT 10. On the sampling days, a pollen-grid was inserted into the pollen-traps for the duration of pollen sampling. |
| Sampling of nectar foraging bees: | Honey bee foragers were sampled from the 3 sampling tunnels after test item application at 0 days after application (DAT), at DAT 3, DAT 7 and DAT 10. On each sampling day, the hive entrance was sealed before sampling and the forager bees returned to the bee hives were collected by using a modified portable vacuum collector with a container filled with dry ice. Nectar was sampled from captured honey bee nectar foragers whose honey stomachs were dissected in the laboratories of the test facility for extraction of nectar. |
| Sample storage: | Flowers, pollen, honey bees and nectar samples were stored deep-frozen at the test facility. |
| Analytical method validation: | S19-20860 (MAC-1940V), Eurofins Agrosience Services Chem GmbH, Hamburg, Germany (2020). The limit of quantification was 0.01 mg/kg. |

Three tunnels treated with the test item were set up for the collection of residue samples (sampling tunnels). Three days before application (DAT -3), honey bee colonies were placed in the tunnels when phacelia was in full flowering (BBCH 65). Honey bee colonies were small, containing approximately 6.000 adult bees each and 3 to 7 brood combs with brood in all stages out of 10 combs in total. The pre-exposure and exposure phase was conducted on a study field located in Reusrath, North Rhine-Westphalia, Germany. The postexposure phase was conducted at the test facility in Leverkusen, Germany. Applications of the test item (ADM.3500.F.2.B) were conducted by spraying the whole area of plants within the tunnels during full bee flight and at full flowering of the crop (BBCH 65). Treated flowers were sampled on DAT 0, 3, 7 and 10. Untreated flowers were sampled at DAT -1 from sampling tunnels and at DAT -1 and 0 from control tunnels. Pollen as well as nectar foraging bees (for nectar preparation) were collected on DAT 0 (after application), 3 (4), 7 and 10. All samples were stored

deep-frozen. Samples of flowers, pollen and nectar were analysed for their content of azoxystrobin, prothioconazole and its metabolite prothioconazole-desthio after extraction via LC-MS/MS. Residues are reported in terms of mg active substance/kg for flowers, pollen or nectar.

The analytical procedure for residue determination was the following: Samples of nectar, pollen and flowers were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturized cell disruption system (FastPrep) was included to the extraction procedure.

The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers.

For prothioconazole, the maximum storage interval from sampling until extraction was 348 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 6 days.

For prothioconazole-desthio, the maximum storage interval from sampling until extraction was 348 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 6 days.

The stability of the analytes in the final extracts of flowers, pollen and nectar upon storage at typically 1 °C to 10 °C for 7 days was demonstrated in the method validation study.

Results and discussions

Residues of prothioconazole in nectar were found to be at 0.21 mg/kg at the day of application. At 3, 7 and 10 DAT residues in nectar were found from max. 0.01 mg/kg at DAT 3 to below the LOD (<0.003 mg/kg). Mean residues of prothioconazole-desthio in nectar were low and the mean residue was 0.06 mg/kg at 0 DAT and decreased to max. 0.01 mg/kg at DAT 3 to below the LOD (<0.003 mg/kg).

Table A 58: Overview of the mean residues of prothioconazole and prothioconazole-desthio in phacelia flowers, pollen and nectar

| Sampling time | Mean residues [mg/kg] (3 tunnels) | | | | | |
|---------------|-----------------------------------|-------------------------|-----------------|-------------------------|-------------------------|--------------------------|
| | Flowers | | Pollen | | Nectar | |
| | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio |
| DAT 0 | 12.33 | 4.23 | 27.83 | 2.43 | 0.21 | 0.06 |
| DAT 3 | 2.93 | 3.83 | 0.26 | 0.58 | < 0.01 - 0.01 | < 0.003 - 0.01 |
| DAT 7 | 0.16 | 0.51 | 0.14 | 0.50 | < 0.003 | < 0.003 |
| DAT 10 | 0.05 | 0.21 | 0.12 | 0.35 | < 0.003 | < 0.003 |

Detailed residues found in each sample are given in the table below.

Table A 59: Detailed summary of the residue in nectar and pollen study 3

Crop residue data from supervised field trials

Active substance (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Phacelia (melliferous crop)
Country: Germany
Indoor/outdoor: Tunnel
Responsible body for reporting (name, address): tier3 solutions GmbH
51381 Leverkusen, Germany

Reference no.:

Commercial product (name):

KCA 6.10.1/03

MCW-2073 SC

Formulation (e.g. SC):

SC

Other active substance in the formulation (common name and content):

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

Residues calculated as:

Prothioconazole, prothioconazole desthio (mg/kg)

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|--|-----------------------------------|------------------------------|---|--|---------------------|---------------------------|---|-------------------|--|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-1 40764 Reusrath, Germany N-EU 2019 | Phacelia (PHCTA) | 1) 17/04/2019 2) 17/06 (BBCH 60); 22/06/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Flowers | 11 1.3 0.19 0.07 | 3.4 2.9 0.49 0.24 | 0 3 7 10 | Analytical method & validation: S19-20860 (MAC-1940V), LC- MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, LOD: 0.003 mg/kg for each analyte, Max. sample storage time: 348 days (sampling to extraction), max. extract storage time (extraction to analysis) 6 days prothioconazole and prothioconazole-desthio). Extract stability tested during the method validation study. Results in all untreated specimens were below LOD. |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Flowers | 12 3.9 0.22 0.03 | 4.2 4.1 0.62 0.15 | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Flowers | 14 3.6 0.07 0.06 | 5.1 4.5 0.43 0.25 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|--|-----------------------------------|------------------------------|---|--|---------------------|-----------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-1 40764 Reusrath, Germany N-EU 2019 | Phacelia (PHCTA) | 1) 17/04/2019 2) 17/06 (BBCH 60); 22/06/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Pollen | 28 0.27 0.18 0.11 | 1.8 0.66 0.50 0.30 | 0 3 7 10 | |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Pollen | 7.5 0.24 0.08 0.10 | 1.2 0.47 0.43 0.28 | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Pollen | 48 0.26 0.16 0.14 | 4.3 0.61 0.58 0.46 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|--|-----------------------------------|------------------------------|---|--|---------------------|--------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-1 40764 Reusrath, Germany N-EU 2019 | Phacelia (PHCTA) | 1) 17/04/2019 2) 17/06 (BBCH 60); 22/06/ (start full flowering, BBCH 65) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Nectar | 0.22 < 0.01 n.d. n.d. | 0.08 n.d. n.d. n.d. | 0 3 7 10 | |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Nectar | 0.17 < 0.01 n.d. n.d. | 0.05 n.d. n.d. n.d. | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 27/06/2019 | BBCH 65 | Nectar | 0.24 0.01 n.d. n.d. | 0.04 0.01 n.d. n.d. | 0 3 7 10 | |

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are nominal rate of active substance
(d) Year must be indicated
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.7.4 Residues in pollen and nectar study 4

| | |
|-------------------|--|
| Comments of zRMS: | <p>In this study, residues of prothioconazole and prothioconazole-desthio were measured in flower, pollen and nectar.</p> <p>The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers. The LOQ value was 0.01 mg/kg in flowers, pollen and nectar.</p> <p>Results: The levels of <u>residues in nectar were below the LOQ</u> after 3, 7 and 10 days of application in all trials.</p> <p>Remark: The maximum storage interval from sampling until extraction was 384 days (more than 12 months) at $\leq -18^{\circ}\text{C}$. According to the results of Study no.: S19-02145 (KCA 6.1/04) the storage stability of prothioconazole was demonstrated in nectar surrogate at $\leq -18^{\circ}\text{C}$ in the dark over a storage period of up to 6 months. For prothioconazole in/on pollen and flowers the relative recoveries were already below 70% after 2 months of storage. So storage stability of prothioconazole was not demonstrated in nectar, pollen and flower. However, prothioconazole-desthio which is a more representative compound, is stable up to 13 months. The study is acceptable.</p> |
|-------------------|--|

| | |
|----------------|--|
| Reference: | KCA 6.10.1/04 |
| Report | <p>Study on the Effect of MCW-2073 on Honey bee Colonies (<i>Apis mellifera</i> L.) under Semi-Field Conditions in Spain Persigehl, M. et al., 2021 Report no.: P19010-2, Sponsor no.: 000102469</p> |
| Guideline(s): | <p>OEPP/EPPO No. 170(4) (2010) OECD ENV/JM/MONO(2007)17 EC Guidance document on residue analytical methods, SANCO/3029/99 rev.4</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |
| Acceptability: | Yes |

Objective of the study

The aim of the study was to determine possible side effects of MCW-2073 SC (azoxystrobin + prothioconazole 200 + 150 g/L) after spray application on honey bees (*Apis mellifera* L.) in tunnel tents under confined semi-field conditions. In addition, Phacelia flowers, pollen and nectar foraging bees (for nectar preparation) were collected for residue analysis. As only the results of the residue analyses are relevant for this Part B Section 7, only the study part and corresponding results connected to the residue determination are summarised in the following.

Materials and methods

| | |
|------------------|---|
| 1. Crop/variety: | Phacelia, surrogate crop |
| Test system: | Three tunnels planted with Phacelia were set up for the collection of residue samples (sampling tunnels) and treated with the test item at BBCH 65. |
| Location: | 40764 Reusrath, Germany |
| No of plots: | Three tunnels for residue sampling (treated plots), four untreated control tunnels (only sampling of flowers at DAT -1 and 0). |

| | |
|------------------------------------|---|
| Bee colonies, breed: | <i>Apis mellifera</i> L. |
| No. of colonies: | Three for the sampling of residues in pollen and nectar, one for each tunnel. |
| Acclimatisation: | Honey bee colonies were placed in the tunnels two days before application. |
| Applied product: | MCW-2073 SC |
| Batch number: | 1032-040218-01; |
| Active substances, actual content: | azoxystrobin: 206.6 (\pm 2.1) g/L, prothioconazole: 148.7 (\pm 2.6) g/L |
| Expiry date: | 01/02/2020 |
| No. of application: | 1x |
| Application rate: | 200 g azoxystrobin/ha, 150 h prothioconazole/ha (1.0 L product/ha) |
| Application: | Crop directed with hand-held boom sprayer |
| Date of application: | 23.05.2019 |
| Stage of crop development: | BBCH 65 |
| Date of sowing: | 12.03.2019 |
| Sampling of flowers: | Phacelia flowers were sampled before the application (DAT -1,) and on DAT 0 after the application (in control and sampling tunnels) and on DAT 3, 7 and 10 (only in sampling tunnels). Flowers were cut at the base of each inflorescence from different plants randomly chosen. |
| Sampling of pollen: | The 3 sampling colonies in the sampling tunnels were fitted with pollen-traps in front of the bee hive entrance for the duration of the sampling period. Pollen was sampled on DAT 0 (after application), DAT 3, DAT 7 and DAT 10. On the sampling days, a pollen-grid was inserted into the pollen-traps for the duration of pollen sampling. |
| Sampling of nectar foraging bees: | Honey bee foragers were sampled from the 3 sampling tunnels after test item application at 0 days after application (DAT), at DAT 3, DAT 7 and DAT 10. On each sampling day, the hive entrance was sealed before sampling and the forager bees returned to the bee hives were collected by using a modified portable vacuum collector with a container filled with dry ice. Nectar was sampled from captured honey bee nectar foragers whose honey stomachs were dissected in the laboratories of the test facility for extraction of nectar. |
| Sample storage: | Flowers, pollen, honey bees and nectar samples were stored deep-frozen at the test facility. |
| Analytical method validation: | S19-20860 (MAC-1940V), Eurofins Agrosience Services Chem GmbH, Hamburg, Germany (2020). The limit of quantification was 0.01 mg/kg. |

Three tunnels treated with the test item were set up for the collection of residue samples (sampling tunnels). Two days before application (DAT -2), honey bee colonies were placed in the tunnels when phacelia was in full flowering (BBCH 65). Honey bee colonies were small, containing approximately 6.000 adult bees each and 3 to 4 brood combs with brood in all stages out of 6 combs in total. The pre-exposure and exposure phase was conducted on a study field located in Liria, Valencia, Spain. The postexposure phase was conducted at the test site in Picassent (Valencia), Spain.

Applications of the test item (ADM.3500.F.2.B) were conducted by spraying the whole area of plants within the tunnels during full bee flight and at full flowering of the crop (BBCH 65).

Treated flowers were sampled on DAT 0, 3, 7 and 10. Untreated flowers were sampled at DAT -1 from sampling tunnels and at DAT -1 and 0 from control tunnels. Pollen as well as nectar foraging bees (for nectar preparation) were collected on DAT 0 (after application), 3, 7 and 10. All samples were stored deep-

frozen. Samples of flowers, pollen and nectar were analysed for their content of azoxystrobin, prothioconazole and its metabolite prothioconazole-desthio after extraction via LC-MS/MS. Residues are reported in terms of mg active substance/kg for flowers, pollen or nectar.

