|  |
| --- |
| REGISTRATION REPORT  Part B  Section 7  Metabolism and Residues  Detailed summary of the risk assessment |
| Product code: SHA 148000 A  Product name(s): **METROPOLITAN**  Chemical active substance:  Metazachlor, 500g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (Authorization) |
| Applicant: XXXX  Submission date: October 2022  Evaluation date: July 2023  MS Finalisation date: October 2023 |

Version history

|  |  |
| --- | --- |
| When | What |
| July 2023 | Version evaluated by zRMS PL |
| August 2023 | Updated by the Applicant |
| September 2023 | Updated by zRMS |
|  |  |

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# Metabolism and residue data (KCA section 6)

This application is to request authorization of Metazachlor 50% SC, suspension concentrate (SC) containing 500 g/L of Metazachlor, for use as an herbicide on winter and spring oil seed rapes. It is used in agricultural situations and under field conditions only.

## Summary and zRMS Conclusion

The applicant's dRR was not rewritten by the zRMS. In the resulted RR comments/corrections/addons were placed on the grey background.

### Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation Metazachlor 50% SC are presented in Table 7.1‑1. They have been selected from the individual GAPs in central zone for Winter and Spring Oilseed Rape and cabbage/cauliflower.

The critical GAP source which covers the intended GAP and allows for granting the authorisation is the GAP from the document Review report for the active substance metazachlor SANCO/140/08 – final rev. 2 (24 January 2012), confirmed with no changes in addition in SANCO/140/08 – final rev. 3 (22 March 2019; see page 6 and 7).

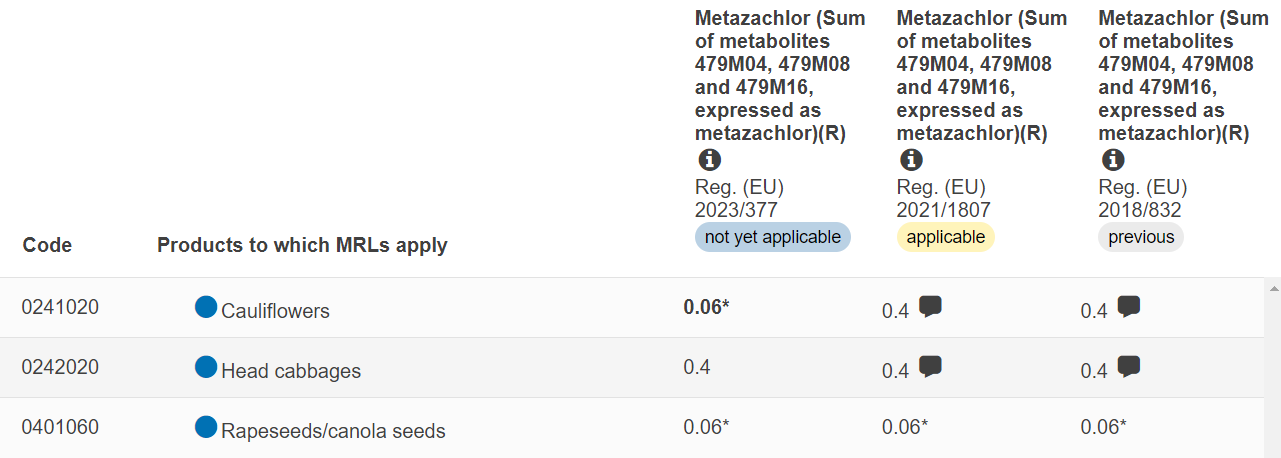
Moreover, in Poland the identical PPP METAZANEX 500 SC is registered in OSR and Brassica for 10 years (Reg.No R-147/2013) and now the data of this PPP are not a subject of data protection.

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

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for Metazachlor as laid down in Reg. (EU) 396/2005 is not expected for OSR and cabbage.

However, for cauliflower new, much more conservative MRL (0,06) will apply on 14/09/2023, and therefore cauliflower cannot be approved with no supporting residue data provided (see the paragraph on residues magnitude).



The chronic and the short-term intakes of Metazachlor residues are unlikely to present a public health concern. As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses except cauliflower. According to available data, no specific mitigation measures should apply.

Data gaps

Noticed data gaps:

~~the applicant in pre-registration mode should recalculate the animal burden consistently with currently required 2017 model. The update inserted into the present report version will be appreciated.~~

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | | 8 | | | | 9 | | | 10 | 11 |
| GAP number (see part B.0)\* | Crop and/  or situation \*\* | Zone | Product code | F, Fn, Fpn G, Gn, Gpn or I\*\*\* | Pests or  Group of pests  controlled | Formulation | | Application | | | | Application rate per treatment | | | PHI  (days) | Conclusion |
| Type | Conc.  of as | method  kind | growth  stage & season | number  min max | interval between applications (min) | **kg or L product / ha**  **a) max. rate per appl.**  b) max. total rate per crop/season | water L/ha  min max | kg as/ha  min max |
| **1** | Winter and Spring Oilseed rape | CEU | Metazachlor 50% SC | F | Broadleaved and grass weeds | SC | 500 g/L | Spray | Pre emergence BBCH 00-09 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | 200-400 | a) 0.75  b) 0.75 | - |  |
| **2** | Winter and Spring Oilseed rape | CEU | Metazachlor 50% SC | F | Broadleaved and grass weeds | SC | 500 g/L | Spray | Post emergence BBCH 10-19 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | 200-400 | a) 0.75  b) 0.75 | -- |  |
| **3** | Cabbage, ~~cauliflower~~ | CEU | Metazachlor 50% SC | F | Annual weeds | SC | 500 g/L | Spray | BBCH 13-16 (7 days after planting) | a) 1  b) 1 | NA | a) 2.0  b) 2.0 | 200-300 | a) 1.0  b) 1.0 | - |  |

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

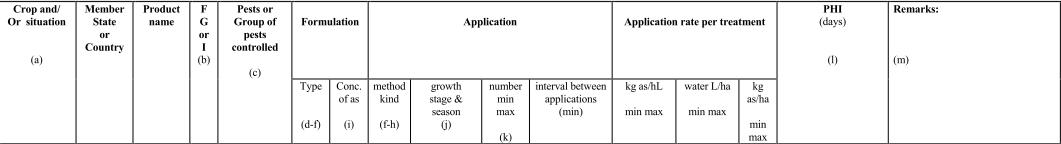
\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

