

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SIP 41061

Product name: SIP 41061

Chemical active substance:

Prothioconazole 400 g/L SC

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization of use)

Applicant: Sipcam Oxon S.p.A.

Submission date: April 2022

MS Finalisation date: March 2023; June 2023

Version history

| When | What |
|------------|-------------------------------|
| April 2022 | First submission by Applicant |
| March 2023 | Initial zRMS assessment |
| June 2023 | zRMS version after commenting |

Table of Contents

| | | |
|----------|--|----------|
| 9 | Ecotoxicology (KCP 10)..... | 6 |
| 9.1 | Critical GAP and overall conclusions..... | 6 |
| 9.1.1 | Overall conclusions..... | 10 |
| 9.1.1.1 | Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) | 10 |
| 9.1.1.2 | Effects on aquatic organisms (KCP 10.2)..... | 10 |
| 9.1.1.3 | Effects on bees (KCP 10.3.1)..... | 11 |
| 9.1.1.4 | Effects on arthropods other than bees (KCP 10.3.2) | 11 |
| 9.1.1.5 | Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5) | 11 |
| 9.1.1.6 | Effects on non-target terrestrial plants (KCP 10.6) | 12 |
| 9.1.1.7 | Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) | 12 |
| 9.1.2 | Grouping of intended uses for risk assessment..... | 12 |
| 9.1.3 | Consideration of metabolites | 14 |
| 9.2 | Effects on birds (KCP 10.1.1)..... | 16 |
| 9.2.1 | Toxicity data | 16 |
| 9.2.1.1 | Justification for new endpoints | 16 |
| 9.2.2 | Risk assessment for spray applications..... | 16 |
| 9.2.2.1 | First-tier assessment (screening/generic focal species) | 17 |
| 9.2.2.2 | Higher-tier risk assessment | 23 |
| 9.2.2.3 | Drinking water exposure..... | 24 |
| 9.2.2.4 | Effects of secondary poisoning..... | 25 |
| 9.2.2.5 | Biomagnification in terrestrial food chains..... | 29 |
| 9.2.3 | Risk assessment for baits, pellets, granules, prills or treated seed..... | 29 |
| 9.2.4 | Overall conclusions..... | 29 |
| 9.3 | Effects on terrestrial vertebrates other than birds (KCP 10.1.2)..... | 30 |
| 9.3.1 | Toxicity data | 30 |
| 9.3.1.1 | Justification for new endpoints | 30 |
| 9.3.2 | Risk assessment for spray applications..... | 30 |
| 9.3.2.1 | First-tier assessment (screening/generic focal species) | 30 |
| 9.3.2.2 | Higher-tier risk assessment..... | 38 |
| 9.3.2.3 | Drinking water exposure..... | 43 |
| 9.3.2.4 | Effects of secondary poisoning..... | 44 |
| 9.3.2.5 | Biomagnification in terrestrial food chains..... | 47 |
| 9.3.3 | Risk assessment for baits, pellets, granules, prills or treated seed..... | 47 |
| 9.3.4 | Overall conclusions..... | 48 |
| 9.4 | Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) | 48 |
| 9.5 | Effects on aquatic organisms (KCP 10.2)..... | 49 |
| 9.5.1 | Toxicity data | 49 |
| 9.5.1.1 | Justification for new endpoints | 50 |
| 9.5.2 | Risk assessment | 51 |
| 9.5.3 | Overall conclusions..... | 94 |
| 9.6 | Effects on bees (KCP 10.3.1)..... | 96 |
| 9.6.1 | Toxicity data | 96 |
| 9.6.1.1 | Justification for new endpoints | 96 |

| | | |
|-------------------|--|------------|
| 9.6.2 | Risk assessment | 97 |
| 9.6.2.1 | Hazard quotients for bees..... | 97 |
| 9.6.2.2 | Higher-tier risk assessment for bees (tunnel test, field studies)..... | 99 |
| 9.6.3 | Effects on bumble bees | 99 |
| 9.6.4 | Effects on solitary bees | 99 |
| 9.6.5 | Overall conclusions..... | 99 |
| 9.7 | Effects on arthropods other than bees (KCP 10.3.2) | 100 |
| 9.7.1 | Toxicity data | 100 |
| 9.7.1.1 | Justification for new endpoints | 101 |
| 9.7.2 | Risk assessment | 101 |
| 9.7.2.1 | Risk assessment for in-field exposure..... | 102 |
| 9.7.2.2 | Risk assessment for off-field exposure | 103 |
| 9.7.2.3 | Additional higher-tier risk assessment..... | 103 |
| 9.7.2.4 | Risk mitigation measures | 104 |
| 9.7.3 | Overall conclusions..... | 104 |
| 9.8 | Effects on non-target soil meso- and macrofauna (KCP 10.4) | 104 |
| 9.8.1 | Toxicity data | 104 |
| 9.8.1.1 | Justification for new endpoints | 106 |
| 9.8.2 | Risk assessment | 106 |
| 9.8.2.1 | First-tier risk assessment..... | 107 |
| 9.8.2.2 | Higher-tier risk assessment..... | 108 |
| 9.8.3 | Overall conclusions..... | 108 |
| 9.9 | Effects on soil microbial activity (KCP 10.5)..... | 110 |
| 9.9.1 | Toxicity data | 110 |
| 9.9.1.1 | Justification for new endpoints | 110 |
| 9.9.2 | Risk assessment | 111 |
| 9.9.3 | Overall conclusions..... | 111 |
| 9.10 | Effects on non-target terrestrial plants (KCP 10.6) | 112 |
| 9.10.1 | Toxicity data | 112 |
| 9.10.1.1 | Justification for new endpoints | 112 |
| 9.10.2 | Risk assessment | 113 |
| 9.10.2.1 | Tier-1 risk assessment (based screening data)..... | 113 |
| 9.10.2.2 | Tier-2 risk assessment (based on dose-response data)..... | 113 |
| 9.10.2.3 | Higher-tier risk assessment..... | 113 |
| 9.10.2.4 | Risk mitigation measures | 114 |
| 9.10.3 | Overall conclusions..... | 114 |
| 9.11 | Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) | 116 |
| 9.12 | Monitoring data (KCP 10.8) | 116 |
| 9.13 | Classification and Labelling | 116 |
| Appendix 1 | Lists of data considered in support of the evaluation..... | 117 |
| Appendix 2 | Detailed evaluation of the new studies | 124 |
| A 2.1 | KCP 10.1 Effects on birds and other terrestrial vertebrates..... | 124 |
| A 2.1.1 | KCP 10.1.1 Effects on birds | 124 |
| A 2.1.2 | KCP 10.1.2 Effects on terrestrial vertebrates other than birds | 128 |
| A 2.1.3 | KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)..... | 128 |
| A 2.2 | KCP 10.2 Effects on aquatic organisms | 128 |

| | | |
|---------|--|-----|
| A 2.2.1 | KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes | 128 |
| A 2.2.2 | KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms..... | 134 |
| A 2.2.3 | KCP 10.2.3 Further testing on aquatic organisms | 134 |
| A 2.3 | KCP 10.3 Effects on arthropods | 134 |
| A 2.3.1 | KCP 10.3.1 Effects on bees | 134 |
| A 2.3.2 | KCP 10.3.2 Effects on arthropods other than bees | 149 |
| A 2.4 | KCP 10.4 Effects on non-target soil meso- and macrofauna..... | 155 |
| A 2.4.1 | KCP 10.4.1 Earthworms | 155 |
| A 2.4.2 | KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms) | 158 |
| A 2.5 | KCP 10.5 Effects on soil nitrogen transformation..... | 165 |
| A 2.6 | KCP 10.6 Effects on terrestrial non-target higher plants..... | 167 |
| A 2.6.1 | KCP 10.6.1 Summary of screening data | 167 |
| A 2.6.2 | KCP 10.6.2 Testing on non-target plants..... | 167 |
| A 2.6.3 | KCP 10.6.3 Extended laboratory studies on non-target plants | 173 |
| A 2.7 | KCP 10.7 Effects on other terrestrial organisms (flora and fauna)..... | 173 |
| A 2.8 | KCP 10.8 Monitoring data..... | 173 |

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|--|--|---|---|---|-----------------------|---|---|--|---|---|--------------------------|---------------|---|------------|---------|-------------------|------|----------------------------|----------------|-------------------|
| Use- No. * | Member state(s) | Crop and/or situation (crop desti- nation / purpose of crop) | F, Fn, Fp n G, Gn, Gp n or I** | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha | Conclusion | | | | | | |
| | | | | | Meth- od / Kind | Timing / Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applica- tions (days) | L product/ha a) max. rate per appl. b) max. total rate per crop/season | g as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | | Birds | Mammals | Aquatic organisms | Bees | Non-target arthro- pods | Soil organisms | Non-target plants |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | | | | | | | |
| 1 | Central EU (DE, PL, CZ, RO, HU, BE, NL, AT, IE) | Wheat (Soft, Durum), Triticale, Rye | F | <i>Septoria</i> spp. <i>Fusarium</i> spp. <i>Puccinia</i> spp. <i>Erysiphe</i> spp. | Spray | BBCH 29-69 | a) 2 | 14 | a) 0.5 b) 1.0 | a) 200 b) 400 | 200-600 | 21 | | A | A | A | A | A | A | A |
| 2 | Central EU (DE, PL, CZ, RO, HU, BE, NL, AT, IE) | Barley | F | <i>Rhynchosporium secalis</i> <i>Puccinia hordei</i> <i>Pyrenophora teres</i> (<i>Helmin- thosporium</i> spp.) | Spray | BBCH 29-61 | a) 2 | 14 | a) 0.5 b) 1.0 | a) 200 b) 400 | 200-600 | 21 | | A | A | A | A | A | A | A |
| 3 | Central EU (DE, CZ, PL, HU, RO, BE, AT, IE) | Oilseed rape | F | <i>Sclerotinia</i> <i>Phoma</i> <i>Pyrenopeziza</i> <i>Oidium</i> | Spray | BBCH 30-71 | a) 2 | 14 | a) 0.45 b) 0.9 | a) 180 b) 360 | 200-600 | 50 | | A | A | A | A | A | A | A |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|-----------|---|--|---------------------------------|---|----------------|--|---|---|--|---|--------------------|------------|---|------------|---------|-------------------|------|--------------------|----------------|-------------------|
| Use-No. * | Member state(s) | Crop and/or situation (crop destination / purpose of crop) | F, Fn, Fp n G, Gn, Gp n or I ** | Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha | Conclusion | | | | | | |
| | | | | | Meth-od / Kind | Timing / Growth stage of crop & season | Max. number a) per use b) per crop/season | Min. interval between applications (days) | L product/ha a) max. rate per appl. b) max. total rate per crop/season | g as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | | Birds | Mammals | Aquatic organisms | Bees | Non-target arthro- | Soil organisms | Non-target plants |
| 4 | Central EU (DE, NL, BE, PL, CZ, AT, IE) | Sugar beet | F | <i>Cercospora beticola</i> <i>Erysiphe betae</i> | Spray | BBCH 39-49 | a) 2 | 14 | a) 0.4 b) 0.8 | a) 160 b) 320 | 200-600 | 28 | | A | A | A | A | A | A | A |
| 5 | Central EU (NL, DE, AT) | Cucurbits edible peel | G* | <i>Oidium (Podosphaera xanthii, Golovinomyces cichoracearum, Sphaerotheca fuliginea)</i> <i>Fusarium spp</i> | Spray | BBCH 11-89 | a) 3 | 10 | a) 0.3 b) 0.9 | a) 120 b) 360 | 200-600 | 10 | | A | A | A | A | A | A | A |
| 6a | Central EU (PL, HU, DE, BE, AT, IE) | Pome fruits (Apple, Quince, Medlar) | F | Scab Stemphylium Oidium | Spray | BBCH 39-85 | a) 2 | 7-9 | a) 0.3 b) 0.6 | a) 120 b) 240 | 500-1500 | 14 | | A | A | A | A | A | A | A |
| 6b | Central EU (PL, HU, DE, BE, AT, IE) | Pome fruits (Pear) | F | Scab Stemphylium Oidium | Spray | BBCH 39-85 | a) 2 | 7-9 | a) 0.3 b) 0.6 | a) 120 b) 240 | 500-1500 | 21 | | A | A | A | A | A | A | A |
| 7 | Central EU (DE, PL, HU, AT) | Stone fruits (Plum, Cherry, Apricot) | F ** | <i>Sphaerotheca spp</i> <i>Monilia spp.</i> | Spray | BBCH 51-85 BBCH 51-70 | a) 2 | 7 | a) 0.4 b) 0.8 | a) 160 b) 320 | 500-1500 | 3 | | A | A | A | A | A | A | A |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
|---------------|---|---|--|---|-----------------------|---|---|--|---|---|--------------------------|---------------|---|------------|---------|-------------------|------|--------------------|----------------|-------------------|
| Use- No. * | Member state(s) | Crop and/or situation (crop desti- nation / purpose of crop) | F, Fn, Fp n G, Gn, Gp n or I ** | Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks: e.g. g safener/ synergist per ha | Conclusion | | | | | | |
| | | | | | Meth- od / Kind | Timing / Growth stage of crop & season | Max. num- ber a) per use b) per crop/ season | Min. interval between applica- tions (days) | L product/ha a) max. rate per appl. b) max. total rate per crop/season | g as/ha a) max. rate per appl. b) max. total rate per crop/season | Water L/ha min/max | | | Birds | Mammals | Aquatic organisms | Bees | Non-target arthro- | Soil organisms | Non-target plants |
| 8 | Central EU (PL, RO, NL, BE, AT, IE) | Carrot (other roots and tubers vege- tables) | F | Leaf blight (<i>Alternaria dauci</i>) Sclerotinia rot (<i>Sclerotinia sclerotiorum</i>) Powdery mildew (<i>Erysiphe heraclei</i>) | Spray | BBCH 16-46 | a) 2 | 21 | a) 0.5 b) 1.0 | a) 200 b) 400 | 500-1000 | 21 | | A | A | A | A | A | 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

** 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

Explanation for column 15 – 21 “Conclusion”

| | |
|---|---|
| A | Acceptable, Safe use |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS |
| N | No safe use |

| | | |
|-----------------------|---|--|
| Remarks table: | <p>(1) Numeration necessary to allow references</p> <p>(2) Use official codes/nomenclatures of EU</p> <p>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(4) 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</p> <p>(5) Scientific names <u>and</u> EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named</p> <p>(6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated</p> | <p>(7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(8) The maximum number of application possible under practical conditions of use must be provided</p> <p>(9) Minimum interval (in days) between applications of the same product.</p> <p>(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products</p> <p>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</p> <p>(13) PHI - minimum pre-harvest interval</p> <p>(14) Remarks may include: Extent of use/economic importance/restrictions</p> |
|-----------------------|---|--|

*** A product SIP 41061 in ecotoxicology section approved for use in cucurbits edible peel only in greenhouses with a durable structure, isolated from the ground (not intended for the walk-in tunnels).**

**** In stone fruit BBCH should be change to 51-70.**

9.1.1 Overall conclusions

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

BIRDS

The risk to birds was assessed according to the EFSA's Bird and Mammal Risk Assessment Guidance Document (EFSA Journal 2009; 7(12):1438). No unacceptable risk for birds is expected from acute or long-term exposure to contaminated food. Furthermore, no unacceptable risks are expected arising from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bioaccumulation in food chains). In conclusion, an acceptable overall risk for birds is indicated for the product. No risk mitigation is required.

MAMMALS

The risk to mammals was assessed according to the EFSA's Bird and Mammal Risk Assessment Guidance Document (EFSA Journal 2009; 7(12):1438). No unacceptable risk for mammals is expected from acute or long-term exposure to contaminated food. Furthermore, no unacceptable risks are expected arising from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bioaccumulation in food chains). In conclusion, an acceptable overall risk for mammals is indicated for the product. No risk mitigation is required.

9.1.1.2 No data available to the applicant knowledge.

9.1.1.3

9.1.1.4 Based on the above risk assessments, which indicate acceptable risk of the product to birds and mammals, no concern to other terrestrial vertebrates is expected.

No conclusion can be drawn to the risk of SIP 41061 on reptiles and amphibians.

9.1.1.5

9.1.1.6 Effects on aquatic organisms (KCP 10.2)

The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Journal 2013;11(7):3290).

For Prothioconazole the PEC/RAC ratios calculated with FOCUS modelling showed an acceptable risk to aquatic organisms at Steps 1-3 for all the intended apart from pome/stone fruits, where Step 4 calculation was required.

For 1,2,4-Triazole, acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1-2 scenarios.

For the metabolite Prothioconazole-desthio an acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Step 4. The mitigation measures required to protect aquatic organisms are discussed in the Part A of this dRR.

9.1.1.7 Effects on bees (KCP 10.3.1)

The risk to bees from exposure to the formulation SIP 41061 was assessed in line with the Terrestrial Guidance document (2002). Both hazard quotients for oral and contact toxicity for honey bees are considerably lower than 50, indicating that the proposed uses of SIP 41061 poses an acceptable risk.

In addition, the risk to bees was assessed according to the EFSA Guidance Document on the risk assessment of plant protection products on bees (EFSA 2013), even though this guidance is not yet adopted and currently under revision. The results of this assessment showed acceptable acute and chronic risk of SIP 41061 to honeybee adults and larvae and to bumble bees, with TER and HQ values well below the triggers already at screening step.

It is therefore possible to conclude that the proposed use of SIP 41061 poses an acceptable risk to bees.

9.1.1.8 Effects on arthropods other than bees (KCP 10.3.2)

The risk assessment for non-target arthropods was carried out according to the provisions of ESCORT 2 document. Based on the results of laboratory (glass-plate) tests on *Aphidius rhopalosiphi* and *Typhlodromus pyri*, acceptable in-field and off-field risk can be concluded for SIP 41061 for all the intended uses. No risk mitigations are needed.

9.1.1.9 Effects on non-target soil meso- and macrofauna (KCP 10.4), Błąd! Nie można odnaleźć źródła odwołania.

SOIL MESO AND MACROFAUNA

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the Guidance Document on terrestrial ecotoxicology (SANCO/10329/2002), considering the EU agreed endpoints and the results of laboratory tests with SIP 41061.

The results of this assessment showed acceptable risk to soil macro-organisms for Prothioconazole and its metabolites, with the exception of the risk of Prothioconazole-desthio to earthworms, which requires further considerations for the crops with worst case use pattern (cereals, carrots, cucurbits). The results of a field study on earthworms, which involved a worst-case use pattern compared to SIP 41061, and a concentration of Prothioconazole-desthio higher than the one expected from the intended uses, showed no ecologically adverse effect on earthworm populations. Therefore, it is possible to conclude that exposure

to Prothioconazole-desthio following application of SIP 41061 poses an acceptable risk to earthworms.

SOIL MICROBIAL ACTIVITY

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the Guidance Document on terrestrial ecotoxicology (SANCO/10329/2002). No significant effects on N-transformation were observed in soil at concentrations of Prothioconazole and its metabolites at rates much higher than the one expected from product application. Therefore, it is possible to conclude that the proposed uses of SIP 41061 pose an acceptable risk to the biological activity of micro-organisms in soil.

9.1.1.10 Błąd! Nie można odnaleźć źródła odwołania.

The evaluation of the risk for non-target plants was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The risk assessment was conducted on the basis of the worst-case application scenario, considering the available endpoints from a vegetative vigour test with SIP 41061. Application of the product according to the intended uses does not present an unacceptable risk for non-target terrestrial plants. No mitigation measures are required.

9.1.1.11 Błąd! Nie można odnaleźć źródła odwołania.

No additional data are considered necessary.

9.1.2 Grouping of intended uses for risk assessment

The following tables document the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2a: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for birds & mammals

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|--|---|--------------------------------------|---|
| <i>Screening assessment</i> | | | |
| Cereals, 2 (14d) x 200 g a.s./ha | Cereals, oilseed rape, sugar beet, carrot | EFSA scenario | |
| Fruiting vegetables, 3 (10d) x 120 g a.s./ha | Cucurbits edible peel | EFSA scenario | |
| Orchards, 2 (7d) x 160 g a.s./ha | Orchards | EFSA scenario | |
| <i>Tier 1 assessment</i> | | | |
| Cereals, BBCH 29-69, 2 (14d) x 200 g a.s./ha | <ul style="list-style-type: none"> Wheat, triticale, rye, BBCH 29-69, 2 (14) x 200 g a.s./ha Barley, BBCH 29-61, 2 (14) x 200 g a.s./ha | EFSA scenario | |
| Oilseed rape, BBCH 30-71, 2 (14d) x 180 g a.s./ha | Oilseed rape, BBCH 30-71, 2 (14d) x 180 g a.s./ha | | EFSA scenario |

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---|--|--------------------------------------|---|
| Sugar beet, BBCH 39-49, 2 (14d) x 160 g a.s./ha | Sugar beet, BBCH 39-49, 2 (14d) x 160 g a.s./ha | | EFSA scenario |
| Fruiting veg, BBCH 11-89, 3 (10d) x 120 g a.s./ha | Cucurbits, BBCH 11-89, 3 (10d) x 120 g a.s./ha | EFSA scenario | |
| Orchards, BBCH 39-85, 2 (9d) x 120 g a.s./ha | Pome fruits, BBCH 39-85, 2 (9d) x 120 g a.s./ha | EFSA scenario | - |
| Orchards, BBCH 51-85, 2 (7d) x 160 g a.s./ha | Stone fruits, BBCH 51-85, 2 (7d) x 160 g a.s./ha | EFSA scenario | - |
| Root and stem vegetables, BBCH 16-46, 2 (21d) x 200 g a.s./ha | Carrot, BBCH 16-46, 2 (21d) x 200 g a.s./ha | | EFSA scenario |

Table 9.1-3b: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for aquatic organisms

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---------------------------------|--|--------------------------------------|--|
| <i>Prothioconazole</i> | | | |
| Winter cereals (BBCH 29) | All field crops apart from rice | Highest PEC surface water | - |
| Pome/Stone fruit (BBCH 51) | Orchards | Highest PEC surface water | - |
| <i>Prothioconazole-desethio</i> | | | |
| -- | All crops are assessed separately | - | Mitigation measures specific for each crop |
| <i>1,2,4-triazole</i> | | | |
| Pome/Stone fruit (BBCH 51) | All crops apart from rice | Highest PEC surface water | - |

Table 9.1-4c: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for bees

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---|-----------------|--|---|
| <i>Assessment according to SANCO/10329/2002 rev.2</i> | | | |
| Cereals, 1 x 200 g a.s./ha | All crops | Highest single application rate | - |
| <i>Assessment according to EFSA (2013)</i> | | | |
| Cereals, 1 x 200 g a.s./ha | All field crops | Highest application rate, mode of application (downward) | - |
| Orchards, 1 x 160 g a.s./ha | Stone fruits | Highest application rate, mode of application (upward) | - |

Table 9.1-5d: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for non-target arthropods

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---|---|--------------------------------------|---|
| Cereals, Carrot, 2 x 0.5 L prod../ha | All the intended uses on field crops with max 2 applications and lower application rate | Highest application rate | |
| Cucurbits, 3 x 0.3 L prod../ha | Cucurbits, 3 x 0.3 L prod../ha | | Highest number of applications |
| Stone fruits, 2 x 0.4 L prod../ha | All the intended uses on orchards with lower application rate | Highest PER _{off-field} | |

Table 9.1-6e: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for soil organisms

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---|---|--|---|
| Cereals (prothioconazole) Carrots (soil metabolites) | Carrots, cereals, cucurbits | Worse use pattern (highest application rate, highest number of applications) resulting in higher PEC _{soil} | - |
| Stone fruits | Stone fruits, pome fruits, sugar beet, oilseed rape | Lower application rate and lower number of applications, resulting in lower PEC _{soil} | - |

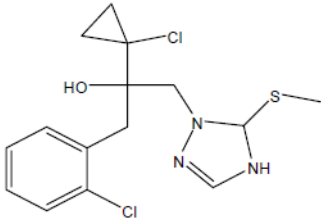
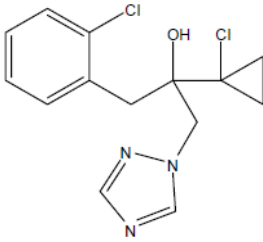
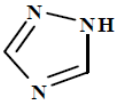
Table 9.1-7f: Critical use pattern of SIP 41061 grouped according to risk envelope approach – risk assessment for non-target plants

| Group | Intended uses | Relevant use parameters for grouping | Relevant parameter or value for sorting |
|---|-----------------|--------------------------------------|---|
| Cereals, Carrot, 2 x 0.5 L prod../ha | All field crops | Highest application rate | - |
| Stone fruits, 2 x 0.4 L prod../ha | All orchards | Highest application rate | Highest drift % |

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of SIP 41061 is indicated in the table.

Table 9.1-8 Metabolites of Prothioconazole

| Metabolite | Molar mass | Chemical structure | Maximum observed occurrence in compartments | Risk assessment required? |
|-----------------------------------|------------|---|---|---------------------------------|
| M01; Prothioconazole- S-methyl | 358.3 |  | Soil: max. 14.6 % | Yes, soil organisms |
| M04: Prothioconazole-desthio | 312.2 |  | Soil: max. 49.4 % (lab) max. 57 % (field studies) Water: max. 32.3 % Sediment: max. 26.9 % | Yes, soil and aquatic organisms |
| M13: 1,2,4-triazole | 69.1 |  | Water: max. 37.2 % | Yes, aquatic organisms |

Prothioconazole-desthio was considered to be the only major metabolite in cereal foliage.

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Acute, short-term, and chronic toxicity studies on birds have been carried out with Prothioconazole and its metabolite Prothioconazole-desthio. Full details of these studies are provided in the respective EU DAR/EU RAR and related documents.

Effects on birds of SIP 41061 were not evaluated as part of the EU assessment of Prothioconazole. However, the provision of further data on the formulation is not considered essential, because the available data are sufficient to conclude about the risk to birds posed by this product.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. For the acute assessment the LD₅₀ are used, since the dietary endpoints are considered overconservative being a “greater than” values. The reproductive assessment is based on the NOEL, which is lower than the ratio LD₅₀/10.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

| Species | Substance | Exposure System | Results | Reference |
|----------------|-------------------------|--------------------------|---|---|
| Bobwhite quail | Prothioconazole | Acute | LD₅₀ > 2000 mg a.s./kg bw | EFSA Scientific Report (2007) 106, 1-98 |
| Bobwhite quail | Prothioconazole | Short-term 5d dietary | LC ₅₀ > 5000 mg a.s./kg diet calc LD ₅₀ > 1413 mg a.s./kg bw/d | |
| Mallard duck | Prothioconazole | Short-term 5d dietary | LC ₅₀ > 5000 mg a.s./kg diet calc LD ₅₀ > 2457 mg a.s./kg bw/d | |
| Bobwhite quail | Prothioconazole | Reproduction 22w dietary | NOEC ≥ 1000 mg a.s./kg diet calc. NOEL ≥ 86 mg a.s./kg bw/d | |
| Mallard duck | Prothioconazole | Reproduction 21w dietary | NOEC = 700 mg a.s./kg diet calc. NOEL = 78 mg a.s./kg bw/d | |
| Bobwhite quail | Prothioconazole-desthio | Acute | LD₅₀ > 2000 mg p.m./kg bw | |
| Bobwhite quail | Prothioconazole-desthio | Short-term 5 d Dietary | LC ₅₀ = 4090 mg p-m./kg diet calc LD ₅₀ > 297 mg p.m./kg bw/d | |
| Bobwhite quail | Prothioconazole-desthio | Reproduction 20w dietary | NOEC = 173 mg p.m./kg diet calc. NOEL = 14.8 mg p.m./kg bw/d | |
| Mallard duck | Prothioconazole-desthio | Reproduction 20w dietary | NOEC ≥ 500 mg p.m./kg diet calc. NOEL = 63 mg p.m./kg bw/d | |

In bold, the endpoints relevant for risk assessment

9.2.1.1 Justification for new endpoints

Not relevant; the selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

9.2.2 Risk assessment for spray applications

The risk assessment was based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach was applied, following the criteria out-

lined in Table 9.1.2a. For the risk assessment of Prothioconazole-desthio, the application rate was calculated from the rate of Prothioconazole adjusted by the ratio of the molecular weight of the metabolite (312.2) and the molecular weight of the parent (344), i.e. $312.2 / 344.26 = 0.907$.

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening risk assessments for Prothioconazole are summarised in the following tables.

Table 9.2-2: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on cereals

| Intended use | | Cereals (covering field crops) | | | | |
|-------------------------------|-----------------------|--|------------------|---------------------------|-----------------------------------|-------------------|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 2 (14d) × 200 | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 1413 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Cereals | Small omnivorous bird | | 158.8 | 1.2 | 38.11 | 52.5 37 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 78 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario | Indicator species | | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Cereals | Small omnivorous bird | | 64.8 | 1.4 x 0.53 | 9.62 | 8.1 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on fruiting vegetables

| Intended use | | Cucurbits (edible and inedible peel) | | | | |
|-------------------------------|-----------------------|--|------------------|--------------------|-----------------------------------|-------------------|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 3 (10d) × 120 | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 1413 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Fruiting vegetables | Small omnivorous bird | | 158.8 | 1.5 | 28.58 | 70.0 49.44 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 78 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario | Indicator species | | SV _m | MAF _m × | DDD _m | TER _{lt} |

| | | | TWA | (mg/kg bw/d) | |
|---------------------|-----------------------|------|------------|--------------|------|
| Fruiting vegetables | Small omnivorous bird | 64.8 | 1.8 x 0.53 | 7.42 | 10.5 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on orchards

| Intended use | | Orchards | | | | |
|-------------------------------|--------------------------|--|------------------|---------------------------|-----------------------------------|----------------------------|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 2 (7d) × 160 | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 1413 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Orchards | Small insectivorous bird | | 46.8 | 1.4 | 10.48 | 190.8 134.83 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 78 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario | Indicator species | | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Orchards | Small insectivorous bird | | 18.2 | 1.6 x 0.53 | 2.47 | 31.6 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The results of the acute and reproductive risk assessments for Prothioconazole-desthio are summarised in the following tables.

Table 9.2-5: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on cereals

| Intended use | | Cereals, BBCH 29-69 | | | | |
|---------------------------|------------------------------|---|-------------------|-----------------------------------|------------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (14d) × 181 (=200 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Cereals | Small omnivorous bird | 158.8 | 1.2 | 34.49 | 58.0 8.6 | |
| Cereals, BBCH 10-29 | Small omnivorous bird lark | 30.5 | 1.2 | 6.62 | 44.6 | |
| Cereals, BBCH 10-29 | Large herbivorous bird goose | 24 | 1.2 | 5.21 | 57 | |
| Cereals, BBCH 30-39 | Small omnivorous bird “lark” | 12 | 1.2 | 2.6 | 114.23 | |

| | | | | | |
|-------------------------------|---------------------------------|-----------------|---------------------------|----------------------------------|-------------------|
| BBCH ≥ 40 | Small omnivorous bird “lark” | 7.2 | 1.2 | 1.56 | 190.38 |
| Reprod. toxicity (mg/kg bw/d) | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Cereals | Small omnivorous bird | 64.8 | 1.4 x 0.53 | 8.70 | 1.7 |
| Cereals, BBCH 10-29 | Small omnivorous bird lark | 16.2 | 1.4 x 0.53 | 2.18 | 6.7 |
| Cereals, BBCH 10-29 | Large herbivorous bird goose | 10.9 | 1.4 x 0.53 | 1.46 | 10.1 |
| Cereals, BBCH ≥ 40 | Small omnivorous bird “lark” | 3.3 | 1.4 x 0.53 | 0.44 | 33.4 |
| Cereals, BBCH 30 -39 | Small omnivorous bird “lark” | 5.4 | 1.4 x 0.53 | 0.73 | 20.4 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-6: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on oilseed rape

| | | | | | |
|--|---|------------------|---------------------------|-----------------------------------|-------------------|
| Intended use | Oilseed rape, BBCH 30-71 | | | | |
| Active substance/product | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | 2 (14d) × 163 (=180 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | | |
| TER criterion | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Oilseed rape | Small omnivorous bird | 158.8 | 1.2 | 31.06 | 64.4 4.67 |
| Oilseed rape, BBCH ≥ 40 | medium herbivorous/granivorous bird “pigeon” | 2 | 1.2 | 0.43 | 690 |
| Oilseed rape, BBCH ≥ 40 | Small omnivorous bird “lark” | 6 | 1.2 | 1.3 | 228 |
| Oilseed rape, BBCH 30-39 | Medium herbivorous/granivorous bird “pigeon” | 2.4 | 1.2 | 0.52 | 571 |
| Oilseed rape, BBCH 30-39 | Small omnivorous bird “lark” | 7.2 | 1.2 | 1.56 | 190 |
| Oilseed rape with seeds, BBCH 30-99 | Small insectivorous bird “dunnock” | 7.4 | 1.2 | 1.6 | 185 |
| Reprod. toxicity (mg/kg bw/d) | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Oilseed rape | Small omnivorous bird | 64.8 | 1.4 x 0.53 | 7.84 | 1.9 |
| Oilseed rape, BBCH ≥ 40 | medium herbivorous/granivorous bird “pigeon” | 0.9 | 1.4 x 0.53 | 0.11 | 136.0 |

| | | | | | |
|--|---|-----|------------|------|-------|
| Oilseed rape, BBCH ≥ 40 | Small omnivorous bird “lark” | 2.7 | 1.4 x 0.53 | 0.33 | 45.3 |
| Oilseed rape, BBCH 30-29 | Medium herbivorous/granivorous bird “pigeon” | 1.1 | 1.4 x 0.53 | 0.13 | 111.2 |
| Oilseed rape, BBCH 30-29 | Small omnivorous bird “lark” | 3.3 | 1.4 x 0.53 | 0.40 | 37.1 |
| Oilseed rape with seeds, BBCH 30-99 | Small insectivorous bird “dunnock” | 2.7 | 1.4 x 0.53 | 0.33 | 45.3 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-7: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on sugar beet

| Intended use | | Sugar beet, BBCH 39-49 | | | | |
|--|-----------------------|---|------------------|---------------------------|-----------------------------------|-------------------|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (14d) × 145 (=160 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Sugar beet | Small omnivorous bird | | 158.8 | 1.2 | 27.63 | 72.4 10.75 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Sugar beet | | Small omnivorous bird | 64.8 | 1.4 x 0.53 | 6.97 | 2.1 |
| Sugar beet, BBCH 20 - 49 | | Small insectivorous bird “wagtail” | 2.8 | 1.4 x 0.53 | 0.30 | 49.1 |
| Sugar beet, BBCH 20 - 49 | | Small insectivorous bird “wagtail” | 9.7 | 1.4 x 0.53 | 1.04 | 14.2 |
| Sugar beet late (summer/ autumn) (BBCH 30-49) | | Small granivorous bird "finch" | 11.4 | 1.4 x 0.53 | 1.23 | 12.1 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-8: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on cucurbits

| Intended use | | Cucurbits, BBCH 11-89 | | | | |
|---------------------------|--|---|--|--|--|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 3 (10d) \times 109 (=120 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | | |

| | | | | | | |
|--|---------------------------------------|------------------------|------------------|---------------------------|-----------------------------------|-------------------|
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Fruiting vegetables | Small omnivorous bird | | 158.8 | 1.5 | 25.96 | 77.9 11.44 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Fruiting vegetables | Small omnivorous bird | | 64.8 | 1.8 x 0.53 | 6.74 | 2.2 |
| Fruiting vegetables, BBCH ≥ 20 | Small insectivorous bird “wagtail” | | 9.7 | 1.8 x 0.53 | 1.01 | 14.7 |
| Fruiting vegetables, BBCH ≥ 50 | Small granivorous bird “finch” | | 3.4 | 1.8 x 0.53 | 0.35 | 41.9 |
| Fruiting vegetables, BBCH ≥ 50 | Small omnivorous bird “lark” | | 3.3 | 1.8 x 0.53 | 0.34 | 43.1 |
| Fruiting vegetables, BBCH 10-19 | Small insectivorous bird “wagtail” | | 11.3 | 1.8 x 0.53 | 1.18 | 12.6 |
| Fruiting vegetables, BBCH 10-19 | Small insectivorous bird “wagtail” | | 11.3 | 1.8 x 0.53 | 1.18 | 12.6 |
| Fruiting vegetables, BBCH 10-49 | Small granivorous bird “finch” | | 11.4 | 1.8 x 0.53 | 1.19 | 12.5 |
| Fruiting vegetables, BBCH 10-49 | Small omnivorous bird “lark” | | 10.9 | 1.8 x 0.53 | 1.13 | 13.1 |
| Fruiting vegetables, Fruit stage BBCH 71-89 | Frugivorous bird “crow” | | 32.0 | 1.8 x 0.53 | 3.33 | 4.45 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-9: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on pome fruits

| Intended use | | Pome fruits, BBCH 39-85 | | | | |
|-------------------------------|---------------------------------|---|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (7d) × 109 (=120 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Orchards | Small omnivorous bird | 46.8 | 1.4 | 7.14 | 280.0 41.59 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |

| | | | | | |
|----------|-----------------------|------|------------|------|-----|
| Orchards | Small omnivorous bird | 18.2 | 1.6 x 0.53 | 1.68 | 8.8 |
|----------|-----------------------|------|------------|------|-----|

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-10: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on stone fruits

| Intended use | | Stone fruits, BBCH 51-85 | | | |
|-------------------------------|---------------------------------|---|---------------------------|-----------------------------------|------------------------------|
| Active substance/product | | Prothioconazole-desthio | | | |
| Application rate (g/ha) | | 2 (7d) × 145 (=160 g a.s./ha * 0.907) | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | |
| TER criterion | | 10 | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Orchards | Small omnivorous bird | 46.8 | 1.4 | 9.5 | 210.5 31.26 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | |
| TER criterion | | 5 | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Orchards | Small omnivorous bird | 18.2 | 1.6 x 0.53 | 2.24 | 6.6 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-11: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on carrots

| Intended use | | Carrots, BBCH 16-46 | | | |
|--|---------------------------------------|---|---------------------------|-----------------------------------|-----------------------------|
| Active substance/product | | Prothioconazole-desthio | | | |
| Application rate (g/ha) | | 2 (21d) × 181 (=200 g a.s./ha * 0.907) | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 2000 mg/kg bw LD ₅₀ > 297 mg a.s./ kg bw/day | | | |
| TER criterion | | 10 | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Root and stem vegetables | Small omnivorous bird | 158.8 | 1.1 | 31.62 | 63.3 9.39* |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | |
| TER criterion | | 5 | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Root and stem vegetables | Small omnivorous bird | 64.8 | 1.2 x 0.53 | 7.46 | 2.0 |
| Root and stem vegetables, BBCH ≥ 20 | Small insectivorous bird “wagtail” | 9.7 | 1.2 x 0.53 | 1.12 | 13.3 |

| | | | | | |
|--|------------------------------------|------|------------|------|------|
| Root and stem vegetables, BBCH \geq 40 | Small granivorous bird “finch” | 3.4 | 1.2 x 0.53 | 0.39 | 37.8 |
| Root and stem vegetables, BBCH \geq 40 | Small omnivorous bird “lark” | 3.3 | 1.2 x 0.53 | 0.38 | 39.0 |
| Root and stem vegetables, BBCH 10-19 | Small insectivorous bird “wagtail” | 11.3 | 1.2 x 0.53 | 1.30 | 11.4 |
| Root and stem vegetables, BBCH 10-39 | Small granivorous bird “finch” | 11.4 | 1.2 x 0.53 | 1.31 | 11.3 |
| Root and stem vegetables, BBCH 10-39 | Small omnivorous bird “lark” | 10.9 | 1.2 x 0.53 | 1.25 | 11.8 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

***TER is very close the trigger value 10 (9.39) based on screening step. In opinion RMS the risk in this case is acceptable.**

Based on the above assessment, acceptable risk can be concluded for all the intended uses of SIP 41061, apart from cucurbits at BBCH 71-89, where Prothioconazole-desthio fails Tier-1 assessment for the frugivorous bird “crow”. The higher-tier assessment for cucurbits at BBCH 71-89 is triggered only by the use in open structures, because the use in close greenhouses is not expected to cause exposure of birds and mammals. It is to be noted that the Tier-1 assessment reported in Table 9.2-8 for this scenario is extremely conservative, because it assumes that the product is applied 3 times between BBCH 71 and BBCH 89 – which is unlikely, considering the minimum interval between applications fixed by the GAP (10 days). Nevertheless, a higher-tier assessment for this scenario is here provided.

zRMS comment:

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). Safe use of prothioconazole and prothioconazole-desthio (M04) for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable for all the intended uses of SIP 41061 crops apart from cucurbits at BBCH 71-89, where prothioconazole-desthio fails Tier-1 assessment for the frugivorous bird “crow”. The refinement risk assessment for birds was provided by Applicant.

9.2.2.2 Higher-tier risk assessment

All the available residues data indicate a fast dissipation of Prothioconazole-desthio from plant material. As reported in the EFSA Conclusion, a DT_{50} of 3.2 days for this metabolite was obtained from 8 trials on wheat (green part of the plant), and this value was used for the higher-tier assessment of birds and mammals in the EU evaluation of Prothioconazole.

As detailed in Section B7 of this dRR, several residue trials on cucurbits were performed applying SIP 41061 according to the intended use, thus providing information on the residual behaviour of Prothioconazole-desthio. In particular, as discussed in the report KINPT_01 (KCP 10.1.1.2), the results of 4 trials on zucchini were considered for kinetic evaluation, and a DT_{50} of 3.8 days was calculated for Prothioconazole-desthio.

As recommended by the EFSA Guidance document (EFSA 2009), this DT_{50} was used for refining MAF and TWA values with a “moving time-window approach”. For this purpose, the tool provided by Belgian authorities¹ was used, obtaining a MAF x TWA of 0.525; the same result was obtained also with the calculator recommended by the authorities of the EU-Northern Zone².

¹ https://fytoweb.be/sites/default/files/guide/attachments/calculation_tool_moving_time_window_det_v2_be_1.xls

² <https://eng.mst.dk/media/211953/bird-mammal-scenario-template-v20-1.xlsm>

Using these refinements, the higher-tier assessment for frugivorous birds results in TER higher than 5, indicating acceptable risk.

Table 9.2-12: Prothioconazole-desthio – Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SIP 41061 on cucurbits

| Intended use | | Cucurbits, BBCH 11-89 | | | | |
|--|---------------------------------|--|------------------------|-------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 3 (10d) × 109 (=120 g a.s./ha * 0.907) | | | | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 14.8 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Fruiting vegetables, Fruit stage BBCH 71-89 | Frugivorous bird “crow” | 32.0 | 0.525 | 1.8 | 8.08 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comment:

The refinement risk assessment for cucurbits at BBCH 71-89 for prothioconazole-desthio is not accepted by RMS based on DT₅₀ = 3.8d as well as refinement value TWA.

The presented by the Applicant refinement risk assessment for the birds was evaluated by the RMS, but found not acceptable due to the uncertainties related to the kinetic analysis of the data of the residue trials. Please see KCP 10.1.1.2 point (Higher tier data on birds and mammals).

Safe use of prothiconazole and prothioconazole-desthio (M04) for birds were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively, indicating the acute and long-term risk is acceptable for all the intended uses of SIP 41061 crops apart from cucurbits at BBCH 71-89, where prothioconazole-desthio fails Tier-1 assessment for the frugivorous bird “crow”. The refinement risk assessment for birds is not accepted by zRMS. However, in this case - SIP 41061 formulation is used in **close greenhouses** (professional greenhouse use). Therefore, in this case - risk for birds is not expected. Otherwise, it is necessary to perform a full risk assessment with refinement.

The refinement risk assessment for cucurbits at BBCH 71-89 for prothioconazole-desthio in close greenhouse should be considered at MSs level.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438). The risk from drinking water was assessed for Prothioconazole and its water-relevant metabolite Prothioconazole-desthio. No risk assessment was performed for Prothioconazole-S.methyl because it is not a water metabolite; no risk assessment was performed for the water metabolite 1,2,4-triazole because according to the EFSA Conclusion (page 40) this metabolite has “lower toxicity than prothioconazole. Not of ecotoxicological relevance.”

