|  |
| --- |
| **REGISTRATION REPORT**  Part B  Section 8  Environmental Fate  Detailed summary of the risk assessment |
| Product code: SHA 148000 A  Product name(s): **METROPOLITAN**  Chemical active substance(s):  Metazachlor, 500 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (Authorisation) |
| Applicant: XXXX  Submission date: October 2022  Evaluation date: July 2023  MS Finalisation date: dd/mm/yyyy |

Version history

|  |  |
| --- | --- |
| When | What |
| December 2022 | Submission to the Polish Ministry of Agriculture and Rural Development |
| March 2023 | Submission to the evaluation unit |
| July 2023 | zRMS finalised dRR evaluation |
|  |  |

Table of Contents

[8 Fate and behaviour in the environment (KCP 9) 4](#_Toc140136169)

[8.1 Critical GAP and overall conclusions 6](#_Toc140136170)

[8.2 Metabolites considered in the assessment 8](#_Toc140136171)

[8.3 Rate of degradation in soil (KCP 9.1.1) 9](#_Toc140136172)

[8.3.1 Aerobic degradation in soil (KCP 9.1.1.1) 9](#_Toc140136173)

[8.3.1.1 Metazachlor and its metabolites 9](#_Toc140136174)

[8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1) 12](#_Toc140136175)

[8.4 Field studies (KCP 9.1.1.2) 13](#_Toc140136176)

[8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1) 13](#_Toc140136177)

[8.4.2 Soil accumulation testing (KCP 9.1.1.2.2) 16](#_Toc140136178)

[8.5 Mobility in soil (KCP 9.1.2) 16](#_Toc140136179)

[8.5.1 Column leaching (KCP 9.1.2.1) 20](#_Toc140136180)

[8.5.2 Lysimeter studies (KCP 9.1.2.2) 21](#_Toc140136181)

[8.5.3 Field leaching studies (KCP 9.1.2.3) 21](#_Toc140136182)

[8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) 22](#_Toc140136183)

[8.7 Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3) 24](#_Toc140136184)

[8.7.1 Justification for new endpoints 24](#_Toc140136185)

[8.7.2 Active substance(s) and relevant metabolite(s) 24](#_Toc140136186)

[8.7.2.1 Metazachlor and its metabolites 25](#_Toc140136187)

[8.7.2.2 PECsoil of METROPOLITAN 28](#_Toc140136188)

[8.8 Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4) 29](#_Toc140136189)

[8.8.1 Justification for new endpoints 30](#_Toc140136190)

[8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1) 31](#_Toc140136191)

[8.8.2.1 Metazachlor and its metabolites 32](#_Toc140136192)

[8.9 Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5) 36](#_Toc140136193)

[8.9.1 Justification for new endpoints 36](#_Toc140136194)

[8.9.2 Metazachlor, relevant metabolite(s) and the formulation (KCP 9.2.5) 36](#_Toc140136195)

[8.9.2.1 PECsw/sed of METROPOLITAN 48](#_Toc140136196)

[8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1) 50](#_Toc140136197)

[Appendix 1 Lists of data considered in support of the evaluation 51](#_Toc140136198)

[Detailed evaluation of the new Annex II studies 51](#_Toc140136199)

[Additional information provided by the applicant (e.g. detailed modelling data) 51](#_Toc140136200)

# Fate and behaviour in the environment (KCP 9)

|  |
| --- |
| **RMS Comments:**  This document describes the acceptable use conditions required for registration of METROPOLITAN (SHA 148000A), a suspension concentrate formulation (SC) containing 500 g/L metazachlor for use as a herbicide in grassland for agricultural use in winter and spring oilseed rape, cabbage and cauliflower.  The active substance metazachlor was included in Annex I of Directive 91/414/EEC with Commission Directive 2008/116/EC. After its replacement by Regulation 1107/2009/EC, metazachlor was approved for use in the EU under Regulation 540/2011/EC.  In August 2016 EFSA revisited degradation rates for metabolites BH479-9, BH479-11 and BH479-12 in Technical Annex to Addendum – Confirmatory Data (final version).  In April 2017, EFSA carried out the peer review of the initial risk assessments by the competent authorities of the rapporteur Member State, the United Kingdom. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory data regarding the groundwater exposure of metabolites and their toxicological relevance triggering an assessment.  This Part B document only reviews data and additional information that has not previously been considered within the EU review process.  Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out. |

All radiolabel studies used [14C-phenyl] metazachlor with a radiochemical purity of 94-99.7%. The recommended maximum field application rate for metazachlor is 750 g a.s./ha in pre and post emergence in oilseed rape and 1000 g a.s./ha in post emergence for cabbage. This equates to a worst-case soil concentration of 1.000 mg a.s./kg, based on the assumptions given in Section B.8.3. All studies where a test substance was used were carried out to GLP unless noted otherwise.