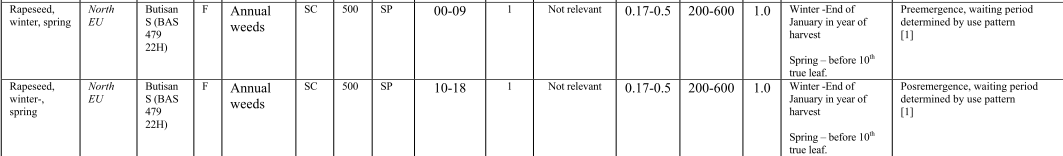
\*\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

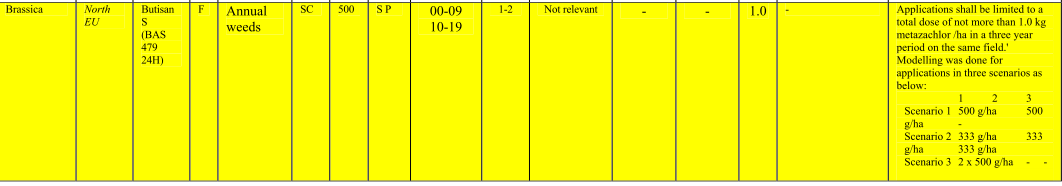
Explanation for Column 11 “Conclusion”

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

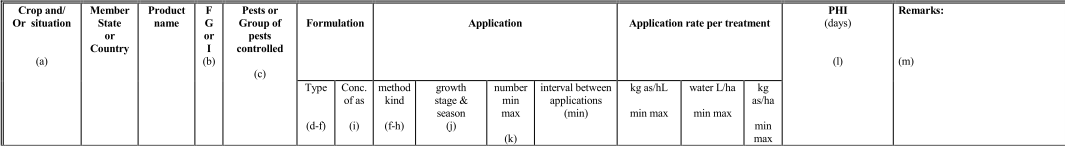
**Review report for the active substance metazachlor SANCO/140/08 – final rev. 2 (24 January 2012; the yellow color is the original color of the updated review)**

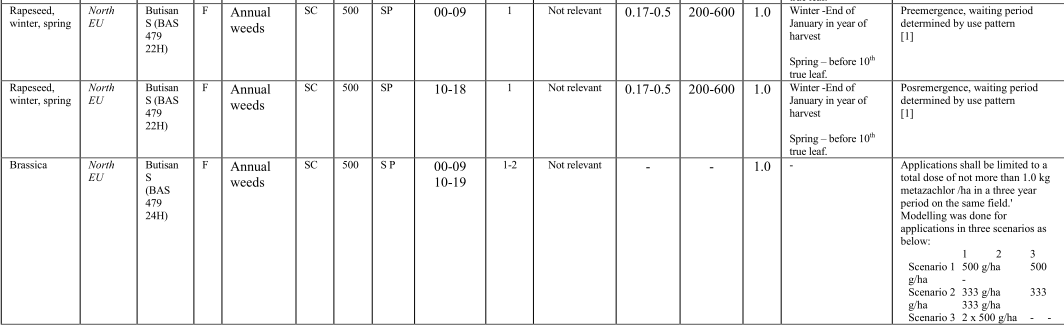






**Review report for the active substance metazachlor SANCO/140/08 – final rev. 3 (22 March 2019)**





### Summary of the evaluation

The preparation Metazachlor 50% SC is composed of Metazachlor

Table 7.1‑2: Toxicological reference values for the dietary risk assessment of Metazachlor

| Reference value | Source | Year | Value | Study relied upon | Safety factor |
| --- | --- | --- | --- | --- | --- |
| Metazachlor | | | | | |
| ADI | EFSA Scientific Report (2008) 145, 1-132, | 2009 | 0.08 mg/kg bw/day | Rat chronic  (FSG) | 100 |
| ARfD | EFSA Scientific Report (2008) 145, 1-132, | 2009 | 0.5 mg/kg bw | Rat  developmental  (BASF, FSG) | 100 |

#### Summary for Metazachlor

Table 7.1‑3: Summary for Metazachlor

| Use-No.\* | Crop | Plant metabolism covered? | Sufficient residue trials? | PHI sufficiently supported? | Sample sto­rage covered by stability data? | MRL compliance | Chronic risk for consumers identified? | Acute risk for consumers identified? |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | Winter and Spring oilseed rape | Yes | Yes | Yes | Yes | Yes | No | No |
| 2 | Winter and Spring oilseed rape | Yes | Yes | Yes | Yes | Yes | No |
| 3 | Cabbage, cauliflower | Yes | Yes | Yes | Yes | Yes | No |

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

The effects of processing and primary metabolism on the nature of Metazachlor residues were investigated in the framework of peer review.

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

Considering available data of magnitude of residue, it is considered suitable to support intended use according to GAP. Further investigation of residues as well as the modification of MRLs in commodities of animal or plant origin is therefore not necessary.

Use 3 (cabbage, cauliflower) requested for SHA148000A are identical to those of the reference product METAZANEX 500 SC registered in Poland (Registration No R-147/2013) for more than 10 years and, therefore, not in a scope of data protection anymore.

It can be concluded that the proposed uses of metazachlor in the formulation SHA148000A do not represent unacceptable chronic or acute risk for the consumer.

#### Summary for product code

Table 7.1‑4: Information on Metazachlor 50% SC (KCA 6.8)

| Crop | PHI for Metazachlor 50% SC  proposed by applicant | PHI/ Withholding period\* sufficiently supported for | PHI for Metazachlor 50% SC  proposed by zRMS | zRMS Comments  (if different PHI proposed) |
| --- | --- | --- | --- | --- |
| Metazachlor |
| Winter Oilseed rape | NR | NR | - | - |
| Spring Oilseed rape | NR | NR | - | - |
| Cabbage, cauliflower | NR | NR | - | - |

NR: not relevant

## Metazachlor

**Table 7.2‑1: General information on Metazachlor**

|  |  |
| --- | --- |
| Active substance (ISO Common Name) | Metazachlor |
| IUPAC | 2-chloro-N-(pyrazol-1-ylmethyl)acet-2′,6′-xylidide |
| Chemical structure |  |
| Molecular formula | C14H16Cl N3O |
| Molar mass | 277.8 g/mol |
| Chemical group | chloroacetanilides |
| Mode of action (if available) | Inhibition of lipid synthesis |
| Systemic | Yes |
| Company | XXXX |
| Rapporteur Member State (RMS) | Spain |
| Approval status | Approved  Date of 01/08/2009 and reference to decision (COMMISSION DIRECTIVE [2008/116/EC](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0116&from=EN). |
| Restriction  (e.g. is restricted to use as “...”) | Only use as herbicide may be authorized |
| Review Report | SANCO/140/08 – final rev. 3 1 (22 March 2019) |
| Current MRL regulation | Regulation (EU) No 2021/1807 |
| Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed | Yes |
| EFSA Journal: Conclusion on the peer review | Yes (EFSA Scientific Report (2008) 145, 1-132) |
| EFSA Journal: conclusion on article 12 | Yes (EFSA Journal 2014;12(4):3634)  Yes (EFSA Journal 2014;12(4):3634) |
| Current MRL applications on intended uses | Status: Reasoned opinion available (EFSA Journal 2014;12(4):3634) |

### Stability of Residues (KCA 6.1)

#### Stability of residues during storage of samples

Storage stability for the Metazachlor residue is carried out in both plant origins commodities/product under the temperature less than -20oC.