Leaf scenario

The leaf scenario is not relevant, since SIP 41061 is not intended to be applied on leafy vegetables form-

ing heads, nor on crop plants with comparable water collecting structures.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 1765 mL/g, Prothioconazole belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. The worst-case use patterns for SIP 41061 are: 2 applications of 200 g a.s./ha with 14 days of interval (use on cereals), and 3 applications at the rate of 120 g a.s./ha with 7 days of interval (use on cucurbits). The effective rates should be calculated multiplying these application rates by the MAF values calculated from the soil DT_{50} of Prothioconazole; due to the fast dissipation of Prothioconazole (2.8 days), the MAF is 1.0 for both use patterns, so the highest effective rate to be used in the risk assessment is therefore 200 g a.s./ha.

| | | | |
|-----------------------------------|---|------------|-----------------|
| Effective application rate (g/ha) | 200 | | |
| Acute toxicity (mg/kg bw) | > 2000 mg/kg bw $LD_{50} > 1413$ mg/kg bw | quotient = | < 0.1 < 0.14 |
| Reprod. toxicity (mg/kg bw/d) | 78 mg/kg bw/d | quotient = | 2.56 |

With a $K(f)_{oc}$ of 575.4 mL/g, Prothioconazole-desthio belongs to the group of more sorptive substances. The soil DT_{50} of Prothioconazole-desthio is 73.3 days, so for the worst-case use patterns mentioned above the MAF values are 1.9 and 2.8 for cereals and cucurbits respectively, and the effective rates are 380 and 338 g a.s./ha. The highest effective rate of 380 g a.s./ha was therefore used in the risk assessment.

| | | | |
|-----------------------------------|--|------------|------------------|
| Effective application rate (g/ha) | 380 | | |
| Acute toxicity (mg/kg bw) | > 2000 mg/kg bw $LD_{50} > 297$ mg a.s./ kg bw/day | quotient = | < 0.19 < 1.28 |
| Reprod. toxicity (mg/kg bw/d) | 14.8 mg/kg bw/d | quotient = | 25.7 |

Based on the above assessments, acceptable risk for birds via drinking water can be concluded for Prothioconazole and its metabolites.

zRMS comment:

Agreed. As SIP 41061 is not intended for leafy crops forming heads, the leaf scenario does not have to be therefore considered based on the proposed uses. Evaluation of exposing for birds through the drinking water puddle scenario for the active substance and metabolite M04, demonstrate that the acceptable risk for birds for proposed use pattern of SIP 41061.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Prothioconazole is in the range 2.00 - 4.16 depending on pH; following a conservative approach, the risk for worm-eating and fish-eating birds and mammals was assessed considering the worst-case Log P_{ow} of 4.16.

Prothioconazole-desthio, relevant for soil and water compartments, has a Log P_{ow} of 3.04, and therefore a risk assessment for worm-eating and fish-eating birds and mammals is required.

The soil metabolite Prothioconazole-S-methyl (M01) has a Log P_{ow} of 4.19, thus triggering a risk assess-

ment for secondary poisoning. According to the EFSA Conclusion (page 38), this metabolite poses low ecotoxicological risk to soil compartment, so a quantitative risk assessment represents a very conservative approach; nevertheless, the risk to vermivorous birds and mammals was assessed, using the toxicological endpoints of Prothioconazole as surrogate. Since Prothioconazole-S-methyl is not relevant for surface water, the risk to fish-eating birds and mammals was not assessed.

According to the EFSA Conclusion (page 33), the water metabolite 1,2,4-triazole has a log Pow <3, and therefore it doesn't pose any risk to birds and mammals via secondary poisoning.

Risk assessment for earthworm-eating birds via secondary poisoning

As explained above, the risk assessment for worm-eating birds was performed for Prothioconazole and its metabolites Prothioconazole-desthio and Prothioconazole-S-methyl.

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Following a risk envelope approach, the highest 21d-TWA PECsoil values were used in the present assessment.

Parameters used by zRMS in the assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole and prothioconazole metabolites via bioaccumulation in earthworms and fish (secondary poisoning)

| Parameter | Prothioconazole | Prothioconazole-desthio (M04) | Prothioconazole-S-methyl (M01) | comments |
|---------------------------------------|---------------------------|-------------------------------|--------------------------------|--|
| log P _{ow} / P _{ow} | 3.4 / 2511.9 3.82/6607 | 3.04 / 1096.5 | 4.19/15448.2 | EFSA Scientific Report (2007) 106, 1-98 |
| Koc | 1765 | 575.4 | 2526 | Geomean (M04 and M01) EFSA Scientific Report (2007) 106, 1-98 |
| foc | 0.02 | 0.02 | 0.02 | Default |

Table 9.2-13: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole | Comments |
|---|------------------------------|---|
| PEC _{soil} (twa = 21 d) (mg/kg soil) | 0.051 | Highest TWA PECsoil, obtained from the use on cereals (please refer to dRR Part B8) |
| log P _{ow} P _{ow} | 4.16 3.4 3.82 2511.9 6607 | EFSA Conclusion 2007 |
| Koc | 1765 | EFSA Conclusion 2007 |
| Foc | 0.02 | Default |
| BCF _{worm} | 4.94 0.87 22.48 | BCF _{worm} = (0.84 + 0.012 × P _{ow}) / foc × Koc |
| PEC _{worm} | 0.25 0.044 1.15 | PEC _{worm} = PEC _{soil} × BCF _{worm/soil} |
| Daily dietary dose (mg/kg bw/d) | 0.26 0.0462 1.2 | DDD = PEC _{worm} × 1.05 |
| NOEL (mg/kg bw/d) | 78 | EFSA Conclusion |
| TER _{it} | 295.0 1688 65 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.2-14: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole-desthio via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole-desthio (M04) | Comments |
|---|-------------------------------|--|
| PEC _{soil} (twa = 21 d) (mg/kg soil) | 0.170 | Highest TWA PEC _{soil} , obtained from the use on carrots (please refer to dRR Part B8) |
| log P _{ow} P _{ow} | 3.04 1096.5 | EFSA Conclusion 2007 |
| Koc | 573.5 | EFSA Conclusion 2007 |
| Foc | 0.02 | Default |
| BCF _{worm} | 1.22 | $BCF_{worm} = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$ |
| PEC _{worm} | 0.21 | $PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$ |
| Daily dietary dose (mg/kg bw/d) | 0.22 | $DDD = PEC_{worm} \times 1.05$ |
| NOEL (mg/kg bw/d) | 14.8 | EFSA Conclusion |
| TER _{lt} | 67.9 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.2-15: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole-S-methyl (M01) via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole-S-methyl | Comments |
|---|----------------------------|--|
| PEC _{soil} (twa = 21 d) (mg/kg soil) | 0.045 | Highest TWA PEC _{soil} , obtained from the use on carrots (please refer to dRR Part B8) |
| log P _{ow} P _{ow} | 4.19 15448.2 | EFSA Conclusion 2007 |
| Koc | 2526 | EFSA Conclusion 2007 |
| Foc | 0.02 | Default |
| BCF _{worm} | 3.70 4.12 | $BCF_{worm} = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$ |
| PEC _{worm} | 0.1854 | $PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$ |
| Daily dietary dose (mg/kg bw/d) | 0.17 0.19467 | $DDD = PEC_{worm} \times 1.05$ |
| NOEL (mg/kg bw/d) | 78 7.8* | endpoint of Prothioconazole Derived endpoint |
| TER _{lt} | 446.7 40.07 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

*Endpoint estimated as parent NOEL/10.

Based on the above assessments, acceptable risk to worm-eating birds can be concluded for Prothioconazole and its soil metabolites.

Risk assessment for fish-eating birds via secondary poisoning

As explained above, the risk assessment for fish-eating birds was performed for Prothioconazole and Prothioconazole-desthio.

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Following a risk envelope approach, the highest 21d-TWA PEC_{sw} values calculated with FOCUS Step 2 were used in the present assessment.

Table 9.2-16a: Assessment of the risk for fish-eating birds due to exposure to Prothioconazole via bioaccumulation in fish (secondary poisoning)

| Parameter | Prothioconazole | comments |
|---------------------------------------|-----------------|--|
| PEC _{sw} (twa = 21 d) (mg/L) | 0.000736 | Highest TWA PEC _{sw} , obtained for pome/stone fruits (please refer to dRR Part B8) |
| BCF _{fish} | 19.7 | EFSA Conclusion, 2007 |
| BMF | not relevant | biomagnification factor (relevant for BCF ≥ 2000) |
| PEC _{fish} | 0.01 | PEC _{fish} = PEC _{water} × BCF _{fish} |
| Daily dietary dose (mg/kg bw/d) | 0.002 | DDD = PEC _{fish} × 0.159 |
| NOEL (mg/kg bw/d) | 78 | |
| TER _{lt} | 33834.0 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.2-16b: Assessment of the risk for fish-eating birds due to exposure to Prothioconazole-desthio via bioaccumulation in fish (secondary poisoning)

| Parameter | Prothioconazole-desthio (M04) | comments |
|---------------------------------------|-------------------------------|--|
| PEC _{sw} (twa = 21 d) (mg/L) | 0.010498 | Highest TWA PEC _{sw} , obtained for cereals (please refer to dRR Part B8) |
| BCF _{fish} | 65 | EFSA Conclusion, 2007 |
| BMF | not relevant | biomagnification factor (relevant for BCF ≥ 2000) |
| PEC _{fish} | 0.68 | PEC _{fish} = PEC _{water} × BCF _{fish} |
| Daily dietary dose (mg/kg bw/d) | 0.11 | DDD = PEC _{fish} × 0.159 |
| NOEL (mg/kg bw/d) | 14.8 | |
| TER _{lt} | 136.4 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

zRMS comment:

The risk for fish-eating birds and earthworms-eating birds due to exposure to prothioconazole and its metabolites (M04) is considered as acceptable for the worst case scenario. Since prothioconazole-S-methyl is not relevant for surface water, the risk to fish-eating birds and mammals was not necessary.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

The risk to birds was assessed according to the EFSA's Bird and Mammal Risk Assessment Guidance Document (EFSA Journal 2009; 7(12):1438). No unacceptable risk for birds is expected from acute or long-term exposure to contaminated food. Furthermore, no unacceptable risks are expected arising from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bioaccumulation in food chains). In conclusion, an acceptable overall risk for birds is indicated for the product. No risk mitigation is required.

zRMS comment:

The acute and chronic risks of SIP 41061 to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from study with active substances, and maximum residues occurring on food items. For active substance all TER values exceed the relevant triggers indicating that SIP 41061 does not pose an unacceptable risk to birds following applications according to recommended use pattern. Evaluation of exposing to mammals through the drinking water demonstrated the acceptable risk. The risk to earthworm - and fish-eating animals from secondary poisoning is low.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Prothioconazole and its metabolite Prothioconazole-desthio. Full details of these studies are provided in the respective EU DAR and related documents. Effects on mammals of SIP 41061 were not evaluated as part of the EU assessment of Prothioconazole. However, the provision of further data on the formulation is not considered essential, because the available data are sufficient to conclude about the risk to mammals posed by this product.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. The reproductive assessment is based on the NOEL, which is lower than the ratio LD₅₀/10.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

| Species | Substance | Exposure System | Results | Reference |
|---------|-------------------------|----------------------------------|--|---|
| Rat | Prothioconazole | Acute, oral | LD ₅₀ (male, female) > 6200 mg a.s./kg bw | EFSA Scientific Report (2007) 106, 1-98 |
| Rat | Prothioconazole | Long-term (2-generation), gavage | NOEL _{parental} = 9.7 mg a.s./kg bw/d NOEL _{reproduction} = 95.6 mg a.s./kg bw/d | |
| Rat | Prothioconazole-desthio | Acute, oral | LD ₅₀ (female) = 2506 mg a.s./kg bw LD ₅₀ (male) = 2806 mg a.s./kg bw | |
| Mouse | Prothioconazole-desthio | Acute, oral | LD ₅₀ (female) = 3459 mg p.m./kg bw LD ₅₀ (male) = 2235 mg p.m./kg bw | |
| Rat | Prothioconazole-desthio | Long-term (2-generation), oral | NOEL _{parental} = 2.5 mg p.m./kg bw/d NOEL _{reproduction} = 10 mg p.m./kg bw/d | |

In bold, the endpoints relevant for risk assessment

9.3.1.1 Justification for new endpoints

Not relevant; the selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied, following the criteria outlined in Table 9.1.2a. For the risk assessment of Prothioconazole-desthio, the application rate was calculated from the rate of Prothioconazole adjusted by the ratio of the molecular weight of the metabolite (312.2) and the molecular weight of the parent (344), i.e. $312.2 / 344.26 = 0.907$.

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive screening risk assessments for Prothioconazole are summarised in the following tables.

Table 9.3-2: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on cereals

| Intended use | | Cereals (covering field crops, excluded cucurbits) | | | | |
|-------------------------------|--------------------------|--|------------------|---------------------------|-----------------------------------|-------------------|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 2 (14d) × 200 | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 6200 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a |
| Cereals | Small herbivorous mammal | | 118.4 | 1.2 | 28.42 | 218.2 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 95.6 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario | Indicator species | | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Cereals | Small herbivorous mammal | | 48.3 | 1.4 x 0.53 | 7.17 | 13.34 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on fruiting vegetables

| Intended use | | Cucurbits | | | | |
|-------------------------------|--------------------------|----------------------------------|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 3 (10d) × 120 | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 6200 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Fruiting vegetables | Small herbivorous mammal | 136.4 | 1.5 | 24.55 | 252.5 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 95.6 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario | Indicator species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Fruiting vegetables | Small herbivorous mammal | 72.3 | 1.8 x 0.53 | 8.28 | 11.55 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-4: Prothioconazole - Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on orchards

| Intended use | | Orchards | | | | |
|--------------------------|--|-----------------|--|--|--|--|
| Active substance/product | | Prothioconazole | | | | |
| Application rate (g/ha) | | 2 (7d) × 160 | | | | |

| | | | | | |
|--------------------------------------|--------------------------|----------------------------------|----------------------------------|--|-------------------------|
| Acute toxicity (mg/kg bw) | | LD ₅₀ > 6200 mg/kg bw | | | |
| TER criterion | | 10 | | | |
| Crop scenario | Indicator species | SV₉₀ | MAF₉₀ | DDD₉₀ (mg/kg bw/d) | TER_a |
| Orchards | Small herbivorous mammal | 136.4 | 1.4 | 30.55 | 202.9 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 95.6 mg/kg bw/d | | | |
| TER criterion | | 5 | | | |
| Crop scenario | Indicator species | SV_m | MAF_m × TWA | DDD_m (mg/kg bw/d) | TER_{lt} |
| Orchards | Small herbivorous mammal | 72.3 | 1.6 x 0.53 | 9.81 | 9.75 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

The results of the acute and reproductive risk assessments for Prothioconazole-desthio are summarised in the following tables. Following a risk-envelope approach, for the use on cucurbits 3 applications were considered for all the scenarios, although for BBCH < 50 only 1 application is intended. For the use on Pome fruits, both the application intervals recommended in the GAP (7-9 days) were considered,

Table 9.3-5: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on cereals

| | | | | | |
|---------------------------------------|---|--|----------------------------------|--|-------------------------|
| Intended use | | Cereals, BBCH 29-69 | | | |
| Active substance/product | | Prothioconazole-desthio | | | |
| Application rate (g/ha) | | 2 (14d) × 181 (=200 g a.s./ha * 0.907) | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | |
| TER criterion | | 10 | | | |
| Crop scenario | Indicator species | SV₉₀ | MAF₉₀ | DDD₉₀ (mg/kg bw/d) | TER_a |
| Cereals | Small herbivorous mammal | 118.4 | 1.2 | 25.72 | 86.9 |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | |
| TER criterion | | 5 | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV_m | MAF_m × TWA | DDD_m (mg/kg bw/d) | TER_{lt} |
| Cereals | Small herbivorous mammal | 48.3 | 1.4 x 0.53 | 6.49 | 1.54 |
| Cereals Early (shoots) | Large herbivorous mammal “lagomorph” | 22.3 | 1.4 x 0.53 | 2.99 | 3.3 |
| Cereals BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 x 0.53 | 0.26 | 39.2 |
| Cereals BBCH ≥ 40 | Small herbivorous mammal “vole “ | 21.7 | 1.4 x 0.53 | 2.91 | 3.4 |
| Cereals BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.4 x 0.53 | 0.31 | 32.4 |
| Cereals BBCH 30 - 39 | Small omnivorous mammal “mouse” | 3.9 | 1.4 x 0.53 | 0.52 | 19.1 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-6: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on oilseed rape

| Intended use | | Oilseed rape, BBCH 30-71 | | | | |
|-------------------------------|--|--|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (14d) × 163 (=180 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Oilseed rape | Small herbivorous mammal | 118.4 | 1.2 | 23.16 | 96.5 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Oilseed rape | Small herbivorous mammal | 48.3 | 1.4 x 0.53 | 5.84 | 1.71 | |
| Oilseed rape, All season | Large herbivorous mammal “lagomorph” | 14.3 | 1.4 x 0.53 | 1.73 | 5.8 | |
| Oilseed rape, BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 x 0.53 | 0.23 | 43.5 | |
| Oilseed rape, BBCH ≥ 40 | Small herbivorous mammal “vole” | 18.1 | 1.4 x 0.53 | 2.19 | 4.6 | |
| Oilseed rape, BBCH ≥ 40 | Small omnivorous mammal “mouse” | 1.9 | 1.4 x 0.53 | 0.23 | 43.5 | |
| Oilseed rape, BBCH 30-39 | Small omnivorous mammal “mouse” rodents | 2.3 | 1.4 x 0.53 | 0.28 | 35.9 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-7: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on sugar beet

| Intended use | | Sugar beet, BBCH 39-49 | | | | |
|-------------------------------|--------------------------|--|-------------------|-----------------------------------|------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (14d) × 145 (=160 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Sugar beet | Small herbivorous mammal | 118.4 | 1.2 | 20.60 | 108.5 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |

| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
|-------------------------------|---|-----------------|---------------------------|----------------------------------|-------------------|
| Sugar beet | Small herbivorous mammal | 48.3 | 1.4 x 0.53 | 5.20 | 1.92 |
| Sugar beet BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.4 x 0.53 | 0.20 | 48.9 |
| Sugar beet BBCH ≥ 40 | Large herbivorous mammal “lagomorph” | 3.6 | 1.4 x 0.53 | 0.39 | 25.8 |
| Sugar beet BBCH ≥ 40 | Small herbivorous mammal “vole” | 18.1 | 1.4 x 0.53 | 1.95 | 5.1 |
| Sugar beet BBCH ≥ 40 | Small omnivorous mammal “mouse” | 1.9 | 1.4 x 0.53 | 0.20 | 48.9 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-8: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on cucurbits

| Intended use | | Cucurbits, BBCH 11-89 | | | | |
|--|---------------------------------------|--|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 3 (10d) × 109 (=120 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Fruiting vegetables | Small herbivorous mammal | 136.4 | 1.5 | 22.30 | 100.2 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Fruiting vegetables | Small herbivorous mammal | 72.3 | 1.8 x 0.53 | 7.52 | 1.3 | |
| Fruiting vegetables BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.8 x 0.53 | 0.20 | 50.6 | |
| Fruiting vegetables BBCH ≥ 50 | Small herbivorous mammal “vole” | 21.7 | 1.8 x 0.53 | 2.26 | 4.4 | |
| Fruiting vegetables BBCH ≥ 50 | Small omnivorous mammal “mouse” | 2.3 | 1.8 x 0.53 | 0.24 | 41.8 | |
| Fruiting vegetables BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.8 x 0.53 | 0.44 | 22.9 | |
| Fruiting vegetables BBCH 10 - 49 | Small herbivorous mammal “vole” | 72.3 | 1.8 x 0.53 | 7.52 | 1.3 | |
| Fruiting vegetables BBCH 10 - 49 | Small omnivorous mammal “mouse” | 7.8 | 1.8 x 0.53 | 0.81 | 12.3 | |
| Fruiting vegetables, Fruit stage BBCH 71-89 | Frugivorous mammal “rat” | 25.2 | 1.8 x 0.53 | 2.62 | 3.8 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-9a: Prothioconazole-desthio – First-tier assessment of the acute and long-term risk for mammals for the use of SIP 41061 on pome fruits (2 appl. with 7 days of interval)

| Intended use | | Pome fruits, BBCH 39-85 | | | | |
|---|--------------------------------------|---------------------------------------|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (7d) × 109 (=120 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Orchards | Small herbivorous mammal | 136.4 | 1.4 | 20.81 | 107.4 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | | | | | |
| Crop scenario | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Orchards | Small herbivorous mammal | 72.3 | 1.6 x 0.53 | 6.68 | 1.50 | |
| Orchard Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” | 4.3 | 1.6 x 0.53 | 0.40 | 25.2 | |
| Orchard Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole” | 21.7 | 1.6 x 0.53 | 2.01 | 5.0 | |
| Orchard Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.6 x 0.53 | 0.21 | 47.0 | |
| Orchard Application crop directed BBCH 20- 40 | Large herbivorous mammal “lagomorph” | 8.6 | 1.6 x 0.53 | 0.79 | 12.6 | |
| Orchard Application crop directed BBCH 20- 40 | Small herbivorous mammal “vole” | 43.4 | 1.6 x 0.53 | 4.01 | 2.5 | |
| Orchard Application crop directed BBCH 20- 40 | Small omnivorous mammal “mouse” | 4.7 | 1.6 x 0.53 | 0.43 | 23.0 | |
| Orchard Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” | 22.7 | 1.6 x 0.53 | 2.10 | 4.8 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-9b: Prothioconazole-desthio – First-tier assessment of the acute and long-term risk for mammals for the use of SIP 41061 on pome fruits (2 appl. with 9 days of interval)

| Intended use | | Pome fruits, BBCH 39-85 | | | | |
|-------------------------------|--------------------------|---------------------------------------|-------------------|-----------------------------------|------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (9d) × 109 (=120 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Orchards | Small herbivorous mammal | 136.4 | 1.3 | 19.33 | 115.6 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |

| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
|--|---|-----------------|---------------------------|----------------------------------|-------------------|
| Orchards | Small herbivorous mammal | 72.3 | 1.5 x 0.53 | 6.27 | 1.60 |
| Orchard Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” | 4.3 | 1.5 x 0.53 | 0.37 | 26.8 |
| Orchard Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole” | 21.7 | 1.5 x 0.53 | 1.88 | 5.3 |
| Orchard Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.5 x 0.53 | 0.20 | 50.2 |
| Orchard Application crop directed BBCH 20- 40 | Large herbivorous mammal “lagomorph” | 8.6 | 1.5 x 0.53 | 0.75 | 13.4 |
| Orchard Application crop directed BBCH 20- 40 | Small herbivorous mammal “vole” | 43.4 | 1.5 x 0.53 | 3.76 | 2.7 |
| Orchard Application crop directed BBCH 20- 40 | Small omnivorous mammal “mouse” | 4.7 | 1.5 x 0.53 | 0.41 | 24.6 |
| Orchard Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” | 22.7 | 1.5 x 0.53 | 1.97 | 5.1 |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-10: Prothioconazole-desthio – First-tier assessment of the acute and long-term risk for mammals due to the use of SIP 41061 on stone fruits

| Intended use | | Stone fruits, BBCH 51-85 | | | | |
|--|---|---------------------------------------|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (7d) × 145 (=160 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Orchards | Small herbivorous mammal | 136.4 | 1.4 | 27.69 | 80.7 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Orchards | Small herbivorous mammal | 72.3 | 1.6 x 0.53 | 8.89 | 1.12 | |
| Orchard Application crop directed BBCH ≥ 40 | Large herbivorous mammal “lagomorph” | 4.3 | 1.6 x 0.53 | 0.53 | 18.9 | |
| Orchard Application crop directed BBCH ≥ 40 | Small herbivorous mammal “vole” | 21.7 | 1.6 x 0.53 | 2.67 | 3.7 | |
| Orchard Application crop directed BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.6 x 0.53 | 0.28 | 35.4 | |
| Orchard Fruit stage BBCH 71-79 currants | Frugivorous mammal “dormouse” | 22.7 | 1.6 x 0.53 | 2.79 | 3.6 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-11: Prothioconazole-desthio – First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SIP 41061 on carrots

| Intended use | | Carrots, BBCH 16-46 | | | | |
|--|---------------------------------------|--|---------------------------|-----------------------------------|-------------------|--|
| Active substance/product | | Prothioconazole-desthio | | | | |
| Application rate (g/ha) | | 2 (21d) × 181 (=200 g a.s./ha * 0.907) | | | | |
| Acute toxicity (mg/kg bw) | | LD ₅₀ = 2235 mg/kg bw | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario | Indicator species | SV ₉₀ | MAF ₉₀ | DDD ₉₀ (mg/kg bw/d) | TER _a | |
| Root and stem vegetables | Small herbivorous mammal | 118.4 | 1.1 | 23.57 | 94.8 | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario Growth stage | Indicator/generic focal species | SV _m | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} | |
| Root and stem vegetables | Small herbivorous mammal | 48.3 | 1.2 x 0.53 | 5.56 | 1.8 | |
| Root and stem vegetables BBCH ≥ 20 | Small insectivorous mammal “shrew” | 1.9 | 1.2 x 0.53 | 0.22 | 45.7 | |
| Root and stem vegetables BBCH ≥ 40 | Small herbivorous mammal “vole” | 21.7 | 1.2 x 0.53 | 2.50 | 4.0 | |
| Root and stem vegetables BBCH ≥ 40 | Small omnivorous mammal “mouse” | 2.3 | 1.2 x 0.53 | 0.26 | 37.8 | |
| Root and stem vegetables BBCH 10 - 19 | Small insectivorous mammal “shrew” | 4.2 | 1.2 x 0.53 | 0.48 | 20.7 | |
| Root and stem vegetables BBCH 10-39 | Small omnivorous mammal “mouse” | 7.8 | 1.2 x 0.53 | 0.90 | 11.1 | |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Based on the above assessment, acceptable risk of Prothioconazole can be concluded for all the intended uses of SIP 41061, while for Prothioconazole-desthio several scenarios trigger higher-tier reproductive-assessment.

zRMS comment:

The risk assessment at first-tier performed according to Document on Risk Assessment for Birds and Mammals EFSA (EFSA Journal 2009; 7(12): 1438 was accepted. Safe use of prothioconazole for mammals were confirmed based on TER_A and TER_{LT} above the trigger values of 10 and 5, respectively. In case, prothioconazole-desthio (M04) several scenarios trigger higher-tier reproductive assessment. The refinement risk assessment is requirement for scenario:

| Crop, growth stage | EFSA scenario | Species |
|---|--|-----------|
| Wheat, Triticale, Rye, BBCH 29 | Cereals early, shoots (BBCH 10-29) | lagomorph |
| Wheat, Triticale, BBCH 40-69; Rye, BBCH 40-61 | Cereals, BBCH \geq 40 | vole |
| Oilseed rape, BBCH 40-71 | Oilseed rape, BBCH \geq 40 | vole |
| Cucurbits, BBCH 11-89 | Fruiting vegetables, BBCH 10-49 | vole |
| | Fruiting vegetables, BBCH \geq 50 | vole |
| Cucurbits, BBCH 70-89 | Fruiting vegetables, BBCH >70 | rat |
| Pome fruits, BBCH 39-40 | Orchards, BBCH 20-40 | vole |
| Stone fruits, BBCH 51-85 | Orchards, BBCH \geq 40 | vole |
| Stone fruits, BBCH 71-79 | Orchards, BBCH 71-79 | dormouse |
| Carrot, BBCH 40-46 | Root and stem vegetables, BBCH ≥ 40 | vole |

The refinement risk assessment for mammals was provided by Applicant below.

9.3.2.2 Higher-tier risk assessment

For Prothioconazole-desthio, the following scenarios need further refinement:

Table 9.3-12: Scenarios that require higher-tier assessments

| Crop, growth stage | EFSA scenario | Species |
|---|--|-----------|
| Wheat, Triticale, Rye, BBCH 29 | Cereals early, shoots (BBCH 10-29) | lagomorph |
| Wheat, Triticale, BBCH 40-69; Rye, BBCH 40-61 | Cereals, BBCH \geq 40 | vole |
| Oilseed rape, BBCH 40-71 | Oilseed rape, BBCH \geq 40 | vole |
| Cucurbits, BBCH 11-89 | Fruiting vegetables, BBCH 10-49 | vole |
| | Fruiting vegetables, BBCH \geq 50 | vole |
| Cucurbits, BBCH 70-89 | Fruiting vegetables, BBCH >70 | rat |
| Pome fruits, BBCH 39-40 | Orchards, BBCH 20-40 | vole |
| Stone fruits, BBCH 51-85 | Orchards, BBCH \geq 40 | vole |
| Stone fruits, BBCH 71-79 | Orchards, BBCH 71-79 | dormouse |
| Carrot, BBCH 40-46 | Root and stem vegetables, BBCH ≥ 40 | vole |

It is to be noted that the higher-tier assessment for cucurbits is triggered only by the use in open structures, because the use in close greenhouses is not expected to cause exposure of birds and mammals. Nevertheless, following a conservative approach, also the use on cucurbits was considered in this higher-tier assessment.

Higher-tier reproductive assessment for large herbivorous mammal “lagomorph” (cereals, BBCH 29)

The EFSA scenario that fails Tier-1 assessment for lagomorph is “cereals, BBCH 10-29”. According to GAP, SIP 41061 can be applied on wheat, triticale, and rye, starting from BBCH 29, i.e. at the very end of the period covered by the EFSA scenario. Therefore, the Tier-1 assessment reported in Table 9.2-5 for lagomorph can be regarded as overconservative, because it is clearly not realistic performing 2 applications with 14 days of interval all together at BBCH 29. Nevertheless, a refinement for this scenario is here provided.

As reported in the EFSA Conclusion of Prothioconazole, a DT_{50} of 3.2 day, obtained from 8 trials on wheat (green part of the plant), can be used for refinement purpose. According to the EFSA Guidance document (EFSA 2009), lagomorph in cereal fields at BBCH 10-29 eat 100% cereals shoots. The DT_{50} provided by the EFSA Conclusion is therefore appropriate for this scenario.

As recommended by EFSA (2009), this DT_{50} was used for refining MAF and TWA values with a “mov-

ing time-window approach”. For this purpose, the tool provided by Belgian authorities³ was used, obtaining a MAF x TWA of 0.389; the same result was obtained also with the calculator recommended by the authorities of the EU-Northern Zone⁴.

Using these refinements, the higher-tier assessment for the herbivorous mammal lagomorph results in TER higher than 5, indicating acceptable risk.

Table 9.3-13: Prothioconazole-desthio – Higher-tier assessment of the long-term/reproductive risk for lagomorph due to the use of SIP 41061 on cereals, BBCH 29

| Intended use | | Cereals (BBCH 29) | | | | | |
|--------------------------------------|--------------------|--|----------------------------------|----|---------------------------|----------------------------------|-------------------|
| Active substance/product | | Prothioconazole-desthio | | | | | |
| Application rate (g/ha) | | 2 (14d) × 181 (=200 g a.s./ha * 0.907) | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | | |
| TER criterion | | 5 | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Large herbivorous mammal “lagomorph” | 100% cereal shoots | 0.41 | 54.2 | 1 | 0.389 | 1.6 | 6.4 |

In bold, the refined parameters

| zRMS comment: Large herbivorous mammal “lagomorph” | | |
|---|------------------------------------|-----------|
| Crop, growth stage | EFSA scenario | Species |
| Wheat, Triticale, Rye, BBCH 29 | Cereals early, shoots (BBCH 10-29) | lagomorph |
| The refinement long-term risk assessment for mammals was accepted by RMS based on DT ₅₀ value for cereals and refined parameter of ftwa 0.22 according to EFSA Conclusion 2007. MAF x TWA of 0.389 was accepted in refinement risk assessment. Safe use of prothioconazole-desthio (M04) for mammals were confirmed based on TER _{LT} above the trigger values of 5, respectively, indicating the long-term risk is acceptable for cereals. | | |

Higher-tier assessment for small herbivorous mammal “vole”

Where appropriate, in agreement with Appendix E of EFSA (2009), the scenarios for the small herbivorous mammal vole were refined using the interception values provided by the Generic Guidance for Tier 1 FOCUS Ground Water Assessments, version 2.2 (2014).

Moreover, following the same approach explained above for lagomorph, the DT₅₀ of 3.2 days, reported in the EFSA Conclusion of Prothioconazole was used for refining MAF and TWA values with a “moving time-window approach”. Using both the tool of the Belgian authorities and the tool of the EU-Northern Zone, the following MAF x TWA values were calculated:

| Intended use | MAF x TWA |
|--|-----------|
| Cereals and oilseed rape, 2 applications with 14d interval | 0.389 |
| Fruiting vegetable (BBCH < 50), 1 application | 0.218 |
| Fruiting vegetable, 3 applications with 10d interval | 0.460 |

³ https://fytoweb.be/sites/default/files/guide/attachments/calculation_tool_moving_time_window_det_v2_be_1.xls

⁴ <https://eng.mst.dk/media/211953/bird-mammal-scenario-template-v20-1.xlsm>

| Intended use | MAF x TWA |
|--|-----------|
| Orchards, 2 applications with 7d interval | 0.427 |
| Root and stem vegetables, 2 applications with 21d interval | 0.220 |

Using these refinements, the higher-tier assessment for the herbivorous mammal vole results in TER values higher than 5, indicating acceptable risk.

Table 9.3-14: Prothioconazole-desthio – Higher-tier assessment of the long-term/reproductive risk for vole due to the use of SIP 41061

| | | | | | | | |
|---------------------------------|------------|--|----------------------------------|-----|------------------------|----------------------------------|-------------------|
| Active substance/product | | Prothioconazole-desthio | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | | |
| TER criterion | | 5 | | | | | |
| Intended use | | Cereals (BBCH ≥ 40) | | | | | |
| Application rate (g/ha) | | 2 (14d) × 181 (=200 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.1 | 0.389 | 0.51 | 19.7 |
| Intended use | | Oilseed rape (BBCH ≥ 40) | | | | | |
| Application rate (g/ha) | | 2 (14d) × 163 (=180 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.2 | 0.389 | 0.91 | 10.9 |
| Intended use | | Cucurbits (BBCH 10-49) | | | | | |
| Application rate (g/ha) | | 1 × 109 (=120 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 1 | 0.218 | 1.71 | 5.8 |
| Intended use | | Fruiting vegetables (BBCH ≥ 50) | | | | | |
| Application rate (g/ha) | | 3 (10d) × 109 (=120 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.2 | 0.460 | 0.72 | 13.8 |
| Intended use | | Pome fruits (BBCH 39-40) | | | | | |
| Application rate (g/ha) | | 2 (7d) × 109 (=120 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.4 | 0.427 | 1.34 | 7.5 |

| Intended use | | Stone fruits (BBCH 51-85) | | | | | |
|---------------------------------|------------|--|----------------------------------|-----|------------------------|----------------------------------|-------------------|
| Application rate (g/ha) | | 2 (7d) × 109 (=120 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.3 | 0.427 | 1.01 | 9.9 |
| Intended use | | Carrot (BBCH 40-46) | | | | | |
| Application rate (g/ha) | | 2 (21d) × 181 (=200 g a.s./ha * 0.907) | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{lt} |
| Small herbivorous mammal “vole” | 100% grass | 1.33 | 54.2 | 0.3 | 0.220 | 0-86 | 11.6 |

In bold, the refined parameters

| zRMS comment: Vole | | |
|--|-------------------------------------|---------|
| Crop, growth stage | EFSA scenario | Species |
| Wheat, Triticale, BBCH 40-69; Rye, BBCH 40-61 | Cereals, BBCH ≥ 40 | vole |
| Oilseed rape, BBCH 40-71 | Oilseed rape, BBCH ≥ 40 | vole |
| Cucurbits, BBCH 11-89 | Fruiting vegetables, BBCH 10-49 | vole |
| | Fruiting vegetables, BBCH ≥ 50 | vole |
| Pome fruits, BBCH 39-40 | Orchards, BBCH 20-40 | vole |
| Stone fruits, BBCH 51-85 | Orchards, BBCH ≥ 40 | vole |
| Carrot, BBCH 40-46 | Root and stem vegetables, BBCH ≥ 40 | vole |
| <p>The refinement long-term risk assessment for vole was accepted by RMS based on DT₅₀ value for cereals and refined parameter of ftwa 0.22 according to EFSA Conclusion 2007. Safe use of prothioconazole-desthio (M04) for vole were confirmed based on TER_{LT} above the trigger values of 5, respectively, indicating the long-term risk is acceptable for cereals, oilseed rape, cucurbits, pome fruits, stone fruits and carrot.</p> <p>The relevance of voles as a focal species suitable representative species for those crops should be consider at national level.</p> | | |

Higher-tier assessment for frugivorous mammal “rat” (cucurbits, BBCH 70-89)

For the higher-tier assessment of the frugivorous mammal rat, the same approach discussed at Point 9.2.2.2 was followed, using the DT₅₀ of 3.8 days obtained from residues on cucurbits and the resulting MAF × TWA of 0.525.

Using this refinement, the higher-tier assessment for the frugivorous mammal rat results in a TER higher than 5, indicating acceptable risk.

Table 9.3-15: Prothioconazole-desthio – Higher-tier assessment of the long-term/reproductive risk for rat due to the use of SIP 41061 on cucurbits, BBCH 70-89

| Intended use | Cucurbits (BBCH 70-89) |
|--------------------------|--|
| Active substance/product | Prothioconazole-desthio |
| Application rate (g/ha) | 3 (10d) × 109 (=120 g a.s./ha * 0.907) |

| | | | | | | | |
|--|-------------|----------------------|--|-----------|------------------------------|--|-------------------------|
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | | |
| TER criterion | | 5 | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD_m (mg/kg food) | DF | MAF_m × TWA | DDD_m (mg/kg bw/d) | TER_{it} |
| Frugivorous mammal “rat” | 100% gourds | 0.73 | 34.3 | 1 | 0.525 | 1.4 | 6.98 |

In bold, the refined parameters

| | | |
|---|-------------------------------|----------------|
| zRMS comment: Frugivorous mammal “rat” (cucurbits, BBCH 70-89) | | |
| Crop, growth stage | EFSA scenario | Species |
| Cucurbits, BBCH 70-89 | Fruiting vegetables, BBCH >70 | rat |
| <p>The refinement long-term risk assessment for frugivorous rat was not accepted by RMS using the DT₅₀ of 3.8 days obtained from residues on cucurbits and the resulting MAF x TWA of 0.525. Safe use of prothioconazole-desthio (M04) for rat were not confirmed.</p> <p>The presented by the Applicant refinement risk assessment for the vertebrates was evaluated by the RMS, but found not acceptable due to the uncertainties related to the kinetic analysis of the data of the residue trials. Please see KCP 10.1.1.2 point (Higher tier data on birds and mammals).</p> <p>However, in this case - SIP 41061 formulation is used in close greenhouses (professional greenhouse use). Therefore, in this case - risk for mammals is not expected. Otherwise, it is necessary to perform a full risk assessment with refinement.</p> <p>The refinement risk assessment for cucurbits at BBCH 70-89 for prothioconazole-desthio in close greenhouse should be considered at MSs level.</p> | | |

Higher-tier assessment for frugivorous mammal “dormouse” (orchards, BBCH 71-79)

The Tier-1 assessment reported in Table 9.2-11 for frugivorous mammals can be considered as overconservative, because it is unlikely that in the time span of BBCH 71-79 two applications with 7 days of interval can be performed. Nevertheless, following a conservative approach, the higher-tier assessment for this scenario was performed for the both the case of 2 applications (extreme worst-case) and the realistic case of 1 application.

As detailed in Section B7 of this dRR, several residue trials on stone fruits were performed applying SIP 41061 according to the intended use, thus providing information on the residual behaviour of Prothioconazole-desthio. In particular, as discussed in the report KINPT_01 (KCP 10.1.1.2), the results of 4 trials performed on apricot and peach were considered for kinetic evaluation, and a DT₅₀ of 6.6 days was calculated for Prothioconazole-desthio.

Following the same approach explained above, this DT₅₀ was used for refining MAF and TWA values with a “moving time-window approach”. Using both the tool of the Belgian authorities and the tool of the EU-Northern Zone, a MAF x TWA of 0.753 was obtained when considering 2 applications, and a refined TWA of 0.403 was calculated for single application. Using this refinement, the higher-tier assessment for frugivorous mammals eating stone fruits results in a TER higher than 5, indicating acceptable risk.

Table 9.3-16: Prothioconazole-desthio – Higher-tier assessment of the long-term/reproductive risk for dormouse due to the use of SIP 41061 on stone fruits, BBCH 71-79

| Intended use | | Stone fruits (BBCH 71-79) | | | | | |
|----------------------------------|-------------|---------------------------------------|----------------------------------|----|---------------------------|----------------------------------|-------------------|
| Active substance/product | | Prothioconazole-desthio | | | | | |
| Application rate (g/ha) | | 2 (7d) × 145 (=160 g a.s./ha * 0.907) | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | | |
| TER criterion | | 5 | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{it} |
| Frugivorous mammal “dormouse” | 100% fruits | 1.16 | 19.5 | 1 | 0.753 | 2.5 | 4.05 |
| Active substance/product | | Prothioconazole-desthio | | | | | |
| Application rate (g/ha) | | 1 × 145 (=160 g a.s./ha * 0.907) | | | | | |
| Reprod. toxicity (mg/kg bw/d) | | NOEL = 10 mg/kg bw/d | | | | | |
| TER criterion | | 5 | | | | | |
| Indicator/generic focal species | Diet | FIR/bw | RUD _m (mg/kg food) | DF | MAF _m × TWA | DDD _m (mg/kg bw/d) | TER _{it} |
| Frugivorous mammal “dormouse” | 100% fruits | 0.73 | 19.5 | 1 | 0.403 | 1.3 | 7.57 |

In bold, the refined parameters

| zRMS comment: Dormouse | | |
|--|----------------------|----------|
| Crop, growth stage | EFSA scenario | Species |
| Stone fruits, BBCH 71-79 | Orchards, BBCH 71-79 | dormouse |
| <p>The refinement long-term risk assessment for dormouse was not accepted by RMS based on DT₅₀ value for stone fruits and refined parameter of DT₅₀ = 6.6d. Safe use of prothioconazole-desthio (M04) for dormouse were not confirmed.</p> <p>The presented by the Applicant refinement risk assessment for the vertebrates was evaluated by the RMS, but found not acceptable due to the uncertainties related to the kinetic analysis of the data of the residue trials. Please see KCP 10.1.1.2 point (Higher tier data on birds and mammals).</p> <p>zRMS proposes a BBCH phase change. In stone fruit BBCH should be change to 51-70. After the BBCH phase change, the risk to mammals is acceptable.</p> | | |

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective

application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 1765 mL/g, Prothioconazole belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. The worst-case use patterns for SIP 41061 are: 2 applications of 200 g a.s./ha with 14 days of interval (use on cereals), and 3 applications at the rate of 120 g a.s./ha with 7 days of interval (use on cucurbits). The effective rates should be calculated multiplying these application rates by the MAF values calculated from the soil DT_{50} of Prothioconazole; due to the fast dissipation of Prothioconazole (2.8 days), the MAF is 1.0 for both use patterns, so the highest effective rate to be used in the risk assessment is therefore 200 g a.s./ha.

| | | | |
|-----------------------------------|-----------------|------------|--------|
| Effective application rate (g/ha) | 200 | | |
| Acute toxicity (mg/kg bw) | > 6200 mg/kg bw | quotient = | < 0.03 |
| Reprod. toxicity (mg/kg bw/d) | 95.6 mg/kg bw/d | quotient = | 2.1 |

With a $K(f)_{oc}$ of 575.4 mL/g, Prothioconazole-desthio belongs to the group of more sorptive substances. The soil DT_{50} of Prothioconazole-desthio is 73.3 days, so for the worst-case use patterns mentioned above the MAF values are 1.9 and 2.8 for cereals and cucurbits respectively, and the effective rates are 380 and 338 g a.s./ha. The highest effective rate of 380 g a.s./ha was therefore used in the risk assessment.

| | | | |
|-----------------------------------|---------------|------------|------|
| Effective application rate (g/ha) | 380 | | |
| Acute toxicity (mg/kg bw) | 2235 mg/kg bw | quotient = | 0.17 |
| Reprod. toxicity (mg/kg bw/d) | 10 mg/kg bw/d | quotient = | 38 |

Based on the above assessments, acceptable risk for birds via drinking water can be concluded for Prothioconazole and its metabolites.

zRMS comment:

Agreed. As SIP 41061 is not intended for leafy crops forming heads, the leaf scenario does not have to be therefore considered based on the proposed uses. Evaluation of exposing for mammals through the drinking water puddle scenario for the active substance and metabolite M04, demonstrate that the acceptable risk for mammals for proposed use pattern of SIP 41061.

9.3.2.4 Effects of secondary poisoning

Risk assessment for earthworm-eating mammals via secondary poisoning

As explained at Point 9.2.2.4, the risk assessment for worm-eating mammals was performed for Prothioconazole and its metabolites Prothioconazole-desthio and Prothioconazole-S-methyl.

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Following a risk envelope approach, the highest 21d-TWA PEC_{soil} values were used in the present assessment.