The analytical procedure for residue determination was the following: Samples of nectar, pollen and flowers were extracted with methanol/L-cystein-solution (50 mg/L)/formic acid (50+50+0.5, v+v+v). After shaking on a platform shaker for 15 minutes the samples were centrifuged and an aliquot was transferred into a HPLC-Vial. For pollen an additional homogenisation step with a miniaturized cell disruption system (FastPrep) was included to the extraction procedure.

The method used was validated in study S19-20860 (MAC-1940V) for the determination of prothioconazole, prothioconazole-desthio and azoxystrobin in nectar, pollen and flowers.

For prothioconazole, the maximum storage interval from sampling until extraction was 384 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 7 days.

For prothioconazole-desthio, the maximum storage interval from sampling until extraction was 384 days at ≤ -18 °C. The maximum storage interval of final sample extracts at typically 1 °C to 10 °C from extraction until injection to LC-MS/MS was 7 days.

The stability of the analytes in the final extracts of flowers, pollen and nectar upon storage at typically 1 °C to 10 °C for 7 days was demonstrated in the method validation study.

Results and discussions

Residues of prothioconazole in nectar were low with 0.08 mg/kg at the day of application. At 3, 7 and 10 DAT residues in nectar were found to be at the LOD (<0.003 mg/kg).

Mean residues of prothioconazole-desthio in nectar were low and the mean residue was 0.03 mg/kg at 0 DAT and decreased to <0.01 mg/kg at DAT 3 to below the LOD (<0.003 mg/kg).

Table A 60: Overview of the mean residues of prothioconazole and prothioconazole-desthio in phacelia flowers, pollen and nectar

| Sampling time | Mean residues [mg/kg] (3 tunnels) | | | | | |
|---------------|-----------------------------------|-------------------------|-----------------|-------------------------|-------------------|-------------------------|
| | Flowers | | Pollen | | Nectar | |
| | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio | Prothioconazole | Prothioconazole-desthio |
| DAT 0 | 4.77 | 7.13 | 50.33 | 4.13 | 0.08 | 0.03 |
| DAT 3 | 0.21 | 2.73 | 0.15 | 0.39 | < 0.003 | < 0.01 |
| DAT 7 | 0.14 | 0.89 | 0.04 | 0.24 | < 0.003 | < 0.003 |
| DAT 10 | $< 0.01 - 0.01$ | 0.30 | $< 0.01 - 0.01$ | 0.16 | < 0.003 | < 0.003 |

Detailed residues found in each sample are given in the table below.

Table A 61: Detailed summary of the residue in nectar and pollen study 4

Crop residue data from supervised field trials

Active substance (common name and content): Prothioconazole, nominal 150 g/L (actual 148.7 g/L)
Crop/crop group: Phacelia (melliferous crop)
Country: Spain
Indoor/outdoor: Tunnel
Responsible body for reporting (name, address): tier3 solutions GmbH
51381 Leverkusen, Germany

Reference no.:

Commercial product (name):

KCA 6.10.1/04

MCW-2073 SC

Formulation (e.g. SC):

SC

Other active substance in the formulation (common name and content):

Azoxystrobin, nominal 200 g/L (actual 206.6 g/L)

Residues calculated as:

Prothioconazole, prothioconazole desthio (mg/kg)

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|--|-----------------------|---|-----------------------------------|------------------------------|---|--|---------------------|------------------------------|---|-------------------|---|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-2 46160 Liria, Valencia, Spain S-EU 2019 | Phacelia (PHCTA) | 1) 12/03/2019 2) 17/05 (start flowering BBCH 60- 63); 23/05/19 (full flowering, BBCH 65); 02/06/19 (end flowering, BBCH 68) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Flowers | 6.8 0.27 0.02 0.01 | 7.5 3.2 0.63 0.34 | 0 3 7 10 | Analytical method & validation: S19-20860 (MAC-1940V), LC-MS/MS For method validation please refer to dRR Part B.5, point KCP 5.1.2. LOQ: 0.01 mg/kg for each analyte, LOD: 0.003 mg/kg for each analyte, Max. sample storage time: 384 days (sampling to extraction), max. extract storage time (extraction to analysis) 7 days for prothioconazole and prothioconazole-desthio. Extract stability tested during the method validation study. Results in all untreated specimens were below LOD. |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Flowers | 3.9 0.21 0.14 <0.01 | 6.8 3.1 2.8 0.25 | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Flowers | 3.6 0.14 0.25 <0.01 | 7.1 1.9 1.01 0.32 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|---|-----------------------|---|-----------------------------------|------------------------------|---|--|---------------------|-----------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-2 46160 Llíria, Valencia, Spain S-EU 2019 | Phacelia (PHCTA) | 1) 12/03/2019 2) 17/05 (start flowering BBCH 60- 63); 23/05/19 (full flowering, BBCH 65); 02/06/19 (end flowering, BBCH 68) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Pollen | 52 0.22 0.07 0.01 | 4.8 0.41 0.26 0.18 | 0 3 7 10 | |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Pollen | 47 0.13 0.02 <0.01 | 3.9 0.36 0.19 0.12 | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Pollen | 52 0.10 0.03 <0.01 | 3.7 0.39 0.26 0.17 | 0 3 7 10 | |

| 1 | 2 | 3 | 4 | | 5 | 6 | 7 | 8 | 8.1 | 9 | 10 |
|---|-----------------------|---|-----------------------------------|------------------------------|---|--|---------------------|------------------------------|---|-------------------|------------------|
| Trial No./ Location/ EU zone/ Year | Commodity/ Variety | Date of 1.Sowing or planting 2.Flowering 3. Harvest | Application rate per treatment | | Dates of treatment or no. of treatments and last date | Growth stage at last treatment or date | Portion analysed | Residues (mg/kg) | | PHI (days) | Details on trial |
| | | | kg a.s./ha (nominal) | Water (L/ha) (nominal) | | | | Prothio- conazole | Prothio- conazole- desthio (sum of isomers) | DALA (days) | |
| | (a) | (b) | (c) | | (d) | | | | | | (e) |
| P19010-2 46160 Llíria, Valencia, Spain S-EU 2019 | Phacelia (PHCTA) | 1) 12/03/2019 2) 17/05 (start flowering BBCH 60- 63); 23/05/19 (full flowering, BBCH 65); 02/06/19 (end flowering, BBCH 68) 3) n/a | Tunnel 1: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Nectar | 0.10 n.d. n.d. n.d. | 0.03 <0.01 n.d. n.d. | 0 3 7 10 | |
| | | | Tunnel 2: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Nectar | 0.08 n.d. n.d. n.d. | 0.03 <0.01 n.d. n.d. | 0 3 7 10 | |
| | | | Tunnel 3: PTZ: 0.150 | 400 | 23/05/2019 | BBCH 65 | Nectar | 0.06 n.d. n.d. n.d. | 0.03 <0.01 n.d. n.d. | 0 3 7 10 | |
| | | | | | | | | | | | |
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- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) These values are nominal rate of active substance
(d) Year must be indicated
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.7.5 Residues in honey study 1

| | |
|-------------------|---|
| Comments of zRMS: | <p>The study was conducted under semi-field conditions (use of insect-proof tunnels) to determine the residue levels of prothioconazole and its metabolites (1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in Phacelia honey specimens following after one foliar application of the formulated product ADM.03500.F.2.B, an EC formulation with a nominal concentration of 250 g/L of prothioconazole applied at the target dose rate of 200 g a.s./ha).</p> <p><u>Prothioconazole</u></p> <p>The analytical method was validated for each reference item on honey in compliance with Guideline SANTE/2020/12830, Rev.1 of 24/02/2021 during another study performed at GIRPA in 2021.</p> <p>These LOQ correspond to a sum of 0.060 mg/kg expressed as prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)).</p> <p>Mature honey specimens were stored during a maximum of 24 days from field sampling event until extraction in the analytical laboratory, thus no storage stability data of the compounds in frozen honey is necessary.</p> <p>Results:</p> <p>Any residues of prothioconazole expressed as prothioconazole-desthio have not been found in mature honey.</p> <p><u>TDMs</u></p> <p>The analytical procedure was validated for the determination of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey according to SANTE/2020/12830, rev.1 for honey with LOQ of 0.01 mg/kg.</p> <p>Mature honey specimens were stored during a maximum of 59 days. In a separates study S19-01126 storage stability of the analytes samples of honey upon storage at $\leq -18^{\circ}\text{C}$ was demonstrated for 153 days which well cover the 59 days of the current study.</p> <p>Results:</p> <p>Residues of TDMs in mature honey were below the LOQ of 0.01 mg/kg for each compound except for TLA in one trial, where low residues were found at 0.02 mg/kg with similar level in the control sample.</p> <p>The study is acceptable.</p> |
|-------------------|---|

| | |
|---------------|--|
| Reference: | KCA 6.10.1/05 |
| Report | <p>Magnitude of the residue of prothioconazole and its metabolites in honey after application of ADM.03500.F.2.B on Phacelia crop under semi-field conditions in Europe- 2021</p> <p>Bougrier, M.A., 2022</p> <p>Study No.: 555-2021, sponsor no.: 000108776</p> |
| Guideline(s): | <p>OECD (2009), Test No. 509: Crop Field Trial, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing;</p> <p>SANTE/11956/2016 rev. 9, Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey, 14 September 2018;</p> <p>SANTE/2020/12830, Rev.1, 24 February 2021; Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes Guidance Documents SANCO/3029/99 and SANCO/825/00);</p> <p>Guidance Document on Pesticide Residue Analytical Methods ENV/JM/MONO(2007)17</p> |
| Deviations: | None with impact on study results |
| GLP: | Yes |

Acceptability: Yes

Objective of the study

The aim of the study was to determine the residue levels of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy, prothioconazole-desthio-5-hydroxy, prothioconazole-desthio-6-hydroxy and prothioconazole-desthio alpha-hydroxy, including their acid-hydrolysable conjugates and of triazole derivative metabolites (1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA)) in Phacelia honey specimens following one foliar application of the formulated product ADM.03500.F.2.B (prothioconazole 250 g/L) to Phacelia grown in tunnels.

Materials and methods

| | |
|------------------------------------|---|
| 1. Crop/variety: | Phacelia, surrogate crop |
| Test system: | Four semi-field trials were set up on Phacelia using bee tunnels, in Northern and Southern Europe. |
| Location: | Northern France, Germany, Denmark and Italy |
| No of plots.: | Two tunnels per trial were set up for the collection of honey (one treated (T) and one untreated (U)) |
| Bee colonies, breed: | <i>Apis mellifera</i> L. |
| Acclimatisation: | Honey bee colonies were placed in the tunnels one days before application. |
| Applied product: | ADM.03500.F.2.B |
| Batch number: | 3178-010519-01; |
| Active substances, actual content: | Prothioconazole: 248.6 g/L |
| Expiry date: | 24/03/2022 |
| No. of application: | 1x |
| Application rate: | 200 g prothioconazole/ha (0.805 L product/ha (using actual concentration)) |
| Application: | Crop directed with hand-held boom sprayer |

| Trial | Crop details | | Application details | | Sampling of honey | |
|---------------|--------------|-----------------------|---------------------|-------------------|-------------------|-------------------|
| | Sowing | Bee hive introduction | Date of application | Crop stage (BBCH) | Date of sampling | Crop stage (BBCH) |
| 555-2021 FR01 | 24/06/21 | 16/08/21 | 17/08/21 | 62 | 27/08/21 | 67 |
| 555-2021 GE02 | 15/07/21 | 05/09/21 | 06/09/21 | 64 | 13/09/21 | 67 |
| 555-2021 DK03 | 30/06/21 | 01/09/21 | 02/09/21 | 64 | 16/09/21 | 67 |
| 555-2021 IT04 | 06/07/21 | 23/09/21 | 24/09/21 | 63 | 07/10/21 | 65-66 |

| | |
|-------------------------------|---|
| Sampling of honey: | Mature honey was sampled. Mature honey was defined as honey sampled from capped honey cells or honey with an expected water between 16% and 20 %. Honey was collected from inside the colony on the empty combs previously added on the day of the test item application event. |
| Sampling timing: | After application, the beehives were left in the tunnels until the honey is ripe, or until honey cell-closure (normally about 7-14 days after introduction of the colonies in the tunnel), or until the end of flowering, whichever was the earliest. |
| Sample storage: | Specimens were stored and shipped deep-frozen at a target temperature below -18°C. |
| Analytical method validation: | Prothioconazole-desthio: Method based on the method 00979/M001, method was fully validated for each reference item on honey during another study performed at GIRPA in 2021 |

(GIRPA study code: B21S-A4-P-01 – Sponsor reference : 000108024)

Triazole derivative metabolites (TDMs): Method was fully validated for determination of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey within this analytical phase (performed at Eurofins, study code: S21-06181-L1).