Table 7.2‑2: Summary of stability data achieved at ≤ ‑ 20°C (unless stated otherwise)

| Matrix | Characteristics of the matrix | Acceptable Maximum Storage duration | Reference |
| --- | --- | --- | --- |
| **Data relied on in EU** |  |  |  |
| Plant products | | | |
| OSR | High Oil Content | 24 months | Lehmann, A. and Mackenroth, C. 2003, 2004 / DAR (UK, 2008) |
| Cabbage | High water Content | 24 months | Lehmann, A. and Mackenroth, C. 2003, 2004 / DAR (UK, 2008) |

Conclusion on stability of residues during storage

Storage stability studies showed that residues of metazachlor in high acid and high water matrices are stable, when stored under deep freeze conditions and analyzed by the common moiety method of analysis.

### Nature of residues in plants, livestock and processed commodities

#### Nature of residue in primary crops (KCA 6.2.1)

The metabolism of Metazachlor was investigated for foliar application or soil application on cereals (maize), pulses and oilseeds (rape seed) and on leafy vegetables (cabbage), using 14C-phenyl-labelled Metazachlor.

Table 7.2‑3: Summary of plant metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop Group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G (a) | Rate  (kg a.s./ha) | No | Sampling (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Leafy vegetables | Cabbage | 14C-phenyl | G, Foliar  spraying | 1.25 | 1 | 34, 147 days |  | Bross, M. and Hoefs, R., 2003 /DAR (UK, 2008) |
| Cereals/Grasses | Maize | 14C-phenyl | G, Soil treatment | 1 | 1 | 78, 118, 146 |  | Hofmann, M., 1990; Bross, M., 1995 /DAR (UK, 2008) |
| Pulses and oilseeds | Oilseed Rape | 14C-phenyl | G, Foliar spraying | 1.25 | 1 | 22, 71 |  | Bross, M. 2003; Rosenwald, J. 2005/ DAR (UK, 2008) |
| G, Soil treatment | 1.25 | 215, 293 |  |
| G, Foliar spray | 0.75 | 41, 94 |  |

Summary of plant metabolism studies reported in the EU

The metabolism of Metazachlor in primary crops belonging to the group of leafy crops, pulses/oilseeds and cereals was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). The metabolic pathway was similar in all crop groups investigated: Metazachlor undergoes rapid metabolization to several metabolites, the predominant ones being 479M04, 479M08 and 479M16.

Conclusion on metabolism in primary crops

Based on the above findings, it is concluded that following soil or foliar applications the residue definition proposed for risk assessment is sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor (EFSA, 2008). For enforcement purposes the major metabolites 479M04, 479M08 and 479M16 are deemed to be sufficient markers.

#### Nature of residue in rotational crops (KCA 6.6.1)

The metabolism studies of Metazachlor are carried out in rotational crops that is lettuce, spinach, white radish, carrot, wheat has been evaluated.

Table 7.2‑4: Summary of metabolism studies in rotational crops

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Crop group | Crop | Label position | Application and sampling details | | | | | Reference |
| Method,  F or G \* | Rate  (kg a.s./ha) | Sowing intervals  (DAT) | Harvest  Intervals (DAT) | Remarks |
| **EU data** | | | | | | | | |
| Root/tuber | Radishes | 14C-phenyl | G, Bare soil | 1.25 | 30, 120, 366 | 92, 107, 199, 447 |  | Bross, M. and Gluessgen W.E. 2003; Laabs, V and Rosenwald, J. 2005 / DAR (UK, 2008) |
| Carrot | 14C-phenyl | F, Bare soil | 0.75 | 30 | 118, 134, 161 |  |
| Leafy vegetables | Lettuce | 14C-phenyl | G, Bare soil | 1.25 | 30, 120, 366 | 85, 107, 184, 434 |  |
| Cabbage | 14C-phenyl | F, Bare soil | 0.75 | 30 | 63, 98, 118 |  |
| Spinach | 14C-phenyl | F, Bare soil | 0.75 | 30 | 69, 73 |  |
| Cereals | Wheat | 14C-phenyl | G, Bare soil | 1.25 | 30, 120, 366 | 237, 289, 178, 261, 421, 513 |  |
| 14C-phenyl | F, Bare soil | 0.75 | 30 | 79, 99, 155 |  |

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The metabolic pathway in rotational crops is like that observed in primary crops, and involves the glutathione route and the oxidative degradation of the chloroacetamide moiety. The parent compound is not present in rotational crops. The major metabolites found are metabolites 479M04 and 479M08.

Conclusion on metabolism in rotational crops

Parent metazachlor was not detected in any sample. Metabolites 479M04, 479M08 and 479M16 were the most abundant compounds in all analysed samples. Metabolism in rotational crops is similar to metabolism in primary crops and in soil. Consequently, a specific residue definition for rotational crops is not deemed necessary.

#### Nature of residues in processed commodities (KCA 6.5.1)

Table 7.2‑5: Nature of the residues in processed commodities

|  |  |  |  |
| --- | --- | --- | --- |
| **Conditions**  **(Duration, Temperature, pH)** | **Identified compound** | **Stable** | **Reference** |
| **EU data** | | | |
| **Pasteurisation** (20 minutes, 90°C, pH 4) | 479M16 | Yes | Hassink, J. 2003 / DAR (UK, 2008) |
| **Baking, boiling, brewing**  (60 minutes, 100°C, pH 5) | 479M16 | Yes |
| **Sterilisation** (20 minutes, 120°C, pH 6) | 479M16 | Yes |

A study is conducted to stimulate the conditions of pasteurization, sterilization, and baking, brewing and boiling. Studies were performed using the [phenyl-U-14C) labelled 479M16 (Metazachlor DAR, 2005)

Conclusion on nature of residues in processed commodities

The effect of processing on the nature of 479M16 was investigated in the framework of the peer review. From these studies, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin (United Kingdom, 2005). The relevant residues for enforcement and risk assessment in processed commodities are therefore expected to be the same as for primary crops.