Parameters used by zRMS in the assessment of the risk for earthworm-eating mammals due to exposure to Prothioconazole and prothioconazole metabolites via bioaccumulation in earthworms and fish (secondary poisoning)

| Parameter | Prothioconazole | Prothioconazole-desthio (M04) | Prothioconazole-S-methyl (M01) | comments |
|---------------------------------------|---------------------------|-------------------------------|--------------------------------|--|
| log P _{ow} / P _{ow} | 3.4 / 2511.9 3.82/6607 | 3.04 / 1096.5 | 4.19/15448.2 | EFSA Scientific Report (2007) 106, 1-98 |
| Koc | 1765 | 575.4 | 2526 | Geomean (M04 and M01) EFSA Scientific Report (2007) 106, 1-98 |
| foc | 0.02 | 0.02 | 0.02 | Default |

Table 9.3-17: Assessment of the risk for earthworm-eating mammals due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole | comments |
|--|------------------------------|--|
| PEC _{soil} (max) (mg/kg soil) | 0.051 | Highest TWA PEC _{soil} , obtained from the use on cereals (please refer to dRR Part B8) |
| log P _{ow} | 4.16 3.4 3.82 2511.9 6607 | EFSA Conclusion 2007 |
| Koc | 1765 | EFSA Conclusion 2007 |
| foc | 0.02 | Default |
| BCF _{worm} | 4.94 0.87 22.48 | $BCF_{worm} = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$ |
| PEC _{worm} | 0.25 0.044 1.146 | $PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$ |
| Daily dietary dose (mg/kg bw/d) | 0.32 0.057 1.47 | $DDD = PEC_{worm} \times 1.28$ |
| NOEL (mg/kg bw/d) | 95.6 | EFSA Conclusion 2007 |
| TER _{lt} | 296.6 1677 63 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.3-18: Assessment of the risk for earthworm-eating mammals due to exposure to Prothioconazole-desthio via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole-desthio (M04) | Comments |
|---|-------------------------------|--|
| PEC _{soil} (twa = 21 d) (mg/kg soil) | 0.170 | Highest TWA PEC _{soil} , obtained from the use on carrots (please refer to dRR Part B8) |
| log Pow P _{ow} | 3.04 1096.5 | EFSA Conclusion 2007 |
| Koc | 573.5 | EFSA Conclusion |
| Foc | 0.02 | Default |
| BCF _{worm} | 1.22 | $BCF_{worm} = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$ |

| Parameter | Prothioconazole-desthio (M04) | Comments |
|---------------------------------|----------------------------------|--|
| PEC _{worm} | 0.21 | PEC _{worm} = PEC _{soil} × BCF _{worm/soil} |
| Daily dietary dose (mg/kg bw/d) | 0.27 | DDD = PEC _{worm} × 1.28 |
| NOEL (mg/kg bw/d) | 10 | EFSA Conclusion |
| TER _{lt} | 37.7 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.3-19: Assessment of the risk for earthworm-eating mammals due to exposure to Prothioconazole-S-methyl (M01) via bioaccumulation in earthworms (secondary poisoning)

| Parameter | Prothioconazole-S-methyl | Comments |
|---|---------------------------|--|
| PEC _{soil} (twa = 21 d) (mg/kg soil) | 0.045 | Highest TWA PEC _{soil} , obtained from the use on carrots (please refer to dRR Part B8) |
| log P _{ow} P _{ow} | 4.19 15448.2 | EFSA Conclusion 2007 |
| K _{oc} | 2526 | EFSA Conclusion 2007 |
| F _{oc} | 0.02 | Default |
| BCF _{worm} | 3.70 4.12 | BCF _{worm} = (0.84 + 0.012 × P _{ow}) / f _{oc} × K _{oc} |
| PEC _{worm} | 0.17 1854 | PEC _{worm} = PEC _{soil} × BCF _{worm/soil} |
| Daily dietary dose (mg/kg bw/d) | 0.21 0.237 | DDD = PEC _{worm} × 1.28 |
| NOEL (mg/kg bw/d) | 95.6 9.56* | endpoint of Prothioconazole Derived endpoint |
| TER _{lt} | 449.1 40.34 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

*Endpoint estimated as parent NOEL/10.

Based on the above assessments, acceptable risk to worm-eating mammals can be concluded for Prothioconazole and its soil metabolites.

Risk assessment for fish-eating mammals via secondary poisoning

As explained at Point 9.2.2.4, the risk assessment for fish-eating mammals was performed for Prothioconazole and Prothioconazole-desthio.

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Following a risk envelope approach, the highest 21d-TWA PEC_{sw} values calculated with FOCUS Step 2 were used in the present assessment.

Table 9.3-20: Assessment of the risk for fish-eating mammals due to exposure to Prothioconazole via bioaccumulation in fish (secondary poisoning)

| Parameter | Prothioconazole | comments |
|---------------------------------------|-----------------|---|
| PEC _{sw} (twa = 21 d) (mg/L) | 0.000736 | Highest TWA PEC _{sw} , obtained for pome/stone |

| Parameter | Prothioconazole | comments |
|---------------------------------|-----------------|---|
| | | fruits (please refer to dRR Part B8) |
| BCF_{fish} | 19.7 | EFSA Conclusion 2007 |
| BMF | not relevant | biomagnification factor (relevant for $BCF \geq 2000$) |
| PEC_{fish} | 0.01 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.002 | $DDD = PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 95.6 | |
| TER_{lt} | 46432.9 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

Table 9.3-21: Assessment of the risk for fish-eating mammals due to exposure to Prothioconazole-desthio via bioaccumulation in fish (secondary poisoning)

| Parameter | Prothioconazole-desthio (M04) | comments |
|---------------------------------|----------------------------------|--|
| PEC_{sw} (twa = 21 d) (mg/L) | 0.010498 | Highest TWA PEC_{sw} , obtained for cereals (please refer to dRR Part B8) |
| BCF_{fish} | 65 | EFSA Conclusion 2007 |
| BMF | not relevant | biomagnification factor (relevant for $BCF \geq 2000$) |
| PEC_{fish} | 0.68 | $PEC_{fish} = PEC_{water} \times BCF_{fish}$ |
| Daily dietary dose (mg/kg bw/d) | 0.10 | $DDD = PEC_{fish} \times 0.142$ |
| NOEL (mg/kg bw/d) | 10 | |
| TER_{lt} | 103.2 | >5, no further refinement |

TER values shown in bold fall below the relevant trigger.

zRMS comment:

The risk for fish-eating mammals and earthworms-eating mammals due to exposure to prothioconazole and its metabolites (M04) is considered as acceptable for the worst case scenario. Since prothioconazole-S-methyl is not relevant for surface water, the risk to fish-eating birds and mammals was not necessary.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

The risk to mammals was assessed according to the EFSA's Bird and Mammal Risk Assessment Guidance Document (EFSA Journal 2009; 7(12):1438). No unacceptable risk for mammals is expected from acute or long-term exposure to contaminated food. Furthermore, no unacceptable risks are expected from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bioaccumulation in food chains). In conclusion, an acceptable overall risk for mammals is indicated for the product. No risk mitigation is required.

zRMS comment:

Accepted.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available to the applicant knowledge.

Based on the above risk assessments, which indicate acceptable risk of the product to birds and mammals, no concern to other terrestrial vertebrates is expected.

No conclusion can be drawn to the risk of SIP 41061 on reptiles and amphibians.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with the active ingredient and with the representative formulation evaluated during the Annex I inclusion. Full details of these studies are provided in the respective EU DAR and related documents (EFSA, 2007), a summary is reported in the Table 9.5-1.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Prothioconazole and its metabolites

| Species | Test Substance* | Exposure | Results* | Reference |
|---|--------------------------|---------------|---|---|
| Prothioconazole | | | | |
| Oncorhynchis mykiss | Prothioconazole | acute | LC ₅₀ = 1.83 mg a.s./L | EFSA Scientific Report (2007) 106, 1-98 |
| Oncorhynchis mykiss | Prothioconazole 250 EC | acute | LC ₅₀ = 1.00 mg a.s./L | |
| Lepomis macrochirus | Prothioconazole | acute | LC ₅₀ = 4.59 mg a.s./L | |
| Cyprinus carpio | Prothioconazole | acute | LC ₅₀ = 6.91 mg a.s./L | |
| Cyprinus carpio | Prothioconazole 250 EC | acute | LC ₅₀ = 3.72 mg a.s./L | |
| Oncorhynchis mykiss | Prothioconazole | chronic (ELS) | NOEC = 0.308 mg a.s./L | |
| Daphnia magna | Prothioconazole | acute | EC ₅₀ = 1.3 mg a.s./L | |
| Daphnia magna | Prothioconazole 250 EC | acute | EC ₅₀ = 0.71 mg a.s./L | |
| Daphnia magna | Prothioconazole | chronic | NOEC = 0.56 mg a.s./L | |
| Pseudokirchneriella subcapitata Raphidocelis subcapitata | Prothioconazole | sub-chronic | E _b C ₅₀ = 1.10 mg a.s./L E _r C ₅₀ = 2.18 mg a.s./L | |
| Pseudokirchneriella subcapitata Raphidocelis subcapitata | Prothioconazole 250 EC | sub-chronic | E _b C ₅₀ = 2.92 mg a.s./L E _r C ₅₀ = 1.11 mg a.s./L | |
| Chironomus riparius | Prothioconazole | chronic | NOEC = 9.14 mg a.s./L | |
| Prothioconazole-desthio | | | | |
| Oncorhynchis mykiss | Prothioconazole-desthio | acute | LC ₅₀ = 6.63 mg p.m./L | EFSA Scientific Report (2007) 106, 1-98 |
| Leuciscus idus melanotus | Prothioconazole-desthio | acute | LC ₅₀ = 13.2 mg p.m./L | |
| Oncorhynchis mykiss | Prothioconazole-desthio | chronic (ELS) | NOEC = 3.34 µg p.m./L | |
| Daphnia magna | Prothioconazole-desthio | acute | EC ₅₀ > 10 mg p.m./L | |
| Daphnia magna | Prothioconazole-desthio | chronic | NOEC = 0.10 mg p.m./L | |
| Scenesedsmus subspicatus | Prothioconazole-desthio | sub-chronic | E _b C ₅₀ = 0.073 mg p.m./L E _r C ₅₀ = 0.55 mg a.s./L | |
| Chironomus riparius | Prothioconazole-desthio | chronic | NOEC = 2.0 mg p.m./L | |
| Prothioconazole-S-methyl ** | | | | |
| Oncorhynchis mykiss | Prothioconazole-S-methyl | acute | LC ₅₀ = 1.8 mg p.m./L | EFSA Scientific |

| Species | Test Substance* | Exposure | Results* | Reference |
|---|--------------------------|-------------|---|---|
| <i>Daphnia magna</i> | Prothioconazole-S-methyl | acute | EC ₅₀ = 2.8 mg p.m./L | Report (2007) 106, 1-98 |
| <i>Pseudokirchneriella subcapitata</i> <i>Raphidocelis subcapitata</i> | Prothioconazole-S-methyl | sub-chronic | E _b C ₅₀ = 3.77 mg p.m./L E _r C ₅₀ = 47.4 mg a.s./L | |
| 1,2,4-triazole | | | | |
| <i>Oncorhynchis mykiss</i> | 1,2,4-triazole | acute | LC ₅₀ = 498 mg p.m./L | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Oncorhynchis mykiss</i> | 1,2,4-triazole | chronic | NOE _r C = 3.2 mg p.m./L | |
| <i>Daphnia magna</i> | 1,2,4-triazole | acute | EC ₅₀ = 900 mg p.m./L | |
| <i>Pseudokirchneriella subcapitata</i> <i>Raphidocelis subcapitata</i> | 1,2,4-triazole | sub-chronic | E _b C ₅₀ = 8.2 mg p.m./L # E _r C ₅₀ = 22.5 mg a.s./L # | |

* endpoints given in bold are used in risk assessment.

** risk assessment not necessary since Prothioconazole-S-methyl was not identified as a major metabolite

Endpoint value according to agreement in PRAPeR expert meeting on triazole metabolites (PRAPeR 13, January 2007).

New studies on daphnia and alga have been performed with the formulated product SIP 41061 and are submitted with this application; the summaries are provided in Appendix 2 and the results are reported in the table below.

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – formulation SIP 31741

| Species | Substance | Exposure System | Results | Reference |
|---|---|-----------------|---|------------------------|
| <i>Daphnia magna</i> | SIP 41061 (Prothioconazole 400 g/L SC) | 48 h | EC ₅₀ = 4.25 mg formulation/L _{nom} corresponding to: 1.50 mg a.s./L | Corboli M., 2021 |
| <i>Pseudokirchneriella subcapitata</i> <i>Raphidocelis subcapitata</i> | SIP 41061 (Prothioconazole 400 g/L SC) | 72 h | E _y C ₅₀ = 2.27 mg formulation/L _{nom} E _r C ₅₀ = 6.10 mg formulation/L _{nom} corresponding to: E _y C ₅₀ = 0.64 mg a.s./L _{mm} E _r C ₅₀ = 1.69 mg a.s./L _{mm} | Mantilacci S., 2021 |

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

Since the endpoints of the formulated product and of the active ingredient are comparable (they differ less than a factor of 3), the risk assessment can be based on the EU agreed endpoints from Table 9.5-1.

9.5.1.1 Justification for new endpoints

Not relevant; the selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

To avoid testing vertebrates, no studies on fish were performed with SIP 41061; this doesn't cause uncertainty to the risk assessment of SIP 41061, for the following reasons:

- the studies performed on daphnia and alga show that SIP 41061 has the same toxicity as Prothioconazole (less than a factor 3 of difference)
- for Prothioconazole the risk to aquatic organisms is not driven by the acute toxicity on fish but by the acute toxicity on daphnia, which is slightly worst-case and provides the lowest RAC;
- as showed at Point 9.5.2, the risk of SIP 41061 to aquatic organisms is driven by assessment of the metabolite Prothioconazole-desthio, which is more toxic to aquatic organisms than the parent Prothioconazole.

zRMS comment:

zRMS agree that the study for formulation SIP 41061 with one active substance - prothioconazole for fish is not required in this case (primarily to limit testing on vertebrate).

The lowest fish acute endpoint for representative formulation 250 EC (with the same amount of the a.s./Las Indifil) in LoEP EFSA Scientific Report (2007), indicated only slight difference in the toxicity in comparison to a.s. endpoints for fish. In addition, when using the lowest fish acute endpoint presented in EFSA Scientific Report (2007) for a formulated product (expressed in a.s. units) an acceptable acute risk is concluded without risk mitigation measures.

| | | | | |
|----------------------------|--------------------------|------------------------------------|-----------------------------------|---|
| <i>Oncorhynchus mykiss</i> | Prothioconazole | Acute | LC ₅₀ = 1.83 mg a.s./L | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Oncorhynchus mykiss</i> | Prothioconazole (EC 250) | Acute | LC ₅₀ = 1.00 mg a.s./L | |
| <i>Fish</i> | SIP 41061 | The study is not required for fish | | |

The Applicant haven't performed a *Lemna gibba* test with SIP 41061. However, in this case, the test with formulation SIP 41061 with *Lemna gibba* is not necessary. SIP 41061 is not a herbicide. It is a fungicide applied at post-emergence of crops. Therefore, no toxic effects of SIP 41061 formulations on aquatic plants are expected.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2, 3 and 4 PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.

Please take note that no risk assessment is necessary for Prothioconazole-S-methyl which was not identified as a major metabolite

To achieve a concise risk assessment, a risk envelope approach was applied for Prothioconazole and 1,2,4-triazole (see Table 9.1-2b for details), while for Prothioconazole-desthio no risk envelope was applied, since specific mitigation measures are required for each crop.

In the following tables, the ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}) for Prothioconazole and its metabolites and regulatory acceptable concentrations for aquatic organisms (RAC) are given per intended use for each FOCUS scenario and each organism group.

Prothioconazole

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SIP 41061 in winter cereals, BBCH 29 (risk envelope for all field crops)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------|------------------------------|----------------------------|----------------------------|--------------------------|----------------------|---|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> <i>Raphidocelis subcapitata</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 1830 | NOEC 308 | EC ₅₀ 1300 | NOEC 560 | E _r C ₅₀ 2180 | NOEC 9140 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 18.3 | 30.8 | 13.0 | 56.0 | 218.0 | 914.0 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 21.72 | 1.187 | 0.705 | 1.671 | 0.388 | 0.100 | 0.024 |
| Step 2 | | | | | | | |
| N-Europe | 1.84 | 0.101 | 0.060 | 0.142 | 0.033 | 0.008 | 0.002 |
| S-Europe | 1.84 | 0.101 | 0.060 | 0.142 | 0.033 | 0.008 | 0.002 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in pome/stone fruit, BBCH 51 (risk envelope for orchards)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|--------------------------|----------------------|---|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> <i>Raphidocelis subcapitata</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 1830 | NOEC 308 | EC ₅₀ 1300 | NOEC 560 | E _r C ₅₀ 2180 | NOEC 9140 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 18.3 | 30.8 | 13.0 | 56.0 | 218.0 | 914.0 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 31.48 | 1.720 | 1.022 | 2.422 | 0.562 | 0.144 | 0.034 |
| Step 2 | | | | | | | |
| N-Europe | 15.57 | 0.851 | 0.506 | 1.198 | 0.278 | 0.071 | 0.017 |
| S-Europe | 13.57 | 0.742 | 0.441 | 1.044 | 0.242 | 0.062 | 0.015 |
| Step 3, single | | | | | | | |
| D3, ditch | 12.45 | 0.680 | 0.404 | 0.958 | 0.222 | 0.057 | 0.014 |
| D4, pond | 0.755 | 0.041 | 0.025 | 0.0581 | 0.013 | 0.003 | 0.0008 |
| D4, stream | 12.65 | 0.691 | 0.411 | 0.973 | 0.226 | 0.058 | 0.014 |
| D5, pond | 0.755 | 0.041 | 0.025 | 0.058 | 0.013 | 0.003 | 0.001 |
| D5, stream | 13.49 | 0.737 | 0.438 | 1.038 | 0.241 | 0.062 | 0.015 |
| R1, pond | 0.754 | 0.041 | 0.024 | 0.058 | 0.013 | 0.003 | 0.0008 |
| R1, stream | 10.10 | 0.552 | 0.328 | 0.777 | 0.180 | 0.046 | 0.011 |
| R2, stream | 13.53 | 0.739 | 0.439 | 1.041 | 0.242 | 0.062 | 0.015 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|--|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| R3, stream | 14.15 | 0.773 | 0.459 | 1.088 | 0.253 | 0.065 | 0.015 |
| R4, stream | 10.09 | 0.551 | 0.328 | 0.7762 | 0.180 | 0.046 | 0.011 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 10.71 | 0.585 | 0.348 | 0.824 | 0.191 | 0.049 | 0.012 |
| D4, pond | 0.963 | 0.053 | 0.031 | 0.0741 | 0.017 | 0.004 | 0.0011 |
| D4, stream | 11.27 | 0.616 | 0.366 | 0.867 | 0.201 | 0.052 | 0.012 |
| D5, pond | 1.126 | 0.062 | 0.037 | 0.087 | 0.020 | 0.005 | 0.001 |
| D5, stream | 12.7 | 0.694 | 0.412 | 0.977 | 0.227 | 0.058 | 0.014 |
| R1, pond | 1.142 | 0.062 | 0.037 | 0.088 | 0.020 | 0.005 | 0.0012 |
| R1, stream | 8.619 | 0.471 | 0.280 | 0.663 | 0.154 | 0.040 | 0.009 |
| R2, stream | 11.55 | 0.631 | 0.375 | 0.888 | 0.206 | 0.053 | 0.013 |
| R3, stream | 12.17 | 0.665 | 0.395 | 0.936 | 0.217 | 0.056 | 0.013 |
| R4, stream | 8.617 | 0.471 | 0.280 | 0.6628 | 0.154 | 0.040 | 0.009 |
| Step 4 (5m spray buffer, no nuzzle reduction) | | | | | | | |
| D5, stream | 11.59 | 0.633 | 0.376 | 0.892 | 0.207 | 0.053 | 0.013 |
| R2, stream | 11.62 | 0.635 | 0.377 | 0.894 | 0.208 | 0.053 | 0.013 |
| R3, stream | 12.16 | 0.664 | 0.395 | 0.935 | 0.217 | 0.056 | 0.013 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Prothioconazole desthio – FOCUS Steps 1-3

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in winter cereals, BBCH 29

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 62.27 | 0.939 | 186.437 | 0.623 | 6.227 | 1.132 | 0.311 |
| Step 2 | | | | | | | |
| N-Europe | 12.40 | 0.187 | 37.126 | 0.124 | 1.240 | 0.225 | 0.062 |
| S-Europe | 10.02 | 0.151 | 30.000 | 0.100 | 1.002 | 0.182 | 0.050 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.062 | 0.001 | 0.186 | 0.001 | 0.006 | 0.001 | 0.000 |
| D4, pond | 0.012 | 0.000 | 0.036 | 0.0001 | 0.001 | 0.000 | 0.0001 |
| D4, stream | 0.056 | 0.001 | 0.168 | 0.001 | 0.006 | 0.001 | 0.000 |
| D5, pond | 0.014 | 0.000 | 0.042 | 0.000 | 0.001 | 0.000 | 0.000 |
| D5, stream | 0.072 | 0.001 | 0.216 | 0.001 | 0.007 | 0.001 | 0.000 |
| D6, ditch | 0.034 | 0.001 | 0.102 | 0.000 | 0.003 | 0.001 | 0.0002 |
| R1, pond | 0.044 | 0.001 | 0.132 | 0.000 | 0.004 | 0.001 | 0.000 |
| R1, stream | 0.360 | 0.005 | 1.078 | 0.004 | 0.036 | 0.007 | 0.002 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| R3, stream | 0.455 | 0.007 | 1.362 | 0.005 | 0.046 | 0.008 | 0.002 |
| R4, stream | 0.564 | 0.009 | 1.689 | 0.0056 | 0.056 | 0.010 | 0.003 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.104 | 0.002 | 0.311 | 0.001 | 0.010 | 0.002 | 0.001 |
| D4, pond | 0.019 | 0.000 | 0.057 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, stream | 0.050 | 0.001 | 0.150 | 0.001 | 0.005 | 0.001 | 0.000 |
| D5, pond | 0.023 | 0.000 | 0.069 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.071 | 0.001 | 0.213 | 0.001 | 0.007 | 0.001 | 0.000 |
| D6, ditch | 0.136 | 0.002 | 0.407 | 0.001 | 0.014 | 0.002 | 0.0007 |
| R1, pond | 0.121 | 0.002 | 0.362 | 0.001 | 0.012 | 0.002 | 0.001 |
| R1, stream | 1.053 | 0.016 | 3.153 | 0.011 | 0.105 | 0.019 | 0.005 |
| R3, stream | 1.015 | 0.015 | 3.039 | 0.010 | 0.102 | 0.018 | 0.005 |
| R4, stream | 1.340 | 0.020 | 4.012 | 0.0134 | 0.134 | 0.024 | 0.007 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in winter cereals, BBCH 69

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 62.27 | 0.939 | 186.437 | 0.623 | 6.227 | 1.132 | 0.311 |
| Step 2 | | | | | | | |
| N-Europe | 4.98 | 0.075 | 14.910 | 0.050 | 0.498 | 0.091 | 0.025 |
| S-Europe | 4.09 | 0.062 | 12.246 | 0.041 | 0.409 | 0.074 | 0.020 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.180 | 0.003 | 0.539 | 0.002 | 0.018 | 0.003 | 0.001 |
| D4, pond | 0.016 | 0.000 | 0.048 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, stream | 0.094 | 0.001 | 0.281 | 0.001 | 0.009 | 0.002 | 0.000 |
| D5, pond | 0.016 | 0.000 | 0.048 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.113 | 0.002 | 0.338 | 0.001 | 0.011 | 0.002 | 0.001 |
| D6, ditch | 0.201 | 0.003 | 0.602 | 0.002 | 0.020 | 0.004 | 0.0010 |
| R1, pond | 0.043 | 0.001 | 0.129 | 0.000 | 0.004 | 0.001 | 0.000 |
| R1, stream | 0.304 | 0.005 | 0.910 | 0.003 | 0.030 | 0.006 | 0.002 |
| R3, stream | 0.436 | 0.007 | 1.305 | 0.004 | 0.044 | 0.008 | 0.002 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| R4, stream | 0.581 | 0.009 | 1.740 | 0.0058 | 0.058 | 0.011 | 0.003 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.158 | 0.002 | 0.473 | 0.002 | 0.016 | 0.003 | 0.001 |
| D4, pond | 0.023 | 0.000 | 0.069 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, stream | 0.081 | 0.001 | 0.243 | 0.001 | 0.008 | 0.001 | 0.000 |
| D5, pond | 0.024 | 0.000 | 0.072 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.097 | 0.001 | 0.290 | 0.001 | 0.010 | 0.002 | 0.000 |
| D6, ditch | 0.176 | 0.003 | 0.527 | 0.002 | 0.018 | 0.003 | 0.0009 |
| R1, pond | 0.135 | 0.002 | 0.404 | 0.001 | 0.014 | 0.002 | 0.001 |
| R1, stream | 0.765 | 0.012 | 2.290 | 0.008 | 0.077 | 0.014 | 0.004 |
| R3, stream | 0.825 | 0.012 | 2.470 | 0.008 | 0.083 | 0.015 | 0.004 |
| R4, stream | 0.581 | 0.009 | 1.740 | 0.0058 | 0.058 | 0.011 | 0.003 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in spring cereals, BBCH 29

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|--------------|-------------------|
| Step 1 | | | | | | | |
| | 62.27 | 0.939 | 186.437 | 0.623 | 6.227 | 1.132 | 0.311 |
| Step 2 | | | | | | | |
| N-Europe | 12.40 | 0.187 | 37.126 | 0.124 | 1.240 | 0.225 | 0.062 |
| S-Europe | 10.02 | 0.151 | 30.000 | 0.100 | 1.002 | 0.182 | 0.050 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.121 | 0.002 | 0.362 | 0.001 | 0.012 | 0.002 | 0.001 |
| D4, stream | 0.016 | 0.000 | 0.048 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, ditch | 0.065 | 0.001 | 0.195 | 0.001 | 0.007 | 0.001 | 0.000 |
| D5, pond | 0.014 | 0.000 | 0.042 | 0.000 | 0.001 | 0.000 | 0.000 |
| D5, stream | 0.071 | 0.001 | 0.213 | 0.001 | 0.007 | 0.001 | 0.000 |
| R4, pond | 0.632 | 0.010 | 1.892 | 0.006 | 0.063 | 0.011 | 0.0032 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.108 | 0.002 | 0.323 | 0.001 | 0.011 | 0.002 | 0.001 |
| D4, stream | 0.024 | 0.000 | 0.072 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, ditch | 0.063 | 0.001 | 0.189 | 0.001 | 0.006 | 0.001 | 0.000 |
| D5, pond | 0.023 | 0.000 | 0.069 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.068 | 0.001 | 0.204 | 0.001 | 0.007 | 0.001 | 0.000 |
| R4, pond | 1.211 | 0.018 | 3.626 | 0.012 | 0.121 | 0.022 | 0.0061 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in winter oilseed rape, BBCH 30

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 56.04 | 0.845 | 167.784 | 0.560 | 5.604 | 1.019 | 0.280 |
| Step 2 | | | | | | | |
| N-Europe | 2.08 | 0.031 | 6.228 | 0.021 | 0.208 | 0.038 | 0.010 |
| S-Europe | 3.68 | 0.056 | 11.018 | 0.037 | 0.368 | 0.067 | 0.018 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.036 | 0.001 | 0.108 | 0.000 | 0.004 | 0.001 | 0.000 |
| D4, pond | 0.012 | 0.000 | 0.036 | 0.0001 | 0.001 | 0.000 | 0.0001 |
| D4, stream | 0.054 | 0.001 | 0.162 | 0.001 | 0.005 | 0.001 | 0.000 |
| D5, pond | 0.013 | 0.000 | 0.039 | 0.000 | 0.001 | 0.000 | 0.000 |
| D5, stream | 0.065 | 0.001 | 0.195 | 0.001 | 0.007 | 0.001 | 0.000 |
| R1, pond | 0.038 | 0.001 | 0.114 | 0.000 | 0.004 | 0.001 | 0.0002 |
| R1, stream | 0.294 | 0.004 | 0.880 | 0.003 | 0.029 | 0.005 | 0.001 |
| R3, stream | 0.519 | 0.008 | 1.554 | 0.005 | 0.052 | 0.009 | 0.003 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.040 | 0.001 | 0.120 | 0.000 | 0.004 | 0.001 | 0.000 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| D4, pond | 0.018 | 0.000 | 0.054 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, stream | 0.047 | 0.001 | 0.141 | 0.000 | 0.005 | 0.001 | 0.000 |
| D5, pond | 0.019 | 0.000 | 0.057 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.057 | 0.001 | 0.171 | 0.001 | 0.006 | 0.001 | 0.000 |
| R1, pond | 0.033 | 0.000 | 0.099 | 0.000 | 0.003 | 0.001 | 0.0002 |
| R1, stream | 0.874 | 0.013 | 2.617 | 0.009 | 0.087 | 0.016 | 0.004 |
| R3, stream | 0.775 | 0.012 | 2.320 | 0.008 | 0.078 | 0.014 | 0.004 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in winter oilseed rape, BBCH 71

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|--------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | ErC ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 56.04 | 0.845 | 167.784 | 0.560 | 5.604 | 1.019 | 0.280 |
| Step 2 | | | | | | | |
| N-Europe | 1.82 | 0.027 | 5.449 | 0.018 | 0.182 | 0.033 | 0.009 |
| S-Europe | 3.15 | 0.048 | 9.431 | 0.032 | 0.315 | 0.057 | 0.016 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| Step 3, single | | | | | | | |
| D3, ditch | 0.128 | 0.002 | 0.383 | 0.001 | 0.013 | 0.002 | 0.001 |
| D4, pond | 0.014 | 0.000 | 0.042 | 0.0001 | 0.001 | 0.000 | 0.0001 |
| D4, stream | 0.062 | 0.001 | 0.186 | 0.001 | 0.006 | 0.001 | 0.000 |
| D5, pond | 0.014 | 0.000 | 0.042 | 0.000 | 0.001 | 0.000 | 0.000 |
| D5, stream | 0.101 | 0.002 | 0.302 | 0.001 | 0.010 | 0.002 | 0.001 |
| R1, pond | 0.071 | 0.001 | 0.213 | 0.001 | 0.007 | 0.001 | 0.0004 |
| R1, stream | 0.466 | 0.007 | 1.395 | 0.005 | 0.047 | 0.008 | 0.002 |
| R3, stream | 0.366 | 0.006 | 1.096 | 0.004 | 0.037 | 0.007 | 0.002 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.112 | 0.002 | 0.335 | 0.001 | 0.011 | 0.002 | 0.001 |
| D4, pond | 0.022 | 0.000 | 0.066 | 0.0002 | 0.002 | 0.000 | 0.0001 |
| D4, stream | 0.068 | 0.001 | 0.204 | 0.001 | 0.007 | 0.001 | 0.000 |
| D5, pond | 0.022 | 0.000 | 0.066 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.088 | 0.001 | 0.263 | 0.001 | 0.009 | 0.002 | 0.000 |
| R1, pond | 0.119 | 0.002 | 0.356 | 0.001 | 0.012 | 0.002 | 0.0006 |
| R1, stream | 0.790 | 0.012 | 2.365 | 0.008 | 0.079 | 0.014 | 0.004 |
| R3, stream | 0.821 | 0.012 | 2.458 | 0.008 | 0.082 | 0.015 | 0.004 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in summer oilseed rape, BBCH 30

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 56.04 | 0.845 | 167.784 | 0.560 | 5.604 | 1.019 | 0.280 |
| Step 2 | | | | | | | |
| N-Europe | 2.08 | 0.031 | 6.228 | 0.021 | 0.208 | 0.038 | 0.010 |
| S-Europe | 3.68 | 0.056 | 11.018 | 0.037 | 0.368 | 0.067 | 0.018 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.116 | 0.002 | 0.347 | 0.001 | 0.012 | 0.002 | 0.001 |
| D4, pond | 0.014 | 0.000 | 0.042 | 0.0001 | 0.001 | 0.000 | 0.0001 |
| D4, stream | 0.059 | 0.001 | 0.177 | 0.001 | 0.006 | 0.001 | 0.000 |
| D5, pond | 0.013 | 0.000 | 0.039 | 0.000 | 0.001 | 0.000 | 0.000 |
| D5, stream | 0.071 | 0.001 | 0.213 | 0.001 | 0.007 | 0.001 | 0.000 |
| R1, pond | 0.060 | 0.001 | 0.180 | 0.001 | 0.006 | 0.001 | 0.0003 |
| R1, stream | 0.549 | 0.008 | 1.644 | 0.005 | 0.055 | 0.010 | 0.003 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.135 | 0.002 | 0.404 | 0.001 | 0.014 | 0.002 | 0.001 |
| D4, pond | 0.020 | 0.000 | 0.060 | 0.0002 | 0.002 | 0.000 | 0.0001 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| D4, stream | 0.073 | 0.001 | 0.219 | 0.001 | 0.007 | 0.001 | 0.000 |
| D5, pond | 0.021 | 0.000 | 0.063 | 0.000 | 0.002 | 0.000 | 0.000 |
| D5, stream | 0.064 | 0.001 | 0.192 | 0.001 | 0.006 | 0.001 | 0.000 |
| R1, pond | 0.106 | 0.002 | 0.317 | 0.001 | 0.011 | 0.002 | 0.0005 |
| R1, stream | 0.645 | 0.010 | 1.931 | 0.006 | 0.065 | 0.012 | 0.003 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in sugarbeet, BBCH 39

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|--------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | ErC ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 49.81 | 0.751 | 149.132 | 0.498 | 4.981 | 0.906 | 0.249 |
| Step 2 | | | | | | | |
| N-Europe | 1.85 | 0.028 | 5.539 | 0.019 | 0.185 | 0.034 | 0.009 |
| S-Europe | 2.56 | 0.039 | 7.665 | 0.026 | 0.256 | 0.047 | 0.013 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.102 | 0.002 | 0.305 | 0.001 | 0.010 | 0.002 | 0.001 |
| D4, pond | 0.034 | 0.001 | 0.102 | 0.0003 | 0.003 | 0.001 | 0.0002 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| D4, stream | 0.042 | 0.001 | 0.126 | 0.000 | 0.004 | 0.001 | 0.000 |
| R1, pond | 0.025 | 0.000 | 0.075 | 0.000 | 0.003 | 0.000 | 0.000 |
| R1, stream | 0.274 | 0.004 | 0.820 | 0.003 | 0.027 | 0.005 | 0.001 |
| R3, stream | 0.328 | 0.005 | 0.982 | 0.003 | 0.033 | 0.006 | 0.0016 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.099 | 0.001 | 0.296 | 0.001 | 0.010 | 0.002 | 0.000 |
| D4, pond | 0.028 | 0.000 | 0.084 | 0.0003 | 0.003 | 0.001 | 0.0001 |
| D4, stream | 0.040 | 0.001 | 0.120 | 0.000 | 0.004 | 0.001 | 0.000 |
| R1, pond | 0.037 | 0.001 | 0.111 | 0.000 | 0.004 | 0.001 | 0.000 |
| R1, stream | 0.275 | 0.004 | 0.823 | 0.003 | 0.028 | 0.005 | 0.001 |
| R3, stream | 0.525 | 0.008 | 1.572 | 0.005 | 0.053 | 0.010 | 0.003 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in fruiting vegetables (BBCH 11)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|--------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | ErC ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| Step 1 | | | | | | | |
| | 36.04 | 0.544 | 107.904 | 0.360 | 3.604 | 0.655 | 0.180 |
| Step 2 | | | | | | | |
| N-Europe | 4.03 | 0.061 | 12.066 | 0.040 | 0.403 | 0.073 | 0.020 |
| S-Europe | 7.67 | 0.116 | 22.964 | 0.077 | 0.767 | 0.139 | 0.038 |
| Step 3, single | | | | | | | |
| D6, ditch | 0.024 | 0.000 | 0.072 | 0.000 | 0.002 | 0.000 | 0.000 |
| R2, stream | 0.117 | 0.002 | 0.350 | 0.0012 | 0.012 | 0.002 | 0.0006 |
| R3, stream | 0.432 | 0.007 | 1.293 | 0.004 | 0.043 | 0.008 | 0.002 |
| R4, stream | 0.700 | 0.011 | 2.096 | 0.007 | 0.070 | 0.013 | 0.004 |
| Step 3, multiple | | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 |
| D6, ditch | 0.038 | 0.001 | 0.114 | 0.000 | 0.004 | 0.001 | 0.0002 |
| R2, stream | 0.226 | 0.003 | 0.677 | 0.002 | 0.023 | 0.004 | 0.001 |
| R3, stream | 0.655 | 0.010 | 1.961 | 0.007 | 0.066 | 0.012 | 0.003 |
| R4, stream | 1.185 | 0.018 | 3.548 | 0.012 | 0.119 | 0.022 | 0.006 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in fruiting vegetables (BBCH 89)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 56.04 | 0.845 | 167.784 | 0.560 | 5.604 | 1.019 | 0.280 |
| Step 2 | | | | | | | |
| N-Europe | 1.84 | 0.028 | 5.509 | 0.018 | 0.184 | 0.033 | 0.009 |
| S-Europe | 3.30 | 0.050 | 9.880 | 0.033 | 0.330 | 0.060 | 0.017 |
| Step 3, single | | | | | | | |
| D6, ditch | 0.064 | 0.001 | 0.192 | 0.001 | 0.006 | 0.001 | 0.000 |
| R2, stream | 0.046 | 0.001 | 0.138 | 0.0005 | 0.005 | 0.001 | 0.0002 |
| R3, stream | 0.277 | 0.004 | 0.829 | 0.003 | 0.028 | 0.005 | 0.001 |
| R4, stream | 0.420 | 0.006 | 1.257 | 0.004 | 0.042 | 0.008 | 0.002 |
| Step 3, multiple | | | | | | | |
| D6, ditch | 0.056 | 0.001 | 0.168 | 0.001 | 0.006 | 0.001 | 0.0003 |
| R2, stream | 0.034 | 0.001 | 0.102 | 0.0003 | 0.003 | 0.001 | 0.0002 |
| R3, stream | 0.468 | 0.007 | 1.401 | 0.005 | 0.047 | 0.009 | 0.002 |
| R4, stream | 1.251 | 0.019 | 3.746 | 0.013 | 0.125 | 0.023 | 0.006 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in pome/stone fruit (BBCH 39)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 43.56 | 0.657 | 130.419 | 0.436 | 4.356 | 0.792 | 0.218 |
| Step 2 | | | | | | | |
| N-Europe | 5.86 | 0.088 | 17.545 | 0.059 | 0.586 | 0.107 | 0.029 |
| S-Europe | 8.19 | 0.124 | 24.521 | 0.082 | 0.819 | 0.149 | 0.041 |
| Step 3, single | | | | | | | |
| D3, ditch | 1.021 | 0.015 | 3.057 | 0.010 | 0.102 | 0.019 | 0.005 |
| D4, pond | 0.207 | 0.003 | 0.620 | 0.002 | 0.021 | 0.004 | 0.001 |
| D4, stream | 0.611 | 0.009 | 1.829 | 0.006 | 0.061 | 0.011 | 0.003 |
| D5, pond | 0.209 | 0.003 | 0.626 | 0.002 | 0.021 | 0.004 | 0.001 |
| D5, stream | 0.774 | 0.012 | 2.317 | 0.008 | 0.077 | 0.014 | 0.004 |
| R1, pond | 0.208 | 0.003 | 0.623 | 0.002 | 0.021 | 0.004 | 0.001 |
| R1, stream | 0.541 | 0.008 | 1.620 | 0.005 | 0.054 | 0.010 | 0.003 |
| R2, stream | 0.619 | 0.009 | 1.853 | 0.006 | 0.062 | 0.011 | 0.003 |
| R3, stream | 0.997 | 0.015 | 2.985 | 0.010 | 0.100 | 0.018 | 0.005 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| R4, stream | 0.573 | 0.009 | 1.716 | 0.006 | 0.057 | 0.010 | 0.003 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 1.135 | 0.0171 | 3.398 | 0.011 | 0.114 | 0.021 | 0.006 |
| D4, pond | 0.359 | 0.0054 | 1.075 | 0.004 | 0.036 | 0.007 | 0.002 |
| D4, stream | 0.550 | 0.008 | 1.647 | 0.006 | 0.055 | 0.010 | 0.003 |
| D5, pond | 0.351 | 0.005 | 1.051 | 0.004 | 0.035 | 0.006 | 0.002 |
| D5, stream | 0.867 | 0.013 | 2.596 | 0.009 | 0.087 | 0.016 | 0.004 |
| R1, pond | 0.343 | 0.005 | 1.027 | 0.003 | 0.034 | 0.006 | 0.002 |
| R1, stream | 0.462 | 0.007 | 1.383 | 0.005 | 0.046 | 0.008 | 0.002 |
| R2, stream | 0.528 | 0.008 | 1.581 | 0.005 | 0.053 | 0.010 | 0.003 |
| R3, stream | 1.039 | 0.016 | 3.111 | 0.010 | 0.104 | 0.019 | 0.005 |
| R4, stream | 0.511 | 0.008 | 1.530 | 0.005 | 0.051 | 0.009 | 0.003 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in pome/stone fruit (BBCH 51)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 43.56 | 0.876 | 173.862 | 0.581 | 5.807 | 1.056 | 0.290 |
| Step 2 | | | | | | | |
| N-Europe | 4.89 | 0.098 | 19.521 | 0.065 | 0.652 | 0.119 | 0.033 |
| S-Europe | 6.25 | 0.126 | 24.940 | 0.083 | 0.833 | 0.151 | 0.042 |
| Step 3, single | | | | | | | |
| D3, ditch | 1.760 | 0.027 | 5.269 | 0.018 | 0.176 | 0.032 | 0.009 |
| D4, pond | 0.277 | 0.004 | 0.829 | 0.003 | 0.028 | 0.005 | 0.001 |
| D4, stream | 0.815 | 0.012 | 2.440 | 0.008 | 0.082 | 0.015 | 0.004 |
| D5, pond | 0.279 | 0.004 | 0.835 | 0.003 | 0.028 | 0.005 | 0.001 |
| D5, stream | 1.032 | 0.016 | 3.090 | 0.010 | 0.103 | 0.019 | 0.005 |
| R1, pond | 0.278 | 0.004 | 0.832 | 0.003 | 0.028 | 0.005 | 0.001 |
| R1, stream | 0.722 | 0.011 | 2.162 | 0.0072 | 0.072 | 0.013 | 0.0036 |
| R2, stream | 0.825 | 0.012 | 2.470 | 0.008 | 0.083 | 0.015 | 0.004 |
| R3, stream | 1.330 | 0.020 | 3.982 | 0.013 | 0.133 | 0.024 | 0.007 |
| R4, stream | 0.764 | 0.012 | 2.287 | 0.008 | 0.076 | 0.014 | 0.004 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| Step 3, multiple | | | | | | | |
| D3, ditch | 1.514 | 0.023 | 4.533 | 0.015 | 0.151 | 0.028 | 0.008 |
| D4, pond | 0.436 | 0.007 | 1.305 | 0.0044 | 0.044 | 0.008 | 0.0022 |
| D4, stream | 0.955 | 0.014 | 2.859 | 0.010 | 0.096 | 0.017 | 0.005 |
| D5, pond | 0.470 | 0.007 | 1.407 | 0.005 | 0.047 | 0.009 | 0.002 |
| D5, stream | 1.155 | 0.017 | 3.458 | 0.012 | 0.116 | 0.021 | 0.006 |
| R1, pond | 0.459 | 0.007 | 1.374 | 0.005 | 0.046 | 0.008 | 0.0023 |
| R1, stream | 0.616 | 0.009 | 1.844 | 0.006 | 0.062 | 0.011 | 0.003 |
| R2, stream | 0.725 | 0.011 | 2.171 | 0.007 | 0.073 | 0.013 | 0.004 |
| R3, stream | 1.386 | 0.021 | 4.150 | 0.014 | 0.139 | 0.025 | 0.007 |
| R4, stream | 0.938 | 0.014 | 2.808 | 0.0094 | 0.094 | 0.017 | 0.005 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in pome/stone fruit (BBCH 85)