Four trials, each involving two tunnels, were set up for the collection of residue samples. One day before application (DAT -1), honeybee colonies were placed in the tunnels.

Applications of the test item (ADM.3500.F.2.B) were conducted by spraying the whole area of plants within the treated tunnels during full bee flight and at flowering of the crop (BBCH 62-64).

Mature honey was sampled on DAT as soon as enough mature honey was available or end of flowering. Mature honey was defined as honey sampled from capped honey cells or honey with an expected water between 16% and 20%. Honey was collected from inside the colony on the empty combs previously added on the day of the test item application event. Honey specimens were collected on the combs using a pipette or a syringe or by gently pushing with a device into the walls of the storage cells, allowing the honey to flow. This collection way always made sure that only honey was collected without any debris (no cell's wall, no pollen etc). All samples were stored deep-frozen.

Honey samples were analysed after extraction for their content of prothioconazole-desthio expressed as follows:

- prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, all expressed as prothioconazole-desthio (sum of isomers) and
- sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)).

The analytical procedure for residue determination was the following: Residues of prothioconazole-desthio, 3-hydroxy-prothioconazole-desthio, 4-hydroxy-prothioconazole-desthio, 5-hydroxy-prothioconazole-desthio, 6-hydroxy-prothioconazole-desthio, alpha-hydroxy-prothioconazole-desthio, all expressed as prothioconazole-desthio (sum of isomers) were extracted from laboratory samples of honey by maceration with a mixture of acetonitrile/water (80:20, v/v).

An hydrolysis step was performed to convert glycoside-bound analogues into the respective hydroxy analytes. Then, extracts were purified by dispersive solid phase extraction. The quantification was performed by liquid chromatography with tandem mass spectrometry detection (LC-MS/MS).

To ensure unambiguous identification, two mass transitions were monitored for each reference item.

The method used was based on method 00979/M001 and validated in GIRPA study code: B21S-A4-P-01 – Sponsor reference : 000108024.

In addition, honey samples were analysed after extraction for their content of triazole derivative metabolites (TDMs) expressed as follows:

- 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA).

The analytical procedure for residue determination was the following: A sample of honey was dissolved in 10 mL of aqueous solution of formic acid 1% (v/v). The solution was transferred through a PES syringe filter into HPLC vial. Quantification and confirmation were performed by use of LC-DMS-MS/MS detection.

For each analyte, one mass transition was evaluated for quantification. For TA, a second mass transition was monitored for confirmation of peak identity but was not used for quantification of samples. For all other analytes (T, TAA and TLA) a second mass transition was not available. Therefore, a different and independent LC-DMS-MS/MS detection was used to confirm the peak identities.

The method used was validated in within the analytical phase (Eurofins) for the determination of for the determination of 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid in honey.

For prothioconazole metabolites, the maximum storage interval from sampling until extraction was 24 days at $\leq -18^{\circ}\text{C}$. Thus, no freezer storage stability study is required. The maximum storage interval of final sample extracts from extraction until injection to LC-MS/MS was $< 24\text{h}$.

For TDMs, the maximum storage interval from sampling until extraction was 59 days at $\leq -18^{\circ}\text{C}$. The maximum storage interval of final sample extracts from extraction until injection to LC-MS/MS was 2 days. The stability of the analytes in the final extracts of honey was proven within the analytical phase using fortified extracts stored under the same conditions together with the field specimens.

Results and discussions

The applicability/suitability of the analytical procedures for honey was demonstrated by concurrent recoveries.

Any residues of prothioconazole expressed as prothioconazole-desthio have not been found in mature honey. All residues were found to be below the LOD of 0.003 mg/kg for each compound.

Residues of TDMs in mature honey were found to be below the LOQ of 0.01 mg/kg for each compound except for TLA in one trial, where low residues were found at 0.02 mg/kg with similar level in the control sample.

Residue results expressed as prothioconazole-desthio in honey are summarised in the following table:

Table A 62: Overview of the residues of prothioconazole expressed as prothioconazole-desthio in honey

| Trial Reference | Matrix | Actual DAA ⁽¹⁾ | Residue results expressed as prothioconazole-desthio (mg/kg) ⁽³⁾ | | | | | | |
|-----------------|--------------|---------------------------|---|---------------------|---------------------|---------------------|---------------------|-----------------------------|--------------------|
| | | | Desthio ⁽²⁾ | 3-OH ⁽²⁾ | 4-OH ⁽²⁾ | 5-OH ⁽²⁾ | 6-OH ⁽²⁾ | α -OH ⁽²⁾ | Sum ⁽²⁾ |
| 555-2021 FR01 | Mature Honey | 10 | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD |
| 555-2021 GE02 | Mature Honey | 7 | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD |
| 555-2021 DK03 | Mature Honey | 14 | <LOQ | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD |
| 555-2021 IT04 | Mature Honey | 14 | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD | <LOD |

(3) **DAA:** Days After Application

(4) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α -OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

(3) **For each compound:**

- LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio
- LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio

For the sum:

- LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio
- LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

Residue results for TDMs in honey are summarised in the following table:

Table A 63: Overview of the TDM residues in honey

| Trial | Matrix | Actual DAA | Residue results (mg/kg) | | | |
|---------------|--------------|------------|-------------------------|----------------------|------------------|----------------------|
| | | | 1,2,4-Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid |
| 555-2021 FR01 | Mature Honey | 10 | <LOD | <LOQ | <LOQ | <LOD |
| 555-2021 GE02 | Mature Honey | 7 | <LOD | <LOQ | <LOD | 0.02 |
| 555-2021 DK03 | Mature Honey | 14 | <LOD | <LOD | <LOQ | <LOD |
| 555-2021 IT04 | Mature Honey | 14 | <LOD | <LOD | <LOD | <LOQ |

DAA: Days After Application

LOQ = 0.01 mg/kg and LOD = 0.003 mg/kg for each analyte

Detailed residues found in each sample are given in the tables below.

Table A 64: Summary of the residue in honey study 1 (Prothioconazole-desthio)

Active Substance: prothioconazole
Crop / crop group: Phacelia / Melliferous crop
Responsible for reporting: Marie-Ange Bougrier / TESTAPI
464, Sarré, 49350 Gennes - France

Commercial Product: ADM.03500.F.2.B
Indoor/glasshouse/outdoor: outdoor (semi-field using bee tunnels)

Other a.s. in formulation: -
Residue calculated as: 1,2,4-Triazole (mg/kg),
Triazole Acetic Acid (mg/kg),
Triazole Alanine (mg/kg),
Triazole Lactic Acid (mg/kg)

Nominal Content of a.s.: 250 g/L
Formulation: EC

| Thiazolo Lactic Acid (mg/kg) | | | | | | | | | | | | | | | |
|---|-----------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|---------------------------|------------------------|------------------------|------------------------|-----------------------|--|
| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽³⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | Desthio ⁽²⁾ | 3-OH ⁽²⁾ | 4-OH ⁽²⁾ | 5-OH ⁽²⁾ | | |
| Northern Europe Northern France 49350 Gennes-Val de-Loire (Pays de la Loire) Semi-field trial 555-2021 FR01 | Phacelia STALA | 1- 24/06/21 | Broadcast foliar application Boom sprayer | 0.2021 (0.2033) | 303 | 0.0667 (0.0671) | 17/08/21 | 62 | Mature honey | <LOD | <LOD | <LOD | <LOD | 10 | Untreated specimen: <LOD |
| | | 2- 13/08/21 to 30/08/21 | | | | | | | | 6-OH ⁽²⁾ | α-OH ⁽²⁾ | Sum ⁽²⁾ | - | 10 | LC-MS/MS Method Validated in the GIRPA study code B21S-A4-P- 01 |
| | | 3- NAP | | | | | | | | <LOD | <LOD | <LOD | - | | |

(1) **DAA** : Days After Application (2) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α-OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

(3) **For each compound:** - LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio - LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio.

For the sum: LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations of the sum were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|--|-----------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|---------------------------|--------------------------------|------------------------|------------------------|-----------------------|---|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽³⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | Desthio ⁽²⁾ | 3-OH ⁽²⁾ | 4-OH ⁽²⁾ | 5-OH ⁽²⁾ | | |
| Northern Europe Germany 47574 Goch (North Rhine- Westphalia) Semi-field trial 555-2021 GE02 | Phacelia STALA | 1- 15/07/21 2- 27/08/21 to 15/09/21 3- NAP | Broadcast foliar application Boom sprayer | 0.1948 (0.1959) | 292 | 0.0667 (0.0671) | 06/09/21 | 64 | Mature honey | <LOD | <LOD | <LOD | <LOD | 7 | Untreated specimen: <LOD |
| | | | | | | | | | | 6-OH ⁽²⁾ | α -OH ⁽²⁾ | Sum ⁽²⁾ | - | 7 | LC-MS/MS Method Validated in the GIRPA study code B21S-A4-P-01 |
| | | | | | | | | | | <LOD | <LOD | <LOD | - | | |

(1) **DAA** : Days After Application

(2) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α -OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

(3) **For each compound**: - LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio - LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio.

For the sum: LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations of the sum were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|--|-----------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|----------------------------------|-------------------------------|-------------------------------|-------------------------------|-----------------------|---|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽³⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | Desthio ⁽²⁾ | 3-OH ⁽²⁾ | 4-OH ⁽²⁾ | 5-OH ⁽²⁾ | | |
| Northern Europe Denmark 5580 Nørre Aby (South Denmark) Semi-field trial 555-2021 DK03 | Phacelia STALA | 1- 30/06/21 | Broadcast foliar application Boom sprayer | 0.2031 (0.2043) | 203 | 0.1000 (0.1006) | 02/09/21 | 64 | Mature honey | <LOQ | <LOD | <LOD | <LOD | 14 | Untreated specimen not collected ⁽⁴⁾ |
| | | 2- 20/08/21 to mid- October 2021 | | | | | | | | 6-OH ⁽²⁾ | α-OH ⁽²⁾ | Sum ⁽²⁾ | - | 14 | LC-MS/MS Method Validated in the GIRPA study code B21S-A4-P-01 |
| | | 3- NAP | | | | | | | | <LOD | <LOD | <LOD | - | | |

(1) **DAA** : Days After Application

(2) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α -OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

(3) **For each compound**: - LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio - LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio.

For the sum: LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations of the sum were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

(4) Not enough mature honey in beehive in the untreated tunnel, but since all residue in treated specimens were found to be < LOQ, untreated specimens were not necessary

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|---|------------------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|----------------------------------|-------------------------------|-------------------------------|-------------------------------|-----------------------|---|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽³⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | Desthio ₍₂₎ | 3-OH ₍₂₎ | 4-OH ₍₂₎ | 5-OH ₍₂₎ | | |
| Southern Europe Italy 12050 Castagnito d'Alba (Piedmont) Semi-field trial 555-2021 IT04 | Phacelia F03942/03214 | 1- 06/07/21 | Broadcast foliar application Boom sprayer | 0.1928 (0.1939) | 289 | 0.0667 (0.0671) | 24/09/21 | 63 | Mature honey | <LOD | <LOD | <LOD | <LOD | 13 | Untreated specimen: <LOD |
| | | 2- 16/09/21 to 30/10/21 | | | | | | | | | | | | | |
| | | 3- NAP | | | | | | | | | | | | | |
| | | | | | | | | | | 6-OH ₍₂₎ | α-OH ₍₂₎ | Sum ₍₂₎ | - | 13 | LC-MS/MS Method Validated in the GIRPA study code B21S-A4-P-0 |
| | | | | | | | | | | <LOD | <LOD | <LOD | - | | Study Max. Storage Interval between: -sampling and extraction: 24 days |
| | | | | | | | | | | | | | | | -extraction and analyses: <24 hours |

(1) **DAA** : Days After Application

(2) **Desthio**=prothioconazole-desthio, **3-OH**= 3-hydroxy-prothioconazole-desthio, **4-OH**= 4-hydroxy-prothioconazole-desthio, **5-OH**= 5-hydroxy-prothioconazole-desthio, **6-OH**= 6-hydroxy-prothioconazole-desthio, **α-OH**= alpha-hydroxy-prothioconazole-desthio, **sum**= sum of prothioconazole-desthio and all metabolites containing the 2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl-2H-1,2,4-triazole moiety, expressed as prothioconazole-desthio (sum of isomers)

(3) **For each compound**: - LOQ (Limit of quantification): **0.010 mg/kg** expressed as prothioconazole-desthio - LOD (Limit of detection) **0.003 mg/kg** expressed as prothioconazole-desthio.