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

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

|  |  |
| --- | --- |
| **Endpoints** | |
| Plant groups covered | Leafy crops (white cabbage); pulses/oilseeds  (Oilseed rape); cereals (maize), Pulses/Oilseeds (oilseed rape) |
| Rotational crops covered | Leafy crops (lettuce); root crop (radish); cereals  (wheat) |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not applicable |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Yes |
| Plant residue definition for monitoring | Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as Metazachlor) |
| Plant residue definition for risk assessment | Sum of metazachlor and its metabolites containing the  2,6-dimethylaniline moiety, expressed as metazachlor |
| Conversion factor from enforcement to RA | Not applicable (if total residues are below LOQ) |

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

The nature of metazachlor residues in commodities of animal origin was investigated in the framework of first review (United Kingdom, 2005). Reported metabolism studies include three studies in lactating goats (two using 14C-phenyl-labelled metazachlor and one using 14C-phenyl-labelled 479M16) and one study in laying hens using 14C-phenyl-labelled metazachlor.

Table 7.2‑7: Summary of animal metabolism studies

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Group | Species | Label position | No of animal | Application details | | Sample details | | Reference |
| Rate  (mg/kg bw/d) | Duration  (days) | Commodity | Time of samp­ling |
| **EU data** | | | | | | | | |
| Lactating ruminants | Goat | 14C-phenyl | 1  1 | 0.16  1.6 | 5 | Milk | twice daily | Xxxx 1997 / DAR (UK, 2008) |
| Urine and faeces | daily |
| Tissues | at sacrifice |
| Lactating ruminants | Goat | 14C-phenyl | 2 | 1.6 | 5 | Milk | twice daily | Xxxx 2003 / DAR (UK, 2008) |
| Urine and faeces | daily |
| Tissues | at sacrifice |
| Lactating ruminants | Goat | 14C-phenyl –  479M16 | 1 | 0.04 | 9 | Milk | twice daily | Xxxx 2003 / DAR (UK, 2008) |
| Urine and faeces | daily |
| Tissues | at sacrifice |
| Laying Poultry | Hen | 14C-phenyl | 12 | 0.75 | 6 | Eggs | Twice, daily | Xxxx 1993; xxxx 2002 / DAR (UK, 2008) |
| 10 | 7 | Excreta | daily |
| Tissues & Blood | at sacrifice |

Summary of new animal metabolism studies

Lactating goats were dosed with either 0.16 mg/kg bw per d of Metazachlor, or 1.6 mg/kg bw per d of Metazachlor (high dose). Studies demonstrate that transfer of residues to milk is relatively low with a TRR of 0.01 mg eq/kg. Highest residue levels were found in liver (0.9 mg eq/kg for low dose, 3-4 mg eq/kg for high dose) and kidney (0.4 mg eq/kg for low dose, 2-4 mg eq/kg for high dose). TRR in muscle and fat were not significant at low dose (<0.01 mg eq/kg) and amounted for 0.04-0.10 mg eq/kg at high dose. The study, on lactating goats dosed with 0.04 mg/kg bw per d of 479M16 demonstrated that transfer of residues to milk and tissues is relatively low, with no TRR above 0.01 mg eq/kg.

Another study was carried out on laying hens, laying hens were dosed with either 0.75 mg/kg bw per d of Metazachlor (low dose) or 7 mg/kg bw per d of Metazachlor (high dose). At low dose, the highest residue levels were found in liver (0.3 mg eq/kg), skin (0.04 mg eq/kg), muscle (0.02 mg eq/kg), egg (up to 0.02 mg eq/kg) and fat (0.01 mg eq/kg). Therefore, no significant residues (i.e., above 0.01 mg/kg) are expected in eggs or tissues at the maximum dietary burden and further investigation is not necessary.

Conclusion on metabolism in livestock

Based on the above finding, it was already concluded that the residue definition proposed for monitoring and risk assessment in animal commodities should be the sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor (EFSA, 2008). EFSA is of the opinion that a common moiety approach is in accordance with the extensive metabolism observed in the ruminant studies.

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

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

|  |  |
| --- | --- |
|  | Endpoints |
| Animals covered | Lactating goats |
| Laying hens |
| Time needed to reach a plateau concentration | No residue observed in milk above 0.01 mg/kg |
| Animal residue definition for monitoring | Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as Metazachlor) |
| Animal residue definition for risk assessment | Sum of metazachlor and its metabolites containing the  2,6-dimethylaniline moiety, expressed as metazachlor |
| Conversion factor | Not applicable |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No (based on Pow for Metazachlor), Pow not  known for metabolites. |

### Magnitude of residues in plants (KCA 6.3)

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

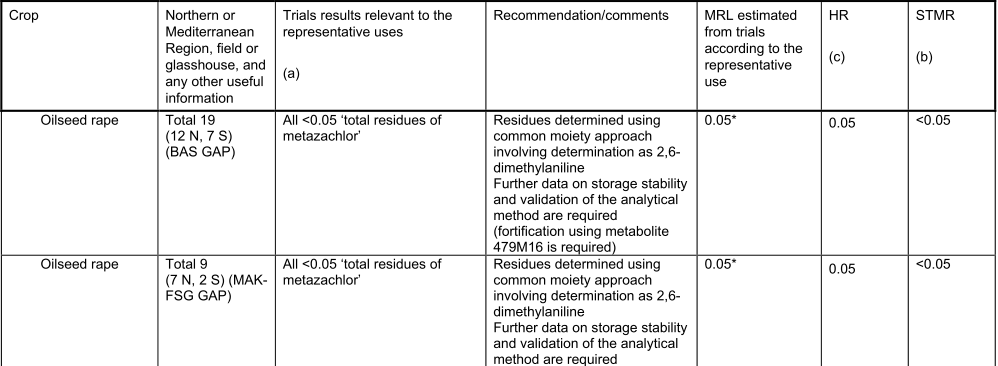
Table 7.2‑9: Summary of EU reported and new data supporting the intended uses of product code and conformity to existing MRL