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-----------------------|------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenedesmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | | | |
| Step 1 | | | | | | | |
| | 43.56 | 0.657 | 130.419 | 0.436 | 4.356 | 0.792 | 0.218 |
| Step 2 | | | | | | | |
| N-Europe | 4.89 | 0.074 | 14.641 | 0.049 | 0.489 | 0.089 | 0.024 |
| S-Europe | 6.25 | 0.094 | 18.713 | 0.063 | 0.625 | 0.114 | 0.031 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.792 | 0.012 | 2.371 | 0.008 | 0.079 | 0.014 | 0.004 |
| D4, pond | 0.094 | 0.001 | 0.281 | 0.001 | 0.009 | 0.002 | 0.0005 |
| D4, stream | 0.374 | 0.006 | 1.120 | 0.004 | 0.037 | 0.007 | 0.002 |
| D5, pond | 0.100 | 0.002 | 0.299 | 0.001 | 0.010 | 0.002 | 0.001 |
| D5, stream | 0.673 | 0.010 | 2.015 | 0.007 | 0.067 | 0.012 | 0.003 |
| R1, pond | 0.094 | 0.001 | 0.281 | 0.001 | 0.009 | 0.002 | 0.0005 |
| R1, stream | 0.317 | 0.005 | 0.949 | 0.003 | 0.032 | 0.006 | 0.002 |
| R2, stream | 0.399 | 0.006 | 1.195 | 0.004 | 0.040 | 0.007 | 0.002 |
| R3, stream | 0.872 | 0.013 | 2.611 | 0.009 | 0.087 | 0.016 | 0.004 |
| R4, stream | 0.434 | 0.007 | 1.299 | 0.0043 | 0.043 | 0.008 | 0.002 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------|-------|------------|----------------|-----------------|---------------------|-------|-------------------|
| Step 3, multiple | | | | | | | |
| D3, ditch | 1.192 | 0.018 | 3.569 | 0.012 | 0.119 | 0.022 | 0.006 |
| D4, pond | 0.150 | 0.002 | 0.449 | 0.002 | 0.015 | 0.003 | 0.001 |
| D4, stream | 0.326 | 0.005 | 0.976 | 0.003 | 0.033 | 0.006 | 0.002 |
| D5, pond | 0.153 | 0.002 | 0.458 | 0.002 | 0.015 | 0.003 | 0.001 |
| D5, stream | 0.539 | 0.008 | 1.614 | 0.005 | 0.054 | 0.010 | 0.003 |
| R1, pond | 0.140 | 0.002 | 0.419 | 0.001 | 0.014 | 0.003 | 0.001 |
| R1, stream | 0.273 | 0.004 | 0.817 | 0.003 | 0.027 | 0.005 | 0.001 |
| R2, stream | 0.332 | 0.005 | 0.994 | 0.003 | 0.033 | 0.006 | 0.002 |
| R3, stream | 0.699 | 0.011 | 2.093 | 0.007 | 0.070 | 0.013 | 0.003 |
| R4, stream | 1.155 | 0.017 | 3.458 | 0.012 | 0.116 | 0.021 | 0.006 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of SIP 41061 in carrots

| Group | PEC _{sw-max} (µg/L) | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|--------------------|---------------------------------|----------------------------|----------------------------|-----------------------------|----------------------|---------------------------------------|----------------------------|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Daphnia magna</i> | <i>Scenesedsmus subspicatus</i> | <i>Chironomus riparius</i> |
| Endpoint (µg/L) | | LC ₅₀ 6630 | NOEC 3.34 | EC ₅₀ > 10000 | NOEC 100 | E _r C ₅₀ 550 | NOEC 2000 |
| AF | | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) | | 66.3 | 0.334 | > 100 | 10 | 55 | 200 |
| FOCUS Scenario | | | | | | | |
| Step 1 | | | | | | | |
| | 62.27 | 0.939 | 186.437 | 0.623 | 6.227 | 1.132 | 0.311 |

| Group | | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sediment dwellers |
|-------------------------------|--------------|------------|----------------|-----------------|---------------------|-------|-------------------|
| Step 2 | | | | | | | |
| N-Europe | 4.63 | 0.070 | 13.862 | 0.046 | 0.463 | 0.084 | 0.023 |
| S-Europe | 8.75 | 0.132 | 26.198 | 0.088 | 0.875 | 0.159 | 0.044 |
| Step 3, single | | | | | | | |
| D3, ditch | 0.130 | 0.002 | 0.389 | 0.001 | 0.013 | 0.002 | 0.001 |
| D6, ditch | 0.045 | 0.001 | 0.135 | 0.000 | 0.005 | 0.001 | 0.000 |
| R1, pond | 0.050 | 0.001 | 0.150 | 0.001 | 0.005 | 0.001 | 0.0003 |
| R1, stream | 0.415 | 0.006 | 1.243 | 0.004 | 0.042 | 0.008 | 0.002 |
| R2 (1 st), stream | 0.106 | 0.002 | 0.317 | 0.001 | 0.011 | 0.002 | 0.001 |
| R2 (2 nd), stream | 0.074 | 0.001 | 0.222 | 0.001 | 0.007 | 0.001 | 0.0004 |
| R3, stream | 0.506 | 0.008 | 1.515 | 0.005 | 0.051 | 0.009 | 0.003 |
| R4, stream | 0.879 | 0.013 | 2.632 | 0.009 | 0.088 | 0.016 | 0.004 |
| Step 3, multiple | | | | | | | |
| D3, ditch | 0.134 | 0.002 | 0.401 | 0.001 | 0.013 | 0.002 | 0.001 |
| D6, ditch | 0.039 | 0.001 | 0.117 | 0.0004 | 0.004 | 0.001 | 0.0002 |
| R1, pond | 0.103 | 0.002 | 0.308 | 0.001 | 0.010 | 0.002 | 0.001 |
| R1, stream | 0.806 | 0.012 | 2.413 | 0.008 | 0.081 | 0.015 | 0.004 |
| R2 (1 st), stream | 0.186 | 0.003 | 0.557 | 0.002 | 0.019 | 0.003 | 0.001 |
| R2 (2 nd), stream | 0.254 | 0.004 | 0.760 | 0.003 | 0.025 | 0.005 | 0.001 |
| R3, stream | 0.550 | 0.008 | 1.647 | 0.006 | 0.055 | 0.010 | 0.003 |
| R4, stream | 1.302 | 0.020 | 3.898 | 0.013 | 0.130 | 0.024 | 0.007 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Prothioconazole desthio – FOCUS Step 4

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in winter cereals (BBCH 29)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R1 stream | 0.360 | 0.163 | - |
| 50 % | | 0.360 | - | - |
| 90 % | | 0.360 | - | - |
| None | R3 stream | 0.455 | 0.208 | - |
| 50 % | | 0.455 | - | - |
| 90 % | | 0.455 | - | - |
| None | R4 stream | 0.564 | 0.256 | - |
| 50 % | | 0.564 | - | - |
| 90 % | | 0.564 | - | - |
| Multiple application | | | | |
| None | R1 stream | 1.053 | 0.478 | 0.250 |
| 50 % | | 1.053 | 0.478 | - |
| 90 % | | 1.053 | 0.478 | - |
| None | R3 stream | 1.015 | 0.463 | 0.243 |
| 50 % | | 1.015 | 0.463 | - |
| 90 % | | 1.015 | 0.463 | - |
| None | R4 stream | 1.340 | 0.609 | 0.319 |
| 50 % | | 1.340 | 0.609 | - |
| 90 % | | 1.340 | 0.609 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R1 stream | 1.08 | 0.49 | - |
| 50 % | | 1.08 | - | - |
| 90 % | | 1.08 | - | - |
| None | R3 stream | 1.36 | 0.62 | - |
| 50 % | | 1.36 | - | - |
| 90 % | | 1.36 | - | - |
| None | R4 stream | 1.69 | 0.77 | - |
| 50 % | | 1.69 | - | - |
| 90 % | | 1.69 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|-----------------------------|----------------------|--------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Multiple application | | | | |
| None | R1 stream | 3.15 | 1.43 | 0.75 |
| 50 % | | 3.15 | 1.43 | - |
| 90 % | | 3.15 | 1.43 | - |
| None | R3 stream | 3.04 | 1.39 | 0.73 |
| 50 % | | 3.04 | 1.39 | - |
| 90 % | | 3.04 | 1.39 | - |
| None | R4 stream | 4.01 | 1.82 | 0.96 |
| 50 % | | 4.01 | 1.82 | - |
| 90 % | | 4.01 | 1.82 | - |

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desithio for the most sensitive organism group based on FOCUS Step 4 calculations – use in winter cereals (BBCH 69)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R3 stream | 0.436 | 0.196 | - |
| 50 % | | 0.436 | - | - |
| 90 % | | 0.436 | - | - |
| None | R4 stream | 0.581 | 0.264 | - |
| 50 % | | 0.581 | - | - |
| 90 % | | 0.581 | - | - |
| Multiple application | | | | |
| None | R1 stream | 0.765 | 0.348 | 0.182 |
| 50 % | | 0.765 | 0.348 | - |
| 90 % | | 0.765 | 0.348 | - |
| None | R3 stream | 0.825 | 0.371 | 0.194 |
| 50 % | | 0.825 | 0.371 | - |
| 90 % | | 0.825 | 0.371 | - |
| None | R4 stream | 0.581 | 0.264 | - |
| 50 % | | 0.581 | - | - |
| 90 % | | 0.581 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R3 stream | 1.31 | 0.59 | - |
| 50 % | | 1.31 | - | - |
| 90 % | | 1.31 | - | - |
| None | R4 stream | 1.74 | 0.79 | - |
| 50 % | | 1.74 | - | - |
| 90 % | | 1.74 | - | - |
| Multiple application | | | | |
| None | R1 stream | 2.29 | 1.04 | 0.54 |
| 50 % | | 2.29 | 1.04 | - |
| 90 % | | 2.29 | 1.04 | - |
| None | R3 stream | 2.47 | 1.11 | 0.58 |
| 50 % | | 2.47 | 1.11 | - |
| 90 % | | 2.47 | 1.11 | - |
| None | R4 stream | 1.74 | 0.79 | - |
| 50 % | | 1.74 | - | - |
| 90 % | | 1.74 | - | - |

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in spring cereals (BBCH 29)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R4 stream | 0.632 | 0.288 | - |
| 50 % | | 0.632 | 0.288 | - |
| 90 % | | 0.632 | 0.288 | - |
| Multiple application | | | | |
| None | R4 stream | 1.211 | 0.545 | 0.284 |
| 50 % | | 1.211 | 0.545 | - |
| 90 % | | 1.211 | 0.545 | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R4 stream | 1.89 | 0.86 | - |
| 50 % | | 1.89 | - | - |
| 90 % | | 1.89 | - | - |
| Multiple application | | | | |
| None | R4 stream | 3.63 | 1.63 | 0.85 |
| 50 % | | 3.63 | 1.63 | - |
| 90 % | | 3.63 | 1.63 | - |

Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in winter oilseed rape (BBCH 30)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R3 stream | 0.519 | 0.234 | - |
| 50 % | | 0.519 | - | - |
| 90 % | | 0.519 | - | - |
| Multiple application | | | | |
| None | R1 ditch | 0.874 | 0.396 | 0.208 |
| 50 % | | 0.874 | 0.396 | - |
| 90 % | | 0.874 | 0.396 | - |
| None | R3 stream | 0.775 | 0.353 | 0.185 |
| 50 % | | 0.775 | 0.353 | - |
| 90 % | | 0.775 | 0.353 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R3 stream | 1.55 | 0.70 | - |
| 50 % | | 1.55 | - | - |
| 90 % | | 1.55 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Multiple application | | | | |
| None | R1 ditch | 2.62 | 1.19 | 0.62 |
| 50 % | | 2.62 | 1.19 | - |
| 90 % | | 2.62 | 1.19 | - |
| None | R3 stream | 2.32 | 1.06 | 0.55 |
| 50 % | | 2.32 | 1.06 | - |
| 90 % | | 2.32 | 1.06 | - |

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desethio for the most sensitive organism group based on FOCUS Step 4 calculations – use in winter oilseed rape (BBCH 71)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R1 stream | 0.466 | 0.211 | - |
| 50 % | | 0.466 | - | - |
| 90 % | | 0.466 | - | - |
| None | R3 stream | 0.366 | 0.214 | - |
| 50 % | | 0.366 | - | - |
| 90 % | | 0.366 | - | - |
| Multiple application | | | | |
| None | R1 stream | 0.790 | 0.354 | 0.185 |
| 50 % | | 0.790 | 0.354 | - |
| 90 % | | 0.790 | 0.354 | - |
| None | R3 stream | 0.821 | 0.375 | 0.197 |
| 50 % | | 0.821 | 0.375 | - |
| 90 % | | 0.821 | 0.375 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R1 stream | 1.40 | 0.63 | - |
| 50 % | | 1.40 | - | - |
| 90 % | | 1.40 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R3 stream | 1.10 | 0.64 | - |
| 50 % | | 1.10 | - | - |
| 90 % | | 1.10 | - | - |
| Multiple application | | | | |
| None | R1 stream | 2.37 | 1.06 | 0.55 |
| 50 % | | 2.37 | 1.06 | - |
| 90 % | | 2.37 | 1.06 | - |
| None | R3 stream | 2.46 | 1.12 | 0.59 |
| 50 % | | 2.46 | 1.12 | - |
| 90 % | | 2.46 | 1.12 | - |

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in summer oilseed rape (BBCH 30)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|----|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R1 stream | 0.549 | 0.249 | - |
| 50 % | | 0.549 | - | - |
| 90 % | | 0.549 | - | - |
| Multiple application | | | | |
| None | R1 stream | 0.645 | 0.293 | - |
| 50 % | | 0.645 | - | - |
| 90 % | | 0.645 | - | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R1 stream | 1.64 | 0.75 | - |
| 50 % | | 1.64 | - | - |
| 90 % | | 1.64 | - | - |
| Multiple application | | | | |
| None | R1 stream | 1.93 | 0.88 | - |
| 50 % | | 1.93 | - | - |
| 90 % | | 1.93 | - | - |

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in sugarbeet (BBCH 39)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|----|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Multiple application | | | | |
| None | R3 stream | 0.525 | 0.240 | - |
| 50 % | | 0.525 | - | - |
| 90 % | | 0.525 | - | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Multiple application | | | | |
| None | R3 stream | 1.57 | 0.72 | - |
| 50 % | | 1.57 | - | - |
| 90 % | | 1.57 | - | - |

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in fruiting vegetables (BBCH 11)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R3 stream | 0.432 | 0.195 | - |
| 50 % | | 0.432 | - | - |
| 90 % | | 0.432 | - | - |
| None | R4 stream | 0.700 | 0.318 | - |
| 50 % | | 0.700 | - | - |
| 90 % | | 0.700 | - | - |
| Multiple application | | | | |
| None | R3 stream | 0.655 | 0.298 | - |
| 50 % | | 0.655 | - | - |
| 90 % | | 0.655 | - | - |
| None | R4 stream | 1.185 | 0.536 | 0.280 |
| 50 % | | 1.185 | 0.536 | - |
| 90 % | | 1.185 | 0.536 | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R3 stream | 1.29 | 0.58 | - |
| 50 % | | 1.29 | - | - |
| 90 % | | 1.29 | - | - |
| None | R4 stream | 2.10 | 0.95 | - |
| 50 % | | 2.10 | - | - |
| 90 % | | 2.10 | - | - |
| Multiple application | | | | |
| None | R3 stream | 1.96 | 0.89 | - |
| 50 % | | 1.96 | - | - |
| 90 % | | 1.96 | - | - |
| None | R4 stream | 3.55 | 1.60 | 0.84 |
| 50 % | | 3.55 | 1.60 | - |
| 90 % | | 3.55 | 1.60 | - |

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in fruiting vegetables (BBCH 89)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R4 stream | 0.420 | 0.191 | - |
| 50 % | | 0.420 | - | - |
| 90 % | | 0.420 | - | - |
| Multiple application | | | | |
| None | R3 stream | 0.468 | 0.214 | - |
| 50 % | | 0.468 | - | - |
| 90 % | | 0.468 | - | - |
| None | R4 stream | 1.251 | 0.569 | 0.298 |
| 50 % | | 1.251 | 0.569 | - |
| 90 % | | 1.251 | 0.569 | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R4 stream | 1.26 | 0.57 | - |
| 50 % | | 1.26 | - | - |
| 90 % | | 1.26 | - | - |
| Multiple application | | | | |
| None | R3 stream | 1.40 | 0.64 | - |
| 50 % | | 1.40 | - | - |
| 90 % | | 1.40 | - | - |
| None | R4 stream | 3.75 | 1.70 | 0.89 |
| 50 % | | 3.75 | 1.70 | - |
| 90 % | | 3.75 | 1.70 | - |

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in pome/stone fruit (BBCH 39)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | D3 ditch | 0.802 | 0.492 | 0.112 |
| 50 % | | 0.401 | 0.246 | - |
| 90 % | | 0.080 | - | - |
| None | D4 stream | 0.525 | 0.322 | - |
| 50 % | | 0.262 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 0.665 | 0.408 | 0.093 |
| 50 % | | 0.332 | 0.204 | - |
| 90 % | | - | - | - |
| None | R1 stream | 0.465 | 0.286 | - |
| 50 % | | 0.232 | - | - |
| 90 % | | - | - | - |
| None | R2 stream | 0.532 | 0.327 | - |
| 50 % | | 0.266 | - | - |
| 90 % | | - | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R3 stream | 0.857 | 0.526 | 0.120 |
| 50 % | | 0.428 | 0.263 | - |
| 90 % | | 0.085 | - | - |
| None | R4 stream | 0.492 | 0.302 | |
| 50 % | | 0.246 | - | - |
| 90 % | | - | - | - |
| Multiple application | | | | |
| None | D3 ditch | 0.875 | 0.516 | 0.133 |
| 50 % | | 0.437 | 0.258 | - |
| 90 % | | 0.087 | - | - |
| None | D4 pond | 0.402 | 0.227 | - |
| 50 % | | 0.200 | - | - |
| 90 % | | - | - | - |
| None | D4 stream | 0.467 | 0.276 | - |
| 50 % | | 0.233 | - | - |
| 90 % | | - | - | - |
| None | D5 pond | 0.394 | 0.222 | - |
| 50 % | | 0.195 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 0.736 | 0.435 | 0.112 |
| 50 % | | 0.368 | 0.217 | - |
| 90 % | | 0.073 | - | - |
| None | R1 pond | 0.385 | 0.218 | - |
| 50 % | | 0.191 | - | - |
| 90 % | | - | - | - |
| None | R1 stream | 0.392 | 0.232 | - |
| 50 % | | 0.355 | - | - |
| 90 % | | 0.355 | - | - |
| None | R2 stream | 0.449 | 0.265 | - |
| 50 % | | 0.224 | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 0.882 | 0.521 | 0.135 |
| 50 % | | 0.441 | 0.261 | - |
| 90 % | | 0.088 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R4 stream | 0.511 | 0.245 | - |
| 50 % | | 0.511 | - | - |
| 90 % | | 0.511 | - | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | D3 ditch | 2.40 | 1.47 | 0.34 |
| 50 % | | 1.20 | 0.74 | - |
| 90 % | | 0.24 | - | - |
| None | D4 stream | 1.57 | 0.96 | - |
| 50 % | | 0.78 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 1.99 | 1.22 | 0.28 |
| 50 % | | 0.99 | 0.61 | - |
| 90 % | | - | - | - |
| None | R1 stream | 1.39 | 0.86 | - |
| 50 % | | 0.69 | - | - |
| 90 % | | - | - | - |
| None | R2 stream | 1.59 | 0.98 | - |
| 50 % | | 0.80 | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 2.57 | 1.57 | 0.36 |
| 50 % | | 1.28 | 0.79 | - |
| 90 % | | 0.25 | - | - |
| None | R4 stream | 1.47 | 0.90 | - |
| 50 % | | 0.74 | - | - |
| 90 % | | 2.40 | 1.47 | 0.34 |
| Multiple application | | | | |
| None | D3 ditch | 2.62 | 1.54 | 0.40 |
| 50 % | | 1.31 | 0.77 | - |
| 90 % | | 0.26 | - | - |
| None | D4 pond | 1.20 | 0.68 | - |
| 50 % | | 0.60 | - | - |
| 90 % | | - | - | - |
| None | D4 stream | 1.40 | 0.83 | - |
| 50 % | | 0.70 | - | - |
| 90 % | | - | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|-------------|-------------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | D5 pond | 1.18 | 0.66 | - |
| 50 % | | 0.58 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 2.20 | 1.30 | 0.34 |
| 50 % | | 1.10 | 0.65 | - |
| 90 % | | 0.22 | - | - |
| None | R1 pond | 1.15 | 0.65 | - |
| 50 % | | 0.57 | - | - |
| 90 % | | - | - | - |
| None | R1 stream | 1.17 | 0.69 | - |
| 50 % | | 1.06 | - | - |
| 90 % | | 1.06 | - | - |
| None | R2 stream | 1.34 | 0.79 | - |
| 50 % | | 0.67 | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 2.64 | 1.56 | 0.40 |
| 50 % | | 1.32 | 0.78 | - |
| 90 % | | 0.26 | - | - |
| None | R4 stream | 1.53 | 0.73 | - |
| 50 % | | 1.53 | - | - |
| 90 % | | 1.53 | - | - |

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in pome/stone fruit (BBCH 51)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|---------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| <i>Single application</i> | | | | |
| None | D3 ditch | 1.383 | 0.848 | 0.194 |
| 50 % | | 0.691 | 0.424 | - |
| 90 % | | 0.138 | - | - |
| None | D4 stream | 0.700 | 0.430 | 0.098 |
| 50 % | | 0.395 | 0.215 | - |
| 90 % | | 0.070 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | D5 stream | 0.887 | 0.545 | 0.124 |
| 50 % | | 0.443 | 0.272 | - |
| 90 % | | 0.089 | - | - |
| None | R1 stream | 0.620 | 0.381 | 0.231 |
| 50 % | | 0.310 | 0.190 | - |
| 90 % | | - | - | - |
| None | R2 stream | 0.709 | 0.435 | 0.165 |
| 50 % | | 0.354 | 0.218 | - |
| 90 % | | 0.122 | - | - |
| None | R3 stream | 1.142 | 0.701 | 0.160 |
| 50 % | | 0.571 | 0.351 | - |
| 90 % | | 0.114 | 0.070 | - |
| None | R4 stream | 0.656 | 0.403 | 0.092 |
| 50 % | | 0.352 | 0.201 | - |
| 90 % | | 0.352 | - | - |
| Multiple application | | | | |
| None | D3 ditch | 1.167 | 0.689 | 0.178 |
| 50 % | | 0.582 | 0.344 | - |
| 90 % | | 0.116 | 0.069 | - |
| None | D4 pond | 0.490 | 0.276 | 0.082 |
| 50 % | | 0.242 | 0.137 | - |
| 90 % | | - | - | - |
| None | D4 stream | 0.811 | 0.479 | 0.124 |
| 50 % | | 0.405 | 0.239 | - |
| 90 % | | 0.239 | 0.048 | - |
| None | D5 pond | 0.528 | 0.298 | - |
| 50 % | | 0.262 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 0.981 | 0.579 | 0.150 |
| 50 % | | 0.490 | 0.290 | - |
| 90 % | | 0.098 | - | - |
| None | R1 pond | 0.515 | 0.291 | - |
| 50 % | | 0.256 | - | - |
| 90 % | | - | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R1 stream | 0.523 | 0.309 | 0.110 |
| 50 % | | 0.498 | 0.215 | - |
| 90 % | | 0.498 | - | - |
| None | R2 stream | 0.616 | 0.364 | 0.094 |
| 50 % | | 0.308 | 0.182 | - |
| 90 % | | 0.270 | - | - |
| None | R3 stream | 1.176 | 0.695 | 0.180 |
| 50 % | | 0.588 | 0.347 | - |
| 90 % | | 0.118 | 0.069 | - |
| None | R4 stream | 0.938 | 0.420 | 0.220 |
| 50 % | | 0.938 | 0.420 | - |
| 90 % | | 0.938 | 0.420 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | D3 ditch | 4.14 | 2.54 | 0.58 |
| 50 % | | 2.07 | 1.27 | - |
| 90 % | | 0.41 | - | - |
| None | D4 stream | 2.10 | 1.29 | 0.29 |
| 50 % | | 1.18 | 0.64 | - |
| 90 % | | 0.21 | - | - |
| None | D5 stream | 2.66 | 1.63 | 0.37 |
| 50 % | | 1.33 | 0.81 | - |
| 90 % | | 0.27 | - | - |
| None | R1 stream | 1.86 | 1.14 | 0.69 |
| 50 % | | 0.93 | 0.57 | - |
| 90 % | | - | - | - |
| None | R2 stream | 2.12 | 1.30 | 0.49 |
| 50 % | | 1.06 | 0.65 | - |
| 90 % | | 0.37 | - | - |
| None | R3 stream | 3.42 | 2.10 | 0.48 |
| 50 % | | 1.71 | 1.05 | - |
| 90 % | | 0.34 | 0.21 | - |
| None | R4 stream | 1.96 | 1.21 | 0.28 |
| 50 % | | 1.05 | 0.60 | - |
| 90 % | | 1.05 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|-------------|-------------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Multiple application | | | | |
| None | D3 ditch | 3.49 | 2.06 | 0.53 |
| 50 % | | 1.74 | 1.03 | - |
| 90 % | | 0.35 | 0.21 | - |
| None | D4 pond | 1.47 | 0.83 | 0.25 |
| 50 % | | 0.72 | 0.41 | - |
| 90 % | | - | - | - |
| None | D4 stream | 2.43 | 1.43 | 0.37 |
| 50 % | | 1.21 | 0.72 | - |
| 90 % | | 0.72 | 0.14 | - |
| None | D5 pond | 1.58 | 0.89 | - |
| 50 % | | 0.78 | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 2.94 | 1.73 | 0.45 |
| 50 % | | 1.47 | 0.87 | - |
| 90 % | | 0.29 | - | - |
| None | R1 pond | 1.54 | 0.87 | - |
| 50 % | | 0.77 | - | - |
| 90 % | | - | - | - |
| None | R1 stream | 1.57 | 0.93 | 0.33 |
| 50 % | | 1.49 | 0.64 | - |
| 90 % | | 1.49 | - | - |
| None | R2 stream | 1.84 | 1.09 | 0.28 |
| 50 % | | 0.92 | 0.54 | - |
| 90 % | | 0.81 | - | - |
| None | R3 stream | 3.52 | 2.08 | 0.54 |
| 50 % | | 1.76 | 1.04 | - |
| 90 % | | 0.35 | 0.21 | - |
| None | R4 stream | 2.81 | 1.26 | 0.66 |
| 50 % | | 2.81 | 1.26 | - |
| 90 % | | 2.81 | 1.26 | - |

Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desethio for the most sensitive organism group based on FOCUS Step 4 calculations – use in pome/stone fruit (BBCH 85)

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|-------------------------|--------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | D3 ditch | 0.534 | 0.239 | - |
| 50 % | | 0.267 | - | - |
| 90 % | | - | - | - |
| None | D4 stream | 0.292 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 0.525 | 0.235 | - |
| 50 % | | 0.263 | - | - |
| 90 % | | - | - | - |
| None | R2 stream | 0.311 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 0.681 | 0.304 | - |
| 50 % | | 0.340 | - | - |
| 90 % | | 0.267 | - | - |
| None | R4 stream | 0.434 | 0.197 | - |
| 50 % | | 0.434 | - | - |
| 90 % | | 0.434 | - | - |
| Multiple application | | | | |
| None | D3 ditch | 0.827 | 0.395 | 0.111 |
| 50 % | | 0.412 | 0.197 | - |
| 90 % | | 0.082 | - | - |
| None | D4 stream | 0.259 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 0.429 | 0.206 | - |
| 50 % | | 0.214 | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 0.560 | 0.267 | - |
| 50 % | | 0.491 | - | - |
| 90 % | | 0.491 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R4 stream | 1.155 | 0.525 | 0.275 |
| 50 % | | 1.155 | 0.525 | - |
| 90 % | | 1.155 | 0.525 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | D3 ditch | 1.60 | 0.72 | - |
| 50 % | | 0.80 | - | - |
| 90 % | | - | - | - |
| None | D4 stream | 0.87 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 1.57 | 0.70 | - |
| 50 % | | 1.57 | 0.70 | - |
| 90 % | | 0.78 | - | - |
| None | R2 stream | 0.93 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 2.04 | 0.91 | - |
| 50 % | | 1.02 | - | - |
| 90 % | | 0.80 | - | - |
| None | R4 stream | 1.30 | 0.59 | - |
| 50 % | | 1.30 | - | - |
| 90 % | | 1.30 | - | - |
| Multiple application | | | | |
| None | D3 ditch | 2.48 | 1.18 | 0.33 |
| 50 % | | 1.23 | 0.59 | - |
| 90 % | | 0.25 | - | - |
| None | D4 stream | 0.78 | - | - |
| 50 % | | - | - | - |
| 90 % | | - | - | - |
| None | D5 stream | 1.28 | 0.62 | - |
| 50 % | | 0.64 | - | - |
| 90 % | | - | - | - |
| None | R3 stream | 1.68 | 0.80 | - |
| 50 % | | 1.47 | - | - |
| 90 % | | 1.47 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R4 stream | 3.46 | 1.57 | 0.82 |
| 50 % | | 3.46 | 1.57 | - |
| 90 % | | 3.46 | 1.57 | - |

Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for the most sensitive organism group based on FOCUS Step 4 calculations – use in carrots

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|---------------|-------|-------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| Single application | | | | |
| None | R1 stream | 0.415 | 0.189 | - |
| 50 % | | 0.415 | - | - |
| 90 % | | 0.415 | - | - |
| None | R3 stream | 0.506 | 0.231 | - |
| 50 % | | 0.506 | - | - |
| 90 % | | 0.506 | - | - |
| None | R4 stream | 0.879 | 0.399 | 0.209 |
| 50 % | | 0.879 | 0.399 | - |
| 90 % | | 0.879 | 0.399 | - |
| Multiple application | | | | |
| None | R1 stream | 0.806 | 0.366 | 0.192 |
| 50 % | | 0.806 | 0.366 | - |
| 90 % | | 0.806 | 0.366 | - |
| None | R3 stream | 0.550 | 0.251 | - |
| 50 % | | 0.550 | - | - |
| 90 % | | 0.550 | - | - |
| None | R4 stream | 1.302 | 0.592 | 0.310 |
| 50 % | | 1.302 | 0.592 | - |
| 90 % | | 1.302 | 0.592 | - |
| Overall RAC = 0.334 µg/L | | PEC/RAC ratio | | |
| Single application | | | | |
| None | R1 stream | 1.24 | 0.57 | - |
| 50 % | | 1.24 | - | - |
| 90 % | | 1.24 | - | - |

| PEC _{sw} [µg/L] | Scenario | STEP 4 | | |
|--------------------------|----------------------|--------|------|------|
| Nozzle reduction | Vegetative strip [m] | None | 10 | 20 |
| | No spray buffer [m] | 5 | 10 | 20 |
| None | R3 stream | 1.51 | 0.69 | - |
| 50 % | | 1.51 | - | - |
| 90 % | | 1.51 | - | - |
| None | R4 stream | 2.63 | 1.19 | 0.63 |
| 50 % | | 2.63 | 1.19 | - |
| 90 % | | 2.63 | 1.19 | - |
| Multiple application | | | | |
| None | R1 stream | 2.41 | 1.10 | 0.57 |
| 50 % | | 2.41 | 1.10 | - |
| 90 % | | 2.41 | 1.10 | - |
| None | R3 stream | 1.65 | 0.75 | - |
| 50 % | | 1.65 | - | - |
| 90 % | | 1.65 | - | - |
| None | R4 stream | 3.90 | 1.77 | 0.93 |
| 50 % | | 3.90 | 1.77 | - |
| 90 % | | 3.90 | 1.77 | - |

1,2,4-Triazole

Table 9.5-42: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for 1,2,4-Triazole for each organism group based on FOCUS Steps 1 and 2 calculations for the use of SIP 41061 in pome/stone fruit, BBCH 51 (risk envelope for all crops)

| Group | | Fish acute | Fish prolonged | Invertebrate acute | Algae |
|-----------------|------------------------------|----------------------------|----------------------------|----------------------------|---|
| Test species | | <i>Oncorhynchus mykiss</i> | <i>Oncorhynchus mykiss</i> | <i>Daphnia magna</i> | <i>Pseudokirchneriella subcapitata</i> |
| Endpoint (µg/L) | | LC ₅₀ 498000 | NOEC 3200 | EC ₅₀ 900000 | E _r C ₅₀ 22500 |
| AF | | 100 | 10 | 100 | 10 |
| RAC (µg/L) | | 4980 | 320 | 9000 | 2250 |
| FOCUS Scenario | PEC _{sw-max} (µg/L) | | | | |
| Step 1 | | | | | |
| | 7.12 | 0.001 | 0.022 | 0.001 | 0.003 |
| Step 2 | | | | | |
| N-Europe | 1.16 | 0.000 | 0.004 | 0.000 | 0.001 |
| S-Europe | 1.96 | 0.000 | 0.006 | 0.000 | 0.001 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.3 Overall conclusions

For Prothioconazole the PEC/RAC ratios calculated with FOCUS modelling showed an acceptable risk to aquatic organisms at Steps 1-3 for all the intended apart from pome/stone fruits, where Step 4 calculation was required.

For 1,2,4-Triazole, acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1-2 scenarios.

For the metabolite Prothioconazole-desthio an acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Step 4. The mitigation measures required to protect aquatic organisms are discussed in the Part A of this dRR.

zRMS comments: The evaluation of the risk for aquatic organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Journal 2013;11(7):3290).

Since the endpoints of the formulated product SIP 41061 and of the active ingredient for *D.magna* are comparable (they differ less than a factor of 3), the risk assessment can be based on the EU agreed endpoints from Table 9.5-1. The toxicity for formulation SIP 41061 and *P.subcapitata* *Raphidocelis subcapitata* are slightly higher than toxicity for substance active - prothioconazole. Therefore, the risk assessment for SIP 41061 and *P.subcapitata* *Raphidocelis subcapitata* have been performed by zRMS.

As a conservative approach, in the table below please find the risk assessment for the lowest fish acute endpoint considering the formulated products SIP 41061: 1.69 mg a.s./L.

Pseudokirchneriella subcapitata
Raphidocelis subcapitata

| Group | Fish acute | |
|---|----------------------|---------|
| Test species | <i>P.subcapitata</i> | |
| Endpoint (µg/L) | LC ₅₀ | 1690 |
| AF | 100 | |
| RAC (µg/L) | 16.80 | 16.90 |
| Winter Cereals | | |
| BBCH 29 risk envelope for all crop field crops | | |
| FOCUS Scenario | PEC (µg/L) | PEC/RAC |
| Step 1 | | |
| | 21.72 | 1.29 |
| Step 2 | | |
| N-Europe | 1.84 | 0.1 |
| S-Europe | 1.84 | 0.1 |
| POME STONE/STONE FRUIT | | |
| BBCH 31 risk envelope for orchards | | |
| FOCUS Scenario | PEC (µg/L) | PEC/RAC |
| Step 1 | | |
| | 31.48 | 1.87 |
| Step 2 | | |
| N-Europe | 15.57 | 0.93 |
| S-Europe | 13.57 | 0.81 |

An acceptable risk when using the lowest fish acute endpoint for SIP 41061 - formulated product. Therefore, it is considered that SIP 41061 will not pose any unacceptable risks in the intended uses.

For prothioconazole the PEC/RAC ratios calculated with FOCUS modelling showed an acceptable risk to aquatic organisms at Steps 1, 3 for all the intended apart from pome/stone fruits, where Step 4 calculation was required.

For 1,2,4-triazole, acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1 2 scenarios.

For the metabolite prothioconazole-desthio an acceptable risk to aquatic organisms was demonstrated for all the intended uses with FOCUS Steps 1-4.

Final decision should be taken into account at MSs level based relevant scenarios.

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Prothioconazole and its representative formulated products. Full details of these studies are provided in the respective EU DAR and related documents). Effects on bees of SIP 41061 were not evaluated as part of the EU assessment of Prothioconazole. New data submitted with this application are listed in **Błąd! Nie można odnaleźć źródła odwołania.** and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

| Species | Substance | Exposure System | Results * | Reference |
|--------------------------|------------------------|---|--|---|
| <i>Apis mellifera</i> | Prothioconazole | Oral | LD ₅₀ > 71 µg a.s./bee | EFSA Conclusion |
| <i>Apis mellifera</i> | Prothioconazole | Contact | LD ₅₀ > 200 µg a.s./bee | EFSA Conclusion |
| <i>Apis mellifera</i> | Prothioconazole EC 250 | Oral | LD ₅₀ ≥ 48.7 µg a.s./bee | EFSA Conclusion |
| <i>Apis mellifera</i> | Prothioconazole EC 250 | Contact | LD ₅₀ ≥ 200 µg a.s./bee | EFSA Conclusion |
| <i>Apis mellifera</i> | SIP 41061 | Oral | LD ₅₀ > 2253.85 µg prod./bee <i>equivalent to:</i> LD₅₀ > 793.36 µg a.s./bee | KCP 10.3.1.1.1/01 Rossini L. (2021a) |
| <i>Apis mellifera</i> | SIP 41061 | Contact | LD ₅₀ > 2272.72 µg prod./bee <i>equivalent to:</i> LD₅₀ > 800.00 µg a.s./bee | KCP 10.3.1.1.1/01 Rossini L. (2021a) |
| <i>Apis mellifera</i> | SIP 41061 | Oral, cronic toxicity | LDD ₅₀ = 279.31 µg prod/bee/d <i>equivalent to:</i> LDD₅₀ > 100.55 µg a.s./bee/d | 10.3.1.2/01 Venturi S. (2020) |
| <i>Apis mellifera</i> | SIP 41061 | Oral, larval toxicity (repeated exposure) | NOED = 200 µg prod/larva/dev. period <i>equivalent to:</i> NOED = 72.00 µg a.s./larva /dev. period | 10.3.1.3/01 Colli M. (2020) |
| <i>Bombus terrestris</i> | SIP 41061 | Oral, acute toxicity | LD ₅₀ > 557.63 µg prod/bee <i>equivalent to:</i> LD₅₀ > 196.29 µg a.s./bee | KCP 10.3.1.1.1/01 Rossini L. (2021b) |
| <i>Bombus terrestris</i> | SIP 41061 | Contact, acute toxicity | LD ₅₀ > 568.18 µg prod/bee <i>equivalent to:</i> LD₅₀ > 200.00 µg a.s./bee | KCP 10.3.1.1.1/01 Rossini L. (2021b) |

* In bold, the endpoints used for the risk assessment of SIP 41061

9.6.1.1 Justification for new endpoints

The EU agreed endpoints for bees in the EFSA Conclusion of Prothioconazole were obtained from acute toxicity studies with representative formulations different from SIP 41061. New studies have been performed with SIP 41061 and submitted in the framework of this application. The results of these studies

are considered more relevant for SIP 41061, and therefore used in the risk assessment.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). To achieve a concise risk assessment, the risk envelope approach was applied. Here, the assessment for the use on cereals also covers the acute risk for bees from all other intended uses, having the highest single application rate (see Table 9.1.2c).

In addition, the risk to bees was also assessed according to the EFSA Guidance Document on the risk assessment of plant protection products on bees (EFSA 2013), even though this guidance is not yet adopted and currently under revision. Again, the risk envelope approach outlined in Table 9.1.2c was applied, assessing the risk for the use on cereals (highest application rate among field crops) and on stone fruits (highest application rate among orchards)

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the acute risk for bees due to the use of SIP 41061 in cereals (risk envelope) - SANCO/10329/2002

| Intended use | | Cereals (risk envelope) | | |
|-------------------------|-----------------------------------|--|---|--|
| Active substance | | Prothioconazole | | |
| Application rate (g/ha) | | 1 × 200 | | |
| Test design | LD ₅₀ (µg a.s./bee) | Single application rate (g a.s./ha) | Q _{HO} , Q _{HC} criterion: Q _H ≤ 50 | |
| Oral toxicity | LD ₅₀ > 793.36 | 200 | < 0.25 | |
| Contact toxicity | LD ₅₀ > 800.00 | | < 0.25 | |

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

The results of the above risk assessment allow to conclude acceptable risk to honeybees.

In addition, a screening risk assessment according to the EFSA 2013 was performed considering the results of the acute and chronic toxicity tests with SIP 41061. The results are reported in the tables below.

Table 9.6-3: Screening assessment of the risk for bees due to the use of SIP 41061 in cereals (risk envelope for field crops) – EFSA 2013

| Cereals (downward application) | | | | | |
|--------------------------------|-------------------------------|--------------------------------|----------|-------|---------|
| Oral route of exposure | Application rate (kg a.s./ha) | "calculation factor" (Ef x SV) | Endpoint | ETR | Trigger |
| HB - acute oral | 0.2 | 7.6 | 793.36 | 0.002 | 0.2 |
| HB - chronic | 0.2 | 7.6 | 100.55 | 0.015 | 0.03 |
| HB - larvae | 0.2 | 4.4 | 72 | 0.012 | 0.2 |
| BB – acute oral | 0.2 | 11.2 | 196.29 | 0.011 | 0.036 |
| Contact route of exposure | Application rate (g a.s./ha) | "calculation factor" (Ef x SV) | Endpoint | HQ | Trigger |
| HB - acute contact | 200 | 1 | 800 | 0.250 | 42 |
| BB - acute contact | 200 | 1 | 200 | 1.000 | 7 |

Table 9.6-4: Screening assessment of the risk for bees due to the use of SIP 41061 in stone fruits (risk envelope for orchards) – EFSA 2013

| Stone fruits (upward application) | | | | | |
|-----------------------------------|-------------------------------|--------------------------------|----------|-------|---------|
| Oral route of exposure | Application rate (kg a.s./ha) | "calculation factor" (Ef x SV) | Endpoint | ETR | Trigger |
| HB - acute oral | 0.16 | 7.6 | 793.36 | 0.002 | 0.2 |
| HB – chronic | 0.16 | 7.6 | 100.55 | 0.015 | 0.03 |
| HB – larvae | 0.16 | 4.4 | 72 | 0.012 | 0.2 |
| BB – acute oral | 0.16 | 11.2 | 196.29 | 0.011 | 0.036 |
| Contact route of exposure | Application rate (g a.s./ha) | "calculation factor" (Ef x SV) | Endpoint | HQ | Trigger |
| HB - acute contact | 160 | 1 | 800 | 0.250 | 42 |
| BB - acute contact | 160 | 1 | 200 | 1.000 | 7 |

The results of the above assessments showed acceptable acute and chronic risk of SIP 41061 to honeybee adults and larvae and to bumble bees, with TER and HQ values well below the triggers even at the screening step.

zRMS comment:

The risk assessment for bees was accepted by RMS.

Based on the acute risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values for adult bees from exposure of SIP 41061 are < 50, indicating an acceptable risk to adult bees.

Based on the chronic risk assessment with the consideration SANCO/10329/2002 rev.2 (final), October 17, 2002), HQ values from exposure of SIP 41061 are >1, indicating an acceptable chronic risk to bees. The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) as according to conclusions of the Central Zone Steering Committee (CZSC), recommendations of EFSA (2013) should not be considered for the zonal evaluations until the guidance is noted at the EU level. Therefore, risk assessment based on indications of EFSA (2013) must be performed at the national level by CMS that do require such evaluation.

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Effects on bumble bees

Acute oral and contact toxicity tests with SIP 41061 on *Bombus terrestris* are available; results are reported in table 9.6-1 and a full summary is provided in Appendix 2 of this Section. The risk assessment performed with these endpoints according to EFSA (2013) showed acceptable risk of SIP 41061 to bumble bees.

9.6.4 Effects on solitary bees

No study performed, no consolidate test guidance available.

9.6.5 Overall conclusions

The risk to bees from exposure to the formulation SIP 41061 was assessed in line with the Terrestrial Guidance document (SANCO/10329/2002). Both hazard quotients for oral and contact toxicity for honeybees resulted considerably lower than 50, indicating acceptable risk for SIP 41061.

In addition, the risk to bees was assessed according to the EFSA Guidance Document on the risk assessment of plant protection products on bees (EFSA 2013), even though this guidance is not yet adopted and currently under revision. The results of this assessment showed acceptable acute and chronic risk of SIP 41061 to honeybee adults and larvae and to bumble bees, with TER and HQ values well below the triggers already at screening step.

It is therefore possible to conclude that the proposed use of SIP 41061 poses an acceptable risk to bees.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with representative formulated product as part of the EU assessment of Prothioconazole. Full details of these studies are provided in the respective EU DAR and in EFSA, 2007. In Table 9.7.1, results were summarised.