For the sum: LOQ (Limit of quantification): **0.060 mg/kg** expressed as prothioconazole-desthio LOD (Limit of detection): **0.018 mg/kg** expressed as prothioconazole-desthio

The calculations of the sum were performed with the value of each reference item when >LOQ, with value of 0.010 mg/kg for results <LOQ and as zero for results <LOD. All Residue results between LOD and LOQ are noted <LOQ

Table A 65: Summary of the residue in honey study 1 (TDMs)

| | | | |
|-----------------------------------|--|-----------------------------------|---|
| Active Substance: | prothioconazole | Commercial Product: | ADM.03500.F.2.B |
| Crop / crop group: | Phacelia / Melliferous crop | Indoor/glasshouse/outdoor: | outdoor (semi-field using bee tunnels) |
| Responsible for reporting: | Marie-Ange Bougrier / TESTAPI 464, Sarré, 49350 Gennes - France | Other a.s. in formulation: | - |
| Nominal Content of a.s.: | 250 g/L | Residue calculated as: | 1,2,4-Triazole (mg/kg), Triazole Acetic Acid (mg/kg), Triazole Alanine (mg/kg), Triazole Lactic Acid (mg/kg) |
| Formulation: | EC | | |

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|---|-----------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|-------------------------|----------------------------|---------------------|----------------------------|-----------------------|--|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽²⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | 1,2,4- Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid | | |
| Northern Europe Northern France 49350 Gennes-Val de-Loire (Pays de la Loire) Semi-field trial 555-2021 FR01 | Phacelia STALA | 1- 24/06/21 2- 13/08/21 to 30/08/21 3- NAP | Broadcast foliar application Boom sprayer | 0.2021 (0.2033) | 303 | 0.0667 (0.0671) | 17/08/21 | 62 | Mature honey | <LOD | <LOQ | <LOQ | <LOD | 10 | Untreated specimen: <LOQ LC-DMS MS/MS Method Validated within the EAS study S21- 06181-L1(MAC- 2143) Study Max. Storage Interval between: -sampling and extraction: 59 days -extraction and analyses: 2 days |

(1) DAA : Days After Application

(2) LOQ (limit of quantification): 0.01 mg/kg for each analyte and LOD (Limit of Detection) : 0.003 mg/kg (30 % of the LOQ) for each analyte.

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|--|-----------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|-------------------------|----------------------------|---------------------|----------------------------|-----------------------|---|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽²⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | 1,2,4- Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid | | |
| Northern Europe Germany 47574 Goch (North Rhine- Westphalia) Semi-field trial 555-2021 GE02 | Phacelia STALA | 1- 15/07/21 2- 27/08/21 to 15/09/21 3- NAP | Broadcast foliar application Boom sprayer | 0.1948 (0.1959) | 292 | 0.0667 (0.0671) | 06/09/21 | 64 | Mature honey | <LOD | <LOQ | <LOD | 0.02 | 7 | Untreated specimen: <LOQ ⁽³⁾ LC-DMS MS/MS Method Validated within the EAS study S21- 06181-L1(MAC- 2143) Study Max. Storage Interval between: -sampling and extraction: 59 days -extraction and analyses: 2 days |

(1) DAA : Days After Application

(2) LOQ (limit of quantification): 0.01 mg/kg for each analyte and LOD (Limit of Detection) : 0.003 mg/kg (30 % of the LOQ) for each analyte.

(3) Excepted for residue of Triazole Lactic Acetic:0.02 mg/kg

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|--|-----------------------|--|---|--|-----------------|--------------------|----------------------|---|---------------------|-------------------------|----------------------------|---------------------|----------------------------|-----------------------|---|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽²⁾ | | | | DAA ⁽¹⁾ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | 1,2,4- Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid | | |
| Northern Europe Denmark 5580 Nørre Aby (South Denmark) Semi-field trial 555-2021 DK03 | Phacelia STALA | 1- 30/06/21 2- 20/08/21 to mid- October 2021 3- NAP | Broadcast foliar application Boom sprayer | 0.2031 (0.2043) | 203 | 0.1000 (0.1006) | 02/09/21 | 64 | Mature honey | <LOD | <LOD | <LOQ | <LOD | 14 | Untreated specimen not collected ⁽³⁾ LC-DMS MS/MS Method Validated within the EAS study S21- 06181-L1(MAC- 2143) Study Max. Storage Interval between: -sampling and extraction: 59 days -extraction and analyses: 2 days |

(1) DAA : Days After Application

(2) LOQ (limit of quantification): 0.01 mg/kg for each analyte and LOD (Limit of Detection): 0.003 mg/kg (30 % of the LOQ) for each analyte.

(3) Not enough mature honey in beehive in the untreated tunnel, but since all residue in treated specimens were found to be < LOQ, untreated specimens were not necessary (See details of the deviation without adverse impact in section 4.2.1 Deviations during the field phase)

| 1 | 2 | 3 | 4 | 5 | | | 6 | 7 | 8 | 9 | | | | 10 | 11 |
|---|------------------------------|---|---|--|-----------------|--------------------|----------------------|---|---------------------|-------------------------|----------------------------|---------------------|----------------------------|-----------------------|--|
| Report No. 555-2021 | Commodity Variety | Date of 1-Sowing 2-Flowering 3-Harvest | Method of treatment | Actual application rate per treatment | | | Date of treatment | BBCH Crop Growth Stage at treatment | Portion analysed | Residues ⁽²⁾ | | | | DAA ₍₁₎ | Remarks |
| | | | | kg (a.s./ha) | Water (L/ha) | kg (a.s./hL) | | | | 1,2,4- Triazole | Triazole Acetic Acid | Triazole Alanine | Triazole Lactic Acid | | |
| Southern Europe Italy 12050 Castagnito d'Alba (Piedmont) Semi-field trial 555-2021 IT04 | Phacelia F03942/03214 | 1- 06/07/21 2- 16/09/21 to 30/10/21 3- NAP | Broadcast foliar application Boom sprayer | 0.1928 (0.1939) | 289 | 0.0667 (0.0671) | 24/09/21 | 63 | Mature honey | <LOD | <LOD | <LOD | <LOQ | 13 | Untreated specimen: <LOQ LC-DMS MS/MS Method Validated within the EAS study S21- 06181-L1(MAC- 2143) Study Max. Storage Interval between: -sampling and extraction: 59 days -extraction and analyses: 2 days |

(1) DAA : Days After Application

(2) LOQ (limit of quantification): 0.01 mg/kg for each analyte and LOD (Limit of Detection) : 0.003 mg/kg (30 % of the LOQ) for each analyte.

TMDI calculations

Prothioconazole except TDMs

| Prothioconazole: prothioconazole-desthio (sum of isomers) (F) | | | |
|---|--|------|--------------------------|
| LOQs (mg/kg) range from: | | 0.01 | to: 0.05 |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | 0.01 | ARfD (mg/kg bw): 0.01 |
| Source of ADI: | | EFSA | Source of ARfD: EFSA |
| Year of evaluation: | | 2007 | Year of evaluation: 2007 |

| Chronic risk assessment:TMDI calculation | | | | | | | | | | |
|--|-----------------------------------|-------------------|--------------------------------|--|------------------------------------|--|------------------------------------|--|------------------------------------|---|
| | Calculated exposure (% of ADI) | | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | commodities not under assessment (in % of ADI) |
| | MS Diet | | | | | | | | | |
| TMDI/NEEDI calculation (based on average food consumption) | 43% | NL toddler | 1.48 | 3% | Milk: Cattle | 2% | Wheat | 1% | Maize/corn | 6% |
| | 32% | GEMS/Food G11 | 1.09 | 4% | Soyabeans | 2% | Wheat | 0.6% | Carrots | 7% |
| | 31% | GEMS/Food G10 | 0.98 | 3% | Soyabeans | 2% | Wheat | 0.4% | Barley | 7% |
| | 29% | GEMS/Food G15 | 0.93 | 3% | Wheat | 2% | Soyabeans | 0.5% | Barley | 8% |
| | 28% | GEMS/Food G08 | 0.95 | 2% | Wheat | 2% | Soyabeans | 0.6% | Barley | 8% |
| | 28% | GEMS/Food G06 | 0.96 | 4% | Wheat | 1% | Soyabeans | 0.4% | Tomatoes | 8% |
| | 28% | GEMS/Food G07 | 0.93 | 3% | Wheat | 2% | Soyabeans | 0.4% | Rapeseeds/canola seeds | 8% |
| | 22% | IE adult | 0.62 | 1% | Wheat | 0.4% | Sweet potatoes | 0.3% | Peas | 3% |
| | 20% | FR child 3 15 yr | 0.83 | 3% | Wheat | 1% | Milk: Cattle | 0.6% | Swine: Other products | 5% |
| | 20% | NL child | 0.88 | 2% | Wheat | 1% | Milk: Cattle | 0.8% | Sugar beet roots | 5% |
| | 18% | ES child | 0.60 | 3% | Wheat | 0.6% | Milk: Cattle | 0.3% | Cocoa beans | 4% |
| | 18% | RO general | 0.65 | 3% | Wheat | 0.6% | Milk: Cattle | 0.4% | Potatoes | 5% |
| | 17% | DE child | 0.90 | 3% | Wheat | 1% | Apples | 1.0% | Milk: Cattle | 5% |
| | 16% | UK infant | 0.74 | 2% | Milk: Cattle | 2% | Wheat | 1% | Carrots | 3% |
| | 16% | FR toddler 2 3 yr | 0.70 | 2% | Wheat | 1% | Milk: Cattle | 0.6% | Carrots | 3% |
| | 14% | DK child | 0.97 | 3% | Rye | 3% | Wheat | 1% | Carrots | 7% |
| | 13% | UK toddler | 0.67 | 2% | Wheat | 1% | Milk: Cattle | 0.8% | Beans | 4% |
| | 12% | PT general | 0.52 | 2% | Wheat | 0.5% | Potatoes | 0.5% | Potatoes | 4% |
| | 12% | ES adult | 0.36 | 1% | Wheat | 0.3% | Barley | 0.2% | Milk: Cattle | 4% |
| | 11% | NL general | 0.46 | 1% | Wheat | 0.4% | Milk: Cattle | 0.3% | Sugar beet roots | 4% |
| | 11% | DE general | 0.51 | 1% | Wheat | 0.6% | Milk: Cattle | 0.4% | Sugar beet roots | 4% |
| | 11% | SE general | 0.59 | 2% | Wheat | 0.7% | Carrots | 0.6% | Milk: Cattle | 3% |
| | 10% | DE women 14-50 yr | 0.50 | 1% | Wheat | 0.6% | Milk: Cattle | 0.5% | Sugar beet roots | 3% |
| | 10% | IT toddler | 0.53 | 4% | Wheat | 0.2% | Other cereals | 0.1% | Carrots | 7% |
| | 9% | FI adult | 0.45 | 3% | Coffee beans | 0.4% | Rye | 0.3% | Carrots | 0.8% |
| | 9% | FR adult | 0.39 | 1% | Wheat | 0.3% | Swine: Other products | 0.2% | Wine grapes | 2% |
| | 8% | FI 3 yr | 0.40 | 0.7% | Wheat | 0.7% | Carrots | 0.5% | Potatoes | 2% |
| | 7% | FR infant | 0.36 | 0.9% | Carrots | 0.8% | Milk: Cattle | 0.5% | Wheat | 0.8% |
| | 7% | IT adult | 0.35 | 2% | Wheat | 0.1% | Tomatoes | 0.1% | Carrots | 4% |
| | 7% | FI 6 yr | 0.32 | 0.6% | Wheat | 0.5% | Carrots | 0.4% | Potatoes | 2% |
| | 7% | UK vegetarian | 0.30 | 1% | Wheat | 0.4% | Beans | 0.2% | Carrots | 2% |
| | 5% | LT adult | 0.28 | 0.6% | Rye | 0.6% | Wheat | 0.3% | Potatoes | 2% |
| 5% | UK adult | 0.26 | 1% | Wheat | 0.2% | Beans | 0.1% | Milk: Cattle | 2% | |
| 5% | DK adult | 0.26 | 0.7% | Wheat | 0.4% | Carrots | 0.3% | Rye | 1% | |
| 4% | PL general | 0.15 | 0.3% | Potatoes | 0.2% | Carrots | 0.2% | Apples | | |
| 2% | IE child | 0.14 | 0.7% | Wheat | 0.2% | Milk: Cattle | 0.1% | Carrots | 1% | |
| The TMDI calculations are for information purpose only. The results of the more refined intake calculations are presented in the spreadsheet "Results". | | | | | | | | | | |

TDMs

TMDI calculation is not applicable, as no MRLs set for triazole derivative metabolites 1,2,4-triazole, triazole alanine, triazole acetic acid, triazole lactic acid.