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Source | Residue zone (N-EU, S-EU, EU, outside EU) | Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition | STMR (mg/kg) | HR (mg/kg) | Unrounded OECD calculator MRL (mg/kg) | Current EU MRL  (mg/kg)  \* | MRL compliance |
| Rape seed | Solymos, E.M. et al., 1999a (1999/10779)  ~~Anonymous 1981f,g,h,I,j,k,m,n; 1982e,f (1981/10389) (1981/10390) (1981/10391)~~  ~~(1981/10392)~~  ~~(1981/10380)~~  ~~(1981/10219)~~  ~~(1981/10220)~~  ~~(1981/10394)~~  ~~(1981/10393)~~  ~~(1981/10395)~~  DAR (UK, 2008) | NEU | GAP: 1x1.0-1.25 kg as/ha, PHI 110-152 days  E/RA: 10x<0.05 | 0.05 | 0.05 | 0.05 | 0.06 | Yes |
| ~~Rape Seed,~~ | ~~Balluff, M. 2002a (2002/1006295);; Anonymous 1980a,b (1980/10650) (1980/10653) (1985/10546) / DAR (UK, 2008)~~ | ~~SEU~~ | ~~GAP: 1x1.0-1.25 kg as/ha, PHI 117-257 days~~  ~~E/RA: 8x<0.05~~ | ~~0.05~~ | ~~0.05~~ | ~~0.05~~ | ~~0.06~~ |  |
|  | ~~Overall supporting data for cGAP~~ | ~~EU~~ | ~~E/RA: 18x<0.05~~ | ~~0.05~~ | ~~0.05~~ | ~~0.05~~ | ~~0.06~~ | ~~Yes~~ |

\* Source of EU MRL: respective Regulation (EU) 2021/1807

Metazachlor (Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor).

**EFSA Scientific Repor****t (2008)** 145, 1-132, **Conclusion on the peer review of metazachlor** Appendix 1 – List of endpoints/ Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)



(a) Numbers of trials in which particular residue levels were reported e.g. 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue i.e. the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

#### Conclusion on the magnitude of residues in plants

**zRMS**: An expiration of metazachlor approval is on 31/10/2026.

**OSR:**

The intended use in oilseed rape can be authorized for two reasons:

1) It is use covered by the representative use acc. SANCO/140/08 – final rev. 2 (24 January 2012) and this reason is prior to the fact that METAZANEX 500 SC, as registered in Poland for 10 years PPP (Registration No R-147/2013), now is not a subject of data protection, because despite this, the applicant cannot provide the residue data for part of requested crops (cabbage and cauliflower).

2) Current MRL consistency: The available data of oilseed rape presented above in the tables of the applicant originated from the old DAR and the document SANCO/140/08 rev. 2, are valid for support the intended use in oilseed rape. These data also are consistent with the currently adopted MRL.

**Cabbage and cauliflower:**

On 24 January 2012, based on the addendum to the DAR, the Appendix II to the SANCO/140/08 report has been amended in order to include the additional supported use in Brassica.

However, in 2014, when EFSA reviewed the existing MRLs for metazachlor according to Article 12 of Regulation (EC) No 396/2005, the following data gaps were noted: 8 residue trials (4 on cauliﬂower and 4 on broccoli) supporting the northern outdoor GAP for ﬂowering brassica and 8 residue trials supporting the northern outdoor GAP for head cabbage. To address the data gaps new residue trials on ﬂowering brassica (broccoli, cauliﬂowers), head cabbages, Brussels sprouts and kales representative for the existing GAPs previously assessed in the framework of the MRL review, were provided. In Review report for metazachlor SANCO/140/08 – final rev. 3 2019 the same GAP in Brassica as in 2012 is supported. However, the applicant has no access to those new data.

The applicant cannot provide also the old residue data for cabbage and cauliflower and the formal access to the data of METAZANEX is useless. For cabbage this is not a problem because the relevant MRL remains the same and will not be exceeded in the light of the accepted representative uses. But cauliflower cannot be approved because there is no possibility to assess the changing MRL consistency. The MRL consistency is not supported.

See for MRLs in the beginning of the report.

Intended GAP is early post-transplanting, and corresponding crop cycle till harvest represents clear case of non-relevant residue situation. Therefore, the expected level of residue in products of plant origin will be <LOQ (0.05 mg/kg) situation, and according to SANTE/2019/12752 enough residue trials at critical GAP within +-25% are available to support use in OSR.

Use in cabbage and cauliflower requested for SHA148000A are identical to those of the reference product METAZANEX 500 SC registered in Poland (Registration No R-147/2013) for more than 10 years and, therefore, not in a scope of data protection anymore. Both products, METROPOLITAN and METAZANEX are suspension concentrate formulation (SC) and intended GAP for cabbage and cauliflower are identical to those approved for reference product METAZANEX. Therefore, residue behaviour of both products can be considered as comparable since the criteria of SANTE/2019/12752 guideline for combining/pooling/merging of residue data sets are meet. Thus, unprotected residue data packaging from METAZANEX can support such intended uses for METROPOLITAN.

From such data it can be concluded that exceedance of the MRL will not occur if SHA148000A is applied according to applicant’s GAP.

The uses on OSR and cabbage and cauliflower are considered acceptable.

### Magnitude of residues in livestock

#### Dietary burden calculation

Metazachlor is authorized for the use on the several crops that might be fed to the livestock. Therefore, the maximum dietary burden was calculated for the different groups of the livestock. For the oilseed rape processing factor of 1 was used because Metazachlor is applied early in the growing season and residues are expected to be below of the LOQ (EFSA, 2014).

Table 7.2‑10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: Metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as Metazachlor. | | | | |
| Cabbage | 0.05 | Median Residue | 1.24 | Highest residue |
| Kale | 0.05 | Median Residue | 0.14 | Highest residue |
| Linseed, rape seed and sunflower seed meal | 0.05 | Median Residue | 0.05 | Median residue |
| Turnips, Swedes | 0.05 | Median Residue | 0.08 | Highest residue |
| Rape forage | 0.50 | Median Residue | 1.24 | Highest residue |

| Feed Commodity | Median dietary burden | | Maximum dietary burden | |
| --- | --- | --- | --- | --- |
| Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor. | | | | |
| Cabbage heads, leaves | 0.05 | Median residue (EFSA, 2014) | 0.16 | Highest residue (EFSA, 2014) |
| Kale, leaves (forage) | 0.05 | Median residue (EFSA, 2014) | 0.14 | Highest residue (EFSA, 2014) |
| Rape, forage | 0.50 | Median residue (EFSA, 2014) | 1.24 | Highest residue (EFSA, 2014) |
| Turnip, roots | 0.05 | Median residue (EFSA, 2014) | 0.08 | Highest residue (EFSA, 2014) |
| Canola (Rape seed) meal | 0.05 | Median residue x PF (1.0) | 0.05 | Median residue x PF (1.0) |
| Flaxseed/Linseed meal | 0.05 | Median residue x PF (1.0) (EFSA, 2014) | 0.05 | Median residue x PF (1.0) (EFSA, 2014) |
| Rape, meal | 0.05 | Median residue x PF (1.0) (EFSA, 2014) | 0.05 | Median residue x PF (1.0) (EFSA, 2014) |
| Sunflower, meal | 0.05 | Median residue x PF (1.0) (EFSA, 2014) | 0.05 | Median residue x PF (1.0) (EFSA, 2014) |

The results of the calculations are reported in Table 7.2‑11. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation on residues is therefore required in all commodities of animal origin.