Considering that SIP 41061 is a different formulated product respect the one evaluated during the Annex I inclusion, new data have been submitted by the applicant in the framework of this application which are listed in Appendix 1 and summarised in Appendix 2. In Table 9.7.2, the results of the studies conducted with SIP 41061 were summarised; in bold, the endpoints considered for the risk assessment.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods - EFSA, 2007

| Species | Substance | Exposure System | Results | Reference |
|----------------------------------|------------------------|--|---|---|
| <i>Typhlodromus pyri</i> | Prothioconazole EC 250 | Laboratory test, coffin cells | Mortality, reproduction LR ₅₀ = 18.7 g a.s./ha ER ₅₀ > 11 g a.s./ha | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Typhlodromus pyri</i> | Prothioconazole EC 250 | Extended laboratory test, bean leaves | Mortality, reproduction LR ₅₀ = 445.5 g a.s./ha ER ₅₀ > 380 g a.s./ha | |
| <i>Typhlodromus pyri</i> | Prothioconazole EC 250 | Extended laboratory test + aged (15d) | Fresh residue: LR ₅₀ > 300 g a.s./ha ER ₅₀ > 300 g a.s./ha Aged residue: LR ₅₀ > 300 g a.s./ha ER ₅₀ > 300 g a.s./ha | |
| <i>Aphidius rhopalosiphi</i> | Prothioconazole EC 250 | Laboratory test, glass plates | Mortality, reproduction LR ₅₀ = 139.9 g a.s./ha ER ₅₀ > 112 g a.s./ha | |
| <i>Aphidius rhopalosiphi</i> | Prothioconazole EC 250 | Extended laboratory test, wheat plants | Mortality, reproduction LR ₅₀ > 600 g a.s./ha ER ₅₀ > 600 g a.s./ha | |
| <i>Coccinella septempunctata</i> | Prothioconazole EC 250 | Laboratory test, glass plates | Mortality, reproduction LR ₅₀ = 229.8 g a.s./ha ER ₅₀ > 180 g a.s./ha | |
| <i>Chrysoperla carnea</i> | Prothioconazole EC 250 | Laboratory test, glass plates | Mortality, reproduction LR ₅₀ > 600 g a.s./ha ER ₅₀ > 600 g a.s./ha | |

| Species | Substance | Exposure System | Results | Reference |
|----------------------------|------------------------|---|---|---|
| <i>Poecilus cupreus</i> | Prothioconazole EC 250 | Laboratory test: quartz sand | Mortality, food consumption LR ₅₀ > 600 g a.s./ha ER ₅₀ > 600 g a.s./ha | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Aleochara bilineata</i> | Prothioconazole EC 250 | Laboratory test: quartz sand | Reproduction ER ₅₀ > 400 g a.s./ha | |
| <i>Poecilus cupreus</i> | Prothioconazole FS 100 | Extended laboratory test: soil (Lufa 2.1)., dressed seeds | Mortality, food consumption LR ₅₀ > 22.47 g a.s./ha ER ₅₀ > 22.47 g a.s./ha | |
| <i>Aleochara bilineata</i> | Prothioconazole FS 100 | Extended laboratory test: soil (Lufa 2.1)., dressed seeds | Reproduction ER ₅₀ > 19.34 g a.s./ha | |
| <i>Pardosa spp.</i> | Prothioconazole FS 100 | Extended laboratory test: soil (Lufa 2.1)., dressed seeds | Mortality, food consumption LR ₅₀ > 22.3 g a.s./ha ER ₅₀ > 22.3 g a.s./ha | |

Table 9.7-2: Endpoints and effect values relevant for the risk assessment for non-target arthropods - new studies submitted by the applicant performed with SIP 41061

| Species | Substance | Exposure System | Results | Reference |
|------------------------------|-----------|--|--|--------------------|
| <i>Aphidius rhopalosiphi</i> | SIP 41061 | Laboratory limit test, glass plates (2D) | Mortality, reproduction LR₅₀, ER₅₀ > 965.91 g prod./ha <i>Equivalent to: 340.0 g a.s./ha</i> | Lucchetti F., 2021 |
| <i>Typhlodromus pyri</i> | SIP 41061 | Laboratory limit test, glass plates (2D) | Mortality, reproduction LR₅₀, ER₅₀ > 965.91 g prod./ha <i>Equivalent to: 340.0 g a.s./ha</i> | Venturi S., 2021 |

Highest rate tested for reproduction

* Negative figures indicate positive effect in reproduction

9.7.1.1 Justification for new endpoints

As explained above, SIP 41061 was not evaluated as part of the EU assessment of Prothioconazole; therefore, only the new studies with SIP 41061 were used in the present risk assessment.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

To achieve a concise risk assessment, the risk envelope approach outlined in Table 9.1.2c was applied. Here, the assessment for the use on cereals and carrots also covers the risk to non-target arthropods from all other field crops with two applications, while the assessment for the use on stone fruits covers all the uses on orchards (worst-case for off-field assessment). A separate assessment was performed for cucurbits, which have the highest number of applications.

9.7.2.1 Risk assessment for in-field exposure

The results of the in-field risk assessment are reported in the table below.

Table 9.7-3: First-tier assessment of the in-field risk for non-target arthropods due to the use of SIP 41061

| | | | |
|--|--|--|--|
| Intended use | Cereals and carrots (risk envelope for field crops with 2 applications) | | |
| Product | SIP 41061 | | |
| Application rate | 2 x 581 g prod/ha (0.5 L prod/ha adjusted for product density*) | | |
| MAF | 1.7 | | |
| Test species | LR₅₀ (g prod./ha) | PER_{in-field} (g prod./ha) | HQ_{in-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 987.7 | 1.02 |
| Intended use | Cucurbits | | |
| Active substance/product | SIP 41061 | | |
| Application rate | 3 x 348.6 g prod/ha (0.3 L prod/ha adjusted for product density*) | | |
| MAF | 2.3 | | |
| Test species | LR₅₀ (lab.) (g prod./ha) | PER_{in-field} (g prod./ha) | HQ_{in-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 801.8 | 0.83 |
| Intended use | Stone fruits (risk envelope for orchards) | | |
| Active substance/product | SIP 41061 | | |
| Application rate | 2 x 464.8 g prod/ha (0.4 L prod/ha adjusted for product density*) | | |
| MAF | 1.7 | | |
| Test species | LR₅₀ (lab.) (g prod./ha) | PER_{in-field} (g prod./ha) | HQ_{in-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 790.2 | 0.82 |

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.
(*) Density = 1.162 kg/L from dRR Part B Section B1,B2,B4

The assessment with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* showed acceptable in-field risk to non-target arthropods.

9.7.2.2 Risk assessment for off-field exposure

The results of the off-field risk assessment are reported in the table below.

Table 9.7-4: First-tier assessment of the off-field risk for non-target arthropods due to the use of SIP 41061

| | | | | | | |
|--|---|--|---|-----------|--|---|
| Intended use | | Cereals and carrots (risk envelope for field crops with 2 applications) | | | | |
| Product | | SIP 41061 | | | | |
| Application rate | | 2 x 581 g prod./ha (0.5 L prod./ha adjusted for product density*) | | | | |
| MAF | | 1.7 | | | | |
| vdf | | 5/ 10 | | | | |
| Test species | LR₅₀ (g prod./ha) | Drift rate (82nd %ile) | PER_{off-field} (g prod./ha) | CF | corrected PER_{off-field} | HQ_{off-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 2.38 % | 4.7/ 2.35 | 10 | 47.0/ 23.5 | 0.05/ 0.024 |
| Intended use | | Cucurbits | | | | |
| Product | | SIP 41061 | | | | |
| Application rate | | 3 x 348.6 g prod./ha (0.3 L prod./ha adjusted for product density*) | | | | |
| MAF | | 2.3 | | | | |
| vdf | | 5/ 10 | | | | |
| Test species | LR₅₀ (g prod./ha) | Drift rate (77th %ile) | PER_{off-field} (g prod./ha) | CF | corrected PER_{off-field} | HQ_{off-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 2.01 % | 3.22/ 1.61 | 10 | 32.2/ 16.1 | 0.03/ 0.017 |
| Intended use | | Stone fruits (risk envelope for orchards) | | | | |
| Product | | SIP 41061 | | | | |
| Application rate | | 2 x 464.8 g prod./ha (0.4 L prod./ha adjusted for product density*) | | | | |
| MAF | | 1.7/ 10 | | | | |
| vdf | | 5 | | | | |
| Test species | LR₅₀ (g prod./ha) | Drift rate (82nd %ile) | PER_{off-field} (g prod./ha) | CF | corrected PER_{off-field} | HQ_{off-field} criterion: HQ ≤ 2 |
| <i>Aphidius rhopalosiphi</i> , <i>Typhlodromus pyri</i> | > 965.91 | 12.13 % | 19.17/ 9.58 | 10 | 191.7/ 95.8 | 0.20/ 0.099 |

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

The assessment with the standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* showed acceptable off-field risk to non-target arthropods.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

Based on the results of laboratory (glass-plate) tests on *Aphidius rhopalosiphi* and *Typhlodromus pyri* performed with SIP 41061, acceptable in-field and off-field risk can be concluded for all the intended uses. No risk mitigations are needed.

zRMS comment:

zRMS agrees with the Applicant's assessment with the in-field risk to non-target arthropods from the proposed use of SIP 41061, above. A low risk is demonstrated to the 2 standard first tier (HQ in-field and HQ off-field ≤ 2). Therefore, this assessment indicates that SIP 41061 poses low risk in-field and off-field for non-target arthropods following application according to the proposed use patterns.

The VDF is set to 5 in the Central zone instead of 10 for only 2-D studies (In this case in 3-D studies VDF correction is 1). However, according to the part of the Bullet Points in Ecotoxicology, by the Central Zone Steering Committee (CZSC April 2022), the use of VDF of 5 is a deviation of the noted EU agreed ESCORT 2 guidance. Therefore, PER off-field with the VDF of 10 was recalculated by RMS. The conclusions of the assessment have not changed. SIP 41061 poses low risk in-field and off-field for non-target arthropods following application according to the proposed use patterns.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Prothioconazole and its metabolites and with the representative formulation evaluated in Annex I inclusion. Full details of these studies are provided in the EU DAR.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of SIP 41061 were not evaluated as part of the EU assessment of Prothioconazole. Toxicity tests on *Eisenia Andrei*, *Hypoaspis aculeifer* and *Folsomia candida* were performed with SIP 41061 and submitted with this application (Table 9.8-2); they are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

| Species | Substance | Exposure System | Results | Reference |
|------------------------|-----------------------|---|---|---|
| <i>Eisenia fetida</i> | Prothioconazole | acute | LC ₅₀ > 1000 mg a.s./kg dw soil LC _{50,corr} > 500 mg a.s./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia foetida</i> | Prothioconazole EC250 | Overspray Chronic 10 % peat content | NOER = 1000 g a.s./ha NOEC = 1.33 mg a.s./kg dw | EFSA Scientific Report (2007) 106, 1-98 |

| Species | Substance | Exposure System | Results | Reference |
|---|--------------------------|--|--|---|
| | | (Endpoint as mg/kg calculated from applied rate, using default assumption 5 cm incorporation and soil bulk density 1.5 g/mL) | NOEC _{corr} = 0.665 mg a.s./kg dw* | |
| <i>Folsomia candida</i> | Prothioconazole | chronic | NOEC = 64 mg a.s./kg dw soil NOEC _{corr} = 32 mg a.s./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Hypoaspis aculeifer</i> | Prothioconazole | chronic | NOEC = 100 mg a.s./kg dw soil NOEC _{corr} = 50 mg a.s./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole EC 250 | acute | LC ₅₀ > 249.3 mg a.s./kg dw soil LC _{50,corr} > 124.7 mg a.s./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole EC 250 | chronic | NOEC = 1.33 mg a.s./kg dw soil NOEC _{corr} = 0.67 mg a.s./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole-desthio | acute | LC ₅₀ > 1000 mg p.m./kg dw soil LC _{50,corr} > 500 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole-desthio | chronic | NOEC = 1 mg p.m./kg dw soil NOEC _{corr} = 0.5 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Folsomia candida</i> | Prothioconazole-desthio | chronic | NOEC = 62.5 mg p.m./kg dw soil NOEC _{corr} = 31.25 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole-S-methyl | acute | LC ₅₀ > 1000 mg p.m./kg dw soil LC _{50,corr} > 500 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Eisenia fetida</i> | Prothioconazole-S-methyl | chronic | NOEC = 100 mg p.m./kg dw soil NOEC _{corr} = 50 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| <i>Folsomia candida</i> | Prothioconazole-S-methyl | chronic | NOEC = 31.6 mg p.m./kg dw soil NOEC _{corr} = 15.8 mg p.m./kg dw soil ^(A) | EFSA Scientific Report (2007) 106, 1-98 |
| Field study (grassland site) | | | | |
| Species: <i>Lumbricus terrestris</i> , <i>L. rubellus</i> , <i>L. castanea</i> , <i>Aporrectodea caliginosa</i> , <i>A. terrestris longa</i> Test item, rate: Prothioconazole EC 250, 3 x 200 g a.s./ha Results: 5 different species identified and assessed. | | | | |

| Species | Substance | Exposure System | Results | Reference |
|--|-----------|-----------------|---------|-----------|
| <p>46% reduction in the number of <i>A. caliginosa</i> juveniles 7 weeks after first application (2 weeks after final application). No adverse effect 5 month after first application.</p> <p>Maximum measured soil PEC: 0.052 mg prothioconazole/kg based on soil sampling depth of 10 cm, which is equivalent to a soil PEC of 0.104 mg prothioconazole/kg over the standard 5 cm depth</p> <p>Desthio metabolite confirmed as being present in field study: maximum concentration recorded 7 days after second application, was 0.106/kg which is equivalent to 0.212 mg desthio/kg over the standard 5 cm depth.</p> | | | | |
| Litter bag test | | | | |
| <p>Time scale: 126 days</p> <p>Test substance: Prothioconazole FS 100 (23.2 g a.s./ha) followed by Prothioconazole EC 250 (3 x 200 g a.s./ha during 26 day period)</p> <p>Results (% field soil litter degradation): after 34 days: test item 51.7, control 52.1; after 95 days: test item 74.3, control 78.4; after 126 days: test item 92.0, control 91.2</p> | | | | |

^A corrected endpoint due to log Pow >2

In bold, the endpoints used in the risk assessment

Table 9.8-2: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) – SIP 41061

| Species | Substance | Exposure System | Results | Reference |
|----------------------------|-----------|--|--|----------------------|
| <i>Eisenia andrei</i> | SIP 41061 | Limit test Mixed into substrate 56 d, chronic 10 % peat content | NOEC = 1000 mg prod/kg dw soil <i>Equivalent to</i> NOEC = 360 mg as/kg dw soil NOEC_{corr} = 180 mg a.s./kg dw soil EC ₁₀ : -- (limit test) | Pecorari F., 2021 |
| <i>Folsomia candida</i> | SIP 41061 | Mixed into substrate 28 d, chronic 5% peat content | NOEC = 1000 mg prod/kg dw soil <i>Equivalent to</i> NOEC = 360 mg as/kg dw soil NOEC_{corr} = 180 mg a.s./kg dw soil EC ₁₀ : -- * | Grandolini G., 2020a |
| <i>Hypoaspis aculeifer</i> | SIP 41061 | Mixed into substrate 14 d, chronic 5% peat content | NOEC _(reproduction) = 180 mg prod/kg dw soil <i>Equivalent to</i> NOEC = 64.8 mg as/kg dw soil NOEC_{corr} = 32.4 mg as/kg dw soil EC ₁₀ : -- * | Grandolini G., 2020b |

In bold, the endpoints used in the risk assessment

* no statistically significant concentration/response was found ($p(F) > 0.05$; i.e.slope of the relationship was not significantly different from 0); for this reason, the ECx could not be valid.

9.8.1.1 Justification for new endpoints

Both the EU agreed endpoints and the endpoints obtained from studies with SIP 41061 were used for risk assessment.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17,

2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for Prothioconazole and its metabolites.

To achieve a concise risk assessment, a risk envelope approach was applied. Here, the highest PEC_{soil} , resulting from the use on cereals and carrots, were used in the risk assessment for non-target soil organisms (see Table 9.1.2e).

Table 9.8-3: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of SIP 41061 on cereals and carrots (risk envelope)

| Intended use | Cereals and carrots (risk envelope) | | |
|---|---|--|--|
| Acute effects on earthworms | | | |
| Product/active substance | LC ₅₀ corr (mg/kg dw) | PEC _{soil} (mg/kg dw) | TER _a (criterion TER ≥ 10) |
| Prothioconazole | ≥ 500 | 0.213 | ≥ 2347.4 |
| Prothioconazole-desthio | ≥ 500 | 0.188 | ≥ 2659.6 |
| Prothioconazole-S-methyl | ≥ 500 | 0.052 | ≥ 9615.4 |
| Chronic effects on earthworms (<i>Eisenia fetida</i>) | | | |
| Product/active substance | EC ₁₀ corr or NOEC (mg/kg dw) | PEC _{soil} (mg/kg dw) | TER _{tt} (criterion TER ≥ 5) |
| Prothioconazole | 0.665 | 0.213 | 3.12 |
| Prothioconazole in SIP 41061 | 180 | 0.213 | 845.0 |
| Prothioconazole-desthio | 0.5 | 0.188 (carrots)* 0.085 (stone fruits)** | 2.7 5.9 |
| Prothioconazole-S-methyl | 50 | 0.052 | 961.5 |
| Chronic effects on other soil macro- and mesofauna (<i>Folsomia candida</i>) | | | |
| Product/active substance | NOECcorr (mg/kg dw) | PEC _{soil} (mg/kg dw) | TER _{tt} (criterion TER ≥ 5) |
| Prothioconazole in SIP 41061 | 180 | 0.213 | 845.0 |
| Prothioconazole | 32 | 0.213 | 150.2 |
| Prothioconazole-desthio | 31.25 | 0.188 | 166.2 |
| Prothioconazole-S-methyl | 15.8 | 0.052 | 303.8 |
| Chronic effects on other soil macro- and mesofauna (<i>Hypoaspis aculeifer</i>) | | | |
| Product/active substance | NOECcorr (mg/kg dw) | PEC _{soil} (mg/kg dw) | TER _{tt} (criterion TER ≥ 5) |
| Prothioconazole in SIP 41061 | 32.4 | 0.213 | 152.1 |
| Prothioconazole | 50 | 0.213 | 234.7 |

TER values shown in bold fall below the relevant trigger.

* PEC_{soil} for carrots, representative for crops with highest application rate and highest number of applications (see Table 9.1.2e)

** PEC_{soil} for stone fruits, representative for crops with lower application rate and lower number of applications (see Table 9.1.2e)

Based on this assessment, acceptable risk to soil macro-organisms is expected from Prothioconazole and its metabolites, with the exception of the risk of Prothioconazole-desthio to earthworms, which requires further consideration for the crops with worst case use pattern.

9.8.2.2 Higher-tier risk assessment

As reported in the EFSA Conclusions of Prothioconazole, an earthworm field study was performed with the product Prothioconazole 250 EC, applied on a natural earthworm population in a grassland area. The product was applied 3 times at a rate of 200 g a.s./ha, which is significantly higher than the worst-case use pattern of SIP 41061 (2 x 200 g a.s./ha). The results of this study showed no ecologically adverse effect on earthworm populations (no adverse effect 5 months after the first application),

As stated in the EFSA Conclusion, for the risk of Prothioconazole-desthio to earthworms “*No adverse effects to be expected, see results of the field study. Desthio-metabolite confirmed as being present in field study: maximum concentration recorded 7 days after second application, was 0.106 mg/kg which is equivalent to 0.212 mg desthio/kg over the standard 5 cm depth*”.

The maximum PEC_{soil} calculated for Prothioconazole-desthio for the intended uses of SIP 41061 is 0.188 mg p.m./kg soil, which is lower than the exposure found in the earthworm field study. Therefore, no unacceptable risk on earthworms is expected from Prothioconazole-desthio following application of SIP 41061 according to the intended use pattern.

9.8.3 Overall conclusions

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the Guidance Document on terrestrial ecotoxicology (SANCO/10329/2002), considering the EU agreed endpoints and the results of laboratory tests with SIP 41061.

The results of this assessment showed acceptable risk to soil macro-organisms for Prothioconazole and its metabolites, with the exception of the risk of Prothioconazole-desthio to earthworms, which requires further considerations for the crops with worst case use pattern. The results of a field study on earthworms, which involved a worst-case use pattern compared to SIP 41061, and a concentration of Prothioconazole-desthio higher than the one expected from the intended uses, showed no ecologically adverse effect on earthworm populations. Therefore, it is possible to conclude that exposure to Prothioconazole-desthio following application of SIP 41061 poses an acceptable risk to earthworms.

zRMS comment:

The chronic TER values for earthworms and other soil macro-organism for ppp SIP 41061 were above the relevant Annex VI trigger of 5.

However in case of a.s. – prothioconazole and its metabolite M04 further refinement was needed.

Taking into account that the risk for a.s. calculated from ppp for earthworm was above the trigger value of 5, the risk is considered acceptable by zRMS.

In addition, no adverse effects are to be expected, as proven by the results of the field study (EFSA Scientific Report, 2007). Desthio-metabolite was confirmed as being present in field study after application of Prothioconazole with a maximum concentration recorded of 0.106 mg/kg at 7 days after second application. The depth of soil from which the sample cores were taken is not stated in the study report, but is highly unlikely to have been less than 5 cm and would more typically be expected to be 10 cm. As such, the maximum PEC for prothioconazole and the metabolite JAU 6476-desthio is likely to be an overestimation, with the level of exposure in the field study being considered more realistic. In the field study, from the 5 identified earthworm species, only the number of juveniles of 1 (*Aporrectodea caliginosa*) was affected. In fact, by the end of the study, an overall increase in the number and biomass of earthworms in the treated plots was observed (11 months of exposure with 3 applications of 200g a.s./ha).

Therefore, it is concluded that SIP 41061 and metabolites such as: M01 and M04 do not pose long-term risk to earthworms and other soil macro- and mesofauna when applied according to the pro-

posed uses rates.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Prothioconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents. Effects on soil microorganisms of SIP 41061 were not evaluated as part of the EU assessment of Prothioconazole. New data submitted with this application is summarised in Table 9.9-2, listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

| Endpoint | Substance | Exposure System | Results | Reference |
|------------------|--------------------------|-----------------|---|--|
| N-mineralisation | Prothioconazole | 28 d | Effect <25% at the rate of 2.0 kg a.s./ha, equivalent to 2.71 mg a.s./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |
| | Prothioconazole-desthio | 42 d | Effect <25% at the rate of 0.2 kg p.m./ha, equivalent to 0.27 mg p.m./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |
| | | 28 d | Effect <25% at the rate of 1.0 kg p.m./ha, equivalent to 1.37 mg p.m./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |
| | Prothioconazole-S-methyl | 28 d | Effect <25% at the rate of 2.0 kg p.m./ha, equivalent to 2.69 mg p.m./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |
| C-mineralisation | Prothioconazole | 28 d | Effect <25% at the rate of 2.0 kg a.s./ha, equivalent to 2.71 mg a.s./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |
| | Prothioconazole-S-methyl | 28 d | Effect <25% at the rate of 2.0 kg p.m./ha, equivalent to 2.69 mg p.m./kg soil | EFSA Scientific Report (2007) 106, 1-98, DAR |

Table 9.9-2: Endpoints and effect values relevant for the risk assessment for soil microorganisms – formulated product SIP 41061

| Endpoint | Substance | Exposure System | Results | Reference |
|------------------|-----------|------------------------------------|---|------------------|
| N-mineralisation | SIP 41061 | 28 d, sandy loam agricultural soil | Effect <25% (8.99%) at the rate of 8.73 mg prod/kg dry soil, equivalent to 3.07 mg a.s./kg dry soil | Rossini L., 2021 |

9.9.1.1 Justification for new endpoints

Since studies with SIP 41061 have been performed, they were used for the risk assessment together with the EU agreed endpoints.

9.9.2 Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach was applied. Here, the assessment for the use on cereals and carrots also covers the risk for the soil microorganisms from all other intended uses (see 9.1.2e).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of SIP 41061 on cereals and carrots (risk envelope)

| | | | |
|------------------------------|--|---|------------------|
| Intended use | Cereals and carrots (risk envelope) | | |
| N-mineralisation | | | |
| Product/active substance | Max. conc. with effects ≤ 25 % (mg/kg dry soil) | PEC _{soil} (mg/kg dry soil) | Risk acceptable? |
| Prothioconazole in SIP 41061 | 3.07 | 0.213 | yes |
| Prohioconazole | 2.71 | 0.213 | yes |
| Prohioconazole-desthio | 1.37 | 0.188 | yes |
| Prohioconazole-S-methyl | 2.69 | 0.052 | yes |

9.9.3 Overall conclusions

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the Guidance Document on terrestrial ecotoxicology (SANCO/10329/2002). No significant effects on N-transformation were observed in soil at concentrations of Prothioconazole and its metabolites at rates much higher than the one expected from product application. Therefore, it is possible to conclude that the proposed uses of SIP 41061 pose an acceptable risk to the biological activity of micro-organisms in soil.

zRMS comments:

The risk assessment for soil micro-organism after exposure of **SIP 41061** has been accepted by the zRMS. The effects on the nitrogen transformations are acceptable (<25%) at concentration which is higher than the maximum relevant PECs for the maximum application rate of **SIP 41061**. The results indicate no adverse effect on nitrogen transformation even at soil concentrations well higher than the ones expected following application of **SIP 41061**. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals and carrots also covers the risk for non-target terrestrial plants from all other intended uses SIP 41061.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with Prothioconazole and its representative formulation evaluated in Annex I first inclusion. Full details of these studies are provided in the respective EU DAR and related documents (see Table 9.10-1).

New studies on the toxicity to non-target terrestrial plants have been conducted with SIP 41061, these new data submitted with this application are summarised in Table 9.10-2, listed in Appendix 1 summarised in Appendix 2.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

| Substance | Most sensitive species | Exposure System | Results | Reference |
|------------------------|---|-----------------|-----------------------------|--|
| Prothioconazole | <i>Amaranthus retroflexus</i> | Pre-emergence | 5% effect at 200 g a.s./ha | EFSA Scientific Report (2007) 106, 1-98, DAR |
| | <i>Amaranthus retroflexus</i> , <i>Beta vulgaris</i> | Post-emergence | 10% effect at 250 g a.s./ha | |
| Prothioconazole EC 250 | <i>Amaranthus retroflexus</i> | Pre-emergence | 5% effect at 200 g a.s./ha | |
| | - | Post-emergence | no effect at 250 g a.s./ha | |

Table 9.10-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants – SIP 41061

| Species | Substance | Exposure System | Results | Reference |
|--|-----------|-----------------------------------|--|---------------------|
| <u>Dicotyledonous:</u> <i>Beta vulgaris</i> <i>Helianthus annuus</i> <i>Fagopyrum</i> <i>Esculentum</i> <i>Lycopersicon esculentum</i> <u>Dicotyledonous:</u> <i>Hordeum vulgare</i> <i>Zea mais</i> | SIP 41061 | Vegetative vigour test 21 days | Plant survival: ER ₅₀ > 570 g prod./ha (for all species) Biomass and fresh shoot weight ER ₅₀ > 570 g prod./ha (for all species) No phtotoxic effects observed | Colli M.. (2022) |

9.10.1.1 Justification for new endpoints

The new endpoints derived from vegetative vigour with SIP 41061 have been taken into consideration to perform the risk assessment.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use on cereals and carrots also covers the risk to non-target terrestrial plants from all other field crops, while the assessment for the use on stone fruits covers all the uses on orchards (highest drift percentages). The results of the in assessment, reported in the table below, show acceptable risk to non-target plants for SIP 41061 applied according to the intended uses.

Table 9.10-3: Assessment of the risk for non-target plants due to the use of SIP 41061

| | | | | |
|---------------------------------|---|---|---|-----------------------------------|
| Intended use | | Cereals and carrots (risk envelope for field crops) | | |
| Active substance/product | | SIP 41061 | | |
| Application rate (g/ha) | | 2 x 581 g prod/ha (0.5 L prod/ha adjusted for product density*) | | |
| MAF | | 1 # | | |
| Test species | ER₅₀ (g prod./ha) | Drift rate (90th %ile) | PER_{off-field} (g prod./ha) | TER criterion: TER ≥ 5 |
| 6 species of non-target plants | > 570 | 2.77 % | 16.1 | > 35.4 |
| Intended use | | Stone fruits (risk envelope for orchards) | | |
| Active substance/product | | SIP 41061 | | |
| Application rate (g/ha) | | 2 x 464.8 g prod/ha (0.4 L prod/ha adjusted for product density*) | | |
| MAF | | 1 # | | |
| Test species | ER₅₀ (g prod./ha) | Drift rate (90th %ile) | PER_{off-field} (g prod./ha) | TER criterion: TER ≥ 5 |
| 6 species of non-target plants | > 570 | 15.73 % | 73.1 | > 7.8 |

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

(*) Density = 1.162 kg/L from dRR Part B Section B1,B2,B4

as recommended by EFSA (2015)⁵ only single application (MAF=1) was considered for the risk assessment of non-target plants

9.10.2.3 Higher-tier risk assessment

Not relevant.

⁵ EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

9.10.2.4 Risk mitigation measures

Not necessary.

9.10.3 Overall conclusions

The evaluation of the risk for non-target plants was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The risk assessment was conducted on the basis of the worst-case application scenario, considering the available endpoints from a vegetative vigour test with SIP 41061. Application of the product according to the intended uses does not present an unacceptable risk for non-target terrestrial plants. No mitigation measures are required.

zRMS comment:

The Applicant submitted a study on the effects of SIP 41061 on non-target terrestrial plants for the vegetative vigour test (OECD 227 "Terrestrial Plant Test: Vegetative Vigour Test). (Effects of the SIP 41061 on terrestrial plants – Vegetative vigour Test. Report No. BT150/21 Colli M., 2022). The study on the effects of SIP 41061 on non-target terrestrial plants in terms of seedling emergence and seedling growth test (OECD Guideline for the Testing of Chemicals No. 208 “Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test”) was not provided by Applicant.

However, in this case – in opinion RMS - the available data are sufficient to indicate acceptable risk for non-target plants, including emergence seed, for these reasons:

- The data reported in the EFSA Conclusion (2007) show very low toxicity to non-target plants for the a.s. prothioconazole and for its representative formulation, both following “pre-emergence test” (= seedling emergence) and following “post-emergence test” (=vegetative vigour). In particular, in the preemergence test the a.s. prothioconazole showed 5% effect at the rate of 200 g a.s./ha, which is the maximum intended rate for SIP 41061.
- Also the vegetative vigour test (limit test) performed with SIP 41061 showed low toxicity to NTPs, with $ER_{50} > 570$ g prod/ha (equivalent to 200.64 g a.s./ha, the only tested rate). As reported in Section B9, the risk assessment based on this endpoint concluded acceptable risk for SIP 41061.
- SIP 41061 is not a herbicide. It is a fungicide applied at post-emergence of crops. Due to the period of application and since the available studies with SIP 41061 and with the a.s. indicate low toxicity to NTPs, a vegetative vigour test appears the study most representative and sufficient to assess the risk of SIP 41061 to NTPs.

Nevertheless, if a quantitative assessment should be provided also for emerging seeds, this could be performed considering the EU endpoint of the a.s. prothioconazole ($ER_{50} > 200$ g a.s./ha) and considering the worst-case $PER_{off-field}$ calculated in section B9 (use on stone fruits). The risk assessment for emerging seeds based the EU data was performed by zRMS.

Assessment of the risk for non-target plants due to the use of SIP 41061

| | | | | |
|--|---|--|---|-----------------------------------|
| Intended use | | Cereals and carrots (risk envelope for field crops) | | |
| Active substance/product | | SIP 41061 | | |
| Application rate (g/ha) | | 2 x 200 g s.a./ha | | |
| MAF | | 1 # | | |
| Test species | ER₅₀ (g a.s./ha) | Drift rate (90th % ile) | PER_{off-field} (g prod./ha) | TER criterion: TER ≥ 5 |
| Seedling emergence EU endpoint of the a.s. prothioconazole | > 200 | 2.77 % | 5.54 | 36.1 |
| Intended use | | Stone fruits (risk envelope for orchards) | | |
| Active substance/product | | SIP 41061 | | |
| Application rate (g/ha) | | 2 x 200 g s.a./ha | | |
| MAF | | 1 # | | |
| Test species | ER₅₀ (g prod./ha) | Drift rate (90th %ile) | PER_{off-field} (g prod./ha) | TER criterion: TER ≥ 5 |
| Seedling emergence EU endpoint of the a.s. prothioconazole | > 200 | 15.73 % | 31.46 | 6.36 |

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

as recommended by EFSA (2015)¹ only single application (MAF=1) was considered for the risk assessment of non-target plants

The results of such assessment, reported in the table above, confirm that SIP 41061, applied according to the intended use, poses acceptable risk to non-target plants, included emerging seeds.

Conclusion:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group cereals and carrots also covers the risk for non-target terrestrial plants from all other intended uses SIP 41061 in group field crops. In addition, an assessment was made for stone fruit. The endpoints with the relevant formulation SIP 41061 and substance active – prothioconazole have been used in the risk assessment. No unacceptable risks are expected due to application of SIP 41061 in the intended uses as TER_{LT} is above trigger of 5.

The risk assessment for non-target plants based on seedling emergence parameter should be considered at MSs level.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

No additional information presented.

9.12 Monitoring data (KCP 10.8)

No additional information presented.

9.13 Classification and Labelling

| | |
|--------------------------------------|--|
| Hazard pictograms: | GHS09 |
| Signal word: | Warning |
| Hazard statement(s): | H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects. |
| Precautionary statement(s): | P273 Avoid release to the environment. P391 Collect spillage. P501 Dispose of contents/container in accordance to national regulations. |
| Additional labelling phrases: | EUH208 "Contains 1,2-benzisothiazol-3-one. May produce an allergic reaction") EUH401 ("To avoid risk to human health and the environment, comply with the instruction for use") |
| | |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | To protect aquatic organism respect an unsprayed buffer zone to surface water bodies. <i>[mitigation reported in Part A of this dRR]</i> |

zRMS comment:

We agree with the classification of the product: H410.

Justification: No acute classification proposed as all measured LC₅₀ values for the formulation were above 1 mg product/L.

Chronic classification was based on NOEC value (Reduction in swim-up and increase in time to swim-up) of 0.308 mg a.s./L_{mm}, content of a.s. in PPP is 400 g => Aquatic chronic 1

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 10.1.1.2 | Infatino A., Bonzini S. | 2022 | Prothioconazole-desthio (M04) residue decline in orchards and cucur-bits – Kinetic evaluation of residue trials. Report N. KINPT_01 Non GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.2.1/01 | Corboli M. | 2021 | Acute immobilization test on <i>Daphnia magna</i> under semi-static conditions with test item SIP 41061. Report N. BT137/21 BioTecnologie BT Srl GLP Unpublished | N | Sipcam Oxon SpA |
| | Fifi A. P. | 2022 | Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 Report N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5 | N | Sipcam Oxon S.p.A. |
| KCP 10.2.1/02 | Mantilacci S. | 2021 | Toxicity evaluation of test item SIP 41061 on green alga <i>Pseudokirchneriella subcapitata</i> in a growth inhibition test Report N. BT138/21 BioTecnologie BT Srl GLP Unpublished | N | Sipcam Oxon SpA |

| 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 |
|-----------------|------------|------|--|-------------------------|--------------------|
| | Fifi A. P. | 2022 | Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 Report N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5 | N | Sipcam Oxon S.p.A. |
| KCP 10.3.1.1/01 | Rossini L. | 2021 | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera</i> L.,) in a laboratory test Report N. BT139/21 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.3.1.1/02 | Rossini L. | 2021 | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test Report N. BT140/21 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.3.1.2/01 | Rossini L. | 2021 | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera</i> L.,) in a laboratory test Report N. BT139/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 10.3.1.1/01 | N | Sipcam Oxon SpA |

| 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 10.3.1.2/02 | Rossini L. | 2021 | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test Report N. BT140/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 10.3.1.1/02 | N | Sipcam Oxon SpA |
| KCP 10.3.1.2 | Venturi S. | 2020 | Chronic oral effects of SIP 41061 on adult worker honeybees (<i>Apis mellifera</i> L.) 10-day feeding laboratory test Report N. BT115/0 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |
| | Aversa S. | 2020 | Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole and Azoxystrobin in water and sugar feeding solutions coming from ecotox laboratory tests (honeybees) Report N. BT214/20 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/03 in dRR Section B5 | N | Sipcam Oxon S.p.A. |
| KCP 10.3.1.3 | Colli M. | 2020 | Effects of SIP 41061 on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. Report N. BT116/20 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |

| 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 |
|-----------------|--------------|------|--|-------------------------|--------------------|
| | Aversa S. | 2020 | Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole and Azoxystrobin in water and sugar feeding solutions coming from ecotox laboratory tests (honeybees) Report N. BT214/20 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/05 in dRR Section B5 | N | Sipcam Oxon S.p.A. |
| KCP 10.3.2.1/01 | Lucchetti F. | 2021 | Effects of SIP 41061 on the parasitic wasp <i>Aphidius rhopalosiphi</i> under Laboratory Conditions Report N. BT141/21 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.3.2.1/02 | Venturi S. | 2021 | Effects of SIP41061 on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under laboratory Conditions. Report N. BT142/21 BioTecnologie BT S.r.l GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.4.1.1 | Pecorari. F. | 2020 | Effects of the product SIP 41061 on reproduction and growth of the earthworm <i>Eisenia Andrei</i> in artificial soil. Report N. BT118/20 BioTecnologie BT S.r.l, GLP Unpublished | N | Sipcam Oxon SpA |

| 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 |
|-----------------|---------------|------|---|-------------------------|--------------------|
| | Aversa S. | 2020 | Validation of an HPLC-MS/MS analytical method for the determination of Prothioconazole in soil coming from ecotox laboratory tests (earthworms) Report N. BT215/20 BioTecnologie BT S.r.l., GLP Unpublished Submitted as KCP 5.1.2/03 in dRR Section B5 | N | Sipcam Oxon S.p.A. |
| KCP 10.4.2.1/01 | Grandolini G. | 2020 | Effects of SIP 41061 on reproduction of the collembolan <i>Folsomia candida</i> in artificial soil. Report N. BT119/20 BioTecnologie BT S.r.l., GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.4.2.1/02 | Grandolini G. | 2020 | Effects of SIP 41061 on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in soil. Report N. BT117/20 BioTecnologie BT S.r.l., GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.5 | Rossini L. | 2021 | Assessment of the effects of the product SIP 41061 on soil microorganisms nitrification. Report No. BT143/21 BioTecnologie BT S.r.l., GLP Unpublished | N | Sipcam Oxon SpA |
| KCP 10.6.2 | Colli M. | 2022 | Effects of the SIP 41061 on terrestrial plants – Vegetative vigour test. Report No. BT150/221 BioTecnologie BT S.r.l., GLP Unpublished | N | Sipcam Oxon SpA |

| 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 |
|------------|------------|------|---|-------------------------|--------------------|
| | Fifi A. P. | 2022 | Validation of the analytical method (SANTE/2020/12830 Rev.1) for the determination of Prothioconazole and Prothioconazole-desthio in aqueous matrix and sugar feeding solutions with product SIP 41061 Report N. BT193/21 BioTecnologie BT S.r.l GLP Unpublished Submitted as KCP 5.1.2/04 in dRR Section B5 | N | Sipcam Oxon S.p.A. |

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

| 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 XX | Author | YYYY | Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished | Y/N | Owner |
| | | | | | |

The following tables are to be completed by MS

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 |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| KCP XX | Author | YYYY | Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished | Y/N | Owner |
| | | | | | |

List of data relied on 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 |
|-------------------|------------------|-------------|--|-------------------------------------|--------------|
| KCP XX | Author | YYYY | Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished | Y/N | Owner |
| | | | | | |

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

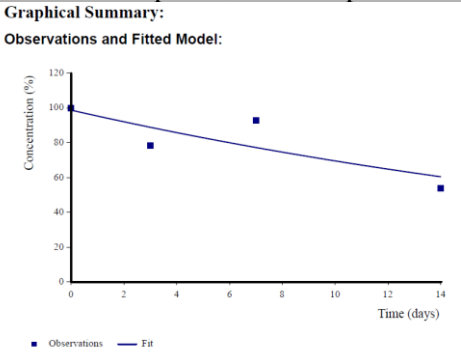
A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.1.3 Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>Comments of zRMS: The presented by the Applicant refinement risk assessment for the vertebrates was evaluated by the RMS, but found not acceptable due to the uncertainties related to the kinetic analysis of the data of the residue trials. However that analysis may be found acceptable in case the Applicant satisfactorily clarifies all identified problems.</p> <p>The Applicant should complete the kinetic report with the following elements:</p> <ol style="list-style-type: none"> 1. The main problem is the dataset quality used in the estimation – the Applicant indicate the source studies and trials, from which the data were taken. However, it does not provide details on the data. It refers to that the full study summary is included in dRR Part B7. Due to only a reference to the one study report (N. BIU-017-21) in dRR B7 zRMS could not check all the database for which the DT₅₀ was calculated. The DT₅₀ study summary is missing along with the summary of the analytical method. Please complete the description with the following element, preferably in tabular form: <ul style="list-style-type: none"> ✓ The trial locations and cropping information on treated plots such as trial location, country, area of application, plot size, type of soil, pH value of soil, content of organic carbon (C%), test system, BBCH crop, Seed rate, date of sowing. ✓ Climatic data of trial site such as data, mean temperature, rainfall (mm), sunshine (h). ✓ Application of SIP 41061 in trial sites such as appl. mode, test item rate (L/ha), water rate (L/ha) 2. Providing full reports: <ul style="list-style-type: none"> ✓ Casalnuovo, L. (2022a) Determination of prothioconazole metabolites residues in raw agricultural commodity zucchini following three applications of SIP41061 (prothioconazole 400 g/L) (Southern Europe, 4 trials, year 2021). Report N. BIU-015-21, Research Center BioSphereS by Biotecnologie BT, GLP, unpublished. ✓ Desiante A. (2022) Determination of prothioconazole metabolites residues in raw agricultural commodity apricot and peach after two applications of SIP41061 (Prothioconazole 400 g/L SC) ✓ Southern Europe, 4 trials, year 2021, Report N. BIU-008-21, Research Center BioSphereS by Biotecnologie BT, GLP, unpublished. 3. The trial should cover a minimum of 5 measurement points. In this case is 4 |
|-------------------|--|

| | |
|--|---|
| | <p>measurement points, for example:</p> <p>Graphical Summary: Observations and Fitted Model:</p>  <p>Please justify, because in specific situations it is possible to accept 4 measurement points. Specific information in this regard is provided in the EFSA guideline "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology".</p> <p>4. The Applicant should explain the detailed reason for conducting the studies only in Italy with 4 locations (Cucurbits) and 3 in Italy and 1 in Spain (Orchards). According to the guidelines, it is recommended to use a minimum of 4 locations. The most common practice is 4 locations in 4 different countries. The presented studies are typical of Southern Europe. Their extrapolation to Central Europe raises great doubts.</p> <p>5. The results of the trials BIU-008-21 I/PR21/PE01 and BIU-008-21S/PR21/PE02 are considered not suitable, for the following reasons:</p> <ul style="list-style-type: none"> - BIU-008-21 I/PR21/PE01: visual fit is not acceptable; χ^2 error for SFO and FOMC is above the trigger of 15%; The calculated curve does not match the observed pattern. The initial concentration is markedly over-estimated by the SFO & FOMC models. In addition, The residuals plot show large deviations (second point almost 40%). - BIU-008-21S/PR21/PE02: visual fit is not acceptable; although the χ^2 error is below 15%, the calculated curve does not match the observed pattern. The residuals plot show large deviations for 2 of 4 points (about 15%). <p>In orchards we have only 2 trials where visual fit is acceptable. Due to DT_{50} (average value) in orchards may be questionable. The Applicant should verify that it have no other data available from which it could derive the DT_{50} value in orchards with an acceptable visual fit.</p> <p>Refinement of DT_{50} should be considered at MSs level.</p> |
|--|---|

| | |
|---------------|--|
| Reference: | KCP 10.1.1.2 |
| Report | Prothioconazole-desthio (M04) residue decline in orchards and cucurbits – Kinetic evaluation of residue trials. Infantino, A. and Bonzini, S., 2022 Study N. KINPT_01 Sipcam Oxon S.p.A |
| Guideline(s): | FOCUS 2014. Generic guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, based on the EC Document SANCO/10058/2005, version 1.1, 440 pp. EFSA Supporting publication 2019:EN-1673: Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology |

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

Materials and Methods

In the present report a kinetic evaluation of residue trials conducted in orchards (**report N. BIU-008-21, Desiante A., 2022 (for full study summary please see dRR Part B7))** and cucurbits (**report N. BIU-015-21 and BIU-017-21, Casalnuovo, L. 2022a and 2022b (for full study summary please see dRR Part B7))** are presented. The evaluation was performed in agreement with EFSA 2019 and FOCUS 2014; the software CAKE version 3.4 was used for kinetic evaluations.