**Metabolites**

There are a number of metabolites of metazachlor and the compartments of the environment where these occur are indicated below. It should also be noted that the metabolite 479M08 (Na salt) (referred to originally as BH479-18) does not actually occur in soil or water but is simply the sodium salt of 479M08 (BH479-8). Ecotox testing frequently took place with 479M08 (Na salt) (i.e. BH479-18) and results were then adjusted to give the end point in terms of 479M08 (BH479-8) using an adjustment factor of 0.933 (this takes account of the difference in molecular weight).

**Surface Water**

The most significant metabolites reliably identified in the water sediment study (Section B.8.6.1) were 479M04 (BH479-4) (still increasing at study termination at 99- 121 days at 3.2-10.9% in water and 1.2-2.7% in sediment) and 479M06 (BH479-6) (concentration increasing at study termination at ca. 8% AR in water and 5% in sediment with the exception of a peak in the mill stream pond of 8.9% AR at day 57 in sediment extracts).

Additional metabolites were identified in soil and may enter surface water via drain flow or run off these are 479M08 (BH479-8), 479M09 (BH479-9), 479M011 (BH479-11) and 479M012 (BH479-12). It should also be noted that the metabolites 479M04 (BH479-4) and 479M06 (BH479-6) were also identified in soil.

**Ground water**

The metabolites 479M04 (BH479-4), 479M08 (BH479-8), 479M09 (BH479-9),479M011 (BH479-11) and 479M012 (BH479-12) may potentially occur in ground water and maximum values predicted are given in Section B.8.8.

**Soil**

It should be noted that the metabolites 479M04 (BH479-4), 479M06 (BH479-6) (anaerobic soil) and 479M08 (BH479-8) are major metabolites occurring at >10% while the metabolites 479M09 (BH479-9), 479M011 (BH479-11) and 479M012 (BH479-12) are minor metabolites occurring at <10%. For calculation of the PECs (Predicted Environmental Concentration soil) see Section B.8.7.

## Critical GAP and overall conclusions

Table 8.1.1: Critical use pattern of the formulated product

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| Use-No. \* | Member state(s) | Crop and/or situation  (Crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn 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 |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max | Groundwater |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | |
| 1 | CEU | **Winter and Spring Oilseed rape** | F | Broadleaved and grass weeds | Spray | Pre emergence BBCH 00-09 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | a) 0.75  b) 0.75 | 200-400 |  |  | R- use restricted to once every three years |
| 2 | CEU | **Winter and Spring Oilseed rape** | F | Broadleaved and grass weeds | Spray | Post emergence BBCH 10-19 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | a) 0.75  b) 0.75 | 200-400 |  |  | R- use restricted to once every three years |
| 3 | CEU | **Cabbage, cauliflower** | F | Annual weeds | Spraying | BBCH 13-16  (7days after planting) | a) 1  b) 1 | - | a) 2.0  b) 2.0 | a) 1.0  b) 1.0 | 200-300 | - | - | R- use restricted to once every three years |

Table 8.1.2: Assessed (critical) uses during approval of metazachlor concerning the Section Environmental Fate

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn 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  (f) |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | CEU | **Winter and Spring Oilseed rape** | F | Broadleaved and grass weeds | Spray | Pre emergence BBCH 00-09 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | a) 0.75  b) 0.75 | 200-400 |  |  |
| 2 | CEU | **Winter and Spring Oilseed rape** | F | Broadleaved and grass weeds | Spray | Post emergence BBCH 10-19 | a) 1  b) 1 | NA | a) 1.5  b) 1.5 | a) 0.75  b) 0.75 | 200-400 |  |  |
| 3 | CEU | **Cabbage, cauliflower** | F | Annual weeds | Spraying | BBCH 13-16  (7days after planting) | a) 1  b) 1 | - | a) 2.0  b) 2.0 | a) 1.0  b) 1.0 | 200-300 | - | - |

## Metabolites considered in the assessment

Table 8.2.1: Metabolites of metazachlor potentially relevant for exposure assessment

| **Metabolite name and code** | **Molar mass** | **Structural/molecular formula** | **Maximum observed occurrence in compartments** | **Exposure assessment required due to** |
| --- | --- | --- | --- | --- |
| N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1- ylmethyl)oxalamide  Code: 479M04/BH 479-4 | 273.3 | Diagram, schematic  Description automatically generated | Maximum observed in soil: 16.2%  Maximum observed in water: 13.3% | PECsoil, PECgw, PECsw/sed |
| N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1- ylmethyl)acetamide  Code: 479M06 BH479-6 | 243.3 |  | Maximum observed in water: 16.45% | PECsoil, PECsw/sed |
| N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid  sodium N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonat  Code: 479M08/BH 479-8/BH 479- 18 | 323.4 | Diagram  Description automatically generated | Maximum observed in soil: 21.6% | PECsoil, PECgw, PECsw/sed |
| N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1- ylmethyl)aminocarbonylmethylsulfinyl acetic acid  Code: 479M09/BH 479-09 | 349.4 | Diagram, schematic  Description automatically generated | Maximum observed in soil: 5.3% | PECsoil, PECgw, PECsw/sed |
| methyl N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfoxide  Code: 479M11/BH 479-11 | 305.4 | Diagram, schematic  Description automatically generated | Maximum observed in soil: 7.5% | PECsoil, PECgw, PECsw/sed |
| N-[(2-hydroxycarbonyl-6-methyl)phenyl]-N- (1H-pyrazol-1-ylmethyl)oxalamide  Code: 479M12/BH 479-12 | 303.2 | Diagram, schematic  Description automatically generated | Maximum observed in soil: 8.29% | PECsoil, PECgw, PECsw/sed |

## Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

### Aerobic degradation in soil (KCP 9.1.1.1)

#### Metazachlor and its metabolites

Table 8.3.1: Summary of aerobic degradation rates for Metazachlor - laboratory studies

| Metazachlor, Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH  (w) | t.oC | MWHC % | DT50a (d) | DT90a (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level Reference |
| Li 35b | loamy sand(b) | 6.4 | 20 | 40 | 13.6 | 45.2 | 11.9 | 0.99 | SFO (MCM) | y/EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | loamy sand | 5.7 | 20 | 40 | 25.3 | 84.0 | 25.3 | 0.98 | SFO (MCM) |
| Limb’hof, Li 10 | sandy loam | 6.7 | 20 | 40 | 8 | 26.6 | 5.8 | 0.994 | SFO (MCM) |
| Bruch Ost | sandy clay loam | 7.2 | 20 | 40 | 10.3 | 34.2 | 8.2 | 0.997 | SFO (MCM) |
| Speyerer Wald | loamy sand | 5.7 | 20 | 40 | 12.5 | 41.5 | 10.7 | 0.985 | SFO |
| Bruch West | sandy clay loam\* | 7.2 | 20 | 40 | 19.7 | 65.4 | 7.2 | 0.998 | SFO (MCM) |
| 7.2 | 20 | 40 | 6.2 | 20.6 | 5.0 | 0.99 | SFO (MCM) |
| 7.2 | 20 | 40 | 3.1 | 10.3 | 5.5 | 0.993 | SFO (MCM) |
| Speyer 2.2 | loamy sand | 5.9 | 20 | 40 | 7.2 | 23.9 | 7.2 | 0.999 | SFO |
| Speyer 2.1 | sand | 6.0 | 20 | 40 | 17.6 | 58.4 | 17.2 | 0.941 | SFO |
| Eigenboden | sandy silt loam | 6.6 | 20 | 40 | 21.9 | 72.7 | 15.7 | 0.803 | SFO |
| Speyer 2.3 | sandy loam\* | 6.0 | 20 | 40 | 10.9 | 36.2 | 9.8 | 0.871 | SFO |
| 6.0 | 10 | 40 | 35.8 | 118.9 | 14.7 | 0.977 | SFO |
| Geometric mean/Median (n=5) | | | | | | | 10.8/11.3 | | | |
| pH-dependency: | | | | | | | n | | | |

MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single ﬁrst-order; MCM: multicompartment model.

\*: All DT50 values from study averaged prior to inclusion in overall geomean calculation.

* 1. DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single ﬁrst-order kinetics.
  2. For this soil (Li 35b), the metabolite BF 479-11 had an experimental half-life of 41.3 days, resulting in a half-life ref of 36.2 days.

Table 8.3.2: Summary of aerobic degradation rates for 479M04 - laboratory studies