Table 7.2‑11: Results of the dietary burden calculation

| Animal species | Median  dietary burden (mg/kg bw/d) | Maximum dietary burden  (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- | --- |
| Risk assessment residue definition: Metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as Metazachlor. | | | | | |
| Dairy ruminant | 0.011 | 0.024 | Cabbage | 0.66 | Yes |
| Meat ruminants | 0.067 | 0.154 | Rape forage | 3.57 | Yes |
| Poultry | 0.008 | 0.014 | Turnips | 0.22 | Yes |
| Pigs | 0.034 | 0.073 | Rape forage | 1.82 | Yes |

| Animal species | Median  dietary burden (mg/kg bw/d) | Maximum dietary burden  (mg/kg bw/d) | Highest contributing commodity | Max dietary burden (mg/kg DM) | Trigger exceeded (Y/N) |
| --- | --- | --- | --- | --- | --- |
| Risk assessment residue definition: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor. | | | | | |
| Cattle (all diets) | 0.009 | 0.020 | Rape forage | 0.53 | Y |
| Cattle (dairy only) | 0.009 | 0.020 | Rape forage | 0.53 | Y |
| Sheep (all diets) | 0.033 | 0.078 | Rape forage | 1.82 | Y |
| Sheep (ewe only) | 0.026 | 0.061 | Rape forage | 1.82 | Y |
| Swine (all diets) | 0.011 | 0.024 | Rape forage | 1.05 | Y |
| Poultry (all diets) | 0.014 | 0.032 | Rape forage | 0.47 | Y |
| Poultry (layer only) | 0.014 | 0.032 | Rape forage | 0.47 | Y |

#### Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

According to the metabolism study in poultry, it is concluded that, after exposure to the maximum dietary burden, residue levels are expected to remain below the enforcement LOQ of 0.05 mg/kg in poultry tissues and eggs. Hence, no poultry feeding study is needed; MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level (EFSA, 2014).

During the peer review, the magnitude of metazachlor residues in ruminants was investigated in a feeding study with lactating cows (UK, 2005). Three groups of lactating cows, each consisting of three animals, were dosed for 28 consecutive days with metazachlor at levels of 0.8, 2.4, and 8 mg/kg in the diet (equivalent to 0.02, 0.08 and 0.26 mg/kg bw). The samples were analysed for metazachlor, including degradation and reaction products which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor (Table 7.2.12). Milk samples from the feeding studies were not analysed as residue levels in milk from the above mentioned metabolism study in ruminants were below the enforcement LOQ of 0.01 mg/kg after exposure to the maximum dietary burden.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants (EFSA, 2014).

Table 7.2‑12: Overview of the values derived from livestock feeding studies

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Commodity | Dietary burden | | Results of the livestock feeding study | | | | | | Median residue  (mg/kg) (b) | Highest residue  (mg/kg) (c) | Calculated MRL  (mg/kg) | CF for RA(d) |
| Med. (mg/kg bw/d) | Max. (mg/kg bw/d) | Dose Level (mg/kg bw/d)(a) | No | Result for enforcement | | Result for RA | |
| Mean (mg/kg) | Max. (mg/kg) | Mean (mg/kg) | Max. (mg/kg) |
| **EU data (EFSA Journal 2014;12(4):3634)** | | | | | | | | | | | | |
| Enforcement residue definition : Sum of Metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as Metazachlor | | | | | | | | | | | | |
| Pig muscle | ~~0.034~~  0.011 | ~~0.073~~  0.024 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| Pig fat | ~~0.034~~  0.011 | ~~0.073~~  0.024 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| Pig liver | ~~0.034~~  0.011 | ~~0.073~~  0.024 | 0.02 | 3 | 0.05 | 0.06 | 0.05 | 0.06 | 0.07 | 0.14 | 0.20 | 1.00 |
| 0.08 | 3 | 0.13 | 0.15 | 0.13 | 0.15 |
| 0.26 | 3 | 0.32 | 0.49 | 0.32 | 0.49 |
| Pig kidney | ~~0.034~~  0.011 | ~~0.073~~  0.024 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| Ruminant muscle | ~~0.067~~  0.009 | ~~0.154~~  0.020 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| Ruminant fat | ~~0.067~~  0.009 | ~~0.154~~  0.020 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| Ruminant liver | ~~0.067~~  0.009 | ~~0.154~~  0.020 | 0.02 | 3 | 0.05 | 0.06 | 0.05 | 0.06 | 0.11 | 0.29 | 0.30 | 1.00 |
| 0.08 | 3 | 0.13 | 0.15 | 0.13 | 0.15 |
| 0.26 | 3 | 0.32 | 0.49 | 0.32 | 0.49 |
| Ruminant kidney | ~~0.067~~  0.009 | ~~0.154~~  0.020 | 0.02 | 3 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05\* | 1.00 |
| 0.08 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |
| 0.26 | 3 | 0.05 | 0.05 | 0.05 | 0.05 |

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported.

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(c): The median conversion factor for enforcement to risk assessment.

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

**Conclusion on feeding studies**

It is concluded that that all residues are established below the enforcement LOQ of 0.05 mg/kg.

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

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

#### Available data for all crops under consideration

No new data were submitted in the framework of this application. The expected level of residue in processed commodities from products of plant or animal origin will be lower than 0.1 mg/kg (DAR 2008).

However ,the magnitude of the residues (sum of Metazachlor and its metabolites containing the 2,6-dimethylaniline moiety) was investigated on the processing products after the application of the active substance in sunflower.

Table 7.2‑13: Overview of the available processing studies

| Processed commodity | Number of studies | Median PF \* | Median CF \*\* | Comments | Reference |
| --- | --- | --- | --- | --- | --- |
| **EU data** | | | | | |
| commodity, sunflower seed | 2 | NA | NA |  | Grolleau, G., 1998/DAR (UK, 2008) |
| commodity, sunflower oil | 2 | NA | NA | - |
| commodity, sunflower presscake | 2 | NA | NA | - |

\* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

\*\* The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

#### Conclusion on processing studies

Non applicable PF and CF as <LOQ (0.05 mg/kg) residue were obtained in different processing commodities. These results clearly indicate that metazachlor residues do not accumulate in sunflower or rape oil or presscake which are destined for human food or animal feed.