Only the trials with at least 4 quantifiable time points and with the first sampling at 0 DALA have been used for this analysis. The other trials have been rejected.

All values between the LOD and LOQ are set to the available measured value. If the actual measured concentration has not been reported, it was used $0.5 \times (\text{LOQ} + \text{LOD})$ and all samples $< \text{LOD}$ are set to $\frac{1}{2} \text{LOD}$.

The goodness of fit was evaluated both visually and based on χ^2 -error (the lower the χ^2 -error the better the fit), as recommended by FOCUS (2014). According to FOCUS (2014), fits are acceptable for a χ^2 -error of up to 15%.

For environmental fate the robustness of the model parameters is additionally evaluated using a t-test. Whenever the t-test indicates that parameters are significantly different from zero ($p < 0.05$) a parameter is considered robust.

Results

The results of the kinetic evaluations is reported below.

Table 1: kinetic evaluation of residues on orchards

| Trial | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
|-----------------------------------|---------------------------|--|--|-------------------|------------------|
| BIU-008-21 I/PR21/AR01 | Run SFO, FOMC | | | | |
| | SFO | 2.65 | M0:N/A K: 0.002 | acceptable | 6.9 |
| | FOMC | 3.3 | M0: N/A α : N/A β : N/A | acceptable | 7 (DT90/3.32) |
| | Conclusion | SFO acceptable | | | |
| | Overall conclusion | SFO is best fit based on visual assessment of fit and χ^2 error | | | |
| BIU-008-21 I/PR21/AR02 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 10.2 | M0:N/A K: 0.026 | acceptable | 6.39 |
| | FOMC | 12.7 | M0: N/A α : N/A β : N/A | acceptable | 6.39 (DT90/3.32) |
| | Conclusion | SFO acceptable | | | |
| | Overall conclusion | SFO is best fit based on visual assessment of fit and χ^2 error | | | |
| BIU-008-21 I/PR21/PE01 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 26 | M0:N/A K: 0.143 | Not acceptable | 8.27 |

| | | | | | |
|------------------------------|---------------------------|---|--|-------------------|------------------|
| | FOMC | 32.5 | M0: N/A α : N/A β : N/A | Not acceptable | 8.28 (DT90/3.32) |
| | Conclusion | SFO and FOMC not acceptable | | | |
| | | | | | |
| | Overall conclusion | SFO and FOMC are not acceptable based on visual assessment of fit and χ^2 error | | | |
| BIU-008-21S/PR21/PE02 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 10.1 | M0:N/A K: 0.100 | Not acceptable | 19.8 |
| | FOMC | 12.6 | M0: N/A α : N/A β : N/A | Not acceptable | 19.8 (DT90/3.32) |
| | Conclusion | SFO and FOMC not acceptable on visual assessment of fit | | | |
| | | | | | |
| | Overall conclusion | SFO and FOMC not acceptable on visual assessment of fit although the χ^2 error is below 15%. | | | |
| | | | | | |

The results of the trials BIU-008-21 I/PR21/AR01 and BIU-008-21 I/PR21/AR02 are considered acceptable. SFO kinetics give a good fit. The calculated curve matches the observed behaviour very well. The residuals are small and randomly scattered around the zero line. The χ^2 errors are below the trigger value of 15% for both kinetic analysis.

The results of the trials BIU-008-21 I/PR21/PE01 and BIU-008-21S/PR21/PE02 are considered not suitable due to not acceptable goodness of the fit.

Table 2: kinetic evaluation of residues on cucurbits

| Trial | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
|-------------------------------|---------------------------|---|--|-------------------|----------------------|
| | Run SFO, FOMC | | | | |
| BIU-015-21 I/PR21/ZU01 | SFO | 11.7 | M0:N/A K: 0.018 | acceptable | 1.69 |
| | FOMC | 2.68 | M0: N/A α : N/A β : N/A | acceptable | 2.59 (DT90/3.32) |
| | Conclusion | SFO acceptable | | | |
| | | | | | |
| | Overall conclusion | SFO is acceptable and therefore recommended | | | |
| BIU-015-21 I/PR21/ZU02 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 8.85 | M0:N/A K: 0.071 | acceptable | 14.1 |
| | FOMC | 2.12 | M0: N/A α : N/A β : N/A | Acceptable | > 10'000 (DT90/3.32) |
| | Conclusion | SFO acceptable | | | |
| | | | | | |
| | Overall conclusion | SFO is acceptable and therefore recommended | | | |
| BIU-017-21 I/PR21/ZU05 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 11.7 | M0:N/A K: 0.017 | acceptable | 1.61 |
| | FOMC | 0.581 | M0: N/A α : N/A β : N/A | Acceptable | 2.43 (DT90/3.32) |
| | Conclusion | SFO acceptable | | | |

| | | | | | |
|-----------------------------------|---------------------------|---|--|-------------------|------------------|
| | | | | | |
| | Overall conclusion | SFO is acceptable and therefore recommended | | | |
| BIU-017-21 I/PR21/ZU06 | Kin Model | X2 error | p (t-test) | Visual fit | DT50 (d) |
| | Run SFO, FOMC | | | | |
| | SFO | 17.8 | M0:N/A K: 0.038 | acceptable | 2.54 |
| | FOMC | 14 | M0: N/A α : N/A β : N/A | Acceptable | 5.37 (DT90/3.32) |
| | Conclusion | SFO not acceptable, FOMC acceptable | | | |
| | | | | | |
| | Overall conclusion | FOMC is best fit based on visual assessment of fit and χ^2 error | | | |

The results of the trials on zucchini are considered acceptable. SFO kinetics give an acceptable fit, with the exception of trial BIU-017-21 I/PR21/ZU06, for which the χ^2 error resulted to be too high in agreement with EFSA (2019) provisions. For the other trials, the residuals are small and randomly scattered around the zero line and the χ^2 errors are below the trigger value of 15%.

Conclusion

Two kinetic analysis are acceptable for orchards with the calculated DT₅₀ values of 6.9 and 6.39 days (6.6 d average).

Four kinetic analysis are acceptable for cucurbits with the calculated DT₅₀ values of 1.69d, 14.1d, 1.61d and 5.37 days (3.8 d geometric mean value).

| | | |
|------------------|---------------------|---|
| A 2.1.2 | KCP 10.1.2 | Effects on terrestrial vertebrates other than birds |
| A 2.1.2.1 | KCP 10.1.2.1 | Acute oral toxicity to mammals |
| A 2.1.2.2 | KCP 10.1.2.2 | Higher tier data on mammals |
| A 2.1.3 | KCP 10.1.3 | Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) |
| A 2.2 | KCP 10.2 | Effects on aquatic organisms |
| A 2.2.1 | KCP 10.2.1 | Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes |
| A 2.2.1.1 | Study 1 | |

| | |
|-------------------|---|
| Comments of zRMS: | The study is acceptable. The validity criteria according OECD 202 (2004) of the test were met. LC _{50, nom} (48 h) = 4.25 mg formulation/L (95% CI: 3.55-5.12 mg formulation/L), expresed to 1.5 mg s.a./L (95% CI: 1.25-1.80 mg s.a./L) (nominal concentration) |
|-------------------|---|

| | |
|--|---|
| | NOEC (48 h) = 1.0 mg formulation/L, expressed to 0.35 mg a.s./L (nominal concentration) |
|--|---|

Reference: KCP 10.2.1/01

Report Acute immobilization test on *Daphnia magna* under semi-static conditions with test item SIP 41061.
Corboli M.
Study N. BT137/21
BioTecnologie BT Srl

Guideline(s): Yes
OECD Guideline for Testing of Chemicals No. 202: "Daphnia sp., Acute Immobilisation Test" adopted April 13, 2004
OECD Series on Testing and Assessment, No. 23, "Guidance Document on Aqueous-phase Aquatic Toxicity Testing of Difficult Test Chemicals", 2nd Ed., February 08, 2019
Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009, Official Journal of the European Union No. L 309: 1 – 50
SANCO/3029/99 rev.4 11/07/00: 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

Deviations: No

GLP: Yes

Acceptability: Yes

Vertebrate study No

Materials and Methods

| | |
|------------------------------------|---|
| 1. Test item: | |
| Name: | SIP 41061 (Prothioconazole 510 g/L SC) |
| Batch number: | 21/0006 |
| Active ingredient content: | Prothioconazole 35.2 % w/w |
| 2. Vehicle and/or control: | M4 medium |
| 3. Test system: | |
| Species: | <i>Daphnia magna</i> |
| Age: | < 24 hours old |
| Source: | In house breeding at the Test Facility |
| Diet: | No feeding during the test |
| Housing (before the test): | Under breeding conditions; the test organisms were fed with algae suspension (<i>Pseudokirchneriella subcapitata</i>) and were maintained in reconstituted water. The organisms were maintained in a thermostatic chamber at the temperature range of 20 ± 2°C, with a photoperiod of 16 hours light and 8 hours dark. |
| 4. Experimental conditions: | |
| Test medium: | The test was performed in M4 medium. The pH of aerated water was in the range of 6 - 9 and the dissolved oxygen was ≥ 3 mg/L. |

| | |
|--------------------------------------|--|
| | The medium and the climatic conditions were selected according to the OECD 202. |
| Temperature: | 20.1 - 20.8°C (temperature of the test medium) |
| Light and photoperiod: | 816 - 983 Lux (16 hours light and 8 hours dark) |
| 5. Experimental period: | 17 th May - 12 th June 2021 |
| 6. Test design and treatment: | <p>A semi-static dose response test was conducted at nominal concentrations of 1.00, 1.78, 3.16, 5.62 and 10.00 mg/L of test item in M4 medium, plus an untreated group.</p> <p>20 daphnids, divided in 4 replicates of 5 daphnids, were used for each group.</p> <p>The test organisms were exposed to the test solutions for 48 hours, with renewal of the solution at 24 hours.</p> <p>The number of mobile and immobile daphnids was counted at 24 and 48 hours after the beginning of the test.</p> <p>The concentration of the active ingredient Prothioconazole and the metabolite Prothioconazole-desthio were determined by UHPLC-MS/MS analyses, in samples of all freshly prepared and aged test solutions.</p> |
| 7. Statistics: | Probit analysis to calculate the LC _x values with 95 % confidence limits. Step-Down Cochran-Armitage test procedure to estimate the LOEC/NOEC values after 48 hours of exposure. |

Results

The percentage of immobilisation (%I) obtained during the test is reported in Table 1, where %I = (number of immobilised organisms / number of exposed organisms) × 100

Table 3: Immobilisation of *Daphnia magna* in percent after 24 and 48 h exposure to the test item

| Code | Nominal test item conc. (mg/L) | Number of exposed daphnids | Response at 24 h | | Response at 48 h | |
|------|--------------------------------|----------------------------|--------------------------------|----|--------------------------------|-----|
| | | | Number of Immobilised daphnids | %I | Number of Immobilised daphnids | %I |
| CTRL | 0.00 | 20 | 0 | 0 | 0 | 0 |
| C1 | 1.00 | 20 | 0 | 0 | 0 | 0 |
| C2 | 1.78 | 20 | 0 | 0 | 0 | 0 |
| C3 | 3.16 | 20 | 0 | 0 | 2 | 10 |
| C4 | 5.62 | 20 | 2 ⁺ | 10 | 14 ⁺ | 70 |
| C5 | 10.00 | 20 | 10 ⁺ | 50 | 20 ⁺ | 100 |

⁺ indicates a significant difference compared to the untreated control
(Step-down Cochran-Armitage Test Procedure ($\alpha = 0.050$; one-sided greater))

No effects on daphnids were observed during the 48 hours of exposure.

The analytical determination of the active ingredient content was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (report N. **BT193/21, please refer to dRR Section B5**). The analytical determination of the active ingredient content in the test solutions showed a mean recovery of 94.39% in fresh samples and 95.66% in aged samples.

Accordingly, the results are presented based on nominal concentrations of the test item and the active ingredient Prothioconazole. Moreover, the analytical determination of Prothioconazole-desthio content showed a quantifiable content of metabolite with a mean content estimated as of 3.17% in fresh samples and 2.27% in aged samples, calculated respect to the nominal concentration of the active ingredient Prothioconazole.

Conclusion

The acute immobilisation test was performed, under semi-static conditions, to assess the effects of the test item SIP 41061 (Prothioconazole 400 g/L SC) on *Daphnia magna*, after 48 hours of exposure. Calculated endpoints based on the nominal concentrations of test item and active ingredient are shown in the following table.

Table 4: Effect concentrations of the test item on *Daphnia magna* after 48 h exposure

| Endpoint (48 hours) | Nominal test item conc. (mg/L) | Confidence limits | | Nominal Prothioconazole conc. (mg a.i./L) | Confidence limits | |
|------------------------|--------------------------------------|-------------------|-------|---|-------------------|-------|
| | | Lower | Upper | | Lower | Upper |
| EC ₁₀ | 3.22 | 2.35 | 3.79 | 1.13 | 0.83 | 1.33 |
| EC ₂₀ | 3.67 | 2.88 | 4.23 | 1.29 | 1.01 | 1.49 |
| EC ₅₀ | 4.72 | 4.07 | 5.47 | 1.66 | 1.43 | 1.93 |
| LOEC | 3.16 | - | - | 1.11 | - | - |
| NOEC | 1.78 | - | - | 0.63 | - | - |

The validity criteria of OECD 202 (2004) were fulfilled, thus the study is valid.

A 2.2.1.2 Study 2

| | |
|-------------------|---|
| Comments of zRMS: | <p>The study is acceptable. The validity criteria according OECD 201 (2006) guideline was met.</p> <p>Validity criteria of the study:</p> <ul style="list-style-type: none"> ❖ the cell concentration increased by a factor of at least 16 within 3 days, corresponding to a specific growth rate of 0.92 day⁻¹; observed in the study: factor 259.24 (mean specific growth rate 1.852 day⁻¹) ❖ the mean coefficient of variation for section-by-section specific growth rates (days 0 - 1, 1 - 2 and 2 - 3) did not exceed 35%; observed in the study: 17.05%. ❖ the coefficient of variation of average specific growth rates during the whole test period in the replicates did not exceed 7%. Observed in the study: 1.46%. <p>E_rC₅₀ (72 h) > 1.69 mg a.s./L (95% CI: 1.53-1.87) based on geometric mean measured concentration</p> <p>E_yC₅₀ (72 h) = 0.64 mg a.s./L (95% CI: 0.61-0.68) based on geometric mean measured concentration</p> |
|-------------------|---|

Reference: KCP 10.2.1/02

Report Toxicity evaluation of test item SIP 41061 on green alga *Pseudokirchneriella subcapitata* in a growth inhibition test
Report N. BT138/21
BioTecnologie BT Srl
Mantilacci S.

Guideline(s): OECD Guideline for Testing of Chemicals, Section 2, No. 201: "Freshwater

Alga and Cyanobacteria, Growth Inhibition Test", adopted March 23, 2006, corrected July 28, 2011

Commission Regulation (EC) No 761/2009, Annex, Part C, C.3.: "Freshwater Algae and Cyanobacteria, Growth Inhibition Test", Official

Deviations: No
GLP: Yes
Acceptability:
Vertebrate study No

Materials and Methods

| | |
|---|---|
| A. MATERIALS | |
| 1. Test item: | |
| Name: | SIP 41061 (Prothioconazole 400 g/L SC) |
| Batch number: | 21/0006 |
| Active ingredient content: | Prothioconazole 35.2 % w/w (409 g/L) |
| 2. Vehicle and/or control: | |
| EPA (AAP) medium | |
| 3. Test system: | |
| Species: | <i>Pseudokirchneriella subcapitata</i> |
| Source: | In house breeding at the Test Facility. |
| Housing (before the test): | At breeding conditions, the test system was maintained in a thermostatic chamber at the temperature range of 23 ± 2 °C and with continuous light intensity in the range of 4440 - 8880 Lux. |
| 4. Experimental conditions: | |
| Test medium: | The test was performed in EPA (AAP) medium. The medium and the climatic conditions were selected according to the OECD 201. |
| Temperature: | 24.2 - 24.5 °C. |
| Light and photoperiod: | Continuous light in the range of 6017 - 6731 Lux. |
| B. STUDY DESIGN AND METHODS | |
| 1. Experimental period: | |
| 17 th May - 14 th June 2021 | |
| 2. Test design and treatment: | |
| A dose-response test was conducted at nominal concentrations of 0.50 - 1.30 - 3.38 - 8.79 - 22.85 mg test item/L in EPA (AAP) medium, plus an untreated group. Three replicates were prepared for the treated groups and for the control group, each replicate containing 100 mL of test solution. The initial cell concentration in the test cultures was 10^4 cells/mL and the cell density in each flask was counted daily during the test. The exposure period was 72 hours. The concentration of the active ingredient Prothioconazole and metabolite Prothioconazole-desthio was determined by UHPLC-MS/MS analyses, in samples of the test solutions at test start and after 24 - 48 - 72 hours of exposure. | |

| | |
|-----------------------|--|
| 3. Statistics: | <p>The determination of the EC_x values with 95% confidence limits was performed by Probit analysis using linear maximum likelihood method.</p> <p>Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm procedure for growth rate and yield was used to estimate the LOEC/NOEC values at 72 hours.</p> |
|-----------------------|--|

Results

The inhibition of growth relative to the untreated control group was calculated in percent based on growth rate (%I_r) and yield (%I_y) and is reported in the following table.

Table 5: Inhibition of growth of *Pseudokirchneriella subcapitata* based on growth rate (I_r) and yield (I_y) in percent after 72 h exposure to test item, in relation to the control

| Code | Nominal test item concentration (mg/L) | Geometric mean measured Prothioconazole concentration (mg a.i./L) | Geometric mean measured Prothioconazole-desthio concentration (mg a.i./L) | %I _r | %I _y |
|------|--|---|---|--------------------|--------------------|
| C1 | 0.50 | 0.10 | 0.013 | 0.65 | 3.66 |
| C2 | 1.30 | 0.37 | 0.014 | 3.46 ⁺ | 17.66 ⁺ |
| C3 | 3.38 | 0.96 | 0.019 | 24.68 ⁺ | 74.63 ⁺ |
| C4 | 8.79 | 2.37 | 0.024 | 68.74 ⁺ | 98.19 ⁺ |
| C5 | 22.85 | 7.74 | 0.076 | 87.85 ⁺ | 99.62 ⁺ |

+ indicates a significant difference compared to the untreated control (Multiple sequentially-rejective Welsh-t-test after Bonferroni-Holm, $\alpha = 0.05$, one-sided smaller)

After 72 hours exposure, no cells with abnormal appearance were observed.

The analytical determination of the active ingredient Prothioconazole and metabolite Prothioconazole-desthio in the test solutions was performed by UHPLC-MS/MS.

The analytical method was validated according to SANTE/2020/12830, Rev.1 in a separate GLP study (report N. **BT193/21**, please see the details method in dRR Section B5).

The analytical determination of the active ingredient Prothioconazole content showed mean recovery of 85.44% in fresh samples and 76.31% in aged samples (not in the range of 80 - 120% respect to the nominal values for all samples).

Accordingly, the assessment of the effects was based on the nominal concentrations of the test item and the geometric mean measured concentrations of the active ingredient.

Moreover, the analytical determination of Prothioconazole-desthio content showed a quantifiable content of metabolite with a mean content estimated as of 1.42% in fresh samples and 2.48% in aged samples, calculated respect to the nominal concentration of the active ingredient Prothioconazole.

Conclusion

The growth inhibition test was performed in order to evaluate the effects of the test item SIP 41061 (Prothioconazole 400 g/L SC) on green alga *Pseudokirchneriella subcapitata*, after 72 hours of exposure to a geometric series of test item concentrations.

The endpoints calculated based on the test item and geometric mean measured concentrations of active ingredient are shown in the following table.

Table 6: Effect concentrations of the test item for growth rate and yield of *Pseudokirchneriella subcapitata* after 72 h exposure (expressed as test item and active ingredient concentration)

| Endpoint (72 hours) | Nominal test item concentration (mg/L) | Geometric mean measured Prothioconazole concentration (mg a.i./L) | Endpoint (72 hours) | Nominal test item concentration (mg/L) | Geometric mean measured Prothioconazole concentration (mg a.i./L) |
|--------------------------------|---|---|--------------------------------|---|---|
| E _y C ₁₀ | 1.04 (0.92 - 1.14) | 0.29 (0.26 - 0.33) | E _r C ₁₀ | 1.88 (1.60 - 2.15) | 0.53 (0.41 - 0.63) |
| E _y C ₂₀ | 1.36 (1.24 - 1.46) | 0.39 (0.35 - 0.42) | E _r C ₂₀ | 2.82 (2.50 - 3.12) | 0.79 (0.66 - 0.90) |
| E _y C ₅₀ | 2.27 (2.15 - 2.39) | 0.64 (0.61 - 0.68) | E _r C ₅₀ | 6.10 (5.68 - 6.55) | 1.69 (1.53 - 1.87) |
| LOE _y C | 1.30 | 0.37 | LOE _r C | 1.30 | 0.37 |
| NOE _y C | 0.50 | 0.10 | NOE _r C | 0.50 | 0.10 |

Values in parentheses () refer to 95% confidence limits

After 72 hours exposure, no cells with abnormal appearance were observed.
The validity criteria of OECD 201 (2011) were fulfilled, thus the study is valid.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.1.2 Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>The study is acceptable. This study was evaluated according to OECD 214 and OECD 2013. The study met the relevant validity criteria.</p> <p><i>Apis mellifera</i> L.</p> <p>The following endpoints are considered valid for use in the risk assessment:</p> <ol style="list-style-type: none"> 1. Oral exposure: LD₅₀ >2253.85 µg product/bee (equivalent to > 793.36 µg a.s./bee); NOED = 2253.85 µg product/bee (equivalent to 793.36 µg a.s./bee) 2. Contact exposure: LD₅₀ >2272.72 µg product/bee (equivalent to > 800 µg a.s./bee); NOED = 2272.2 µg product/bee (equivalent to 800 µg a.s./bee) |
|-------------------|--|

| | |
|------------------|---|
| Reference: | KCP 10.3.1.1.1/01 |
| Report | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera</i> L.) in a laboratory test Report N. BT139/21 Rossini L., 2021 BioTecnologie BT S.r.l |
| Guideline(s): | OECD 213 (1998) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Vertebrate study | No |

Material and methods

| A. MATERIALS | |
|----------------------------------|---|
| 1. Test Item | |
| Name | SIP 41061 (Prothioconazole 400 g/L SC) |
| Indication | Agrochemical |
| Batch No. | 21/0006 |
| Analysed content of a.s. | w/v: 409 g/L w/w: 35.2% |
| Density | 1.162 kg/L |
| 2. Reference item | |
| Name | Perfektion Top |
| Indication | Insecticide |
| Batch No. | 10222732A |
| Analysed a.s. content | Dimethoate: 371.56 g/kg or 393.85 g/L |
| 3. Control | |
| Oral test | 50% (w/v) aqueous sucrose solution |
| Contact test | Deionised water + 0.5% v/v Triton X-100 |
| 4. Test system | |
| Species | <i>Apis mellifera</i> L. |
| Age | Adult workers |
| Source | Healthy colonies (hive no. 20) maintained at BioTecnologie BT S.r.l. |
| Acclimatisation | Up to 2 hours under experimental conditions |
| Diet | 50% (w/v) aqueous sucrose solution |
| 5. Experimental conditions | |
| Temperature | 22.8 – 24.6°C (avg. 24.2°C) |
| Relative humidity | 43.7 – 72.1% (avg. 58.2%) |
| Photoperiod | 24 hours darkness (except during observations) |
| B. STUDY DESIGN AND METHODS | |
| 1. Test guidelines | OECD TG 213 (1998) and OECD TG 214 (1998) |
| 2. Experimental period | From 18 th to 21 st May 2021 |
| 3. Oral Test (OECD TG 213, 1998) | A dose-response test was performed with five increasing doses of the test item (nominal: 117.77, 259.09, 570.00, 1254.00 and 2758.00 µg test item/bee) dispersed in a 50% (w/v) aqueous sucrose solution and provided <i>ad libitum</i> to honeybees over a period of max. 6 h. A control group with untreated 50% (w/v) aqueous sucrose solution and three reference item groups exposed to nominal dosages of 0.19, 0.43 and 0.94 µg reference item/bee were tested in parallel. Three replicates with 10 honeybees each were tested for each treatment group and |

| | |
|----------------------|--|
| | control. 200 µL of oral solution (20 µL/bee were administered to each replicate (cage). After treatment the honeybees were fed <i>ad libitum</i> with untreated diet. |
| 4. Statistics | Oral test (48h): NOED evaluated with the Chi ² 2x2 test with Bonferroni correction ($\alpha = 0.05$, one-sided greater). Contact test (48h): NOED evaluated with the Fisher's exact binomial test ($\alpha = 0.05$, one-sided greater). Reference item: the LD ₅₀ (with 95% confidence limits) was calculated with Probit analysis (using linear weighted regression). The software ToxRatPro 3.3.0 was used for the statistical analysis. |

Results Oral test

In all treatment groups, the nominal doses were recalculated on the basis of the actual consumed diets.

No behavioural abnormalities were observed during the course of the test in the survived organisms. The results of the oral test are summarized in Table 1, the endpoints in Table 2.

The 24-hour LD₅₀ value of the reference item was 0.11 µg a.s./bee (95%-confidence limits: 0.09 – 0.12).

Table 7 Acute oral toxicity of SIP 41061 to adult honeybees - Mortality

| Groups ¹ | Doses [µg prod/bee] | 4 hours | | 24 hours | | 48 hours | | 72 hours | | | | | |
|---------------------|---------------------|------------------------|-------|----------|-------|----------|----------------|----------|--------|----------------|-------|--------|----------------|
| Test item | | | | | | | | | | | | | |
| | Nominal | Effective ² | M [%] | CM [%] | M [%] | CM [%] | S ³ | M [%] | CM [%] | S ³ | M [%] | CM [%] | S ³ |
| Control | - | - | 0.0 | n/a | 3.3 | n/a | n/a | 6.7 | n/a | n/a | 10.0 | n/a | n/a |
| T1 | 117.77 | 115.59 | 0.0 | 0.0 | 3.3 | 0.0 | - | 13.3 | 7.1 | - | 13.3 | 3.7 | - |
| T2 | 259.09 | 255.37 | 0.0 | 0.0 | 0.0 | 0.0 | - | 0.0 | 0.0 | - | 6.7 | 0.0 | - |
| T3 | 570.00 | 562.74 | 0.0 | 0.0 | 0.0 | 0.0 | - | 13.3 | 7.1 | - | 16.7 | 7.4 | - |
| T4 | 1254.00 | 1243.41 | 0.0 | 0.0 | 6.7 | 3.5 | - | 13.3 | 7.1 | - | 16.7 | 7.4 | - |
| T5 | 2758.00 | 2253.85 | 10.0 | 10.0 | 13.3 | 10.3 | - | 20.0 | 14.3 | - | 30.0 | 22.2 | - |

M = mortality; CM = corrected mortality, using the Abbott's formula (1925) modified by Schneider-Orelli (1947) – negative values were replaced with 0; S = statistical significance; "+" = significant; "-" = not-significant; n/a = not applicable. ¹All groups, except for control(s), are defined by a letter (T for test item, R for Reference item dimethoate) and a number (starting from 1 that indicates the lowest concentration/dose). ²Calculated based on actual consumption. ³Chi² 2x2 table test with Bonferroni correction ($\alpha = 0.05$, one-sided greater).

Table 8 Acute oral toxicity of SIP 41061 to adult honeybees - Endpoints

| Time | 24 hours | | 48 hours | | 72 hours | |
|---------------------------------|-----------|------------------|-----------|------------------|-----------|------------------|
| | Test item | Active substance | Test item | Active substance | Test item | Active substance |
| LD₅₀ [µg/bee] | > 2253.85 | > 793.36 | > 2253.85 | > 793.36 | > 2253.85 | > 793.36 |
| NOED [µg/bee] | 2253.85 | 793.36 | 2253.85 | 793.36 | 2253.85 | 793.36 |

Conclusion

The toxic effects of the test item SIP 41061 (Prothioconazole 400 g/L SC) to adult honeybees (*Apis mellifera* L.) after oral and topical exposure, were assessed in a GLP compliant laboratory test according to the Test Guidelines OECD 213 and OECD 214.

The oral LD₅₀ after 72 hours was evaluated to be greater than 2253.85 µg test item/bee, equivalent to 793.36 µg Prothioconazole/bee.

The validity criteria with regards to control mortality and toxicity on the reference item were met, because the average mortality in the control group was 10.0% at the end of the test and the LD₅₀-24h of the toxic standard was 0.11 µg dimethoate/bee. No behavioural abnormalities were noted.

A 2.3.1.3 Study 2

| | |
|-------------------|---|
| Comments of zRMS: | <p>The study is acceptable. This study was evaluated according to OECD 246 and OECD 247. The study met the relevant validity criteria.</p> <p>Validity criteria of the study:</p> <ol style="list-style-type: none"> the average mortality of the control group was, at the end of the test: <ul style="list-style-type: none"> Acute oral test: 0%; Acute contact test: 0%; the average, control-corrected mortality of the reference item groups was 100% at the end of the test, at the doses of 4 µg a.s./bb (for the oral test) and 10 µg a.s./bb (for the contact test). <p><i>Bombus terrestris</i> L.</p> <p>The following endpoints are considered valid for use in the risk assessment:</p> <ol style="list-style-type: none"> Oral exposure: LD₅₀ > 557.63 µg product/bb (equivalent to > 196.29 µg a.s./bb); NOED ≥ 557.63 µg product/bb (equivalent to ≥ 196.29 µg a.s./bb) Contact exposure: LD₅₀ > 568.18 µg product/bb (equivalent to > 200 µg a.s./bb); NOED ≥ 568.18 µg product/bb (equivalent to ≥ 200 µg a.s./bb) |
|-------------------|---|

| | |
|------------------|---|
| Reference: | KCP 10.3.1.1.1/02 |
| Report | <p>Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test</p> <p>Rossini L., 2021</p> <p>Report N. BT140/21</p> <p>BioTecnologie BT S.r.l</p> |
| Guideline(s): | Laboratory study based on the OECD Guidelines for the testing of chemicals 246 and 247 (2017) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Vertebrate study | No |

Material and methods

| | |
|-------------------------|---|
| 1. Test item | |
| Name: | SIP 41061 |
| Description: | Agrochemical |
| Batch: | 21/0006 |
| A.s. and CAS: | Prothioconazole: 178928-70-6 |
| Content of a.s.: | 409 g/L – 35.2% |
| 2. Test system | |
| Species: | <i>Bombus terrestris</i> L. |
| Age: | Adult workers |
| Source: | Healthy colonies provided by BioPlanet S.r.l. |

Diet: 50 % (w/v) aqueous sucrose solution

3. Experimental conditions

Temperature: 23.8 - 25.1 °C (avg. 24.3°C)

Humidity: 57.0 – 62.6% (avg. 60.2%)

Photoperiod: 24 hours darkness (except during observations)

4. Experimental period

From 12th to 14th October 2021 (Biological phase); from 20th to 22nd October 2021 (Analytical phase)

5. Oral Test

The acute oral toxicity test in the laboratory was performed as a limit test: the test item was dissolved in a 50% (w/v) aqueous sucrose solution (nominal concentration: 568.18 µg test item/bb). 40 µL of the treated solution was provided to adult worker bumblebees over a period of 4 h. A control group (untreated 50% (w/v) aqueous sucrose solution) and a reference item group exposed to nominal dosage of 4.0 µg dime-thoate/bb were tested in parallel. Sixty bumblebees for the control and for the test item group and forty bumblebees for the reference item group were tested: evaluations of the consumptions were done to identify non-feeder bumblebees in each group, where present. After treatment, the bumblebees were fed *ad libitum* with untreated diet.

6. Observations

Assessments on mortality and any behavioural abnormality were performed at 4, 24 and 48 hours after treatment for both tests.

7. Statistics

Due to the results, no statistics was performed.

Results oral test

Based on the mean food intake per treatment group, the actual test item uptake per treatment group was calculated. Where non-feeder bumblebees were identified at the end of the 4-hour exposure period, they were excluded from the calculations of the mean mortalities of each group as well as of the endpoints. The results of the acute oral toxicity test show no effects of the test item on mortality at the end of the test. No behavioural abnormalities were observed. The results of the oral test are summarized in Table 1, the endpoints in Table 2. The mortality of the reference item was 100% at the end of the test period.

Table 9 Acute oral toxicity of SIP 41061 to adult bumblebees - Mortality

| Groups | Doses [µg/bb] | | 4 hours | | 24 hours | | 48 hours | |
|----------------|---------------|------------------------|---------|--------|----------|--------|----------|--------|
| Test item | | | | | | | | |
| | Nominal | Effective ¹ | M [%] | CM [%] | M [%] | CM [%] | M [%] | CM [%] |
| Control | - | - | 0.00 | n/a | 0.00 | n/a | 0.00 | n/a |
| Ta | 568.18 | 557.63 | 0.00 | 0.00 | 3.33 | 3.33 | 3.33 | 3.33 |
| Reference item | | | | | | | | |
| | Nominal | Effective ¹ | M [%] | CM [%] | M [%] | CM [%] | M [%] | CM [%] |
| R | 4.0 | 3.67 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 |

M = mortality; CM = corrected mortality, using the Abbott's formula (1925) modified by Schneider-Orelli (1947); negative values were replaced with 0.00; n/a = not applicable. ¹Calculated based on actual consumption.

Table 10 Acute oral toxicity of SIP 41061 to adult bumblebees - Endpoints

| Endpoint [µg/bee] | 24 hours | | 48 hours | |
|------------------------|-----------|------------------|-----------|------------------|
| | Test item | Active substance | Test item | Active substance |
| NOED | ≥ 557.63 | ≥ 196.29 | ≥ 557.63 | ≥ 196.29 |
| LD₅₀ | > 557.63 | > 196.29 | > 557.63 | > 196.29 |

Conclusion

The toxicity effects of the test item SIP 41061 to adult worker bumblebees (*Bombus terrestris* L.) after

oral or topical exposure, were assessed in a GLP compliant laboratory test.

In the oral test the actual test item uptake per treatment group was calculated based on the mean food intake per treatment group. Non-feeder bumblebees were identified and excluded from the calculations of the endpoint.

Since no effects on mortality were observed, the oral NOED was 557.63 µg test item/bb equivalent to 196.29 µg Prothioconazole/bb after 24 and 48 hours, and the oral LD50 was evaluated to be > 557.63 µg test item/bb equivalent to 196.29 µg Prothioconazole/bb after 24 and 48 hours.

The validity criteria with regards to control mortality and toxicity on the reference item were met, because the average mortality in the control group and in the reference item group was 0% and 100% , respectively, at the end of the test.

No behavioural abnormalities were noted.

A 2.3.1.3.1 KCP 10.3.1.1.2 Acute contact toxicity to bees

Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>The study is acceptable. This study was evaluated according to OECD 214 and OECD 2013. The study met the relevant validity criteria.</p> <p><i>Apis mellifera L.</i></p> <p>The following endpoints are considered valid for use in the risk assessment:</p> <ol style="list-style-type: none"> 1. Oral exposure: LD₅₀ >2253.85 µg product/bee (equivalent to > 793.36 µg a.s./bee); NOED = 2253.85 µg product/bee (equivalent to 793.36 µg a.s./bee) 2. Contact exposure: LD₅₀ >2272.72 µg product/bee (equivalent to > 800 µg a.s./bee); NOED = 2272.2 µg product/bee (equivalent to 800 µg a.s./bee) |
|-------------------|--|

| | |
|------------------|---|
| Reference: | KCP 10.3.1.2/01 Submitted as KCP 10.3.1.1/01 |
| Report | <p>Acute oral and acute contact toxicity effects of SIP 41061 to adult worker honeybees (<i>Apis mellifera L.</i>) in a laboratory test</p> <p>Report N. BT139/21</p> <p>Rossini L., 2021</p> <p>BioTecnologie BT S.r.l</p> |
| Guideline(s): | OECD 214 (1998) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Vertebrate study | No |

Material and methods

| A. MATERIALS | |
|--------------------------|--|
| 1. Test Item | |
| Name | SIP 41061 (Prothioconazole 400 g/L SC) |
| Indication | Agrochemical |
| Batch No. | 21/0006 |
| Analysed content of a.s. | w/v: 409 g/L w/w: 35.2% |
| Density | 1.162 kg/L |
| 2. Reference item | |

| | |
|--|--|
| Name | Perfektion Top |
| Indication | Insecticide |
| Batch No. | 10222732A |
| Analysed a.s. content | Dimethoate: 371.56 g/kg or 393.85 g/L |
| 3. Control | |
| Oral test | 50% (w/v) aqueous sucrose solution |
| Contact test | Deionised water + 0.5% v/v Triton X-100 |
| 4. Test system | |
| Species | <i>Apis mellifera</i> L. |
| Age | Adult workers |
| Source | Healthy colonies (hive no. 20) maintained at BioTecnologie BT S.r.l. |
| Acclimatisation | Up to 2 hours under experimental conditions |
| Diet | 50% (w/v) aqueous sucrose solution |
| 5. Experimental conditions | |
| Temperature | 22.8 – 24.6°C (avg. 24.2°C) |
| Relative humidity | 43.7 – 72.1% (avg. 58.2%) |
| Photoperiod | 24 hours darkness (except during observations) |
| B. STUDY DESIGN AND METHODS | |
| 1. Test guidelines | OECD TG 213 (1998) and OECD TG 214 (1998) |
| 2. Experimental period | From 18 th to 21 st May 2021 |
| 4. Contact Test (OECD TG 214, 1998) | <p>A limit test was performed with a single dose of the test item (2272.72 µg test item/bee). Adult worker honeybees were topically exposed to the test item dissolved in deionized water, by direct application to the thorax (droplets). The wetting agent (Triton X-100) was used at a concentration of 0.5% v/v in the preparation. Two control groups (only water and water + wetting agent) and three reference item groups (at the doses of 0.19, 0.43 and 0.94 µg reference item/bee) were tested in parallel.</p> <p>Five replicates with 10 honeybees each were tested for each test item treatment group and for each control group. Three replicates with 10 honeybees each were tested for each reference item group. A treatment volume of 3 µL/bee was used for the controls and the test item groups and a treatment volume of 2 µL/bee was used for the reference item group.</p> |
| 4. Statistics | <p>Oral test (48h): NOED evaluated with the Chi² 2x2 test with Bonferroni correction ($\alpha = 0.05$, one-sided greater).</p> <p>Contact test (48h): NOED evaluated with the Fisher's exact binomial test ($\alpha = 0.05$, one-sided greater).</p> <p>Reference item: the LD₅₀ (with 95% confidence limits) was calculated with Probit analysis (using linear weighted regression). The software ToxRatPro 3.3.0 was used for the statistical analysis.</p> |

Results Contact test

The results of the acute contact toxicity test suggest no adverse effects of the test item 48 hours after test initiation. No behavioural abnormalities were observed. The results of the contact test are reported in Table 3, the endpoints in Table 4. The 24-hour LD₅₀ value of the reference item was 0.15 µg a.s./bee (95%-confidence limits: 0.03 – 0.75).

Table 11 Acute contact toxicity of SIP 41061 to adult honeybees

| Groups ¹ | Doses [µg/bee] | 4 hours | | 24 hours | | | 48 hours | | |
|----------------------|----------------|---------|--------|----------|--------|----------------|----------|--------|----------------|
| | Test item | M [%] | CM [%] | M [%] | CM [%] | S ² | M [%] | CM [%] | S ² |
| Control | - | 0.0 | n/a | 0.0 | n/a | n/a | 4.0 | n/a | n/a |
| Wetting agent | - | 0.0 | n/a | 10.0 | n/a | n/a | 10.0 | n/a | - |

| | | | | | | | | | |
|------------------------|---------|-----|-----|-----|-----|-----|-----|-----|---|
| control | | | | | | | | | |
| Pooled controls | - | 0.0 | n/a | 5.0 | n/a | n/a | 7.0 | n/a | - |
| T1 | 2272.72 | 0.0 | 0.0 | 2.0 | 0.0 | - | 4.0 | 0.0 | - |

M = mortality; CM = corrected mortality (with the pooled controls), using the Abbott's formula (1925) modified by Schneider-Orelli (1947) – negative values were replaced with 0; S = statistical significance; “+” = significant; “-” = not-significant; n/a = not applicable.

CM^a = corrected mortality (with the first 3 replicates of the pooled control), using the Abbott's formula (1925) modified by Schneider-Orelli (1947)

¹All groups, except for control(s), are defined by a letter (T for test item, R for Reference item dimethoate) and a number (starting from 1 that indicates the lowest concentration/dose). ²Step-down Cochran-Armitage test ($\alpha = 0.05$, one-sided greater).

Table 12 Acute contact toxicity of SIP 41061 to adult honey bees – Endpoints

| Time | 24 hours | | 48 hours | |
|---------------------------------|-----------|------------------|-----------|------------------|
| | Test item | Active substance | Test item | Active substance |
| LD₅₀ [µg/bee] | > 2272.72 | > 800.00 | > 2272.72 | > 800.00 |
| NOED [µg/bee] | 2272.72 | 800.00 | 2272.72 | 800.00 |

Conclusion

The toxic effects of the test item SIP 41061 (Prothioconazole 400 g/L SC) to adult honeybees (*Apis mellifera* L.) after oral and topical exposure, were assessed in a GLP compliant laboratory test according to the Test Guidelines OECD 213 and OECD 214.

The contact LD₅₀ after 48 hours was estimated to be greater than 2272.72 µg test item/bee, 800.00 µg Prothioconazole/bee.

The validity criteria with regards to control mortality and toxicity on the reference item were met, because the average mortality in the control and wetting agent control groups was 4.0% and 10%, respectively at the end of the test and the LD₅₀-24h of the toxic standard was 0.15 µg a.s./bee. No behavioural abnormalities were noted.

Study 2

| | |
|-------------------|---|
| Comments of zRMS: | <p>The study is acceptable. This study was evaluated according to OECD 246 and OECD 247. The study met the relevant validity criteria.</p> <p>Validity criteria of the study:</p> <ol style="list-style-type: none"> the average mortality of the control group was, at the end of the test: <ul style="list-style-type: none"> Acute oral test: 0%; Acute contact test: 0%; the average, control-corrected mortality of the reference item groups was 100% at the end of the test, at the doses of 4 µg a.s./bb (for the oral test) and 10 µg a.s./bb (for the contact test). <p><i>Bombus terrestris</i> L.</p> <p>The following endpoints are considered valid for use in the risk assessment:</p> <ol style="list-style-type: none"> Oral exposure: LD₅₀ > 557.63 µg product/bb (equivalent to > 196.29 µg a.s./bb); NOED ≥ 557.63 µg product/bb (equivalent to ≥ 196.29 µg a.s./bb) Contact exposure: LD₅₀ > 568.18 µg product/bb (equivalent to > 200 µg a.s./bb); NOED ≥ 568.18 µg product/bb (equivalent to ≥ 200 µg a.s./bb) |
|-------------------|---|

| | |
|------------------|--|
| Report | Acute oral and acute contact toxicity effects of SIP 41061 to adult worker bumblebees <i>Bombus terrestris</i> L., Laboratory Limit Test Rossini L., 2021 Report N. BT140/21 BioTecnologie BT S.r.l |
| Guideline(s): | Laboratory study based on the OECD Guidelines for the testing of chemicals 246 and 247 (2017) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Vertebrate study | No |

Material and methods

1. Test item

| | |
|-------------------------|------------------------------|
| Name: | SIP 41061 |
| Description: | Agrochemical |
| Batch: | 21/0006 |
| A.s. and CAS: | Prothioconazole: 178928-70-6 |
| Content of a.s.: | 409 g/L – 35.2% |

2. Test system

| | |
|-----------------|---|
| Species: | <i>Bombus terrestris</i> L. |
| Age: | Adult workers |
| Source: | Healthy colonies provided by BioPlanet S.r.l. |
| Diet: | 50 % (w/v) aqueous sucrose solution |

3. Experimental conditions

| | |
|---------------------|--|
| Temperature: | 23.8 - 25.1 °C (avg. 24.3°C) |
| Humidity: | 57.0 – 62.6% (avg. 60.2%) |
| Photoperiod: | 24 hours darkness (except during observations) |

4. Experimental period

From 12th to 14th October 2021 (Biological phase); from 20th to 22nd October 2021 (Analytical phase)

5. Contact Test

The acute contact toxicity test in the laboratory was performed as a limit test: adult worker bumblebees were topically exposed to a single dose of the test item (568.18 µg test item/bb) dissolved in deionised water, by direct application to the thorax (droplets). A control group treated with water and a reference item group exposed to nominal dosage of 10.0 µg dimethoate/bee were tested in parallel. The wetting agent (Triton X-100) was used at a concentration of 0.5 % v/v in the preparation of the water control and reference item groups. Fifty bumblebees for the control and for the test item group and thirty bumblebees for the reference item group were tested.