| 479M04, Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH  (w) | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level Reference |
| \*(a)Li 35b | loamy sand | 6.4 | 20 | 40 | 578 | 1919 | 507 | 0.99 | SFO (MCM) | y/EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | loamy sand | 5.7 | 20 | 40 | Uncertain value RSD too high | | | 0.98 | SFO (MCM) |
| Limb’hof, Li 10 | sandy loam | 6.7 | 20 | 40 | Uncertain value RSD too high | | | 0.994 | SFO (MCM) |
| Bruch Ost | sandy clay loam | 7.2 | 20 | 40 | 102.8 | 341.3 | 82.3 | 0.997 | SFO (MCM) |
| Bruch West | sandy clay loam\* | 7.2 | 20 | 40 | 90.1 | 299.1 | 72.1 | 0.999 | SFO (MCM) |
| 7.2 | 20 | 40 | 59.3 | 196.9 | 104.4 | 0.993 | SFO (MCM) |
| Bruch West | sandy clay loam\* | 7.2 | 20 | 40 | 277.3 | 920.6 | 93.7 | 0.92 | SFO |
| 7.2 | 20 | 40 | 70.7 | 234.7 | 52.6 | 0.97 | SFO |
| 7.2 | 20 | 40 | 47.5 | 157.7 | 77.7 | 0.99 | SFO |
| Bruch Ost | clayey loam | 7.6 | 20 | 40 | Uncertain values with poor data ﬁt | | | 0.62 | SFO |
| LUFA 2.2 | loamy sand | 6.0 | 20 | 40 | Uncertain values with poor data ﬁt | | | 0.36 | SFO |
| Limb’hof, Li 10 | loamy sand | 6.4 | 20 | 40 | 161.2 | 535.2 | 108.6 | 0.90 | SFO |
| (a)Speyer 2.1 | sand | 5.7 | 20 | 50 | 296 | 983 | 286 | 0.978 | SFO |
| Speyer 2.2 | loamy sand | 6.0 | 20 | 50 | Poor data ﬁt | | | 0.539 |  |
| Speyer 2.3 | sandy loam | 7.6 | 20 | 50 | 214 | 710.5 | 183 | 0.956 | SFO |
| Speyer 2.3 | sandy loam | 6.5 | 20 | 60 | 43.3 | 143.9 | 39.0 | 0.9837 | SFO |
| Speyer 3A | loam | 7.0 | 20 | 60 | 22.4 | 74.5 | 19.2 | 0.9704 | SFO |
| Speyer 5M | sandy loam | 7.1 | 20 | 60 | 50.6 | 168.1 | 48.83 | 0.9668 | SFO |
| LUFA 2.2 | loamy sand(d) | 6.2 | 20 | 40 | 249 | 827 | 189.8 | –(c) | SFO |
| LUFA 3A | loam(d) | 7.8 | 20 | 40 | 53.4 | 178 | 30.3 | –(c) | SFO |
| Li 10 | loamy sand(d) | 7.0 | 20 | 40 | 126.5 | 420 | 104.8 | –(c) | SFO |
| Geometric mean/Medianb (n=5) | | | | | | | 76.3/77.2 | | | |
| pH-dependency: | | | | | | | n | | | |

MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single ﬁrst-order; MCM: multicompartment model.

\*: All DT50 values from study averaged prior to inclusion in overall geomean calculation.

(a): DT50 longer than twice the study length.

(b): DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single ﬁrst-order kinetics.

(c): v2 values were 3.2% (LUFA 2.2 soil), 8.7% (LUFA 3A soil), and 5.1% (Li 10 soil).

(d): Metabolite dosed study.

Table 8.3.3: Summary of aerobic degradation rates for 479M08 - laboratory studies

| 479M08, Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level  Reference |
| (a)Speyer 2.2 | loamy sand | 5.7 | 20 | 40 | 331 | 1100 | 331 | 0.7234 | SFO | y/EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Speyer 3A | loam | 7.1 | 20 | 40 | 60.15 | 199.7 | 51.01 | 0.971 | SFO |
| PTRL | clay loam | 6.8 | 20 | 40 | 180 | 597.6 | 133.2 | 0.9220 | SFO |
| (a)Speyer 2.1 | sand | 5.7 | 20 | 50 | 375 | >1000 | 362 | 0.769 | SFO |
| Speyer 2.2 | loamy sand | 6.0 | 20 | 50 | Poor data ﬁt | | | 0.066 | SFO |
| Speyer 2.3 | sandy loam | 7.6 | 20 | 50 | Poor data ﬁt | | | 0.697 | SFO |
| Speyer 2.3 | sandy loam | 6.5 | 20 | 60 | 105.8 | 351.5 | 95.33 | 0.9667 | SFO |
| Speyer 3A | loam | 7.0 | 20 | 60 | 60.8 | 202.0 | 52.11 | 0.9875 | SFO |
| Speyer 5M | sandy loam | 7.1 | 20 | 60 | 110.2 | 366.1 | 106.3 | 0.9600 | SFO |
| Geometric mean/Median b(n=7) | | | | | | | 123.2/106.3 | | | |
| pH-dependency: y/n | | | | | | | n | | | |

MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single ﬁrst-order.

1. : DT50 longer than twice the study length.
2. : DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single ﬁrst-order kinetics.

Table 8.3.4: Summary of aerobic degradation rates for 479M09 - laboratory studies

| 479M09, Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level  Reference |
| LUFA 2.2 – | loamy sand | 6.2 | 20 | 40 | 19.0 | 63 | 16.4 | 4.0 | SFO | y/EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 5M – | sandy loam | 7.9 | 20 | 40 | 39.0 | 129 | 25.9 | 3.0 | SFO |
| Li 10 – | loamy sand | 7.0 | 20 | 40 | 13.8 | 45.9 | 11.4\* | 11.9 | DFOP |
| Geometric mean (n=3) | | | | | | | 16.9 | | | |
| pH-dependency: | | | | | | | n | | | |