### Magnitude of residues in representative succeeding crops

The magnitude of the residues (sum of Metazachlor and its metabolites containing the 2,6-dimethylaniline moiety) was investigated on the several succeeding crops (lettuce/spinach, carrot, and wheat) that taken after the application of the active substance.

#### Field rotational crop studies (KCA 6.6.2)

Table 7.2‑14: Summary of available studies in field rotational crops

| Primary crop | Rate (kg a.s./ha)  (GS at application or PHI) | Residue levels in succeeding crops | | | |
| --- | --- | --- | --- | --- | --- |
| Succeeding crop group | Succeeding crop | Sowing intervals  (DAT) | Reference /  Remarks |
|  | | | | | |
| Oilseed Rape | 1.0-1.25 kg a.s./ha  (BBCH 0-12) | Leafy vegetables | Lettuce, spinach | 30, 120, 366 | Schulz, H., 2005a,b; Jones, S., 2003) / DAR (UK, 2008) |
| Root and tuber vegetables | Carrot | 30, 120, 366 |
| Cereals | Wheat | 30, 120, 366 |

Conclusion on rotational crops studies

Rotational crop studies are carried out on the Root crops (Radish), leafy crops (lettuce,) and cereals (wheat).

The results of the study show that no residues above the limit of quantitation of metazachlor are taken up into edible parts of follow crops. Considering that the application rate of metazachlor within the EU is up to 1 kg a.s./ha, metazachlor residue levels in crops grown in rotation are not expected to impact MRLs for plant and animal products, provided that metazachlor is applied in compliance with the GAPs proposed.

### Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of product code. Therefore, other special studies are not needed.

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

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

#### Input values for the consumer risk assessment

The assessment of the potential chronic and acute dietary consumer risk due to exposure to residues of Metazachlor was performed using the EFSA calculation model “PRIMo” (Pesticide Residue Intake Model) rev.3.1, which is presented in Appendix 3. Input MRL vales are based on Reg. (EU) No 2021/1807.

#### Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2‑16: Consumer risk assessment

|  |  |
| --- | --- |
| TMDI (% ADI) according to EFSA PRIMo 3.1 | 3 % (based on NL toddler) |
| IESTI (% ARfD) according to EFSA PRIMo 3.1 | Unprocessed commodities  Results for children:  9% Swedes/rutabagas  Results for adults:  6% Swedes/rutabagas  Processed commodities  Results for children:  9% Turnips/boiled  Results for adults:  3% Turnips/boiled |

The calculation of the TMDI was performed taking into account all the crops to which metazachlor may be applied. The summary of the calculation using the EFSA model rev 3.1 is presented in Appendix 3. With the current EFSA model the chronic risk assessment reaches a maximum of 3% of ADI. The diet with the highest TMDI is “NL toddler”. For this diet, the highest contributor is milk with 0.7% of ADI.

Acute dietary exposure was performed taking into account all the crops with corresponding MRL values. Final values resulted to be acceptable for acute exposure for processed and unprocessed commodities.

Based on the above calculation, it can be concluded that the proposed uses of metazachlor in the formulation SHA148000A do not represent unacceptable chronic or acute risk for the consumer.

## References

|  |
| --- |
| EFSA Scientific Report (2008) 145, 1-132 Conclusion on the peer review of Metazachlor.  EFSA Journal 2014;12(4):3634 Reasoned opinion on the review of the existing maximum residue levels (MRLs) for Metazachlor according to Article 12 of Regulation (EC) No 396/2005.  EFSA Journal 2019 doi: 10.2903/j.efsa.2019.5819 Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for Metazachlor in various commodities. |
| Draft Assessment Report for active substance Metazachlor of Council Directive 91/414/EEC, Volume 3, Annex B, part 3, B.7, June 2005.  EFSA Pesticide Database for Metazachlor input MRL values Commission Reg. (EU) No 2021/1807. |
|  |
|  |
|  |

1. Lists of data considered in support of the evaluation

No new studies are submitted

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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