6. Observations

Assessments on mortality and any behavioural abnormality were performed at 4, 24 and 48 hours after treatment for both tests.

7. Statistics

Due to the results, no statistics was performed.

Results contact test

The results of the acute contact toxicity test show no effects of the test item on mortality at the end of the test. No behavioural abnormalities were observed. The results of the contact test are summarized in Table 3, the endpoints in Table 4. The mortality of the reference item was 100% at the end of the test period.

Table 13 Acute contact toxicity of SIP 41061 to adult bumblebees - Mortality

| Groups | Doses [µg/bb] | 4 hours | | 24 hours | | 48 hours | |
|----------------|----------------|---------|--------|----------|--------|----------|--------|
| | Test item | M [%] | CM [%] | M [%] | CM [%] | M [%] | CM [%] |
| Control | - | 0.00 | n/a | 0.00 | n/a | 0.00 | n/a |
| Ta | 568.18 | 0.00 | 0.00 | 0.00 | 0.00 | 2.00 | 2.00 |
| | Reference item | M [%] | CM [%] | M [%] | CM [%] | M [%] | CM [%] |
| R | 10.0 | 3.33 | 3.33 | 63.33 | 63.33 | 80.00 | 80.00 |

M = mortality; CM = corrected mortality, using the Abbott's formula (1925) modified by Schneider-Orelli (1947); n/a = not applicable.

Table 14 Acute contact toxicity of SIP 41061 to adult bumblebees - Endpoints

| Endpoint [µg/bee] | 24 hours | | 48 hours | |
|------------------------|-----------|------------------|-----------|------------------|
| | Test item | Active substance | Test item | Active substance |
| NOED | ≥ 568.18 | ≥ 200.00 | ≥ 568.18 | ≥ 200.00 |
| LD₅₀ | > 568.18 | > 200.00 | > 568.18 | > 200.00 |

Conclusion

The toxicity effects of the test item SIP 41061 to adult worker bumblebees (*Bombus terrestris* L.) after oral or topical exposure, were assessed in a GLP compliant laboratory test.

Since no effects on mortality were observed, the contact NOED was 568.18 µg test item/bb corresponding to 200 µg Prothioconazole/bb after 24 and 48 hours, and the contact LD₅₀ was evaluated to be > 568.18 µg test item/bb corresponding to 200 µg Prothioconazole/bb after 24 and 48 hours.

The validity criteria with regards to control mortality and toxicity on the reference item were met, because the average mortality in the control group and in the reference item group was 0% and 80%, respectively, at the end of the test.

No behavioural abnormalities were noted.

A 2.3.1.4 KCP 10.3.1.2. Chronic toxicity to bees

| | |
|-------------------|---|
| Comments of zRMS: | <p>The study is considered valid. It is GLP, performed according to relevant guideline and all validity criteria given in OECD 245 (2017) are met.</p> <p>Validity criteria of the study:</p> <ul style="list-style-type: none"> - The average mortality for the control did not exceed 15% at the end of the test: 10.0%; - The average mortality in the reference item treatment was ≥ 50% at the end of the test: 100%. <p>Agreed endpoints:</p> <p>The NOEC was 4000.00 mg SIP 41061/kg diet (1440 mg a.s./kg diet), corresponding to a NOEDD of 89 µg SIP 41061/bee/day (32.24 µg a.s./bee/day).</p> <p>The LC₅₀ was estimated to be greater than 10000.00 mg SIP 41061/kg diet (3600.00 mg a.s./kg diet), corresponding to a LDD₅₀ greater than 279.309 µg SIP 41061/bee/day (100.55 µg a.s./bee/day).</p> |
|-------------------|---|

| | |
|--------------------------------------|---|
| Reference: | KCP 10.3.1.2 |
| Report | Chronic oral effects of SIP 41061 on adult worker honeybees (<i>Apis mellifera</i> L.) 10-day feeding laboratory test Venturi S., 2020 Report N. BT115/0 BioTecnologie BT S.r.l |
| Guideline(s): | Laboratory study according to OECD Test Guideline 245 “Honey bee (<i>Apis mellifera</i> L.), Chronic Oral Toxicity test (10-day feeding test in the laboratory)” (09-Oct-2017). |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Duplication (if vertebrate study) | No |

Materials

| | |
|-----------------------------------|---|
| 1. Test item | |
| Name: | SIP41061 (Prothioconazole 400 g/L SC) |
| Description: | Fungicide |
| Batch: | 20006/P01 |
| A.s. and CAS: | Prothioconazole: 178928-70-6 |
| Content of a.s.: | 415.8 g/L or 36% w/w |
| 2. Test system | |
| Species: | <i>Apis mellifera</i> L. |
| Age: | Adult workers (maximum 2 days old) |
| Source: | Healthy colonies (hives no. 4, 13 and 15) maintained at BioTecnologie BT S.r.l. |
| Acclimation: | 24 hours |
| Diet: | 50% (w/v) aqueous sucrose solution |
| 3. Experimental conditions | |
| Temperature: | 31.0-35.0°C (avg. 33.0°C) |
| Humidity: | 50.0-70.0% (avg. 60.1%) |
| Photoperiod: | 24 hours darkness (except during observations) |

Study design and method

| | |
|-----------------------------------|--|
| 1. Experimental period | |
| | From 10 th to 20 th June 2020 (Biological phase); from 29 th to 30 th June 2020 (Analytical phase) |
| 2. Experimental treatments | |
| | The test item was dissolved in deionized water and subsequently diluted: the obtained water stock solutions were used to prepare the feeding solutions with 50% (w/v) aqueous sucrose solution. Both water stock and feeding solutions of the test item were prepared freshly every day and administered to the bees, for a period of 10 days (from Day 0 to Day 9 of the test). The reference item Dimethoate was tested at 1.00 mg a.s./kg diet. |
| 3. Study design | |

Table 15 Trial layout (f.s. = feeding solution)

| Groups | Concentrations | No. bees/cage | No. replicates | ID Code |
|---------------|----------------------|---------------|----------------|------------------|
| | mg test item/kg f.s. | | | |
| Water Control | 0.00 | 10 | 3 | Ca, Cb, Cc |
| T1 | 256.00 | 10 | 3 | T1a, T1b, T1c |
| T2 | 640.00 | 10 | 3 | T2a, T2b, T2c |
| T3 | 1600.00 | 10 | 3 | T3a, T3b, T3c |
| T4 | 4000.00 | 10 | 3 | T4a, T4b, T4c |
| T5 | 10000.00 | 10 | 3 | T5a, T5b, T5c |
| Ref. item | 1.00 | 10 | 3 | Ra, Rb, Rc |
| Evaporation | - | 0 | 3 | EVAa, EVAb, EVAc |

4. Observations

Mortality and sub-lethal effects were recorded every 24 ± 2 h, from D1 to D10 of the test. The amount of feeding solution consumed was determined by weighing the feeders at the start and at the end of each 24-h period of feeding.

5. Statistics

The software ToxRatPro 3.3.0 was used for the statistical analysis.

Results

Table 16 Summarized mean food uptake over the course of the study (f.s. = feeding solution)

| Groups | Concentrations | Mean uptake* | |
|----------------|----------------------|------------------|----------------------|
| | | Feeding solution | Test item |
| | mg test item/kg f.s. | mg diet/bee/day | µg test item/bee/day |
| Water Control | 0.00 | 33.75 | 0.000 |
| T1 | 256.00 | 26.76 | 6.852 |
| T2 | 640.00 | 20.31 | 12.999 |
| T3 | 1600.00 | 24.18 | 38.690 |
| T4 | 4000.00 | 22.39 | 89.567 |
| T5 | 10000.00 | 27.93 | 279.309 |
| | mg ref. item/kg f.s. | mg diet/bee/day | µg ref. item/bee/day |
| Reference item | 1.00 | 13.49 | 0.013 |

*adjusted for evaporation from the feeders.

Table 17 Mean Mortality (%M) and Mean Corrected Mortality (%CM) at the end of the test (on Day 10)

| Groups | Concentrations | Doses | Cumulative Mortality | | | |
|----------------|----------------------|----------------------|----------------------|-----|--------|----------------|
| | mg test item/kg f.s. | µg test item/bee/day | %M | SD | %CM | S ¹ |
| Water Control | 0.00 | 0.000 | 10.0 | 1.0 | n/a | n/a |
| T1 | 256.00 | 6.852 | 3.3 | 0.6 | -7.4 | - |
| T2 | 640.00 | 12.999 | 20.0 | 1.0 | 11.1 | - |
| T3 | 1600.00 | 38.690 | 13.3 | 1.5 | 3.7 | - |
| T4 | 4000.00 | 89.567 | 16.7 | 2.1 | 7.4 | - |
| T5 | 10000.00 | 279.309 | 53.3 | 2.5 | 48.1 | + |
| | mg ref. item/kg f.s. | µg ref. item/bee/day | | | | |
| Reference item | 1.00 | 0.013 | 100.0 | 0.0 | 100.00 | n/a |

SD = Standard Deviation; S = statistical significance; "+" = significant; "-" = not-significant;

¹Step-down Cochran-Armitage Test Procedure ($\alpha = 0.05$, one-sided greater).

The analytical determination of the active ingredient content in the water and in the sugar solutions was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (report N. **BT214/20**, please refer to **dRR Section B5**). The analytical determination of the active ingredient content in the test solutions showed a mean recovery of 99.6-101.0% in

water and 105.4-108.8% in the sugar solutions. Since the content of active substance was determined to be within 20% of the nominal value in the water and in the sugar solutions, the endpoints were calculated with the nominal concentrations and doses of the test item and of the active ingredient Prothioconazole.

Conclusion

The effects of SIP41061 on adult worker honeybees (*Apis mellifera* L.) were assessed in a 10-day oral chronic test.

The test item had significant lethal effects when administered for 10 consecutive days at the concentration of 10000.00 mg/kg diet, corresponding to a dose (based on daily mean uptake of food) of 279.309 µg test item/bee/day.

Therefore, the NOEC was 4000.00 mg test item/kg diet (1440 mg a.s./kg diet), corresponding to a NOEDD of 89 µg test item/bee/day (32.24 µg a.s./bee/day).

The LC₅₀ was estimated to be greater than 10000.00 mg test item/kg diet (3600.00 mg a.s./kg diet), corresponding to a LDD₅₀ greater than 279.309 µg test item/bee/day (100.55 µg a.s./bee/day).

A 2.3.1.5 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

| | |
|-------------------|---|
| Comments of zRMS: | <p>zRMS comment:</p> <p>The study is considered valid. It is GLP, performed according to relevant guideline and all validity criteria given in OECD 239 (2016) are met.</p> <p>Deviation:</p> <p>1. Temperature was out of the range for more than two hours (maximum 3 hours). Minimum value of temperature was 33.2°C.</p> <p>This deviation had no impact on the outcome of the study.</p> <p>Mortality</p> <p>NOED = 200.00 µg prod./larva/developmental period (corresponding to 72.00 µg prothioconazole/larva/developmental period) equivalent to 1298.70 mg prod./kg diet (corresponding to 467.53 mg prothioconazole/kg diet).</p> <p>EMERGENCY</p> <p>The NOED and the NOEC for adult emergence rate were determined to be 200.00 µg prod./larva (corresponding to 72.00 µg prothioconazole/larva) and 1298.70 mg prod./kg diet (corresponding to 467.53 mg prothioconazole/kg diet, respectively).</p> |
|-------------------|---|

| | |
|---------------|---|
| Reference: | KCP 10.3.1.3/01 |
| Report | Effects of SIP 41061 on honeybees (<i>Apis mellifera</i> L.) 22-day larval toxicity test with repeated exposure. Report N. BT116/20 Colli M., 2020 |
| Guideline(s): | Laboratory study according to OECD Guidance Document No. 239 "Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure" (15-Jul-2016) |
| Deviations: | Yes Deviation description: temperature was out of the range for more than two hours (maximum 3 hours). Minimum value of temperature was 33.2°C. Period of occurrence: during the first treatment day on D3, 20th May 2020. Impact on the study: none. |
| GLP: | Yes |

Acceptability:

Duplication No
(if vertebrate study)

Material and methods

| | | | | | | |
|--|---|---|--|--------------------------------|--------------------------|---------------------|
| 1. Test item | | | | | | |
| Name: | SIP41061 (Prothioconazole 400 g/L SC) | | | | | |
| Indication: | Fungicide | | | | | |
| Batch: | 20006/P01 | | | | | |
| Active substances: | Prothioconazole: 415.8 g/L – 36% w/w | | | | | |
| Density: | 1.155 g/mL | | | | | |
| 2. Test system | | | | | | |
| Species: | <i>Apis mellifera</i> L. | | | | | |
| Age: | 3 days old larvae (D3) | | | | | |
| Source: | Healthy colony maintained at BioTecnologie BT S.r.l. | | | | | |
| Diet: | Dependent on developmental stage: Diet A, Diet B and Diet C (see par. 4.2.1) | | | | | |
| 3. Experimental conditions | | | | | | |
| Temperature: | range 34.0 – 35.0°C (average measured 34.5°C) | | | | | |
| Humidity: | range from D1 to D8 = 90.0 – 100.0% (average measured 97.3%), range from D8 to D15: 75.0 – 85.0% (average measured 79.1%), range from D15 to D22: 50.0 – 80.0% (average measured 72.4%) | | | | | |
| Photoperiod: | 24 h darkness (except during observations) | | | | | |
| STUDY DESIGN AND METHODS | | | | | | |
| 1. Experimental period: from 20 th May to 08 th June 2020 | | | | | | |
| 2. Experimental treatments | | | | | | |
| The test item was dissolved in ultrapure water in order to get the highest stock solution (S5). The other stock solutions (from S4 to S1) were obtained by sequential dilution. The stock solutions were mixed into the diet in a range of five increasing concentrations and administered daily to the larvae at a constant concentration, from day 3 (D3) to 6 (D6) of the test. Three replicates of 12 larvae each were prepared for each experimental group. The reference item Dimethoate was dissolved in deionized water and simultaneously tested at a single concentration (equivalent to a cumulative dose of 7.39 µg a.s./larva). | | | | | | |
| 3. Study design | | | | | | |
| Table 18 Trial layout | | | | | | |
| Treatment | Dose [µg prod./larva] | Dose [µg a.s./larva] | Concentration [mg prod./kg diet] | No. of larvae/replicate | No. of replicates | ID codes |
| Control | 0.00 | 0.00 | 0.00 | 12 | 3 | CTRLa, CTRLb, CTRLc |
| Test item (T1) | 50.00 | 18.00 | 324.68 | 12 | 3 | T1a, T1b, T1c |
| Test item (T2) | 100.00 | 36.00 | 649.35 | 12 | 3 | T2a, T2b, T2c |
| Test item (T3) | 200.00 | 72.00 | 1298.70 | 12 | 3 | T3a, T3b, T3c |
| Test item (T4) | 400.00 | 144.00 | 2597.40 | 12 | 3 | T4a, T4b, T4c |
| Test item (T5) | 800.00 | 288.00 | 5194.81 | 12 | 3 | T5a, T5b, T5c |
| Treatment | Dose [µg a.s./larva] | Concentration [mg a.s./kg diet] | No. of larvae/replicate | No. of replicates | ID codes | |
| Reference item | 7.39 | 48.00 | 12 | 3 | Ra, Rb, Rc | |
| 4. Observations | | | | | | |
| Assessments on mortality and any developmental/behavioral abnormality were performed from D4 to D8 and on D15 and on D22. The pupal mortality and the adults' emergence rate on D22 were also assessed. | | | | | | |
| 5. Statistics | | | | | | |

The Software Tox Rat Pro 3.3.0 was used to perform the statistics.

Results

In the following table the study results are summarized.

Table 19 Mortality and Corrected Mortality (CM) of larvae (on D8)

| Treatment | Dose [µg prod./larva] | Concentration [mg prod./kg diet] | Larvae mortality on D8 | | |
|----------------|--------------------------|-------------------------------------|------------------------|----------------|-------|
| | | | Mean [%] | CM - Mean [%] | Sign. |
| Control | 0.00 | 0.00 | 5.56 | n.a. | n.a. |
| Test item (T1) | 50.00 | 324.68 | 2.78 | 0.00 | - |
| Test item (T2) | 100.00 | 649.35 | 2.78 | 0.00 | - |
| Test item (T3) | 200.00 | 1298.70 | 5.56 | 0.00 | - |
| Test item (T4) | 400.00 | 2597.40 | 94.44 | 94.12 | + |
| Test item (T5) | 800.00 | 5194.81 | 100.00 | 100.00 | + |

n.a. = not applicable

+ : significant; - : non-significant (Step-down Cochran-Armitage test - $\alpha = 0.05$, one-sided greater).

Table 20 Pupal Mortality

| Treatment | Dose [µg prod./larva] | Concentration [mg prod./kg diet] | Pupal mortality from D8 to D15* | Pupal mortality from D8 to D22** |
|----------------|--------------------------|-------------------------------------|------------------------------------|-------------------------------------|
| | | | Mean [%] | Mean [%] |
| Control | 0.00 | 0.00 | 5.88 | 11.76 |
| Test item (T1) | 50.00 | 324.68 | 0.00 | 2.86 |
| Test item (T2) | 100.00 | 649.35 | 5.71 | 5.71 |
| Test item (T3) | 200.00 | 1298.70 | 14.71 | 20.59 |
| Test item (T4) | 400.00 | 2597.40 | 50.00 | 50.00 |
| Test item (T5) | 800.00 | 5194.81 | ---- | ---- |

*calculated in percentage comparing the number of dead pupae from D8 to D15 to the number of alive pupae on D8

**calculated in percentage comparing the number of dead pupae from D8 to D22 to the number of alive pupae on D8

Table 21 Total mortality and corrected mortality (CM) from D3 to D22 and emergence on D22

| Treatment | Dose [µg prod./larva] | Concentration [mg prod./kg diet] | Mortality (larvae + pupae) on D22 | | | Adult emergence on D22* | |
|----------------|--------------------------|-------------------------------------|--------------------------------------|----------------|-------|----------------------------|-------|
| | | | Mean [%] | CM - Mean [%] | Sign. | Mean [%] | Sign. |
| Control | 0.00 | 0.00 | 16.67 | n.a. | n.a. | 83.33 | n.a. |
| Test item (T1) | 50.00 | 324.68 | 5.56 | 0.00 | - | 94.44 | - |
| Test item (T2) | 100.00 | 649.35 | 8.33 | 0.00 | - | 91.67 | - |
| Test item (T3) | 200.00 | 1298.70 | 25.00 | 10.00 | - | 75.00 | - |
| Test item (T4) | 400.00 | 2597.40 | 97.22 | 96.67 | + | 2.78 | + |
| Test item (T5) | 800.00 | 5194.81 | 100.00 | 100.00 | + | 0.00 | + |

n.a. = not applicable

+ : significant; - : non-significant (Step-down Cochran-Armitage test - $\alpha = 0.05$, one-sided greater).

*n° adult emerged/n° initial larvae x 100

The analytical determination of the active ingredient content in the water stock solutions was performed by UHPLC-MS/MS. The analytical method was validated according to SANCO/3029/99 rev.4 in a separate GLP study (report N. **BT214/20, please refer to dRR Section B5**). The analytical determination of the active ingredient content in the water stock solutions showed a mean recovery of 90.11–99.06%. Since the content of active substance was determined to be within 20% of the nominal value in the water stock solutions, the endpoints were calculated with the nominal concentrations and doses of the test item and of the active ingredient Prothioconazole.

Conclusion

The effects of the test item SIP41061 on the larval development and subsequent adult emergence of honeybees (*Apis mellifera* L.), were tested in a GLP compliant laboratory study.

The validity criteria with regards to control larval mortality on D8, control adults' emergence on D22 and toxicity on the reference item were met.

Regarding the effects on larvae on D8 (developmental period), the test item SIP41061 caused statistically significant mortality starting from the dose of 400.00 µg prod./larva. Therefore, the NOED for larvae on D8 was determined to be 200.00 µg prod./larva/developmental period (corresponding to 72.00 µg Prothioconazole/larva/developmental period) equivalent to 1298.70 mg prod./kg diet (corresponding to 467.53 mg Prothioconazole/kg diet).

Regarding the effects on adult emergence on D22, the test item SIP41061 caused statistically significant reduction in emergence rate at the two highest tested doses.

The NOED and the NOEC for adult emergence rate were determined to be 200.00 µg prod./larva (corresponding to 72.00 µg Prothioconazole/larva) and 1298.70 mg prod./kg diet (corresponding to 467.53 mg Prothioconazole/kg diet, respectively).

The mortality data allowed the extrapolation of the ED/EC₁₀, ED/EC₂₀ and ED/EC₅₀.

Table 22 Summary results for all endpoints in terms of formulated product

| Critical dose [µg prod./larva] | Mortality D8 | Emergence D22 |
|--|-----------------------------|--|
| ED ₁₀ | 290.35 (c.l. 95%: n.d.) | 200.01 (c.l. 95%: 170.87 – 222.89) |
| ED ₂₀ | 305.09 (c.l. 95%: n.d.) | 220.57 (c.l. 95%: 193.65 – 244.23) |
| ED ₅₀ | 335.41 (c.l. 95%: n.d.) | 265.99 (c.l. 95%: 240.07 – 298.13) |
| NOED | 200.00 | 200.00 |
| Critical concentration [mg prod./kg diet] | Mortality D8 | Emergence D22 |
| EC ₁₀ | 2062.92 (c.l. 95%: n.d.) | 1300.37 (c.l. 95%: 1090.25 – 1463.67) |
| EC ₂₀ | 2141.95 (c.l. 95%: n.d.) | 1437.80 (c.l. 95%: 1247.00 – 1616.36) |
| EC ₅₀ | 2284.11 (c.l. 95%: n.d.) | 1707.19 (c.l. 95%: 1519.52 – 1977.45) |
| NOEC | 1298.70 | 1298.70 |

ED/EC_x evaluated by Probit analysis.

n.d. = not determined due to mathematical reason

c.l.: confidence limits

A 2.3.1.6 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.7 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <u><i>Aphidius rhopalosiphi</i></u> |
| | The study is considered as acceptable. All validity criteria were met. |
| | The following validity criteria were met during the study: |

| | |
|--|--|
| | <ul style="list-style-type: none"> - in the control group, the arithmetic mean mortality (dead and escaped) is $\leq 13\%$ (actual value: 2.0%); - in the control group, the mean parasitisation is ≥ 5 aphid mummies/female (actual value: 11.0); - in the control group, no more than two females fail to produce mummies (one female failed); - in the reference item group, the corrected mean mortality is in the range 75 - 100% (actual value: 100.0%). <p>Agreed endpoints:</p> <p>Mortality parameter: The LR_{50} was estimated to be greater than 965.91 g test item/ha (340 g a.s./ha). The $NOER_{mortality}$ was estimated to be greater or equal than 965.91 g test item/ha (340 g a.s./ha).</p> <p>Reproduction parameter: The ER_{50} was calculated to be greater than 965.91 g test item/ha (340 g a.s./ha). The $NOER_{reproduction}$ was estimated to be greater or equal than 965.91 g test item/ha (340 g a.s./ha).</p> |
|--|--|

| | |
|------------------|---|
| Reference: | KCP 10.3.2.1/01 |
| Report | Effects of SIP 41061 on the parasitic wasp <i>Aphidius rhopalosiphi</i> under Laboratory Conditions Report N. BT141/21 Lucchetti F., 2021 BioTecnologie BT S.r.l |
| Guideline(s): | ESCORT I Guidance Document (Barrett K.L. et al., eds. 1994) ESCORT II Guidance Document (Candolfi et al., eds. 2001) Mead – Briggs M. A., Brown K., Candolfi M.P., Coulson M. J. M., Miles M., Moll M., Nienstedt K., Schuld M., Ufer A. and McIndoe E. (2000): A laboratory test for evaluating the effects of plant protection products on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani Perez) (Hymenoptera, Braconidae), pp. 13-25. In: Candolfi M.P., (2000): IOBC/WPRS Guideline of the ring-testing group (Mead-Briggs et al., 2009) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Vertebrate study | No |

The effects of the product SIP41061 (Prothioconazole 400 g/L) on the survival and the reproduction of the aphid parasitoid *Aphidius rhopalosiphi* De Stefani-Perez (Hymenoptera: Braconidae) were tested in a laboratory study in compliance with the principles of Good Laboratory Practice (GLP).

Material and methods

| 8. Test item | |
|-----------------|---|
| Name | SIP41061 (Prothioconazole 400 g/L) |
| Description | Agricultural chemicals |
| Batch | 21/0006 |
| a.s. and CAS | Prothioconazole [178928-70-6] |
| Content of a.s. | 35.2% w/w (409 g/L) |

| | | | | | | | | | | | | | | | | | | | |
|-----------------------------|--|--|----------------------------|--|--|--------|-------------------|--|------------------|-------------|---------|---|---|------------------|--------|-----|----------------|------|------|
| 9. Test system | | | | | | | | | | | | | | | | | | | |
| Species: | Aphidius rhopalosiphi De Stefani-Perez (Hymenoptera: Braconidae) | | | | | | | | | | | | | | | | | | |
| Age: | Adults (less than 48 hours old) | | | | | | | | | | | | | | | | | | |
| Source: | Biotechnologie BT S.r.l. internal breeding – Batch AR300821 | | | | | | | | | | | | | | | | | | |
| Diet: | Culture and mortality exposure phase: water-honey solution (3:1 v/v), ad libitum. Parasitisation phase: honeydew from aphids (Sitobion avenae). | | | | | | | | | | | | | | | | | | |
| 10. Experimental conditions | | | | | | | | | | | | | | | | | | | |
| Temperature: | Target: | 20.0 ± 2.0°C | | | | | | | | | | | | | | | | | |
| | Mortality phase: | 19.7 – 20.6°C (avg. 20.0°C) | | | | | | | | | | | | | | | | | |
| | Parasitisation phase: | 20.2 – 21.8°C (avg. 20.9°C) | | | | | | | | | | | | | | | | | |
| | Mummies’ maturation phase: | 18.6 – 21.1°C (avg. 20.0°C) | | | | | | | | | | | | | | | | | |
| Humidity: | Target: | 60.0 – 90.0% (mortality), not required for parasitisation and mummies maturation | | | | | | | | | | | | | | | | | |
| | Mortality phase: | 64.3 – 73.2% (avg. 68.0%) | | | | | | | | | | | | | | | | | |
| Photoperiod: | 16 hours light, 8 hours darkness | | | | | | | | | | | | | | | | | | |
| Light intensity: | Target: | 400 – 1200 lux (mortality), 400 – 6500 lux (parasitisation), up to 20000 lux (mummies maturation). | | | | | | | | | | | | | | | | | |
| | Mortality phase: | 3 lux (during the darkness period) – 1085 lux (during the lightning period) avg. 717 lux. | | | | | | | | | | | | | | | | | |
| | Parasitisation phase: | 3 lux (during the darkness period) – 1136 lux (during the lightning period) avg. 691 lux. | | | | | | | | | | | | | | | | | |
| | Mummies’ maturation phase: | 0 lux (during the darkness period) – 19502 lux (during the lightning period). | | | | | | | | | | | | | | | | | |
| STUDY DESIGN AND METHODS | | | | | | | | | | | | | | | | | | | |
| 6. Guidelines | IOBC/WPRS Guidelines: Mead-Briggs et al. (2000) and Mead-Briggs et al. (2009) | | | | | | | | | | | | | | | | | | |
| 7. Experimental period | From 14 th to 28 th September 2021 | | | | | | | | | | | | | | | | | | |
| 8. Experimental treatments | One application rate of the test item (table 1) was sprayed on glass plates. Deionized water and a dimethoate formulation (400 g a.s./L) were applied to prepare the negative and the positive control, respectively. Application volume was 200 L solution/ha. Five replicates per experimental group were prepared, each one with 10 adult wasps (including minimum 5 females/replicate). | | | | | | | | | | | | | | | | | | |
| 9. Test units | During the exposure phase, each test unit consisted of two circular glass plates (Ø: 10 cm), assembled to cages – keeping the sprayed sides inside – with an aluminium frame (Ø: 10 cm, height: 1.5 cm, width: 1 cm). During the reproduction phase each test unit consisted of a pot containing 10-40 barley seedlings each, approx. 6-10 days old, infested with more than 100 (both adults and nymphs) cereal aphids (Sitobion avenae) and were confined using clear Plexiglas cylinders (Ø: ca. 10 cm, height: ca. 20 cm) covered with filter paper to allow ventilation. | | | | | | | | | | | | | | | | | | |
| 10. Application rates | <table><tr><td colspan="3">Table 23 Application rates</td></tr><tr><td rowspan="2">Groups</td><td colspan="2">Application rates</td></tr><tr><td>[g test item/ha]</td><td>[g a.s./ha]</td></tr><tr><td>Control</td><td>0</td><td>0</td></tr><tr><td>Test item 1 (T1)</td><td>965.91</td><td>340</td></tr><tr><td>Reference item</td><td>0.32</td><td>0.12</td></tr></table> | | Table 23 Application rates | | | Groups | Application rates | | [g test item/ha] | [g a.s./ha] | Control | 0 | 0 | Test item 1 (T1) | 965.91 | 340 | Reference item | 0.32 | 0.12 |
| Table 23 Application rates | | | | | | | | | | | | | | | | | | | |
| Groups | Application rates | | | | | | | | | | | | | | | | | | |
| | [g test item/ha] | [g a.s./ha] | | | | | | | | | | | | | | | | | |
| Control | 0 | 0 | | | | | | | | | | | | | | | | | |
| Test item 1 (T1) | 965.91 | 340 | | | | | | | | | | | | | | | | | |
| Reference item | 0.32 | 0.12 | | | | | | | | | | | | | | | | | |
| 11. Observations | The conditions of the wasps were recorded at 2, 24 and 48 hours after start of exposure. The parasitized aphids (mummies) were counted 12 days after the fecundity phase started. Behavioural abnormalities were also recorded. | | | | | | | | | | | | | | | | | | |
| 12. Statistics | The software ToxRat Pro 3.3.0 was used for the statistical evaluation of the results The Fisher’s Exact Binomial Test was performed in order to verify the statistical significance of the mortality data when comparing the test item treatment data with control data. STUDENT-t test Homogeneous Variances was used to verify the statistical significance of the reproduction data when comparing the test item treatment data with control data | | | | | | | | | | | | | | | | | | |

Results

After 48 hours, the mean mortality of wasps was: 2.0% in the untreated control, 2.0% in the Test item and 100% in the group treated with the reference item.

The effect on survival of the SIP41061 treatment at the tested application rate, compared to the untreated control group, was not statistically significant (Fisher's Exact Binomial Test).

The LR_{50} was estimated to be greater than 965.91 g test item/ha (340 g a.s./ha).

The $NOER_{mortality}$ was estimated to be greater or equal than 965.91 g test item/ha (340 g a.s./ha).

The mean reproduction rate was: 11.0 mummies/female in the control and 10.9 mummies/female in the test item. The reduction of the reproduction in the treated group was determined to be 0.6% (Table 2).

The effect on the reproduction of SIP41061 at the tested application rate, compared to the untreated control group, was not statistically significant (STUDENT-t test Homogeneous Variances).

The ER_{50} was calculated to be greater than 965.91 g test item/ha (340 g a.s./ha).

The $NOER_{reproduction}$ was estimated to be greater or equal than 965.91 g test item/ha (340 g a.s./ha).

No behavioral abnormalities of the treated organisms were observed during the test.

A summary of the results obtained at the end of the test are showed in the table below.

Table 24 Summary of mortality and reproductive performance results

| Treatment groups | Application rates | | Mortality 48 hours AT | | Reproductive capacity | | |
|------------------|-------------------|-------------|-----------------------|--------|--------------------------------|--------|-------|
| | [g test item./ha] | [g a.s./ha] | M [%] | CM [%] | Mean number of mummies/females | SD [±] | R [%] |
| Control | 0 | 0 | 2.0 | n/a | 11.0 | 7.75 | n/a |
| Test item T1 | 965.91 | 340 | 2.0 | 0.0 | 10.9 | 6.86 | 0.6 |
| Reference item | 0.32 | 0.12 | 100.0 | 100.0 | - | - | - |

AT = after treatment; M% = Mean Mortality; CM% = Corrected Mean Mortality; SD = Standard deviation; R% = Reduction in reproduction relative to the control; n/a = not applicable.

Conclusion

The effects of the test item SIP41061 on the survival and the reproduction of the aphid parasitoid *Aphidius rhopalosiphi* De Stefani-Perez (Hymenoptera: Braconidae) were investigated in a GLP compliance single rate laboratory test following the IOBC/WPRS guidelines.

No significant effect on survival was found at the tested SIP41061 application rate when compared to the control. The LR_{50} value was estimated to be greater than 965.91 g test item/ha (340 g a.s./ha). The $NOER_{mortality}$ was estimated > 965.91 g test item/ha (340 g a.s./ha).

Regarding the effect on the reproduction, a reduction of 0.6% in the mean number of mummies per female was observed in the treated group compared to the control. Therefore, the ER_{50} was estimated to be greater than 965.91 g test item/ha (340 g a.s./ha). According to the STUDENT-t test Homogeneous Variances, the observed reduction in reproduction was not statistically significant. Thus, the $NOER_{reproduction}$ was estimated > 965.91 g test item/ha (340 g a.s./ha).

All validity criteria were met.

No behavioral abnormalities of the treated organisms were observed during the test.

Study 2

| | |
|-------------------|--|
| Comments of zRMS: | <p><u><i>Typhlodromus pyri</i></u></p> <p>The study is considered as acceptable. All validity criteria were met.</p> <p>The following validity criteria were met during the study:</p> <ul style="list-style-type: none"> the arithmetic mean mortality of the control group (dead and escaped) was 20% on day 7; |
|-------------------|--|

| | |
|--|---|
| | <ul style="list-style-type: none"> the cumulative mean number of eggs per female of the control group (from day 7 to day 14) was 6.68 eggs/female; the arithmetic mean mortality of the reference item group (control corrected) of protonymphs on day 7 was 83.34%. <p>Agreed endpoints: <i>Typhlodromus pyri</i> LR₅₀ for mortality the ER₅₀ for reproduction were evaluated to be > 965.91 g/ha. (corresponding to 340 g prothioconazole/ha)</p> |
|--|---|

| | |
|--------------------------------------|--|
| Reference: | KCP 10.3.2.1/02 |
| Report | Effects of SIP41061 on the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari: Phytoseiidae) under laboratory Conditions Venturi S., 2021 BioTecnologie BT S.r.l. Report N. BT142/21 |
| Guideline(s): | ESCORT I Guidance Document (Barrett K.L. et al., eds. 1994) ESCORT II Guidance Document (Candolfi et al., eds. 2001) Blümel S., Bakker F.M., Baier B., Brown K., Candolfi M.P., Gobmann A., Grimm C., Jackel B., Nienstedt K., Schirra K.J., Ufer A. and Waltersdorfer A. (2000): Laboratory residual contact test with the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) for regulatory testing of plant protection products. In: Candolfi et al. (2000): Guidelines to evaluate side-effects of plant protection products to non-target arthropods. IOBC/WPRS Gent, Belgium, 121-143. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC –SANCO/10329/2002 rev 2. |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Duplication (if vertebrate study) | No |

Material and methods

4. Experimental period

| | |
|---|--|
| Temperature: | 23.7-26.4°C (average measured: 25.0°C) |
| Relative humidity: | 56.0-76.8% (average measured: 73.0%) |
| Description: | Agricultural chemicals |
| Photoperiod: | 16 hours light, 8 hours darkness |
| Active substance(s) and CAS number(s): | Prothioconazole [178928-70-6] |
| Content of a.s.: | 35.2% w/w (409 g/L) |

2. Test system

| | |
|-----------------|---------------------------------------|
| Species: | <i>Typhlodromus pyri</i> Scheuten |
| Age: | Protonymphs (24 hours old) |
| Source: | Katz Biotech AG |
| Diet: | Pollen and <i>Tetranychus urticae</i> |
| Water: | 50% deionized water + 50% tap water |

From 08th to 22nd November 2021

5. Treatments

The laboratory test was performed as a limit test: a single test item concentration in water (corresponding to the application rate 965.91 g/ha) was sprayed on glass plates; deionized water and a Dimethoate solution (12.0 g a.s./ha) were sprayed as control and reference item, respectively. Twenty protonymphs were transferred onto each plate – representing a single replicate – after the sprayed residues dried, within one hour from application. Three replicates per experimental group were prepared.

6. Observations

The survival of mites was assessed on day 7 after exposure started. The number of surviving females, laid and hatched eggs was recorded in three assessments during the reproduction phase, from day 7 to day 14.

7. Statistics

Statistical significance of the data was determined with Chi² 2x2 Table for survival (one-sided greater, alpha = 0.05) and Student-t test for Homogeneous Variances for reproductive capacity (one-sided smaller, alpha = 0.05). The software ToxRatPro 3.3.0 was used for the statistical analysis.

Results

The study results were summarised in the below table.

Table 25 Summary of mortality and reproduction results

| Group | Application rate [g/ha] | | Mortality | | | Reproductive capacity | | | |
|---------|-------------------------|-------------------------|-----------|-------|----------------|-----------------------|------|-------|----------------|
| | Product | Active substance | M% | CM% | S ¹ | Eggs/♀ | SD | R% | S ² |
| Control | - | - | 20.00 | n/a | n/a | 6.68 | 1.53 | n/a | n/a |
| T1 | 965.91 | Prothioconazole: 340.00 | 25.00 | 6.25 | - | 7.28 | 1.15 | -8.98 | - |
| R | 32.30 | Dimethoate: 12.0 | 86.67 | 83.34 | n/a | n/a | | | |

M% = Mean Mortality; CM% = Corrected Mean Mortality; Eggs/♀ = Mean number of eggs per female; SD = Standard deviation; R% = Reduction in Reproduction; n/a = not applicable; S = statistical significance; “-” = not significant; “+” = significant.

¹Chi² 2x2 Table (one-sided greater, alpha = 0.05); ²Student-t test for Homogeneous Variances (one-sided smaller, alpha = 0.05).

Conclusion

The effects of SIP41061 on the survival and the reproduction of the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) were investigated in a GLP rate-response test under laboratory conditions, following the IOBC/WPRS guidelines.

The test item was applied at 965.91 g/ha, corresponding to 340.0 g Prothioconazole/ha.

No significant effects were observed either on the survival and on the reproductive capacity; thus, the NOER for survival and the NOER for reproduction were both determined to be ≥ 965.91 g/ha, corresponding to ≥ 340.0 g Prothioconazole/ha, and both the LR₅₀ for mortality the ER₅₀ for reproduction were evaluated to be > 965.91 g/ha.

- | | | |
|-----------|--------------|--|
| A 2.3.2.2 | KCP 10.3.2.2 | Extended laboratory testing, aged residue studies with non-target arthropods |
| A 2.3.2.3 | KCP 10.3.2.3 | Semi-field studies with non-target arthropods |
| A 2.3.2.4 | KCP 10.3.2.4 | Field studies with non-target arthropods |

A 2.3.2.5 KCP 10.3.2.5 Other routes of exposure for non-target arthropods

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.1.1 Study 1

| | |
|-------------------|---|
| Comments of zRMS: | The study is considered as acceptable. All validity criteria were met. |
| | According to the OECD Guideline No. 222, the test is valid because the following criteria were satisfied in the control group: |
| | <ul style="list-style-type: none">each replicate (containing ten adults) had produced ≥ 30 juveniles at the end of the test (being 99, 85, 69, 84, 70, 71, 92 and 90 for the replicates a, b, c, d, e, f, g and h);the coefficient of variation (% RSD or CV) of reproduction was $\leq 30\%$ (being 13.73 %);adult mortality over the initial 4 weeks of the test was $\leq 10\%$ (being 0.0 %). |
| | Deviation from the study: None |
| | Agreed endpoints: |

| Endpoint values (mg of test item/kg dry artificial soil) | | |
|--|---------------|------------------------------------|
| Endpoint | NOEC | LC ₅₀ /EC ₅₀ |
| Mortality | ≥ 1000.0 | > 1000.0 |
| Reproduction | ≥ 1000.0 | > 1000.0 |

| |
|---|
| <ul style="list-style-type: none">For survival, no mortality was caused by the test item to the exposed earthworms up to the highest tested concentration. The NOEC value resulted to be equal/greater than 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil). The LC₅₀ was estimated to be greater than 1000.0 mg of test item/kg dry artificial soil.For biomass, no adverse effects on growth of survived earthworms resulted to be after 28 days of exposure at all the tested concentrations. The NOEC value resulted to be equal/greater than 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil).For reproduction, no adverse effects were assessed up to the concentration of 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil), that corresponding to the NOEC value for this endpoint. The EC₅₀ was estimated to be greater than 1000.0 mg of test item/kg dry artificial soil. |
|---|

| | |
|--------------------------------------|---|
| Reference: | KCP 10.4.1.1 |
| Report | Effects of the product SIP 341061 on reproduction and growth of the earthworm <i>Eisenia Andrei</i> in artificial soil. Pecorari. F., 202 Report N. BT118/20 BioTecnologie BT S.r.l, Todi, Italy |
| Guideline(s): | OECD 222 (2004) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | |
| Duplication (if vertebrate study) | Not relevant, no vertebrate study |

The effects of the test item SIP 41061 on reproduction of the earthworm *Eisenia andrei* were tested according to the guidelines OECD 222 (2016) and ISO 11268-2 (2012) and in compliance with the Principles of Good Laboratory Practice (GLP).

Material and methods

| | |
|-------------------------------------|--|
| 1. Test Item | |
| Name | SIP 41061 (Prothioconazole 400 g/L SC) |
| Indication | Fungicide |
| Batch No. | 20006/P01 |
| Content of a.s. (analysed) | Prothioconazole: 415.8 g/L – 36% w/w |
| 2. Test system | |
| Species | <i>Eisenia andrei</i> |
| Batch | EA230120 |
| Age | Adults (about eight months old with clitellum) |
| Weight at dosing | 250 mg ÷ 600 mg including gut content (range outlined in the OECD guideline No. 222) |
| Source | BioTecnologie BT internal breeding |
| Acclimatization | About one day (at the same environmental conditions of the test) |
| Diet | Vegetables (carrots and potatoes) |
| Water | Deionized water |
| 3. Experimental conditions | |
| Artificial soil | 10 % sphagnum peat; 20 % kaolin clay; 70 % industrial sand, no CaCO ₃ was needed as the pH value of the artificial soil was within the range as indicated by OECD guideline No. 222 |
| Temperature | 18.9 – 21.3°C (average: 20.3 °C) |
| Water content in the test container | About 25.60 mL of water/100 g of dry soil (50 % of the maximum WHC) |
| Photoperiod | 16 h light + 8 h darkness |
| Light intensity | 481 - 631 lux |
| STUDY DESIGN AND METHODS | |
| 1. Experimental period | 24 th September – 02 nd December 2020 |

| 2. Experimental treatment | The test item solution was prepared from a stock solution and mixed with the artificial soil. The treated soil was then wetted up to reach about the 50 % of maximum WHC of the artificial soil (water holding capacity) and introduced in the test containers. After 4 weeks of exposure to the treated soil, the surviving earthworms were removed from the exposure cages, and weighed. 8 weeks after the treatments the reproduction performance was evaluated by the assessment of the number of juveniles produced. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|----------------------------|------------------------|----------------|---------------------|--|-----------------------|--|--|--|--|--|-----------|-------------------------------------|----------------------------|------------------------|----------------|---------------------|-------------------------|-----|-----|----|---|-----------------|----------------|--------|-------|----|---|-------------|
| 3. Application concentrations | <table><tr><th colspan="6">Table 1. Trial layout</th></tr><tr><th>Treatment</th><th>mg test item/kg dry artificial soil</th><th>mg a.s./kg soil dry weight</th><th>No. earthworms/ vessel</th><th>No. replicates</th><th>Identification Code</th></tr><tr><td>Control (water treated)</td><td>0.0</td><td>0.0</td><td>10</td><td>8</td><td>Ctrl a ÷ Ctrl h</td></tr><tr><td>Test item (T1)</td><td>1000.0</td><td>360.0</td><td>10</td><td>8</td><td>T1 a ÷ T1 h</td></tr></table> | | | | | | Table 1. Trial layout | | | | | | Treatment | mg test item/kg dry artificial soil | mg a.s./kg soil dry weight | No. earthworms/ vessel | No. replicates | Identification Code | Control (water treated) | 0.0 | 0.0 | 10 | 8 | Ctrl a ÷ Ctrl h | Test item (T1) | 1000.0 | 360.0 | 10 | 8 | T1 a ÷ T1 h |
| Table 1. Trial layout | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Treatment | mg test item/kg dry artificial soil | mg a.s./kg soil dry weight | No. earthworms/ vessel | No. replicates | Identification Code | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control (water treated) | 0.0 | 0.0 | 10 | 8 | Ctrl a ÷ Ctrl h | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item (T1) | 1000.0 | 360.0 | 10 | 8 | T1 a ÷ T1 h | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. Observations | The conditions of the exposed earthworms were recorded at 4 weeks after their introduction. The weight of the test system was measured at the beginning of the test and after 4 weeks. At the end of the test, 8 weeks after treatment, the number of cocoons and hatched juveniles was determined. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. Statistics | The software ToxRat Pro 3.3.0 was used to perform the statistical analysis. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Results

In the below table mortality, biomass and reproduction results were summarized.