Table 8.3.5: Summary of aerobic degradation rates for 479M11 - laboratory studies

| 479M11, Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level  Reference |
| LUFA 2.2 | loamy sand(c) | 6.2 | 20 | 40 | 52.4 | 174 | 39.9\* | 9.6 | FOMC | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 3A | loam(c) | 7.8 | 20 | 40 | 28.4 | 94.3 | 16.1\* | 4.5 | DFOP |
| Li 10 | loamy sand(c) | 7.0 | 20 | 40 | 21.0 | 69.8 | 17.4\* | 7.6 | DFOP |
| Li 35b | loamy sand | 6.4 | 20 | 40 | 41.3 | 137.1 | 36.2(b) | - | SFO |
| Geometric mean(n=4) | | | | | | | 25.2 | | | |
| pH-dependency: | | | | | | | n | | | |

MWHC: maximum water-holding capacity; DT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single ﬁrst-order.

\*: Back calculated from overall DT90 value according to FOCUS kinetics.

(b): Value from parent applied study (see footnote to parent data table).

(c): Metabolite dosed study.

Table 8.3.6: Summary of aerobic degradation rates for 479M12 - laboratory studies

| 479M12 Laboratory studies, aerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level y/n/ Reference |
| LUFA 2.2 | loamy sand | 6.2 | 20 | 40 | 63 | 210 | 54.3 | 6.2 | SFO | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 5M | sandy loam | 7.9 | 20 | 40 | 140 | 465 | 93.0 | 4.0 | SFO |
| Li 10 | loamy sand | 7.0 | 20 | 40 | 148 | 492 | 122.5 | 7.0 | SFO |
| Geometric mean(n=3) | | | | | | | 85.2 | | | |
| pH-dependency: | | | | | | | n | | | |

### Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3.7: Summary of anaerobic degradation rates for metazachlor - laboratory studies

| Metazachlor, Laboratory studies, anaerobic conditions | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | pH | t.oC | MWHC % | DT50 (d) | DT90 (d) | DT50 (d) 20°C  pF2/10kPa | Chi2 (%) | Kinetic model | Evaluated on EU level  Reference |
| Li 35b | sandy loam | 6.5 | 20 | Flooded soil | 25 | 83 | N/A | 0.995 | FOMC | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| German standard soil 2.2 | sandy loam | 5.8 | 20 | Flooded soil | 11.6 | 38.5 | N/A | 0.994 | DFOP |
| Geometric mean(n=2) | | | | | | | 17 | | | |
| pH-dependency: | | | | | | | n | | | |

## Field studies (KCP 9.1.1.2)

### Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Triggering endpoints

Table 8.4.1: Summary of aerobic degradation rates for metazachlor - field studies: Triggering endpoints

| Metazachlor, Field studies – Triggering endpoints | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DissT50 (d)  actual | DT90 (d) actual | **DT50**  (days) Norm. \* | Kinetic  parameters | St.  (X2) | Method of calculation | Evaluated on EU level Reference |
| Sandy loam | Bothkamp (DE) | 6.5 | 0–25 | 15.0 | 49.8 | 9.8 | - | 0.959 | SFO (MCM) | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Slightly loamy sand | Havixbeck (DE) | 6.5 | 0–25 | 7.3 | 24.2 | 5.1 | - | 0.994 | SFO (MCM) |
| Sandy silty loam | Lippetal- Brockhausen (DE) | 6.7 | 0–25 | 12.2 | 40.5 | 7.5 | - | 0.995 | SFO (MCM) |
| Sandy loam | Niederhofen (DE) | 6.1 | 0–10 | 12.4 | 41.2 | 8.4 | - | 0.999 | SFO (MCM) |
| Sand | Utrera (ES) | 6.5 | 0–10 | 2.8 | 9.3 | 2.0 | - | 0.992 | SFO (MCM) |
| Loamy sand | Manzanilla (ES) | 7.5 | 0–25 | 8.2 | 27.2 | 6.4 | - | 0.974 | SFO (MCM) |
| Silty sand | Grossharrie (DE) | 6.0 | 0–10 | 10.9 | 36.2 | 8.4 | - | 0.983 | SFO (MCM) |
| Loamy sand | Bja€rred (SE) | 6.1 | 0–50 | 21.3 | 70.7 | 14.4 | - | 0.924 | SFO (MCM) |
| Geometric mean/median | | | | 9.8/11.5 |  | 6.8/8.0 |  | |  |  |

DissT50: period required for 50% dissipation; DT90: period required for 90% dissipation; SFO: single ﬁrst-order; MCM: multicompartment model.

\*: Normalised DT50 values were corrected to 20°C using a Q10 value of 2.2 and Walker equation coefﬁcient of 0.7, but were not corrected for soil moisture content.

(a): DT90 values calculated by multiplying DT50 values by 3.32 since DT50 values are calculated using single ﬁrst-order kinetics.