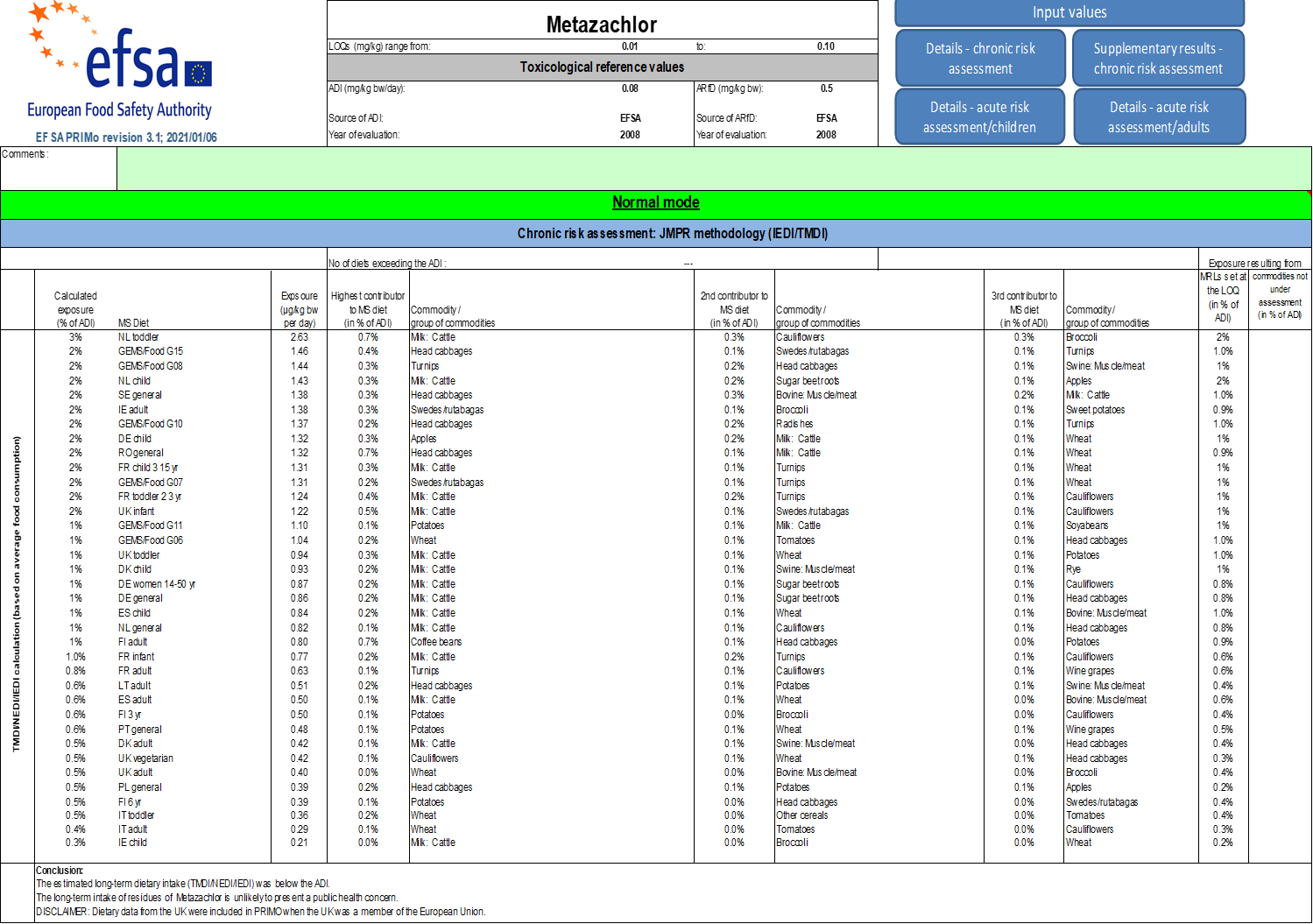
List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| 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 |
| --- | --- | --- | --- | --- | --- |
| 7.2 | Lehmann A.,  Mackenroth C. | 2003 | Investigation of the storage stability of BAS 479  H (Metazachlor) in water- and oil-containing  plant material  BASF AG, Agrarzentrum Limburgerhof;  Limburgerhof; Germany Fed.Rep.  2003/1000952  Yes  unpublished | N | BASF |
| 7.2 | Lehmann A.,  Mackenroth C. | 2004 | Investigation of the storage stability of BAS 479  H (Metazachlor) in water- and oil-containing  plant material  BASF AG, Agrarzentrum Limburgerhof;  Limburgerhof; Germany Fed.Rep.  2004/1000751  Yes  unpublished | N | BASF |
| 7.2 | Hofmann M. | 1990 | Plant uptake study with 14C-Metazachlor in a BAS 485 43 H formulation in maize (soil application)  1990/0500  BASF AG, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | N | BASF |
| 7.2 | Bross M. | 1995 | The metabolism of Metazachlor in maize: Identification and quantification of metabolites  1995/11169  BASF AG, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | N | BASF |
| 7.2 | Bross M.,  Hoefs R. | 2003 | The metabolism of 14C-Metazachlor (14C-Reg.No. 114 252) in white cabbage  2002/1007084  BASF AG, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | N | BASF |
| 7.2 | Bross M. | 2003 | The metabolism of 14C-Metazachlor (14C-Reg.No. 114 252) in rape  2003/1000958  BASF AG, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | N | BASF |
| 7.2 | Rosenwald J. | 2005 | [14C]Metazachlor: Metabolism in summer oilseed rape under outdoor conditions  1984-0775-005  yes  Unpublished | N | Adama |
| 7.2 | Bross M.,  Glaessgen W.E. | 2003 | Confined rotational crop study with 14C-Metazachlor (14C-BAS 479 H)  2003/1000960  BASF AG, Limburgerhof, Germany Fed.Rep.  yes  Unpublished | N | BASF |
| 7.2 | Laabs V.,  Rosenwald J. | 2005 | [14C]Metazachlor: Residues in rotational crops  2024-0775-004  yes  Unpublished | N | Adama |
| 7.2 | Hassink, J. | 2003 | Hydrolysis of Reg.No. 323 355 at 90°C, 100°C  and 120°C  BASF AG, Agrarzentrum Limburgerhof;  Limburgerhof; Germany Fed.Rep.  2003/1001010  Yes  unpublished | N | BASF |
| 7.2 | xxxx | 2002 | Nature of the residues of (14C)-Metazachlor in egg-laying White leghorn hens: Metabolite profiling, isolation and identification.  2002/1007096  Xxx  GLP  Unpublished | Y | BASF |
| 7.2 | xxxx | 1993 | Nature of the residue of 14C-Metazachlor in egg-laying White leghorn hens.  1993/11015  Xxxx  GLP  Unpublished | Y | BASF |
| 7.2 | xxxx | 1997 | The metabolism of (14)Metazachlor (14C)-LAB 114252) in lactating goats.  1997/11283  Xxxx  GLP  Unpublished | Y | BASF |
| 7.2 | xxxx | 2003 | (14)-Metazachlor: absorption, distribution, metabolism and excretion following repeated oral administration to the dairy goat.  2003/1000959  Xxxx  GLP  Unpublished | Y | BASF |
| 7.2 | xxxx | 2003 | 14C-Reg.No. 323355 (BH479-21; Metabolite of BAS 479 H, Metazachlor)-Absorption, distribution and excretion after repeated oral administration in a lactating goat.  2003/1001493  Xxxx  GLP  Unpublished | Y | BASF |
| 7.2 | xxxx | 2003 | The metabolism of 14C-Reg.No.323355 (metabolite of BAS 479H, Metazachlor) in lactating goats.  2003/1001494.  Xxxx  GLP  Unpublished | Y | BASF |
| 7.2 | Grolleau G. | 1998 | Magnitude of the residue of Quinmerac + Metazachlor in sunflower raw agricultural commodity and processed fractions - Northern and southern France - 1997  1998/10724  European Agricultural Services, Lyon, France  yes  Unpublished | N | BASF |
| 7.2 | Jones, S. | 2003 | Study on the residue behaviour of BAS 479 H in rotational crops after application of BAS 479 22 H under field conditions in the United Kingdom, Germany and Denmark, 2002  2003/1013926  BASF plc, Gosport Hampshire PO13 0AU, United Kingdom  yes  Unpublished | N | BASF |
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1. Detailed evaluation of the additional studies relied upon

No additional studies submitted.

1. Pesticide Residue Intake Model (PRIMo)
   1. TMDI calculations



* 1. IEDI calculations

As, Metazachlor TMDI calculations does not exceed the ADI, therefore there’s no need of IEDI calculations.

* 1. IESTI calculations - Raw commodities



* 1. IESTI calculations - Processed commodities



1. Additional information provided by the applicant

No additional information provided by the applicant.