A 3.1 IEDI calculations

Prothioconazole except TDMs

| Prothioconazole: prothioconazole-desthio (sum of isomers) (F) | | | |
|---|------|---------------------|----------|
| LOQs (mg/kg) range from: | | 0.01 | to: 0.05 |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | 0.01 | ARfD (mg/kg bw): | 0.01 |
| Source of ADI: | EFSA | Source of ARfD: | EFSA |
| Year of evaluation: | 2007 | Year of evaluation: | 2007 |

| Normal mode | | | | | | | | | | | |
|---|--|-------------------|---------------------------------|--|-------------------------------------|--|-------------------------------------|--|-------------------------------------|--|--|
| Chronic risk assessment: JMPR methodology (IEDI/TMDI) | | | | | | | | | | | |
| | | | No of diets exceeding the ADI : | | | | | | | Exposure resulting from | |
| | Calculated exposure (% of ADI) | MS Diet | Expsoure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities no under assessment (in % of ADI) |
| TMDI/NED/IEDI calculation (based on average food consumption) | 15% | NL toddler | 1.48 | 3% | Milk: Cattle | 2% | Wheat | 1% | Maize/corn | 4% | 4% |
| | 11% | GEMS/Food G11 | 1.09 | 4% | Soyabeans | 2% | Wheat | 0.6% | Carrots | 2% | 3% |
| | 10% | GEMS/Food G10 | 0.98 | 3% | Soyabeans | 2% | Wheat | 0.4% | Barley | 1% | 3% |
| | 10% | DK child | 0.97 | 3% | Rye | 3% | Wheat | 1% | Carrots | 0.8% | 6% |
| | 10% | GEMS/Food G06 | 0.96 | 4% | Wheat | 1% | Soyabeans | 0.4% | Tomatoes | 2% | 4% |
| | 10% | GEMS/Food G08 | 0.95 | 2% | Wheat | 2% | Soyabeans | 0.6% | Barley | 1% | 4% |
| | 9% | GEMS/Food G07 | 0.93 | 3% | Wheat | 2% | Soyabeans | 0.4% | Rapeseeds/canola seeds | 1% | 3% |
| | 9% | GEMS/Food G15 | 0.93 | 3% | Wheat | 2% | Soyabeans | 0.5% | Barley | 1% | 4% |
| | 9% | DE child | 0.90 | 3% | Wheat | 1% | Apples | 1.0% | Milk: Cattle | 3% | 3% |
| | 9% | NL child | 0.88 | 2% | Wheat | 1% | Milk: Cattle | 0.8% | Sugar beet roots | 3% | 3% |
| | 8% | FR child 3 15 yr | 0.83 | 3% | Wheat | 1% | Milk: Cattle | 0.6% | Swine: Other products | 2% | 3% |
| | 7% | UK infant | 0.74 | 2% | Milk: Cattle | 2% | Wheat | 1% | Carrots | 0.9% | 2% |
| | 7% | FR toddler 2 3 yr | 0.70 | 2% | Wheat | 1% | Milk: Cattle | 0.6% | Carrots | 2% | 2% |
| | 7% | UK toddler | 0.67 | 2% | Wheat | 1% | Milk: Cattle | 0.8% | Beans | 1% | 2% |
| | 7% | RO general | 0.65 | 3% | Wheat | 0.6% | Milk: Cattle | 0.4% | Potatoes | 1.0% | 3% |
| | 6% | IE adult | 0.62 | 1% | Wheat | 0.4% | Sweet potatoes | 0.3% | Peas | 2% | 2% |
| | 6% | ES child | 0.60 | 3% | Wheat | 0.6% | Milk: Cattle | 0.3% | Cocoa beans | 1% | 3% |
| | 6% | SE general | 0.59 | 2% | Wheat | 0.7% | Carrots | 0.6% | Milk: Cattle | 1.0% | 2% |
| | 5% | IT toddler | 0.53 | 4% | Wheat | 0.2% | Other cereals | 0.1% | Carrots | 0.8% | 4% |
| | 5% | PT general | 0.52 | 2% | Wheat | 0.5% | Potatoes | 0.5% | Potatoes | 0.9% | 2% |
| | 5% | DE general | 0.51 | 1% | Wheat | 0.6% | Milk: Cattle | 0.4% | Sugar beet roots | 2% | 2% |
| | 5% | DE women 14-50 yr | 0.50 | 1% | Wheat | 0.6% | Milk: Cattle | 0.5% | Sugar beet roots | 2% | 2% |
| | 5% | NL general | 0.46 | 1% | Wheat | 0.4% | Milk: Cattle | 0.3% | Sugar beet roots | 1% | 2% |
| | 5% | FI adult | 0.45 | 3% | Coffee beans | 0.4% | Rye | 0.3% | Carrots | 3% | 0.7% |
| | 4% | FI 3 yr | 0.40 | 0.7% | Wheat | 0.7% | Carrots | 0.5% | Potatoes | 0.9% | 2% |
| | 4% | FR adult | 0.39 | 1% | Wheat | 0.3% | Swine: Other products | 0.2% | Wine grapes | 1% | 1% |
| | 4% | ES adult | 0.36 | 1% | Wheat | 0.3% | Barley | 0.2% | Milk: Cattle | 0.9% | 2% |
| | 4% | FR infant | 0.36 | 0.9% | Carrots | 0.8% | Milk: Cattle | 0.5% | Wheat | 0.6% | 0.5% |
| | 4% | IT adult | 0.35 | 2% | Wheat | 0.1% | Tomatoes | 0.1% | Carrots | 0.7% | 2% |
| | 3% | FI 6 yr | 0.32 | 0.6% | Wheat | 0.5% | Carrots | 0.4% | Potatoes | 0.7% | 1% |
| | 3% | UK vegetarian | 0.30 | 1% | Wheat | 0.4% | Beans | 0.2% | Carrots | 0.6% | 1% |
| | 3% | LT adult | 0.28 | 0.6% | Rye | 0.6% | Wheat | 0.3% | Potatoes | 0.4% | 1% |
| 3% | DK adult | 0.26 | 0.7% | Wheat | 0.4% | Carrots | 0.3% | Rye | 0.5% | 1.0% | |
| 3% | UK adult | 0.26 | 1% | Wheat | 0.2% | Beans | 0.1% | Milk: Cattle | 0.5% | 1% | |
| 2% | PL general | 0.15 | 0.3% | Potatoes | 0.2% | Carrots | 0.2% | Apples | 0.5% | | |
| 1% | IE child | 0.14 | 0.7% | Wheat | 0.2% | Milk: Cattle | 0.1% | Carrots | 0.1% | 0.7% | |
| | Conclusion: The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F) Reg. (EU) 2019/552 Annex II (F) is unlikely to present a public health concern. | | | | | | | | | | |

TDMs:
1,2,4-triazole (1,2,4-T)

| | | |
|--|---------------------|------|
| <h1 style="text-align: center;">1,2,4-Triazole</h1> | | |
| LOQs (mg/kg) range from: | | to: |
| <h2 style="background-color: #f2f2f2;">Toxicological reference values</h2> | | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): | 0.1 |
| Source of ADI: | Source of ARfD: | EC |
| Year of evaluation: | Year of evaluation: | 2021 |

| Normal mode | | | | | | | | | | | |
|---|-----------------------------------|-------------------|--------------------------------|--|------------------------------------|--|------------------------------------|--|------------------------------------|--|---|
| Chronic risk assessment: JMPR methodology (IED/TMDI) | | | | | | | | | | | |
| | | | | No of diets exceeding the ADI : | | | | Exposure resulting from | | | |
| | Calculated exposure (% of ADI) | | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity/ group of commodities | MRLs set at the LOQ (in % of ADI) | commodities under assessment (in % of ADI) |
| | MS Diet | | | | | | | | | | |
| TMDI(NED/IEDI) calculation (based on average food consumption) | 51% | NL toddler | 11.71 | 42% | Milk: Cattle | 2% | Maize/corn | 1% | Bananas | | 44% |
| | 31% | UK infant | 7.05 | 27% | Milk: Cattle | 0.9% | Bovine: Muscle/meat | 0.6% | Wheat | | 29% |
| | 25% | FR toddler 2 3 yr | 5.76 | 20% | Milk: Cattle | 0.8% | Bovine: Muscle/meat | 0.7% | Wheat | | 23% |
| | 24% | NL child | 5.44 | 17% | Milk: Cattle | 2% | Sugar beet roots | 0.9% | Wheat | | 20% |
| | 22% | FR child 3 15 yr | 5.04 | 16% | Milk: Cattle | 1% | Bovine: Muscle/meat | 1.0% | Wheat | | 19% |
| | 19% | UK toddler | 4.28 | 14% | Milk: Cattle | 0.9% | Bovine: Muscle/meat | 0.9% | Wheat | | 16% |
| | 18% | DE child | 4.23 | 14% | Milk: Cattle | 0.9% | Wheat | 0.9% | Oranges | | 16% |
| | 14% | DK child | 3.30 | 9% | Milk: Cattle | 1% | Rye | 1% | Swine: Muscle/meat | | 13% |
| | 14% | SE general | 3.23 | 9% | Milk: Cattle | 3% | Bovine: Muscle/meat | 0.7% | Wheat | | 13% |
| | 13% | ES child | 3.08 | 9% | Milk: Cattle | 1.0% | Bovine: Muscle/meat | 1.0% | Wheat | | 12% |
| | 13% | FR infant | 3.06 | 12% | Milk: Cattle | 0.3% | Sugar beet roots | 0.2% | Bovine: Muscle/meat | | 12% |
| | 12% | DE women 14-50 yr | 2.83 | 9% | Milk: Cattle | 1.0% | Sugar beet roots | 0.5% | Wheat | | 10% |
| | 12% | DE general | 2.82 | 9% | Milk: Cattle | 0.9% | Sugar beet roots | 0.6% | Swine: Muscle/meat | | 10% |
| | 12% | RO general | 2.75 | 8% | Milk: Cattle | 1% | Wheat | 0.6% | Swine: Muscle/meat | | 10% |
| | 11% | GEMS/Food G11 | 2.42 | 5% | Milk: Cattle | 0.8% | Soyabeans | 0.8% | Wheat | | 8% |
| | 10% | GEMS/Food G15 | 2.29 | 5% | Milk: Cattle | 1.0% | Wheat | 0.7% | Swine: Muscle/meat | | 8% |
| | 10% | GEMS/Food G07 | 2.25 | 4% | Milk: Cattle | 0.9% | Wheat | 0.6% | Bovine: Muscle/meat | | 8% |
| | 9% | NL general | 2.15 | 6% | Milk: Cattle | 0.6% | Sugar beet roots | 0.5% | Bovine: Muscle/meat | | 8% |
| | 9% | GEMS/Food G08 | 2.10 | 4% | Milk: Cattle | 1% | Swine: Muscle/meat | 0.9% | Wheat | | 7% |
| | 9% | GEMS/Food G10 | 2.09 | 4% | Milk: Cattle | 0.9% | Wheat | 0.7% | Soyabeans | | 6% |
| | 7% | GEMS/Food G06 | 1.63 | 2% | Milk: Cattle | 2% | Wheat | 0.4% | Sugar canes | | 4% |
| | 7% | IE adult | 1.50 | 3% | Milk: Cattle | 0.5% | Wheat | 0.3% | Bovine: Muscle/meat | | 5% |
| | 6% | ES adult | 1.44 | 3% | Milk: Cattle | 0.5% | Bovine: Muscle/meat | 0.5% | Wheat | | 5% |
| | 6% | DK adult | 1.30 | 4% | Milk: Cattle | 0.5% | Swine: Muscle/meat | 0.4% | Bovine: Muscle/meat | | 5% |
| | 6% | FR adult | 1.28 | 3% | Milk: Cattle | 0.5% | Wheat | 0.4% | Bovine: Muscle/meat | | 5% |
| | 5% | LT adult | 1.06 | 3% | Milk: Cattle | 0.5% | Swine: Muscle/meat | 0.2% | Rye | | 4% |
| | 4% | UK adult | 0.88 | 2% | Milk: Cattle | 0.5% | Bovine: Muscle/meat | 0.4% | Wheat | | 3% |
| | 4% | UK vegetarian | 0.85 | 2% | Milk: Cattle | 0.4% | Wheat | 0.2% | Oranges | | 3% |
| | 3% | IE child | 0.74 | 2% | Milk: Cattle | 0.3% | Wheat | 0.1% | Swine: Muscle/meat | | 3% |
| | 2% | IT toddler | 0.56 | 1% | Wheat | 0.3% | Other cereals | 0.1% | Bananas | | 1% |
| | 2% | PT general | 0.52 | 0.9% | Wheat | 0.2% | Potatoes | 0.2% | Rice | | 0.9% |
| | 2% | FI 3 yr | 0.38 | 0.3% | Bananas | 0.3% | Wheat | 0.2% | Potatoes | | 0.6% |
| | 2% | IT adult | 0.37 | 0.9% | Wheat | 0.2% | Other cereals | 0.1% | Oranges | | 0.9% |
| 1% | FI 6 yr | 0.29 | 0.2% | Wheat | 0.2% | Potatoes | 0.2% | Bananas | | 0.4% | |
| 0.7% | FI adult | 0.17 | 0.2% | Rye | 0.1% | Oranges | 0.1% | Wheat | | 0.3% | |
| 0.5% | PL general | 0.13 | 0.1% | Potatoes | 0.1% | Apples | 0.1% | Head cabbages | | | |
| Conclusion: The estimated long-term dietary intake (TMDI/NED/IEDI) was below the ADI. The long-term intake of residues of 1,2,4-Triazole is unlikely to present a public health concern. | | | | | | | | | | | |

Triazole alanine (TA)

Toxicological reference values

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI :

| | |
|--|-------------------------|
| | Exposure resulting from |
|--|-------------------------|

TMDI/NEDI/EDI calculation (based on average food consumption)

| |
|--------------------|
| Conclusion: |
|--------------------|

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Triazole alanine (TA) is unlikely to present a public health concern.