Table 8.4.2: Summary of aerobic degradation rates for 479M04 - field studies: Triggering endpoints

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 479M04, Field studies – Triggering endpoints | | | | | | | | | | | |
| Soil type | Location | pH | Depth (cm) | DissT50 (d)  actual | DT90 (d) actual | DT50 (days) Norm. \* | f.f. | Kinetic  parameters | St.  (X2) | Method of calc. | Evaluated on EU level Reference |
| Slightly loamy sand | Havixbeck (DE) | 6.5 | 0–37 | 138.7 | 460.5 | 54.6 | - | - | 0.994 | SFO (MCM) | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Sandy loam | Niederhofen (DE) | 6.1 | 0–10 | 52.8 | 175.3 | 49.9 | - | - | 0.999 | SFO (MCM) |
| Silty sand | Grossharrie (DE) | 6.0 | 0–50 | 65.8 | 218.5 | 66 | - | - | 0.983 | SFO (MCM) |
| Geometric mean/median | | | | 78.4/65.8 |  | 56.4/54.6 |  | | |  |  |

Table 8.4.3: Summary of aerobic degradation rates for 479M08 - field studies: Trigger-ing endpoints

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 479M08, Field studies – Triggering endpoints | | | | | | | | | | | |
| Soil type | Location | pH | Depth (cm) | DissT50  (d)  actual | DT90 (d) actual | DT50 (days) Norm. \* | f.f. | Kinetic  parameters | St.  (X2) | Method of calc. | Evaluated on EU level Reference |
| Loamy sand | Meckenheim (DE) | 5.3 | 0–75 | 171 | 567.7 | 116.4 | - | - | 0.768 | SFO | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Silty sandy loam | Lippetal- Brockhausen (DE) | 6.4 | 0–50 | 59.7 | 198.2 | 43.4 | - | - | 0.933 | SFO |
| Silty sand | Grossharrie (DE) | 6.0 | 0–50 | 108.8 | 361.2 | NC | - | - | 0.983 | SFO (MCM) |
| Geometric mean/median | | | | 103.6/108.8 |  | 71.1/79.9 |  | | |  |  |

Modelling endpoints

Table 8.4.4: Summary of aerobic degradation rates for metazachlor- field studies: Modelling endpoints

| Metazachlor, Field studies – Modelling endpoints | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DT50 (d)  20°C, pF2 | Fit, Kinetic | Evaluated on EU level  Reference |
| Sandy loam | Bothkamp (DE) | 6.5 | 0–25 | 9.8 | SFO (MCM) | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Slightly loamy sand | Havixbeck (DE) | 6.5 | 0–25 | 5.1 | SFO (MCM) |
| Sandy silty loam | Lippetal- Brockhausen (DE) | 6.7 | 0–25 | 7.5 | SFO (MCM) |
| Sandy loam | Niederhofen (DE) | 6.1 | 0–10 | 8.4 | SFO (MCM) |
| Sand | Utrera (ES) | 6.5 | 0–10 | 2.0 | SFO (MCM) |
| Loamy sand | Manzanilla (ES) | 7.5 | 0–25 | 6.4 | SFO (MCM) |
| Silty sand | Grossharrie (DE) | 6.0 | 0–10 | 8.4 | SFO (MCM) |
| Loamy sand | Bja€rred (SE) | 6.1 | 0–50 | 14.4 | SFO (MCM) |
| Geometric mean (n=8) | | | | 6.8 |  |  |
| pH-dependency | | | | n |  | |

Table 8.4.5: Summary of aerobic degradation rates for 479M04 - field studies: Modelling endpoints

| 479M04, Field studies – Modelling endpoints | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DT50 (d)  20°C, pF2 | f.f. | Fit, Kinetic | Evaluated on EU level  Reference |
| Slightly loamy sand | Havixbeck (DE) | 6.5 | 0–37 | 54.6 | - | SFO | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Sandy loam | Niederhofen (DE) | 6.1 | 0–10 | 49.9 | - | SFO |
| Silty sand | Grossharrie (DE) | 6.0 | 0–50 | 66 | - | SFO (MCM) |
| Geometric mean (n=3) | | | | 56.4 |  |  |  |
| pH-dependency | | | | n |  |  | |

Table 8.4.6: Summary of aerobic degradation rates for 479M08 - field studies: Modelling endpoints

| 479M08, Field studies – Modelling endpoints | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil type | Location | pH | Depth (cm) | DT50 (d)  20°C, pF2 | f.f. | Fit, Kinetic | Evaluated on EU level  Reference |
| Loamy sand | Meckenheim (DE) | 5.3 | 0–75 | 116.4 | - | SFO | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Silty sandy loam | Lippetal- Brockhausen (DE) | 6.4 | 0–50 | 43.4 | - | SFO |
| Silty sand | Grossharrie (DE) | 6.0 | 0–50 | NC | - | SFO (MCM) |
| Maximun | | | | 116.4 |  |  |  |
| pH-dependency | | | | n |  |  | |

### Soil accumulation testing (KCP 9.1.1.2.2)

Accumulation of parent metazachlor will not occur. For the critical notified uses on oilseed rape grown in rotation according to good agricultural practice, and on ornamental trees and shrubs with one application per crop with the crops grown for at least three years, one application will occur every 3 years and soil accumulation of metabolites will not occur. When used in consecutive years accumulation of the metabolites 479M04 and 479M08 is possible.

## Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.5.1: Summary of soil adsorption/desorption for metazachlor

| Metazachlor | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil name | Soil type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| Pfungstadt | Loam | 0.58 | 7.3 | 0.48368 | 83.4 | 0.848 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Neuhofen | loamy sand | 2.66 | 7.2 | 2.2026 | 82.8 | 0.798 |
| LUFA | Sand | 0.51 | 7.0 | 0.3699 | 72.5 | 0.877 |
| Speyer 2.1 | Sand | 0.56 | 6.0 | – | – | – |
| Speyer 2.2 | loamy sand | 2.27 | 6.1 | – | – | – |
| Speyer 2.3 | sandy loam | 1.18 | 6.6 | – | – | – |
| Agroplan | sandy silt | 1.75 | 6.0 | – | – | – |
| Borstel | silty sand | 1.29 | 6.3 | 1.251 | 97.0 | 0.91 |
| Rendzina Soest | loamy silt | 4.10 | 7.5 | 2.656 | 64.8 | 0.93 |
| LUFA 2.2 | loamy sand | 2.30 | 5.7 | 1.787 | 77.7 | 0.94 |
| LUFA 2.3 | sandy loam | 1.20 | 6.5 | 0.646 | 53.8 | 0.93 |
| - | clay loam | 1.4 | 6.8 | 2.2 | 157.1 | 0.7 |
| - | clay loam | 1.2 | 7.2 | 2 | 166.7 | 0.72 |
| - | Loam | 1.9 | 6 | 3.3 | 173.7 | 0.82 |
| - | Clay | 2 | 7 | 4.4 | 220.0 | 0.68 |
| - | sandy clay loam | 0.7 | 7.3 | 0.81 | 115.7 | 1.2 |
| - | sandy clay loam | 1.4 | 7.4 | 1.1 | 78.6 | 1.1 |
| - | clay loam | 1.7 | 7.3 | 1.5 | 88.2 | 0.75 |
| - | sandy clay loam | 2.2 | 6.5 | 3.1 | 140.9 | 0.88 |
| - | sandy clay loam | 1.3 | 6.6 | 2 | 153.8 | 0.89 |
| - | clay loam | 1.5 | 6.8 | 3.1 | 206.7 | 0.74 |
| - | 11 – silty clay loam | 1.2 | 5 | 1.5 | 125.0 | 1.0 |
| - | 12 – sandy loam | 2.4 | 6.4 | 2.7 | 112.5 | 0.79 |
| - | 13 – sandy clay loam | 2 | 6.4 | 2.2 | 110.0 | 0.70 |
| - | 14 – clay loam | 1.4 | 6.4 | 2.1 | 150.0 | 0.76 |
| - | 15 – clay | 2.2 | 6.8 | 2.4 | 109.1 | 1.0 |
| - | 16 – sandy clay loam | 2.2 | 6.6 | 3.8 | 172.7 | 0.79 |
| - | 17 – sandy loam | 0.6 | 6.3 | 0.89 | 148.3 | 0.95 |
| - | 18 – sandy clay loam | 1.5 | 6.6 | 2.1 | 140.0 | 0.91 |
| Median\*(n=29) | | | | | 110 | 0.877 |  |
| pH-dependency | | | | | n | | |

\*: Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n = 29). Averaging Kdoc and Kfoc values is acceptable in this speciﬁc case because the values are similar and 1/n is close to 1. For 1/n value, n = 25.

Table 8.5.2: Summary of soil adsorption/desorption for 479M04

| 479M04 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| LUFA 2.1 | sand | 0.7 | 5.8 | 0.014 | 2 | 1.058 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | sand/loamy sand | 2.5 | 5.8 | 0.053 | 2 | 0.983 |
| LUFA 2.3 | sandy loam | 1.0 | 6.8 | 0.024 | 2 | 1.027 |
| Limburgerhof Bruch West | sandy loam | 1.5 | 7.5 | 0.008 | 1 | 0.745 |
| Limburgerhof Bruch Ost | sandy loam | 3.1 | 7.0 | 0.5602 | 18 | 0.6369 |
| LUFA 2.1 | sand | 0.7 | 6.1 | 0.659 | 94 | 1.538 |
| LUFA 2.2 | loamy sand | 2.29 | 6.0 | 1.5702 | 69 | 1.439 |
| LUFA 2.3 | sandy loam | 1.34 | 6.9 | 0.1181 | 9 | 0.7799 |
| BBA 2.1 | sand | 0.49 | 5.7 | – | – | – |
| BBA 2.2 | silty sand | 1.48 | 6.0 | – | – | – |
| BBA 2.3 | silty sand | 0.76 | 7.0 | – | – | – |
| Median\* (n=11) | | | | | 9.1 | 1.0 |  |
| pH-dependency | | | | | n | | |

\*: Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n = 11). Averaging Kdoc and Kfoc values is acceptable in this speciﬁc case because the values are similar and 1/n is close to 1. For the 1/n value, n = 8.