Table 2. Mortality of the earthworms after 4 weeks of exposure

| Treatment | mg test item/kg dry artificial soil | mg a.s./kg dry artificial soil | % Mean mortality |
|----------------|-------------------------------------|--------------------------------|------------------|
| Control | 0.0 | 0.0 | 0.0 |
| Test item (T1) | 1000.0 | 360.0 | 0.0 |

Table 3. Mean increase in biomass of the adults after 4 weeks of exposure

| Treatment | mg test item/kg dry artificial soil | mg a.s./kg dry artificial soil | Mean increase in biomass | |
|----------------|-------------------------------------|--------------------------------|--------------------------|-------|
| | | | % | mg |
| Control | 0.0 | 0.0 | 1.46 | 5.05 |
| Test item (T1) | 1000.0 | 360.0 | 21.68 | 86.85 |

Table 4. Reproduction performance at the end of the test (8 weeks after treatment)

| Treatment | mg test item/kg dry artificial soil | Mean no. of unhatched co-coon | Mean number of juveniles | % Reduction in reproduction | ±SD | CV% | Sig. ¹ |
|-------------------------|-------------------------------------|-------------------------------|--------------------------|-----------------------------|-------|-------|-------------------|
| Control (water treated) | 0.0 | 0.00 | 82.50 | n/a | 11.33 | 13.73 | n/a |
| Test item (T1) | 1000.0 | 0.00 | 75.13 | 8.93 | 9.20 | 12.25 | - |

¹significance for $\alpha=0.05$, one-sided smaller (Student t-test, ToxRat Pro 3.3.0)

- not statistically significant; + statistically significant

n/a= not applicable; SD= standard deviation; CV%= coefficient variation (%)

Conclusion

The effects of the test item SIP 41061 on survival, biomass and reproduction of the earthworm *Eisenia andrei* in artificial soil was assessed in a laboratory study according to the OECD Guideline 222 (2016) and ISO Guideline 11268 (2012).

For survival, no mortality was caused by the test item to the exposed earthworms up to the highest tested concentration. The NOEC value resulted to be equal/greater than 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil). The LC₅₀ was estimated to be greater than 1000.0 mg of test item/kg dry artificial soil.

For biomass, no adverse effects on growth of survived earthworms resulted to be after 28 days of exposure at all the tested concentrations. The NOEC value resulted to be equal/greater than 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil).

For reproduction, no adverse effects were assessed up to the concentration of 1000.0 mg test item/kg dry artificial soil (equivalent to 360.0 g Prothioconazole/kg dry artificial soil), that corresponding to the NOEC value for this endpoint. The EC₅₀ was estimated to be greater than 1000.0 mg of test item/kg dry artificial soil.

No unhatched cocoons were found at the test concentration at the end of the test.

No abnormal behaviour of the adult earthworms was observed during the exposure phase of the test.

The nominal Prothioconazole concentrations in the soil were analytically confirmed with a highly specific HPLC-MS/MS method fully validated according to SANCO/3029/99 rev. 4 in a separate GLP study (report N. **BT215/20, please refer to dRR Section B5**). The recoveries of the active substance in the soil substrate were in the range of $\pm 20\%$ of nominal concentrations at day 0 of the test. Endpoints were estimated on the basis of nominal concentrations.

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.1.1 Study 1

| | |
|-------------------|--|
| Comments of zRMS: | <p>The study is considered as acceptable. All validity criteria were met.</p> <p>According to the OECD test guideline No. 232, the test is considered valid if, at the end of the test,</p> <ul style="list-style-type: none"> • the control mortality does not exceed 20%, • a minimum mean number of 100 juveniles is produced in the control, and • the coefficient of variation (CV) of the number of juveniles in the control does not exceed 30%. <p>In the present test, mortality in the control was 6.3%; the mean number of offspring in the control vessels was 1002.8 and the CV for the number of juveniles in the control was 11.1%. Considering these results, the validity criteria of the study are satisfied.</p> <p>Deviation from the study: During the test, the temperature went over of the outlined range (18.0-22.0 °C) for some periods from 03rd to 04th September 2020. The maximum registered value was 24.0 °C and the average temperature during the test was 20.7 °C. The light intensity went under the outlined range (400-800 lux) for some hours from 04th to 14th September 2020. The minimum registered</p> |
|-------------------|--|

| | |
|--|---|
| | <p>value was 325 lux.</p> <p>This deviation had no impact on the outcome of the study.</p> <p>Agreed endpoints: The NOEC for SIP 41061 is therefore equal or higher than 1000 mg test item/kg dry soil (corresponding to: 360.00 mg Prothioconazole/ kg dry soil) for both mortality and reproduction tests. No adverse effects regarding morphology and colour were observed in the extracted collembolans.</p> |
|--|---|

| | |
|--------------------------------------|---|
| Reference: | KCP 10.4.2.1/01 |
| Report | <p>Effects of SIP 41061 on reproduction of the collembolan <i>Folsomia candida</i> in artificial soil.</p> <p>Report N. BT119/20</p> <p>Grandolini G., 2020</p> <p>BioTecnologie BT S.r.l., Todi - Italy</p> |
| Guideline(s): | OECD 232 (2009) |
| Deviations: | <p>Yes</p> <p>Description: During the test, the temperature went over of the outlined range (18.0-22.0 °C) for some periods from 03rd to 04th September 2020. The maximum registered value was 24.0 °C and the average temperature during the test was 20.7 °C.</p> <p>The light intensity went under the outlined range (400-800 lux) for some hours from 04th to 14th September 2020. The minimum registered value was 325 lux.</p> <p>Effects on the outcome of the study: this deviation from the recommended ranges showed no disturbances in the test performance demonstrated by the validity criteria that were met in the control group.</p> <p>Date: 01st October 2020</p> |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication (if vertebrate study) | Not relevant, no vertebrate study |

The effects of the test item SIP 41061 on the reproductive output of the collembolan *Folsomia candida* in an artificial soil substrate after four weeks of exposure were tested following the guidelines OECD 232 (2016) and ISO 11267 (2014) and in compliance with the Principles of Good Laboratory Practice (GLP).

| A. MATERIALS | |
|--------------------------|--|
| 1. Test Item | |
| Name | SIP 41061 |
| Batch No. | 20006/P01 |
| Active substances | Prothioconazole: 415.8 g/L – 36% w/w |
| 2. Reference Item | |
| Name | Boric Acid |
| Batch No. | BCBR9954V |
| Purity | 100.1% |
| 3. Test system | |
| Species | <i>Folsomia candida</i> (synchronized females were used) |
| Age | Juveniles (9 days) |

| | | | | | | |
|-------------------------------------|--|--|---|-------------------------|----------------|---------------------|
| Source | BioTecnologie BT S.r.l. (internal breeding) | | | | | |
| Diet | Granulated dried baker's yeast | | | | | |
| Breeding conditions | The organisms are kept in plastic boxes in the culturing substrate (plaster of Paris with activated charcoal), reared in a climatic room maintained at 20 ± 2°C and with a light intensity range of 400 and 800 Lux. | | | | | |
| 4. Experimental conditions | | | | | | |
| Artificial soil | 5% sphagnum peat; 20% kaolin clay; 75% industrial sand | | | | | |
| Temperature | 19.1 – 24.0°C (See Annex V and Deviation N°1) | | | | | |
| Water content in the test container | About 20.09 mL of water/100 g of dry soil (50% of the maximum WHC) | | | | | |
| Photoperiod | 16 hours light + 8 hours darkness | | | | | |
| Light Intensity | 325 – 582 lux (See Annex V and Deviation N°1) | | | | | |
| STUDY DESIGN AND METHODS | | | | | | |
| 1. Experimental period | 02 nd September 2020 – 01 st October 2020 | | | | | |
| 2. Experimental treatment | The test item was diluted in deionised water in order to obtain the test concentrations. The solutions were prepared the same day of the application and used within one hour from the preparation. Preparation of solutions was recorded and presented in the raw data. An amount of solution necessary to reach the final moisture content was prepared. The solutions were thoroughly mixed with the soil substrate before being introduced into the test containers. | | | | | |
| 3. Application concentrations | Table 1 Trial layout for the exposure of <i>Folsomia candida</i> to SIP 41061 during 28 days under laboratory conditions | | | | | |
| | Treatments | Concentration [mg prod./ kg of dry soil] | Concentration [mg a.s./ kg of dry soil] (nominal value) | No. collembolan/ vessel | No. replicates | Identification Code |
| | Control | 0.00 | 0.00 | 10 | 8 | Ca ÷ Ch |
| | Test item – T1 | 95.26 | Prothioconazole: 34.29 | 10 | 4 | T1a ÷ T1d |
| | Test item – T2 | 171.47 | Prothioconazole: 61.73 | 10 | 4 | T2a ÷ T2d |
| | Test item – T3 | 308.64 | Prothioconazole: 111.11 | 10 | 4 | T3a ÷ T3d |
| | Test item – T4 | 555.56 | Prothioconazole: 200.00 | 10 | 4 | T4a ÷ T4d |
| | Test item – T5 | 1000.00 | Prothioconazole: 360.00 | 10 | 4 | T5a ÷ T5d |
| | a Concentration chosen on the basis of the results of a range-finding test. | | | | | |
| 4. Observations | The number of the surviving collembolans was recorded 4 weeks after introduction (test end). In addition, the number of juveniles was determined at test end. | | | | | |
| 5. Statistics | Appropriate statistical methods were used to analyse mortality and fecundity data for significance (e.g. Chi ² 2x2 table Test with Bonferroni Correction, one sided greater, α=0.05 and Dunnett’s Multiple t-test Procedure one-sided smaller, α=0.05). For the statistical analysis the software ToxRat Pro. 3.3.0. was used. | | | | | |

Results

The study results are summarized in below tables.

Mortality:

Table 2 Mortality of the adult collembolans exposed to the test item SIP 41061 after 4 weeks (control and treatment groups)

| Treatment | mg test item/ kg of dry soil | mg a.s./ kg of dry soil | Mean mortality in % | *Significance |
|----------------|---------------------------------|----------------------------|------------------------|---------------|
| Control | 0.00 | 0.00 | 6.25 | n.a. |
| Test item – T1 | 95.26 | Prothioconazole: 34.29 | 12.50 | - |
| Test item – T2 | 171.47 | Prothioconazole: 61.73 | 5.00 | - |
| Test item – T3 | 308.64 | Prothioconazole: 111.11 | 2.50 | - |
| Test item – T4 | 555.56 | Prothioconazole: 200.00 | 12.50 | - |
| Test item – T5 | 1000.00 | Prothioconazole: 360.00 | 0.00 | - |

* + : significant compared to the control; - : not significant compared to the control (Chi² 2x2 table Test with Bonferroni Correction, one sided greater, $\alpha=0.05$, ToxRat Pro 3.3.0); n.a.: not applicable.

Reproduction:

Table 3 Reproductive performance of the introduced collembolans after 4 weeks in the control and in the treatment groups exposed to the test item SIP 41061

| Treatment | mg test item/kg of dry soil | mg a.s./kg of dry soil | Mean number of juveniles / vessel | % reduction in reproduction | ±SD | CV% | *Significance |
|----------------|--------------------------------|---------------------------|---|--------------------------------|--------|-------|---------------|
| Control | 0.00 | 0.00 | 1002.75 | n.a | 111.28 | 11.0 | n.a. |
| Test item – T1 | 95.26 | Prothioconazole: 34.29 | 962.00 | 4.06 | 135.50 | 14.09 | - |
| Test item – T2 | 171.47 | Prothioconazole: 61.73 | 1001.25 | 0.15 | 98.82 | 9.87 | - |
| Test item – T3 | 308.64 | Prothioconazole: 111.11 | 918.25 | 8.43 | 146.70 | 15.98 | - |
| Test item – T4 | 555.56 | Prothioconazole: 200.00 | 881.75 | 12.07 | 102.43 | 11.62 | - |
| Test item – T5 | 1000.00 | Prothioconazole: 360.00 | 916.75 | 8.58 | 102.17 | 11.15 | - |

* + : significant compared to the control; - : not significant compared to the control (Dunnett's Multiple t-test Procedure one-sided smaller, $\alpha=0.05$, ToxRat Pro 3.3.0); n.a.: not applicable, SD – Standard deviation, CV% - Coefficient of variation

Conclusion

The effects of SIP 41061 on survival and reproduction of the collembolan *Folsomia candida* in artificial soil were assessed in a GLP laboratory study according to OECD test guideline No. 232.

In the present test, mean mortality, mean number of offspring and CV for the number of juveniles in the control group satisfied the validity criteria.

The results showed no statistically significant adverse effects (on the test system) of the test item SIP 41061 when

mixed into an artificial soil at all concentrations tested.

The NOEC for SIP 41061 is therefore equal or higher than 1000 mg test item/kg dry soil (corresponding to: 360.00 mg Prothioconazole/ kg dry soil) for both mortality and reproduction tests.

No adverse effects regarding morphology and colour were observed in the extracted collembolans.

A 2.4.2.1.1

Study 2

| | |
|-------------------|--|
| Comments of zRMS: | <p>The study is considered as acceptable. All validity criteria were met. According to the OECD Guideline N° 226, the test was considered valid because the following criteria were satisfied in the water treated control:</p> <ul style="list-style-type: none"> - mean adult female mortality didn't exceed 20% at the end of the test; - the mean number of juveniles per vessel was at least 50 at the end of the test; - the coefficient of variation calculated for the number of juvenile mites per replicate was lower than 30% at the end of the test. <p>Deviation from the study: none</p> <p>Agreed endpoints:</p> <p>In terms of mortality, the NOEC was determined to be higher than or equal of 324.00 mg as/Kg dry soil). The LC₅₀ value was not determined because it was not tested but is possible to conclude that the LC₅₀ value is greater than the maximum tested concentration (64.80 mg Prothioconazole/kg dry soil).</p> <p>In terms of reproduction performance, the NOEC was determined to be 180.00 mg Prothioconazole/kg dry soil). The EC₅₀ value was not determined because it was not tested but is possible to conclude that the EC₅₀ value is greater than the maximum tested concentration.</p> |
|-------------------|--|

Reference: KCP 10.4.2.1/02

Report Effects of SIP 41061 on reproduction of the predatory mite *Hypoaspis aculeifer* in soil.
Report N. BT117/20
Grandolini G., 2020
BioTecnologie BT S.r.l., Todi – Italy

Guideline(s): OECD 226 (2008)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant, no vertebrate study

The effects of the test item SIP 41061 on the reproductive output of the predatory mite *Hypoaspis aculeifer* in an artificial soil substrate after 14 days of exposure were tested, following OECD guidelines and according to GLP regulations.

Material and methods

| A. MATERIALS | |
|-----------------------|--|
| 1. Test Item | |
| Name | SIP 41061 |
| Batch No. | 20006/P01 |
| Active substance | Prothioconazole: 415.8 g/L – 36% w/w |
| Density | 1.155 kg/L |
| 2. Test system | |
| Species | <i>Hypoaspis aculeifer</i> (synchronized adults females were used) |
| Strain | Not relevant |
| Age | Females (34 days old) |

| Source | BioTecnologie BT S.r.l. (internal breeding) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|-------------------------------|---|--|------------------------------------|--|------------------------|------------------|------------------------|---------|------|------|----|---|---------|----------------|-------|---------------------------|----|---|-----------|----------------|-------|---------------------------|----|---|-----------|----------------|--------|---------------------------|----|---|-----------|----------------|--------|---------------------------|----|---|-----------|----------------|--------|----------------------------|----|---|-----------|
| Diet | <i>Tyrophagus putrescentiae</i> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Water | Deionised water | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. Experimental conditions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Artificial soil | 5% sphagnum peat; 20% kaolin clay; 75% industrial sand | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Temperature | 20.5 – 21.1°C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Water content | (in the test container) approximately 17.45 mL of water/100 g of dry soil (45% of the maximum WHC) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Photoperiod | 16 hours light + 8 hours darkness | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Light Intensity | 465 - 521 lux | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| B. STUDY DESIGN AND METHODS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Experimental period | 06 th August 2020 – 21 th August 2020 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. Experimental treatment | <p>The test item solutions were mixed with the soil substrate before introducing it into the test containers (24.02 g wet soil per vessel). The individual mites were carefully transferred into each test vessel (allocated randomly to the test vessel) and placed onto the surface of the soil.</p> <p>After 14 days of exposure to the treated soil, the surviving mites were removed from the exposure vessels, and counted. The reproduction performance was evaluated by the assessment of the number of juveniles produced per test vessel. The presence of juvenile mites was assessed by heat extraction.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. Application concentrations | <div>Table 26. Trial layout</div> <table><tr><th>Treatments</th><th>mg of test item/ kg of dry soil</th><th>mg of a.s./ kg of dry soil (nominal value)</th><th>N° mites/ vessel</th><th>N° replicates</th><th>Identification Code</th></tr><tr><td>Control</td><td>0.00</td><td>0.00</td><td>10</td><td>8</td><td>Ca ÷ Ch</td></tr><tr><td>Test item – T1</td><td>30.86</td><td>Prothioconazole: 11.11</td><td>10</td><td>4</td><td>T1a ÷ T1d</td></tr><tr><td>Test item – T2</td><td>55.56</td><td>Prothioconazole: 20.00</td><td>10</td><td>4</td><td>T2a ÷ T2d</td></tr><tr><td>Test item – T3</td><td>100.00</td><td>Prothioconazole: 36.00</td><td>10</td><td>4</td><td>T3a ÷ T3d</td></tr><tr><td>Test item – T4</td><td>180.00</td><td>Prothioconazole: 64.80</td><td>10</td><td>4</td><td>T4a ÷ T4d</td></tr><tr><td>Test item – T5</td><td>324.00</td><td>Prothioconazole: 116.64</td><td>10</td><td>4</td><td>T5a ÷ T5d</td></tr></table> | Treatments | mg of test item/ kg of dry soil | mg of a.s./ kg of dry soil (nominal value) | N° mites/ vessel | N° replicates | Identification Code | Control | 0.00 | 0.00 | 10 | 8 | Ca ÷ Ch | Test item – T1 | 30.86 | Prothioconazole: 11.11 | 10 | 4 | T1a ÷ T1d | Test item – T2 | 55.56 | Prothioconazole: 20.00 | 10 | 4 | T2a ÷ T2d | Test item – T3 | 100.00 | Prothioconazole: 36.00 | 10 | 4 | T3a ÷ T3d | Test item – T4 | 180.00 | Prothioconazole: 64.80 | 10 | 4 | T4a ÷ T4d | Test item – T5 | 324.00 | Prothioconazole: 116.64 | 10 | 4 | T5a ÷ T5d |
| Treatments | mg of test item/ kg of dry soil | mg of a.s./ kg of dry soil (nominal value) | N° mites/ vessel | N° replicates | Identification Code | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | 0.00 | 0.00 | 10 | 8 | Ca ÷ Ch | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item – T1 | 30.86 | Prothioconazole: 11.11 | 10 | 4 | T1a ÷ T1d | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item – T2 | 55.56 | Prothioconazole: 20.00 | 10 | 4 | T2a ÷ T2d | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item – T3 | 100.00 | Prothioconazole: 36.00 | 10 | 4 | T3a ÷ T3d | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item – T4 | 180.00 | Prothioconazole: 64.80 | 10 | 4 | T4a ÷ T4d | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test item – T5 | 324.00 | Prothioconazole: 116.64 | 10 | 4 | T5a ÷ T5d | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. Observations | The number of the surviving mites was recorded at 14 days after their introduction. At the end of the test, 14 days after treatment, the number of juveniles was determined. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. Statistics | The software ToxRat Pro Version 3.3.0 was used to perform the statistical analysis. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Results

The study results are summarised in the below tables.

Adults' mortality:

Table 27. Mortality of the adults after 14 days of exposure

| Treatments | mg of test item/ kg of dry soil | mg of a.s./ kg of dry soil | % Mean mortality | *Sig |
|------------|------------------------------------|-------------------------------|---------------------|------|
| Control | 0.00 | 0.00 | 5.00 | === |

| | | | | |
|----------------|--------|-------------------------|-------|---|
| Test item – T1 | 30.86 | Prothioconazole: 11.11 | 10.00 | - |
| Test item – T2 | 55.56 | Prothioconazole: 20.00 | 7.50 | - |
| Test item – T3 | 100.00 | Prothioconazole: 36.00 | 7.50 | - |
| Test item – T4 | 180.00 | Prothioconazole: 64.80 | 5.00 | - |
| Test item – T5 | 324.00 | Prothioconazole: 116.64 | 7.50 | - |

* + : significant; - : non-significant (Chi² 2x2 Table test with Bonferroni correction α 0.05, one sided greater)

The NOEC appears to be higher than or equal of 324.00 mg prod. /kg dry soil (corresponding to 324.00 mg as/Kg dry soil). The LC₅₀ value was not determined but is possible to conclude that the LC₅₀ value is greater than the maximum tested concentration.

Reproduction performance:

Table 28. Reproduction performance

| Treatments | mg of test item/ kg of dry soil | mg of a.s./ kg of dry soil | Mean number of juveniles/vessel | % reduction in reproduction | ±SD | CV% | *Sig |
|----------------|------------------------------------|-------------------------------|------------------------------------|--------------------------------|-------|-------|------|
| Control | 0.00 | 0.00 | 304 | === | 44.29 | 14.57 | === |
| Test item – T1 | 30.86 | Prothioconazole: 11.11 | 290.3 | 4.52 | 79.11 | 27.26 | - |
| Test item – T2 | 55.56 | Prothioconazole: 20.00 | 272.5 | 10.36 | 39.00 | 14.31 | - |
| Test item – T3 | 100.00 | Prothioconazole: 36.00 | 282.8 | 6.99 | 41.61 | 14.72 | - |
| Test item – T4 | 180.00 | Prothioconazole: 64.80 | 260.0 | 14.47 | 54.98 | 21.15 | - |
| Test item – T5 | 324.00 | Prothioconazole: 116.64 | 237.8 | 21.79 | 41.95 | 17.64 | + |

* +: significant; - : non-significant (Williams multiple Sequential t-test, α 0.05, one-sided smaller); SD= standard deviation; CV= coefficient of variation

All the tested concentrations, except the highest concentration equivalent to 324.00 mg prod./kg dry soil (corresponding to 324.00 mg as/Kg dry soil) showed a reproduction performance statistically similar to the control group. The NOEC was determined to be 180.00 mg prod./kg dry soil (equivalent to 64.80 mg Prothioconazole/kg dry soil).

Conclusion

The effects of the test item SIP 41061 on the reproduction performance of the predatory mite *Hypoaspis aculeifer* were tested in a GLP compliant laboratory study.

In terms of mortality, the NOEC was determined to be higher than or equal of 324.00 mg prod./kg dry soil (corresponding to 324.00 mg as/Kg dry soil). The LC₅₀ value was not determined but is possible to conclude that the LC₅₀ value is greater than the maximum tested concentration.

In terms of reproduction performance, the NOEC was determined to be 180.00 mg prod./kg dry soil (equivalent to 64.80 mg Prothioconazole/kg dry soil). The EC₅₀ value was not determined but is possible to conclude that the LC₅₀ value is greater than the maximum tested concentration.

The validity criteria with regards to control mortality, to number of juveniles produced in the control and to the CV% of offspring number in the control were met.

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.5.1.1 Study 1

Comments of zRMS:

The study is considered as acceptable. All validity criteria were met.

The following validity criteria were met during the study:
Following the OECD Guideline 216 (2000), the results of the study are considered valid if the variation among replicates (CV%) of untreated samples is less than $\pm 15\%$. The validity criterion was met:

Variation among replicates of untreated samples

| DAT | CV% |
|--------|------|
| DAT 0 | 0.69 |
| DAT 7 | 0.27 |
| DAT 14 | 0.37 |
| DAT 28 | 0.01 |

DAT = Days after treatment

Deviation from the study: none

Agreed endpoints:

Results of the test

| TREATMENT | DAT 0 | | DAT 7 | | DAT 14 | | DAT 28 | |
|----------------|---|-------------------------------------|---|-------------------------------------|---|-------------------------------------|---|-------------------------------------|
| | Mean* mg NO ₃ / kg dry soil | Deviation from control (%) | Mean* mg NO ₃ / kg dry soil/day | Deviation from control (%) | Mean* mg NO ₃ / kg dry soil/day | Deviation from control (%) | Mean* mg NO ₃ / kg dry soil/day | Deviation from control (%) |
| Control | 65.177 | === | -2.330 | === | 0.817 | === | 2.597 | === |
| Test item (T1) | 64.723 | 0.70 | 1.397 | 159.94 | 1.470 | -80.00 | 2.643 | -1.80 |
| Test item (T2) | 64.080 | 1.68 | 0.470 | 120.17 | 1.433 | -75.51 | 2.363 | 8.99 |

* Mean = Mean value of three replicates

At the tested concentrations, 28 days after treatment, the following % deviations from control were calculated:

- -1.80% at the concentration of 1.75 mg of test item/kg of dry soil equivalent to 0.62 mg of prothioconazole/kg of dry soil.
- 8.99% at the concentration of 8.73 mg of test item/kg of dry soil equivalent to 3.07 mg of prothioconazole/kg of dry soil.

No negative effect > 25% at 28 d at 8.73 mg product/kg dry weight of soil (3.07 mg a.s./ kg dry weight of soil)

| | |
|---------------|---|
| Reference: | KCP 10.5/01 |
| Report | Assessment of the effects of the product SIP 41061 on soil microorganisms nitrification. Report No. BT143/21 Rossini L., 2021 Biotechnologie BT S.r.l. |
| Guideline(s): | Yes OECD 216 (2000) OECD 217 (2000) |
| Deviations: | No |

GLP: Yes
Acceptability: Yes
Duplication (if vertebrate study) Not relevant, no vertebrate study

The effects of the test item SIP 41061 on soil microbial nitrification (*nitrogen transformation test*) processes were studied according to OECD Guidelines 216, adopted on the 21st January 2000. The intended application rate is 200 g as/ha, according to the Sponsor the test item was mixed into a sandy loam agricultural soil (LUF A soil, type 2.3) at the following concentrations:

- T1 concentration (application rate x 2): 1136.36 g of product/ha corresponding to 400 g of a.s./ha
- T2 concentration (application rate x 10): 5681.80 g of product/ha corresponding to 2000 g of a.s./ha

Table 29. Trial layout

| Treatments ^o | mg of test item/ kg of dry soil | mg of a.i./ kg of dry soil | Identification Code |
|-------------------------|------------------------------------|-------------------------------|------------------------|
| Control | 0.00 | 0.00 | Ca ÷ Cc |
| Test item (T1) | 1.75 | 0.62 | T1a ÷ T1c |
| Test item (T2) | 8.73 | 3.07 | T2a ÷ T2c |

^oUntreated control, T1 and T2: 3 replicates per treatment group

The control consisted of soil treated with deionized water, incubated under the same conditions as the treated soil, in the dark at 20 ± 2°C.

The reference item (Dinoseb acetate) was tested in the annual quality control to confirm the normal reaction of the soil against herbicides.

Results

The influence of the test item on the nitrification of a lucerne meal was investigated and the results obtained in treated samples were compared to untreated samples data. The nitrogen transformation rate was assessed after 0, 7, 14 and 28 days after the test item application (DAT). The results at 28 days of treatment are reported in the following tables.

Table 30. Results of the test after 28 days after treatment

| TREAT- MENT | DAT 0 | | DAT 7 | | DAT 14 | | DAT 28 | |
|-------------------|---|---|---|---|---|---|-------------------------------------|--|
| | Mean* mg NO ₃ / kg dry soil/day | Mean* mg NO ₃ / kg dry soil/day | Mean* mg NO ₃ / kg dry soil/day | Mean* mg NO ₃ / kg dry soil/day | Mean* mg NO ₃ / kg dry soil/day | Mean* mg NO ₃ / kg dry soil/day | Deviation from control (%) | Devia- tion from control (%) |
| Control | 65.18 | === | -2.33 | === | 0.817 | === | 2.597 | === |
| Test item (T1) | 64.72 | 0.70 | 1.397 | 159.94 | 1.47 | -80.0 | 2.643 | -1.80 |
| Test item (T2) | 64.08 | 1.68 | 0.47 | 120.17 | 1.43 | -75.51 | 2.363 | 8.99 |

* Mean = Mean value of three replicates

Conclusion

At the tested concentrations, 28 days after treatment, the following % deviations from control were calcu-

lated:

- -1.80% at the concentration of 1.75 mg of test item/kg of dry soil equivalent to 0.62 mg of Prothioconazole/kg of dry soil.
- 8.99% at the concentration of 8.73 mg of test item/kg of dry soil equivalent to 3.07 mg of Prothioconazole/kg of dry soil.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.2.1 Study 1

| Comments of zRMS: | <p>The study is considered as acceptable. All validity criteria were met.</p> <p>The following validity criteria were met during the study:</p> <ul style="list-style-type: none"> - the seedling emergence is at least 70% in control and treated groups; and only in the control groups; - the plants do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species; - the mean plant survival is at least 90% at the end of the test (being 100%); - environmental conditions for particular species are identical and growing media contain the same amount of soil matrix, support media or substrate from the same source. <p>Deviations in the study:</p> <ul style="list-style-type: none"> - on 25th January 2022, the photoperiod was 24 hours dark and 0 hours light, due to a technical issue. <p>This deviation had no impact on the outcome of the study (as demonstrated by the lack of visual phytotoxic effects in the plants of the control).</p> <p>Agreed endpoints:</p> <p>Effect of the test item on the vegetative vigour of six terrestrial plant species at day 21</p> <table border="1"> <thead> <tr> <th rowspan="2">Species</th><th colspan="2">Mortality</th><th colspan="2">Biomass as fresh shoot weight</th></tr> <tr> <th>ER₅₀ [g test item/ha]</th><th>NOEAR [g test item/ha]</th><th>ER₅₀ [g test item/ha]</th><th>NOEAR [g test item/ha]</th></tr> </thead> <tbody> <tr> <td><i>Beta vulgaris</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> <tr> <td><i>Helianthus annuus</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> <tr> <td><i>Fagopyrum esculentum</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> <tr> <td><i>Lycopersicon esculentum</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> <tr> <td><i>Hordeum vulgare</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> <tr> <td><i>Zea mais</i></td><td>> 570.00</td><td>570.00</td><td>> 570.00</td><td>570.00</td></tr> </tbody> </table> | | | | Species | Mortality | | Biomass as fresh shoot weight | | ER ₅₀ [g test item/ha] | NOEAR [g test item/ha] | ER ₅₀ [g test item/ha] | NOEAR [g test item/ha] | <i>Beta vulgaris</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | <i>Helianthus annuus</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | <i>Fagopyrum esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | <i>Lycopersicon esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | <i>Hordeum vulgare</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | <i>Zea mais</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
|--------------------------------|--|---------------------------|--------------------------------------|---------------------------|---------|-----------|--|-------------------------------|--|--------------------------------------|---------------------------|--------------------------------------|---------------------------|----------------------|----------|--------|----------|--------|--------------------------|----------|--------|----------|--------|-----------------------------|----------|--------|----------|--------|--------------------------------|----------|--------|----------|--------|------------------------|----------|--------|----------|--------|-----------------|----------|--------|----------|--------|
| Species | Mortality | | Biomass as fresh shoot weight | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | ER ₅₀ [g test item/ha] | NOEAR [g test item/ha] | ER ₅₀ [g test item/ha] | NOEAR [g test item/ha] | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Beta vulgaris</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Helianthus annuus</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Fagopyrum esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Lycopersicon esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Hordeum vulgare</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Zea mais</i> | > 570.00 | 570.00 | > 570.00 | 570.00 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| | |
|--|---|
| | The NOEAR for mortality was 570.00 g test item/ha (equivalent to 200.64 g a.s./ha) for all species. The ER ₅₀ values for mortality were all above the tested application rate of 570.00 g test item/ha (equivalent to 200.64 g a.s./ha) since none of the tested species showed mortality. No phytotoxic effects (necrosis, plants deformations, changes in colour) were observed in all treated plants. |
|--|---|

| | |
|--------------------------------------|---|
| Reference: | KCP 10.6.2/02 |
| Report | Effects of the SIP 41061 on terrestrial plants – Vegetative vigour Test. Report No. BT150/21 Colli M., 2022 Biotechnologie BT S.r.l. |
| Guideline(s): | Yes OECD Guideline N. 227 (2006) |
| Deviations: | Yes <u>Deviation no. 1 issued on 09th February 2022</u> <u>Description:</u> on 25th January 2022, the photoperiod was 24 hours dark and 0 hours light, due to a technical issue. <u>Impact on the study:</u> this deviation had no impact on the outcome of the study (as demonstrated by the lack of visual phytotoxic effects in the plants of the control). |
| GLP: | Yes |
| Acceptability: | Yes |
| Duplication (if vertebrate study) | Not relevant, no vertebrate study |

The effects on non-target terrestrial plants of the test item SIP 41061 (Prothioconazole 400 g/L SC) were tested in a GLP study carried out in a climatic chamber over a period of 21 days according to OECD Test Guideline No. 227 (2006).

Material and methods

| | |
|--------------------------------------|--|
| 1. Test item | |
| Name: | SIP 41061 |
| Indication: | Fungicide |
| Batch: | 21/0006 |
| Active substance and CAS No.: | Prothioconazole [178928-70-6] |
| Active substance content | w/w: 35.2% - w/v: 409 g/L |
| 2. Test system | |
| Species: | Dicotyledonous: <i>Beta vulgaris</i> , <i>Helianthus annuus</i> , <i>Fagopyrum esculentum</i> , <i>Lycopersicon esculentum</i> Monocotyledonous: <i>Hordeum vulgare</i> , <i>Zea mais</i> |
| Stage: | Plants at BBCH 12 – 14 (2 to 4 true leaf stage) |
| Soil: | Standard soil type 2.3 (Lufa Speyer – Germany) |
| 3. Experimental conditions | |
| Temperature: | 18.1°C – 22.1°C; average: 21.2°C |
| Humidity: | 24.7% – 79.5%; average: 57.9% |
| Photoperiod: | 16 hours light and 8 hours darkness |

| | |
|---|--|
| Light intensity (during the light- ness period): | 329.4 $\mu\text{E}/\text{m}^2/\text{s}$ – 355.4 $\mu\text{E}/\text{m}^2/\text{s}$ (PAR: photosynthetically active radiation) |
|---|--|

Experimental period: from 19th January 2022 to 09th February 2022 (including the analytical phase)
Six (6) different plant species were grown from the seeds, in pots containing standard soil type 2.3 (Lufa Speyer – Germany), until the 2 to 4 true leaf stage was reached. Then, the test item was sprayed on the plant and leaf surfaces. After application of the test item, the plants were evaluated against untreated control plants for effects on vegetative vigour and growth at various intervals up to 21 days after treatment. The experimental design consisted of 1 test item treatment group and an untreated group (deionised water) with 24 or 25 plants per group (12 replicate pots with 2 plants each or 5 replicate pots with 5 plants each, depending on species).
The test item solution was prepared in deionised water immediately before application and were applied with spray equipment calibrated to deliver an output of 400 L/ha ($\pm 10\%$). The pots were then placed on a bench top in a climatic chamber under controlled test conditions for 21 days.
The following table shows an overview of the application rate and number of replicates for each test species.

Table 31 Test species, application rate and number of replicates

| Test species | Common name | Application rates [g test item/ha] | Replicates/ application rate | Plants/ replicate | Number of plants per treatment |
|--------------------------------|-------------|---------------------------------------|------------------------------------|----------------------|---|
| <i>Beta vulgaris</i> | Sugar beet | 570.00 | 5 | 5 | 25 |
| <i>Helianthus annuus</i> | Sunflower | | 12 | 2 | 24 |
| <i>Fagopyrum esculentum</i> | Buckwheat | | 5 | 5 | 25 |
| <i>Lycopersicon esculentum</i> | Tomato | | 12 | 2 | 24 |
| <i>Hordeum vulgare</i> | Barley | | 12 | 2 | 24 |
| <i>Zea mais</i> | Corn | | 5 | 5 | 25 |

Effects on plants as mortality and visual phytotoxicity (deformations, modifications in colour, necrosis) were recorded at 7, 14 and 21 days after the treatment (DAT). At the end of the test, the biomass (fresh shoot weight) was measured in addition.

Mortality and biomass data for each plant species were analysed using appropriate statistical methods. The level of effects at the test application rate and the lack of reaching a 50% effect at the test application rate were reported.

The software ToxRat Pro version 3.3.0 was used to perform the statistical analysis.

A sample of the test item solution used for the treatment was analysed in order to verify the correct application of the test item. The analysis of the a.s. content in the sample was carried out with an analytical method validated in the GLP study **BT193/21** (please refer to dRR Section B5 for full study details).

Results

No visible phytotoxic effects (deformations, modification in colour and necrosis) were observed at the surviving plants. The results for mortality and biomass as fresh weight for each species are summarised in the following table.

Table 32. Effects of the test item on the vegetative vigour of ten terrestrial plant species at day 21 [g test item/ha]

| Species | Mortality | Biomass as fresh shoot weight |
|---------|-----------|-------------------------------|
|---------|-----------|-------------------------------|

| | ER₅₀ [g test item/ha] | NOEAR [g test item/ha] | ER₅₀ [g test item/ha] | NOEAR [g test item/ha] |
|--------------------------------|---|---|---|---|
| <i>Beta vulgaris</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
| <i>Helianthus annuus</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
| <i>Fagopyrum esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
| <i>Lycopersicon esculentum</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
| <i>Hordeum vulgare</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |
| <i>Zea mais</i> | > 570.00 | 570.00 | > 570.00 | 570.00 |

Visual phytotoxicity

The phytotoxic effects (indicated as deformations, modifications in colour and necrosis) are reported in the following tables.

Deformations in % at the end of the test

| Treatment | <i>Beta vulgaris</i> | <i>Helianthus annuus</i> | <i>Fagopyrum esculentum</i> | <i>Lycopersicon esculentum</i> | <i>Hordeum vulgare</i> | <i>Zea mays</i> |
|----------------|----------------------|--------------------------|-----------------------------|--------------------------------|------------------------|-----------------|
| Control | 0 | 0 | 0 | 0 | 0 | 0 |
| Test item (T1) | 0 | 0 | 0 | 0 | 0 | 0 |

Modification in colour in % at the end of the test

| Treatment | <i>Beta vulgaris</i> | <i>Helianthus annuus</i> | <i>Fagopyrum esculentum</i> | <i>Lycopersicon esculentum</i> | <i>Hordeum vulgare</i> | <i>Zea mays</i> |
|----------------|----------------------|--------------------------|-----------------------------|--------------------------------|------------------------|-----------------|
| Control | 0 | 0 | 0 | 0 | 0 | 0 |
| Test item (T1) | 0 | 0 | 0 | 0 | 0 | 0 |

Necrosis in % at the end of the test

| Treatment | <i>Beta vulgaris</i> | <i>Helianthus annuus</i> | <i>Fagopyrum esculentum</i> | <i>Lycopersicon esculentum</i> | <i>Hordeum vulgare</i> | <i>Zea mays</i> |
|----------------|----------------------|--------------------------|-----------------------------|--------------------------------|------------------------|-----------------|
| Control | 0 | 0 | 0 | 0 | 0 | 0 |
| Test item (T1) | 0 | 0 | 0 | 0 | 0 | 0 |

Seedlings emergence in control and treated groups

| Species | No. total plants needed for the test | No. total sowed seeds | No. total emerged seedlings | Seedling emergence [%] |
|--------------------------------|--------------------------------------|-----------------------|-----------------------------|------------------------|
| <i>Beta vulgaris</i> | 50 | 70 | 69 | 98.57 |
| <i>Helianthus annuus</i> | 48 | 72 | 71 | 98.61 |
| <i>Fagopyrum esculentum</i> | 50 | 70 | 68 | 97.14 |
| <i>Lycopersicon esculentum</i> | 48 | 72 | 71 | 98.61 |
| <i>Zea mays</i> | 48 | 72 | 72 | 100 |
| <i>Hordeum vulgare</i> | 50 | 70 | 68 | 97.14 |

Effects of the test item on fresh shoot weight of the species *Beta vulgaris* and *Helianthus annuus*

| Treatment | Application rate [g test item/ha] | <i>Beta vulgaris</i> | | <i>Helianthus annuus</i> | |
|---|--------------------------------------|---------------------------------|----------|---------------------------------|----------|
| | | Mean weight [g/replicate] | R [%] | Mean weight [g/replicate] | R [%] |
| Control | 0 | 8.20 | n.a. | 5.46 | n.a. |
| Test item (T1) | 570.0 | 9.24 | -12.69 | 5.73 | -4.93 |
| ER₅₀ [g test item/ha] | | >570.00 | | >570.00 | |
| NOEAR [g test item/ha] | | 570.00 Student T-test | | 570.00 Student T-test | |

n.a. = not available/applicable - c.l. = confidence limits - R = reduction in fresh shoot weight

Effects of the test item on fresh shoot weight of the species *Fagopyrum esculentum* and *Lycopersicon esculentum*

| Treatment | Application rate [g test item/ha] | <i>Fagopyrum esculentum</i> | | <i>Lycopersicon esculentum</i> | |
|---|--------------------------------------|---------------------------------|----------|---------------------------------|----------|
| | | Mean weight [g/replicate] | R [%] | Mean weight [g/replicate] | R [%] |
| Control | 0 | 10.34 | n.a. | 4.95 | n.a. |
| Test item (T1) | 570.0 | 9.83 | 4.91 | 6.43 | -29.89 |
| ER₅₀ [g test item/ha] | | >570.00 | | >570.00 | |
| NOEAR [g test item/ha] | | 570.00 Student T-test | | 570.00 Student T-test | |

n.a. = not available/applicable - c.l. = confidence limits - R = reduction in fresh shoot weight

Effects of the test item on fresh shoot weight of the species *Hordeum vulgare* and *Zea mays*

| Treatment | Application rate [g test item/ha] | <i>Hordeum vulgare</i> | | <i>Zea mays</i> | |
|---|--------------------------------------|---------------------------------|----------|---------------------------------|----------|
| | | Mean weight [g/replicate] | R [%] | Mean weight [g/replicate] | R [%] |
| Control | 0 | 3.22 | n.a. | 6.46 | n.a. |
| Test item (T1) | 570.0 | 3.24 | -0.68 | 7.95 | -23.14 |
| ER₅₀ [g test item/ha] | | >570.00 | | >570.00 | |
| NOEAR [g test item/ha] | | 570.00 Student T-test | | 570.00 Student T-test | |

n.a. = not available/applicable - c.l. = confidence limits - R = reduction in fresh shoot weight

Conclusion

The effects on non-target terrestrial plants of the test item SIP 41061 were tested in a GLP study carried out in a climatic chamber over a period of 21 days according to OECD Test Guideline No. 227 (2006). The validity criteria of OECD 227 were met.

The analytical results demonstrated that the active substance content in the test item solution used to treat the plants was in the range of $\pm 20\%$ of the nominal concentration.

The mean active substance recovery was 92.91%. Therefore, the endpoints of the test were calculated with respect to the nominal concentrations of the test item.

The NOEAR for mortality was 570.00 g test item/ha (equivalent to 200.64 g a.s./ha) for all species.

The ER₅₀ values for mortality were all above the tested application rate of 570.00 g test item/ha (equivalent to 200.64 g a.s./ha) since none of the tested species showed mortality.

No phytotoxic effects (necrosis, plants deformations, changes in colour) were observed in all treated plants.

Regarding the effects on biomass, measured as fresh shoot weight, all tested species showed a no statistically significant reduction compared to the untreated control.

The resulting NOEAR was 570.00 g test item/ha (equivalent to 200.64 g a.s./ha) for each tested species.

Due to the lack of effects $> 50\%$ until the end of the test, the ER₅₀ values for all the tested species were assigned to be > 570.00 g test item/ha (equivalent to 200.64 g a.s./ha).

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

No new additional studies have been submitted.

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

No new additional studies have been submitted.

A 2.8 KCP 10.8 Monitoring data

No new additional studies have been submitted.