Triazole acetic acid (TAA)

| | | | |
|---------------------------------------|---------------------|------|--|
| LOQs (mg/kg) range from: | | to: | |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): | 1 | |
| Source of ADI: | Source of ARfD: | EC | |
| Year of evaluation: | Year of evaluation: | 2018 | |

| Normal mode | | | | | | | | | | | |
|--|--------------------------------|-------------------|---------------------------------|--|----------------------------------|--|------------------------------------|--|----------------------------------|-----------------------------------|--|
| Chronic risk assessment: JMPR methodology (IEDI/TMDI) | | | | | | | | | | | |
| | | | No of diets exceeding the ADI : | | | | | Exposure resulting from | | | |
| | Calculated exposure (% of ADI) | MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities under assessment (in % of ADI) |
| TMDI/NEDI calculation (based on average food consumption) | 1% | NL toddler | 13.58 | 0.6% | Maize/corn | 0.3% | Wheat | 0.2% | Milk: Cattle | | 0.6% |
| | 0.9% | DK child | 9.17 | 0.4% | Rye | 0.3% | Wheat | 0.0% | Milk: Cattle | | 0.9% |
| | 0.9% | GEMS/Food G06 | 8.99 | 0.6% | Wheat | 0.1% | Rice | 0.1% | Maize/corn | | 0.6% |
| | 0.7% | IT toddler | 6.81 | 0.5% | Wheat | 0.1% | Other cereals | 0.0% | Rice | | 0.5% |
| | 0.6% | GEMS/Food G10 | 6.42 | 0.3% | Wheat | 0.1% | Rice | 0.1% | Maize/corn | | 0.4% |
| | 0.6% | GEMS/Food G15 | 6.21 | 0.4% | Wheat | 0.1% | Barley | 0.1% | Maize/corn | | 0.5% |
| | 0.6% | GEMS/Food G08 | 6.17 | 0.3% | Wheat | 0.1% | Barley | 0.0% | Rye | | 0.5% |
| | 0.6% | DE child | 6.13 | 0.3% | Wheat | 0.1% | Rye | 0.1% | Milk: Cattle | | 0.5% |
| | 0.6% | NL child | 5.93 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Sugar beet roots | | 0.5% |
| | 0.6% | FR child 3 15 yr | 5.93 | 0.4% | Wheat | 0.1% | Milk: Cattle | 0.0% | Rice | | 0.5% |
| | 0.6% | RO general | 5.84 | 0.4% | Wheat | 0.1% | Maize/corn | 0.0% | Milk: Cattle | | 0.5% |
| | 0.6% | GEMS/Food G07 | 5.64 | 0.3% | Wheat | 0.0% | Barley | 0.0% | Rice | | 0.4% |
| | 0.5% | UK infant | 5.22 | 0.2% | Wheat | 0.1% | Milk: Cattle | 0.1% | Maize/corn | | 0.4% |
| | 0.5% | GEMS/Food G11 | 5.18 | 0.3% | Wheat | 0.1% | Barley | 0.0% | Soyabeans | | 0.4% |
| | 0.5% | ES child | 5.06 | 0.4% | Wheat | 0.0% | Rice | 0.0% | Milk: Cattle | | 0.4% |
| | 0.5% | UK toddler | 4.85 | 0.3% | Wheat | 0.1% | Milk: Cattle | 0.0% | Rice | | 0.4% |
| | 0.5% | PT general | 4.69 | 0.3% | Wheat | 0.1% | Rice | 0.0% | Maize/corn | | 0.3% |
| | 0.5% | FR toddler 2 3 yr | 4.57 | 0.2% | Wheat | 0.1% | Milk: Cattle | 0.0% | Rice | | 0.4% |
| | 0.4% | IT adult | 4.15 | 0.3% | Wheat | 0.1% | Other cereals | 0.0% | Rice | | 0.3% |
| | 0.4% | SE general | 3.94 | 0.3% | Wheat | 0.0% | Milk: Cattle | 0.0% | Rice | | 0.3% |
| | 0.3% | DE general | 3.46 | 0.1% | Wheat | 0.0% | Rye | 0.0% | Barley | | 0.3% |
| | 0.3% | DE women 14-50 yr | 3.39 | 0.2% | Wheat | 0.0% | Rye | 0.0% | Milk: Cattle | | 0.3% |
| | 0.3% | IE adult | 3.36 | 0.2% | Wheat | 0.0% | Buckwheat and other pseudo-cereals | 0.0% | Rice | | 0.2% |
| | 0.3% | ES adult | 3.02 | 0.2% | Wheat | 0.0% | Barley | 0.0% | Rice | | 0.2% |
| | 0.3% | NL general | 2.91 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Barley | | 0.2% |
| | 0.3% | FI 3 yr | 2.73 | 0.1% | Wheat | 0.1% | Rye | 0.0% | Oat | | 0.2% |
| | 0.2% | FR adult | 2.49 | 0.2% | Wheat | 0.0% | Milk: Cattle | 0.0% | Rice | | 0.2% |
| | 0.2% | LT adult | 2.45 | 0.1% | Rye | 0.1% | Wheat | 0.0% | Rice | | 0.2% |
| | 0.2% | UK vegetarian | 2.34 | 0.2% | Wheat | 0.0% | Rice | 0.0% | Milk: Cattle | | 0.2% |
| | 0.2% | FI 6 yr | 2.13 | 0.1% | Wheat | 0.0% | Rye | 0.0% | Rice | | 0.2% |
| 0.2% | UK adult | 1.99 | 0.1% | Wheat | 0.0% | Rice | 0.0% | Milk: Cattle | | 0.2% | |
| 0.2% | DK adult | 1.78 | 0.1% | Wheat | 0.0% | Rye | 0.0% | Milk: Cattle | | 0.2% | |
| 0.1% | FR infant | 1.48 | 0.1% | Wheat | 0.1% | Milk: Cattle | 0.0% | Sugar beet roots | | 0.1% | |
| 0.1% | IE child | 1.34 | 0.1% | Wheat | 0.0% | Rice | 0.0% | Milk: Cattle | | 0.1% | |
| 0.1% | FI adult | 1.19 | 0.1% | Rye | 0.0% | Wheat | 0.0% | Oat | | 0.1% | |
| 0.0% | PL general | 0.18 | 0.0% | Apples | 0.0% | Potatoes | 0.0% | Table grapes | | | |
| Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health concern. | | | | | | | | | | | |

| <h2 style="text-align: center;">Triazole lactic acid (TLA)</h2> | | |
|---|---------------------|-------------|
| LOQs (mg/kg) range from: | | to: |
| <h3 style="text-align: center;">Toxicological reference values</h3> | | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): | 0.3 |
| Source of ADI: | Source of ARfD: | EC |
| Year of evaluation: | Year of evaluation: | 2018 |

| Normal mode | | | | | | | | | | | |
|--|-----------------------------------|-------------------|---------------------------------|--|-------------------------------------|--|-------------------------------------|--|-------------------------------------|--|---|
| Chronic risk assessment: JMPR methodology (IEDI/TMDI) | | | | | | | | | | | |
| | | | No of diets exceeding the ADI : | | | | | | Exposure resulting from | | |
| | Calculated exposure (% of ADI) | MS Diet | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | MRLs set at the LOQ (in % of ADI) | commodities under assessment (in % of ADI) |
| TMDI/NEDI/IEDI calculation (based on average food consumption) | 1% | NL toddler | 3.35 | 0.6% | Milk: Cattle | 0.1% | Apples | 0.1% | Maize/corn | | 0.7% |
| | 0.6% | DE child | 1.71 | 0.2% | Milk: Cattle | 0.1% | Apples | 0.1% | Oranges | | 0.3% |
| | 0.6% | NL child | 1.70 | 0.2% | Milk: Cattle | 0.1% | Apples | 0.0% | Wheat | | 0.3% |
| | 0.5% | UK infant | 1.63 | 0.4% | Milk: Cattle | 0.0% | Potatoes | 0.0% | Wheat | | 0.4% |
| | 0.5% | FR toddler 2-3 yr | 1.45 | 0.3% | Milk: Cattle | 0.0% | Apples | 0.0% | Wheat | | 0.3% |
| | 0.5% | FR child 3-15 yr | 1.40 | 0.2% | Milk: Cattle | 0.0% | Oranges | 0.0% | Wheat | | 0.3% |
| | 0.4% | UK toddler | 1.16 | 0.2% | Milk: Cattle | 0.0% | Wheat | 0.0% | Oranges | | 0.3% |
| | 0.4% | GEMS/Food G11 | 1.11 | 0.1% | Soyabeans | 0.1% | Milk: Cattle | 0.0% | Potatoes | | 0.1% |
| | 0.4% | GEMS/Food G10 | 1.06 | 0.1% | Soyabeans | 0.1% | Milk: Cattle | 0.0% | Wheat | | 0.1% |
| | 0.3% | GEMS/Food G07 | 1.05 | 0.1% | Milk: Cattle | 0.0% | Soyabeans | 0.0% | Wheat | | 0.1% |
| | 0.3% | GEMS/Food G06 | 1.02 | 0.1% | Wheat | 0.0% | Tomatoes | 0.0% | Soyabeans | | 0.1% |
| | 0.3% | DK child | 1.00 | 0.1% | Milk: Cattle | 0.0% | Rye | 0.0% | Wheat | | 0.2% |
| | 0.3% | GEMS/Food G08 | 1.00 | 0.1% | Milk: Cattle | 0.0% | Soyabeans | 0.0% | Wheat | | 0.1% |
| | 0.3% | GEMS/Food G15 | 0.99 | 0.1% | Milk: Cattle | 0.0% | Soyabeans | 0.0% | Wheat | | 0.1% |
| | 0.3% | RO general | 0.97 | 0.1% | Milk: Cattle | 0.0% | Wheat | 0.0% | Potatoes | | 0.2% |
| | 0.3% | SE general | 0.97 | 0.1% | Milk: Cattle | 0.0% | Bovine: Muscle/meat | 0.0% | Potatoes | | 0.2% |
| | 0.3% | ES child | 0.97 | 0.1% | Milk: Cattle | 0.0% | Wheat | 0.0% | Oranges | | 0.2% |
| | 0.3% | DE women 14-50 yr | 0.88 | 0.1% | Milk: Cattle | 0.0% | Apples | 0.0% | Oranges | | 0.2% |
| | 0.3% | DE general | 0.84 | 0.1% | Milk: Cattle | 0.0% | Apples | 0.0% | Oranges | | 0.2% |
| | 0.3% | FR infant | 0.78 | 0.2% | Milk: Cattle | 0.0% | Apples | 0.0% | Potatoes | | 0.2% |
| | 0.3% | IE adult | 0.78 | 0.0% | Milk: Cattle | 0.0% | Sweet potatoes | 0.0% | Wheat | | 0.1% |
| | 0.2% | NL general | 0.75 | 0.1% | Milk: Cattle | 0.0% | Potatoes | 0.0% | Apples | | 0.1% |
| | 0.2% | ES adult | 0.57 | 0.0% | Milk: Cattle | 0.0% | Oranges | 0.0% | Wheat | | 0.1% |
| | 0.2% | PT general | 0.56 | 0.0% | Potatoes | 0.0% | Wine grapes | 0.0% | Wheat | | 0.0% |
| | 0.2% | FR adult | 0.52 | 0.0% | Milk: Cattle | 0.0% | Wine grapes | 0.0% | Wheat | | 0.1% |
| | 0.1% | IT toddler | 0.43 | 0.0% | Wheat | 0.0% | Tomatoes | 0.0% | Other cereals | | 0.0% |
| | 0.1% | DK adult | 0.42 | 0.1% | Milk: Cattle | 0.0% | Wine grapes | 0.0% | Apples | | 0.1% |
| | 0.1% | LT adult | 0.39 | 0.0% | Milk: Cattle | 0.0% | Potatoes | 0.0% | Apples | | 0.1% |
| | 0.1% | FI 3 yr | 0.38 | 0.0% | Potatoes | 0.0% | Cucumbers | 0.0% | Apples | | 0.0% |
| | 0.1% | UK vegetarian | 0.37 | 0.0% | Milk: Cattle | 0.0% | Wheat | 0.0% | Oranges | | 0.1% |
| | 0.1% | UK adult | 0.35 | 0.0% | Milk: Cattle | 0.0% | Wine grapes | 0.0% | Wheat | | 0.1% |
| | 0.1% | IT adult | 0.35 | 0.0% | Wheat | 0.0% | Tomatoes | 0.0% | Lettuces | | 0.0% |
| 0.1% | FI 6 yr | 0.30 | 0.0% | Potatoes | 0.0% | Wheat | 0.0% | Cucumbers | | 0.0% | |
| 0.1% | PL general | 0.23 | 0.0% | Potatoes | 0.0% | Apples | 0.0% | Tomatoes | | 0.0% | |
| 0.1% | IE child | 0.20 | 0.0% | Milk: Cattle | 0.0% | Wheat | 0.0% | Potatoes | | 0.0% | |
| 0.1% | FI adult | 0.19 | 0.0% | Potatoes | 0.0% | Apples | 0.0% | Tomatoes | | 0.0% | |
| Conclusion: The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Triazole lactic acid (TLA) is unlikely to present a public health concern. | | | | | | | | | | | |

A 3.2 IESTI calculations - Raw commodities

Prothioconazole except TDMs

| Prothioconazole: prothioconazole-desthio (sum of isomers) (F) | | | |
|---|--|------|--------------------------|
| LOQs (mg/kg) range from: | | 0.01 | to: 0.05 |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | 0.01 | ARfD (mg/kg bw): 0.01 |
| Source of ADI: | | EFSA | Source of ARfD: EFSA |
| Year of evaluation: | | 2007 | Year of evaluation: 2007 |

| Show results of IESTI calculation only for crops with GAPs under assessment | | | | | | | | |
|---|--|------------------|----------------------------|---------------------|--|------------------------|----------------------------|---------------------|
| Unprocessed commodities | Results for children | | | | Results for adults | | | |
| | No. of commodities for which ARfD/ADI is exceeded (IESTI): --- | | | | No. of commodities for which ARfD/ADI is exceeded (IESTI): --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 9% | Wheat | 0.1 / 0.06 | 0.87 | 5% | Wheat | 0.1 / 0.06 | 0.50 |
| | 4% | Barley | 0.2 / 0.07 | 0.39 | 3% | Barley | 0.2 / 0.07 | 0.34 |
| | 4% | Rye | 0.05 / 0.06 | 0.38 | 3% | Rye | 0.05 / 0.06 | 0.29 |
| | 1% | Rapeseeds/canola | 0.15 / 0.08 | 0.11 | 0.4% | Rapeseeds/canola seeds | 0.15 / 0.08 | 0.04 |
| | 0.7% | Oat | 0.05 / 0.06 | 0.07 | 0.4% | Oat | 0.05 / 0.06 | 0.04 |
| | Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) | | | | | | | |

TDMs: 1,2,4-triazole (1,2,4-T)

| 1,2,4-Triazole | | | |
|--------------------------------|--|---------------------|--|
| LOQs (mg/kg) range from: | | to: | |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | ARfD (mg/kg bw): | |
| | | 0.1 | |
| Source of ADI: | | Source of ARfD: | |
| | | EC | |
| Year of evaluation: | | Year of evaluation: | |
| | | 2021 | |

| Show results of IESTI calculation only for crops with GAPs under assessment | | | | | | | | |
|---|--|----------------------|----------------------------|---------------------|--|--------------------|----------------------------|---------------------|
| Unprocessed commodities | Results for children | | | | Results for adults | | | |
| | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 20% | Milk: Cattle | 0 / 0.16 | 20 | 6% | Milk: Cattle | 0 / 0.16 | 6.2 |
| | 4% | Milk: Goat | 0 / 0.16 | 3.9 | 3% | Milk: Goat | 0 / 0.16 | 2.9 |
| | 3% | Swine: Muscle/meat | 0 / 0.21 | 2.5 | 2% | Milk: Sheep | 0 / 0.16 | 2.4 |
| | 2% | Bovine: Liver | 0 / 0.25 | 2.0 | 1% | Bovine: Muscle | 0 / 0.24 | 1.4 |
| | 2% | Bovine: Muscle/meat | 0 / 0.24 | 1.7 | 1% | Sheep: Muscle/meat | 0 / 0.24 | 1.1 |
| Unprocessed commodities | 1% | Sheep: Muscle/meat | 0 / 0.24 | 1.3 | 1% | Swine: Muscle/meat | 0 / 0.21 | 1.0 |
| | 1% | Bovine: Kidney | 0 / 0.28 | 1.1 | 1% | Bovine: Liver | 0 / 0.25 | 1.00 |
| | 0.7% | Wheat | 0 / 0.05 | 0.72 | 0.7% | Sheep: Liver | 0 / 0.25 | 0.70 |
| | 0.7% | Poultry: Muscle/meat | 0 / 0.04 | 0.68 | 0.6% | Bovine: Kidney | 0 / 0.28 | 0.59 |
| | 0.6% | Milk: Sheep | 0 / 0.16 | 0.57 | 0.6% | Swine: Kidney | 0 / 0.25 | 0.55 |
| | 0.5% | Eggs: Chicken | 0 / 0.04 | 0.50 | 0.5% | Poultry: Muscle | 0 / 0.04 | 0.47 |
| | 0.4% | Bovine: Fat tissue | 0 / 0.19 | 0.40 | 0.4% | Wheat | 0 / 0.05 | 0.42 |
| | 0.3% | Swine: Kidney | 0 / 0.25 | 0.32 | 0.4% | Goat: Muscle | 0 / 0.24 | 0.37 |
| | 0.3% | Rye | 0 / 0.05 | 0.32 | 0.3% | Swine: Fat tissue | 0 / 0.16 | 0.32 |
| | 0.3% | Barley | 0 / 0.05 | 0.28 | 0.3% | Swine: Liver | 0 / 0.19 | 0.27 |
| Expand/collapse list | | | | | | | | |
| Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) | | | | | | | | |

Triazole alanine (TA)

| Triazole alanine (TA) | |
|--------------------------------|---------------------------------|
| LOQs (mg/kg) range from: | to: |
| Toxicological reference values | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): 0.3 |
| Source of ADI: | Source of ARfD: EC |
| Year of evaluation: | Year of evaluation: 2018 |

Show results of IESTI calculation only for crops with GAPs under assessment

| Unprocessed commodities | Results for children | | | | Results for adults | | | |
|-------------------------|--|----------------------|----------------------------|---------------------|--|------------------------|----------------------------|---------------------|
| | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 3% | Wheat | 0 / 0.62 | 9.0 | 2% | Wheat | 0 / 0.62 | 5.2 |
| | 1% | Rye | 0 / 0.62 | 3.9 | 1% | Rye | 0 / 0.62 | 3.0 |
| | 1% | Barley | 0 / 0.62 | 3.5 | 1% | Barley | 0 / 0.62 | 3.0 |
| | 0.9% | Bovine: Liver | 0 / 0.35 | 2.8 | 0.5% | Bovine: Liver | 0 / 0.35 | 1.4 |
| | 0.8% | Milk: Cattle | 0 / 0.02 | 2.5 | 0.4% | Bovine: Muscle | 0 / 0.23 | 1.3 |
| | 0.6% | Poultry: Muscle/meat | 0 / 0.11 | 1.9 | 0.4% | Poultry: Muscle | 0 / 0.11 | 1.3 |
| | 0.6% | Bovine: Muscle/meat | 0 / 0.23 | 1.7 | 0.4% | Sheep: Muscle/meat | 0 / 0.23 | 1.1 |
| | 0.5% | Swine: Muscle/meat | 0 / 0.13 | 1.6 | 0.3% | Poultry: Liver | 0 / 0.22 | 1.0 |
| | 0.5% | Rapeseeds/canola | 0 / 1.04 | 1.4 | 0.3% | Sheep: Liver | 0 / 0.35 | 0.98 |
| | 0.4% | Sheep: Muscle/meat | 0 / 0.23 | 1.3 | 0.3% | Milk: Cattle | 0 / 0.02 | 0.77 |
| | 0.3% | Bovine: Kidney | 0 / 0.22 | 0.83 | 0.2% | Swine: Muscle/meat | 0 / 0.13 | 0.63 |
| | 0.2% | Eggs: Chicken | 0 / 0.06 | 0.74 | 0.2% | Rapeseeds/canola seeds | 0 / 1.04 | 0.55 |
| | 0.2% | Oat | 0 / 0.62 | 0.69 | 0.2% | Swine: Kidney | 0 / 0.22 | 0.48 |
| | 0.2% | Milk: Goat | 0 / 0.02 | 0.48 | 0.2% | Swine: Liver | 0 / 0.34 | 0.48 |
| | 0.1% | Swine: Liver | 0 / 0.34 | 0.42 | 0.2% | Bovine: Kidney | 0 / 0.22 | 0.46 |
| | Expand/collapse list | | | | | | | |
| | Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) | | | | | | | |

Triazole acetic acid (TAA)

| Triazole acetic acid (TAA) | |
|--------------------------------|--------------------------|
| LOQs (mg/kg) range from: | to: |
| Toxicological reference values | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): 1 |
| Source of ADI: | Source of ARfD: EC |
| Year of evaluation: | Year of evaluation: 2018 |

| Show results of IESTI calculation only for crops with GAPs under assessment | | | | | | | | |
|---|--|----------------------|----------------------------|---------------------|--|--------------------|----------------------------|---------------------|
| Unprocessed commodities | Results for children | | | | Results for adults | | | |
| | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | | No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 1% | Wheat | 0 / 0.79 | 11 | 0.7% | Wheat | 0 / 0.79 | 6.6 |
| | 0.5% | Rye | 0 / 0.79 | 5.0 | 0.4% | Rye | 0 / 0.79 | 3.8 |
| | 0.4% | Barley | 0 / 0.79 | 4.4 | 0.4% | Barley | 0 / 0.79 | 3.8 |
| | 0.4% | Milk: Cattle | 0 / 0.03 | 3.7 | 0.1% | Milk: Cattle | 0 / 0.03 | 1.2 |
| | 0.09% | Oat | 0 / 0.79 | 0.88 | 0.06% | Milk: Goat | 0 / 0.03 | 0.55 |
| | 0.07% | Milk: Goat | 0 / 0.03 | 0.73 | 0.05% | Oat | 0 / 0.79 | 0.51 |
| | 0.05% | Poultry: Muscle/meat | 0 / 0.03 | 0.51 | 0.05% | Milk: Sheep | 0 / 0.03 | 0.45 |
| | 0.05% | Bovine: Kidney | 0 / 0.13 | 0.49 | 0.04% | Poultry: Muscle | 0 / 0.03 | 0.35 |
| | 0.04% | Eggs: Chicken | 0 / 0.03 | 0.37 | 0.03% | Bovine: Kidney | 0 / 0.13 | 0.27 |
| | 0.04% | Swine: Muscle/meat | 0 / 0.03 | 0.36 | 0.02% | Swine: Kidney | 0 / 0.1 | 0.22 |
| | 0.02% | Bovine: Liver | 0 / 0.03 | 0.24 | 0.02% | Bovine: Muscle | 0 / 0.03 | 0.17 |
| | 0.02% | Bovine: Muscle/meat | 0 / 0.03 | 0.22 | 0.01% | Swine: Muscle/meat | 0 / 0.03 | 0.15 |
| | 0.02% | Rapeseeds/canola | 0 / 0.12 | 0.17 | 0.01% | Sheep: Muscle/meat | 0 / 0.03 | 0.14 |
| | 0.02% | Sheep: Muscle/meat | 0 / 0.03 | 0.16 | 0.01% | Poultry: Liver | 0 / 0.03 | 0.14 |
| | 0.01% | Swine: Kidney | 0 / 0.1 | 0.13 | 0.01% | Eggs: Chicken | 0 / 0.03 | 0.13 |
| | Expand/collapse list | | | | | | | |
| | Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) | | | | | | | |

Triazole lactic acid (TLA)

| | | | |
|---|--|---------------------------------|--|
| <h2 style="text-align: center;">Triazole lactic acid (TLA)</h2> | | | |
| LOQs (mg/kg) range from: | | to: | |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | ARfD (mg/kg bw): 0.3 | |
| Source of ADI: | | Source of ARfD: EC | |
| Year of evaluation: | | Year of evaluation: 2018 | |

| Show results of IESTI calculation only for crops with GAPs under assessment | | | | | | | | |
|--|--|----------------------|-----------------------------|-------|--|-----------------|-----------------------------|------|
| Unprocessed commodities | Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | | Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | | MRL / input for RA Exposure | | Highest % of ARfD/ADI | | MRL / input for RA Exposure | |
| | Commodities | | (mg/kg) (µg/kg bw) | | Commodities | | (mg/kg) (µg/kg bw) | |
| | 1% | Milk: Cattle | 0 / 0.03 | 3.7 | 0.4% | Milk: Cattle | 0 / 0.03 | 1.2 |
| | 0.2% | Milk: Goat | 0 / 0.03 | 0.73 | 0.2% | Milk: Goat | 0 / 0.03 | 0.55 |
| | 0.2% | Poultry: Muscle/meat | 0 / 0.03 | 0.51 | 0.2% | Milk: Sheep | 0 / 0.03 | 0.45 |
| | 0.1% | Eggs: Chicken | 0 / 0.03 | 0.37 | 0.1% | Poultry: Muscle | 0 / 0.03 | 0.35 |
| | 0.1% | Bovine: Liver | 0 / 0.04 | 0.32 | 0.06% | Wheat | 0 / 0.02 | 0.18 |
| | 0.1% | Wheat | 0 / 0.02 | 0.32 | 0.06% | Bovine: Muscle | 0 / 0.03 | 0.17 |
| 0.07% | Bovine: Muscle/meat | 0 / 0.03 | 0.22 | 0.05% | Bovine: Liver | 0 / 0.04 | 0.16 | |
| 0.06% | Bovine: Fat tissue | 0 / 0.09 | 0.19 | 0.05% | Sheep: Muscle/meat | 0 / 0.03 | 0.14 | |
| 0.05% | Sheep: Muscle/meat | 0 / 0.03 | 0.16 | 0.05% | Poultry: Liver | 0 / 0.03 | 0.14 | |
| 0.05% | Rye | 0 / 0.02 | 0.14 | 0.04% | Eggs: Chicken | 0 / 0.03 | 0.13 | |
| 0.04% | Barley | 0 / 0.02 | 0.12 | 0.04% | Sheep: Liver | 0 / 0.04 | 0.11 | |
| 0.04% | Bovine: Kidney | 0 / 0.03 | 0.11 | 0.04% | Rye | 0 / 0.02 | 0.11 | |
| 0.04% | Milk: Sheep | 0 / 0.03 | 0.11 | 0.04% | Barley | 0 / 0.02 | 0.11 | |
| 0.03% | Rapeseeds/canola | 0 / 0.07 | 0.09 | 0.03% | Bovine: Fat tissue | 0 / 0.09 | 0.09 | |
| 0.01% | Poultry: Liver | 0 / 0.03 | 0.03 | 0.02% | Bovine: Kidney | 0 / 0.03 | 0.06 | |
| Expand/collapse list | | | | | | | | |
| Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) | | | | | | | | |

A 3.3 IESTI calculations - Processed commodities

| | | | |
|--|--|-------------|---------------------------------|
| Prothioconazole: prothioconazole-desthio (sum of isomers) (F) | | | |
| LOQs (mg/kg) range from: | | 0.01 | to: 0.05 |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | 0.01 | ARfD (mg/kg bw): 0.01 |
| Source of ADI: | | EFSA | Source of ARfD: EFSA |
| Year of evaluation: | | 2007 | Year of evaluation: 2007 |

| Show results of IESTI calculation only for crops with GAPs under assessment | | | | | | | | |
|--|---|-----------------------------|----------------------------|---------------------|---|-----------------------|----------------------------|---------------------|
| Processed commodities | Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | | Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 7% | Wheat / milling (flour) | 0.1 / 0.06 | 0.73 | 5% | Barley / beer | 0.2 / 0.01 | 0.50 |
| | 3% | Wheat / milling (wholemea | 0.1 / 0.06 | 0.33 | 3% | Wheat / bread/pizza | 0.1 / 0.06 | 0.26 |
| | 3% | Barley / cooked | 0.2 / 0.07 | 0.25 | 2% | Wheat / pasta | 0.1 / 0.06 | 0.23 |
| | 2% | Rye / boiled | 0.05 / 0.06 | 0.22 | 2% | Wheat / bread | 0.1 / 0.06 | 0.21 |
| | 2% | Oat / boiled | 0.05 / 0.06 | 0.22 | 0.9% | Oat / boiled | 0.05 / 0.06 | 0.09 |
| | 2% | Rye / milling (wholemeal)-l | 0.05 / 0.06 | 0.21 | | | | |
| 2% | Oat / milling (flakes) | 0.05 / 0.06 | 0.18 | | | | | |
| 1% | Barley / milling (flour) | 0.2 / 0.07 | 0.13 | | | | | |
| 0.5% | Rapeseeds / oils | 0.15 / 0.16 | 0.05 | | | | | |
| Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Prothioconazole: prothioconazole-desthio (sum of isomers) (F) For processed commodities, no exceedance of the ARfD/ADI was identified. | | | | | | | | |

| | | |
|---|---------------------|-------------|
| <h1 style="text-align: center;">1,2,4-Triazole</h1> | | |
| LOQs (mg/kg) range from: _____ to: _____ | | |
| <h2 style="text-align: center;">Toxicological reference values</h2> | | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): | 0.1 |
| Source of ADI: | Source of ARfD: | EC |
| Year of evaluation: | Year of evaluation: | 2021 |

| | | | | | | | | |
|--|---|-----------------------------|----------------------------|---------------------|---|-----------------------|----------------------------|---------------------|
| Processed commodities | Results for children | | | | Results for adults | | | |
| | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 0.6% | Wheat / milling (flour) | 0 / 0.05 | 0.60 | 0.4% | Barley / beer | 0 / 0.01 | 0.36 |
| | 0.3% | Wheat / milling (wholemeal) | 0 / 0.05 | 0.28 | 0.2% | Wheat / bread/pizza | 0 / 0.05 | 0.22 |
| | 0.2% | Rye / boiled | 0 / 0.05 | 0.18 | 0.2% | Wheat / pasta | 0 / 0.05 | 0.19 |
| | 0.2% | Oat / boiled | 0 / 0.05 | 0.18 | 0.2% | Wheat / bread | 0 / 0.05 | 0.17 |
| | 0.2% | Barley / cooked | 0 / 0.05 | 0.18 | 0.08% | Oat / boiled | 0 / 0.05 | 0.08 |
| | | | | | | | | |
| Expand/collapse list | | | | | | | | |
| | | | | | | | | |
| Conclusion: | | | | | | | | |
| No exceedance of the toxicological reference value was identified for any unprocessed commodity. | | | | | | | | |
| A short term intake of residues of 1,2,4-Triazole is unlikely to present a public health risk. | | | | | | | | |
| For processed commodities, no exceedance of the ARfD/ADI was identified. | | | | | | | | |

| | | | |
|--|--|---------------------------------|--|
| <h1 style="text-align: center;">Triazole alanine (TA)</h1> | | | |
| LOQs (mg/kg) range from: | | to: | |
| Toxicological reference values | | | |
| ADI (mg/kg bw/day): | | ARfD (mg/kg bw): 0.3 | |
| Source of ADI: | | Source of ARfD: EC | |
| Year of evaluation: | | Year of evaluation: 2018 | |

| | | | | | | | | |
|---|---|-----------------------------|----------------------------|---------------------|---|-----------------------|----------------------------|---------------------|
| Processed commodities | Results for children | | | | Results for adults | | | |
| | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 3% | Wheat / milling (flour) | 0 / 0.62 | 7.5 | 1% | Barley / beer | 0 / 0.12 | 4.5 |
| | 1% | Wheat / milling (wholemeal) | 0 / 0.62 | 3.4 | 0.9% | Wheat / bread/pizza | 0 / 0.62 | 2.7 |
| | 0.8% | Rye / boiled | 0 / 0.62 | 2.3 | 0.8% | Wheat / pasta | 0 / 0.62 | 2.4 |
| | 0.8% | Oat / boiled | 0 / 0.62 | 2.3 | 0.7% | Wheat / bread | 0 / 0.62 | 2.2 |
| | 0.8% | Barley / cooked | 0 / 0.62 | 2.3 | 0.3% | Oat / boiled | 0 / 0.62 | 0.94 |
| | | | | | | | | |
| Expand/collapse list | | | | | | | | |
| | | | | | | | | |
| Conclusion: | | | | | | | | |
| No exceedance of the toxicological reference value was identified for any unprocessed commodity. | | | | | | | | |
| A short term intake of residues of Triazole alanine (TA) is unlikely to present a public health risk. | | | | | | | | |
| For processed commodities, no exceedance of the ARfD/ADI was identified. | | | | | | | | |

| <h1>Triazole acetic acid (TAA)</h1> | |
|--|---------------------------------|
| LOQs (mg/kg) range from: _____ to: _____ | |
| <h2>Toxicological reference values</h2> | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): 1 |
| Source of ADI: | Source of ARfD: EC |
| Year of evaluation: | Year of evaluation: 2018 |

| | | | | | | | | |
|--|---|----------------------------|---------------------------|---------------------|---|----------------------------|---------------------------|---------------------|
| Processed commodities | Results for children | | | | Results for adults | | | |
| | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | | No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | Highest % of ARfD/ADI | Processed commodities | MRL /input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL /input for RA (mg/kg) | Exposure (µg/kg bw) |
| | 1.0% | Wheat / milling (flour) | 0 / 0.79 | 9.6 | 0.6% | Barley / beer | 0 / 0.16 | 5.7 |
| | 0.6% | Sugar beets (root) / sugar | 0 / 0.6 | 5.5 | 0.3% | Wheat / bread/pizza | 0 / 0.79 | 3.5 |
| | 0.4% | Wheat / milling (wholemea | 0 / 0.79 | 4.4 | 0.3% | Wheat / pasta | 0 / 0.79 | 3.0 |
| | 0.3% | Rye / boiled | 0 / 0.79 | 2.9 | 0.3% | Wheat / bread | 0 / 0.79 | 2.8 |
| | 0.3% | Oat / boiled | 0 / 0.79 | 2.9 | 0.2% | Sugar beets (root) / sugar | 0 / 0.6 | 2.2 |
| 0.3% | Barley / cooked | 0 / 0.79 | 2.9 | 0.1% | Oat / boiled | 0 / 0.79 | 1.2 | |
| 0.3% | Rye / milling (wholemeal)-l | 0 / 0.79 | 2.8 | 0.03% | Sugar canes / sugar | 0 / 0.05 | 0.28 | |
| 0.2% | Oat / milling (flakes) | 0 / 0.79 | 2.4 | 0.00% | Chicory roots / processed | 0 / 0.05 | 0.02 | |
| 0.1% | Barley / milling (flour) | 0 / 0.79 | 1.4 | | | | | |
| 0.0% | Sugar canes / sugar | 0 / 0.05 | 0.46 | | | | | |
| 0.0% | Rapeseeds / oils | 0 / 0.24 | 0.07 | | | | | |
| 0.0% | Chicory roots / processed | 0 / 0.05 | 0.04 | | | | | |
| Expand/collapse list | | | | | | | | |
| | | | | | | | | |
| Conclusion: | | | | | | | | |
| No exceedance of the toxicological reference value was identified for any unprocessed commodity. | | | | | | | | |
| A short term intake of residues of Triazole acetic acid (TAA) is unlikely to present a public health risk. | | | | | | | | |
| For processed commodities, no exceedance of the ARfD/ADI was identified. | | | | | | | | |

| | |
|---|---------------------------------|
| <h2 style="text-align: center;">Triazole lactic acid (TLA)</h2> | |
| LOQs (mg/kg) range from: | to: |
| <h3 style="text-align: center;">Toxicological reference values</h3> | |
| ADI (mg/kg bw/day): | ARfD (mg/kg bw): 0.3 |
| Source of ADI: | Source of ARfD: EC |
| Year of evaluation: | Year of evaluation: 2018 |

| | | | | | | | | |
|--|--|---------------------------|----------------|---------------------|--|-----------------------|----------------|---------------------|
| Processed commodities | Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | | Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): | | | |
| | --- | | | | --- | | | |
| | IESTI | | | | IESTI | | | |
| | | | MRL / input | | | | MRL / input | |
| | Highest % of ARfD/ADI | Processed commodities | for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | for RA (mg/kg) | Exposure (µg/kg bw) |
| | 0.1% | Wheat / milling (flour) | 0 / 0.02 | 0.27 | 0.1% | Barley / beer | 0 / 0 | 0.16 |
| | 0.0% | Wheat / milling (wholemea | 0 / 0.02 | 0.12 | 0.03% | Wheat / bread/pizza | 0 / 0.02 | 0.10 |
| | 0.0% | Rye / boiled | 0 / 0.02 | 0.08 | 0.03% | Wheat / pasta | 0 / 0.02 | 0.08 |
| | 0.0% | Oat / boiled | 0 / 0.02 | 0.08 | 0.03% | Wheat / bread | 0 / 0.02 | 0.08 |
| | 0.0% | Barley / cooked | 0 / 0.02 | 0.08 | 0.01% | Oat / boiled | 0 / 0.02 | 0.03 |
| | | | | | | | | |
| Expand/collapse list | | | | | | | | |
| | | | | | | | | |
| Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Triazole lactic acid (TLA) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified. | | | | | | | | |