Table 8.5.3: Summary of soil adsorption/desorption for 479M08

| 479M08 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| LUFA 2.1 | sand | 0.7 | 5.8 | 0.037 | 5 | 0.811 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | sand/loamy sand | 2.5 | 5.8 | 0.129 | 5 | 0.904 |
| LUFA 2.3 | sandy loam | 1.0 | 6.8 | 0.058 | 6 | 0.806 |
| Limburgerhof Bruch West | sandy loam | 1.5 | 7.5 | 0.063 | 4 | 0.833 |
| Limburgerhof Bruch Ost | clay loam | 0.5 | 5.8 | 0.3927 | 78.5 | 0.727 |
| LUFA 2.1 | loamy sand | 2.4 | 6.0 | 0.3674 | 15.3 | 1.117 |
| LUFA 2.2 | sandy loam | 1.1 | 6.5 | 0.3130 | 28.5 | 0.829 |
| LUFA 2.3 | sandy loam | 3.27 | 7.8 | 0.3263 | 10.0 | 1.103 |
| BBA 2.1 | sand | 0.49 | 5.7 | – | – | – |
| BBA 2.2 | silty sand | 1.48 | 6.0 | – | – | – |
| BBA 2.3 | silty sand | 0.76 | 7.0 | – | – | – |
| Median\* (n=11) | | | | | 10 | 0.831 |
| pH-dependency | | | | | n | | |

\*: Median Koc value was derived from combined set of Kfoc and Kdoc values (therefore n = 11). Averaging Kdoc and Kfoc values is acceptable in this speciﬁc case because the values are similar and 1/n is close to 1. For the 1/n value, n = 8.

Table 8.5.4: Summary of soil adsorption/desorption for 479M06

| 479M06 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| LUFA 2.1 | sand | 0.7 | 5.8 | 0.363 | 52 | 0.924 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | sand/loamy sand | 2.5 | 5.8 | 1.562 | 62 | 0.928 |
| LUFA 2.3 | sandy loam | 1.0 | 6.8 | 0.575 | 57 | 0.907 |
| Limburgerhof Bruch West | sandy loam | 1.5 | 7.5 | 0.666 | 44 | 0.905 |
| Median (n=4) | | | | | 54 | 0.92 |  |
| pH-dependency | | | | | n | | |

Table 8.5.5: Summary of soil adsorption/desorption for 479M09

| 479M09 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| La Gironda | silt clay loam | 3.84 | 7.5 | 0.188 | 4.9 | 0.891 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | loamy sand | 1.72 | 5.7 | 0.099 | 5.8 | 0.965 |
| Li 10 | loamy sand | 0.73 | 6.0 | 0.050 | 6.8 | 0.826 |
| Arithmetic mean (n=3) | | | | | 5.8 | 0.897 |  |
| pH-dependency | | | | | n | | |

Table 8.5.6: Summary of soil adsorption/desorption for 479M11

| 479M11 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| LUFA 2.2 | loamy sand | 1.84 | 5.6 | 0.367 | 20.0 | 1.005 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 3A | loam | 3.15 | 7.0 | 0.571 | 18.1 | 0.698 |
| Li 10 | loamy sand | 0.91 | 6.4 | 0.214 | 23.5 | 0.873 |
| Arithmetic mean (n=3) | | | | | 20.5 | 0.859 |  |
| pH-dependency | | | | | n | | |

Table 8.5.7: Summary of soil adsorption/desorption for 479M12

| 479M12 | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Soil Name | Soil Type | OC  (%) | pH  (-) | Kf  (mL/g) | Kfoc  (mL/g) | 1/n  (-) | Evaluated on EU level  Reference |
| La Gironda | silt clay loam | 3.84 | 7.5 | 0.197 | 5.1 | 0.997 | y/ EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| LUFA 2.2 | loamy sand | 1.72 | 5.7 | 0.167 | 9.7 | 0.927 |
| Li 10 | loamy sand | 0.73 | 6.0 | 0.087 | 12.0 | 0.962 |
| Arithmetic mean (n=3) | | | | | 8.9 | 0.963 |  |
| pH-dependency | | | | | n | | |

### Column leaching (KCP 9.1.2.1)

Table 8.5.8: Distribution of radioactivity in aged soil leaching study; values are given in % radioactivity

|  |  |  |
| --- | --- | --- |
|  | **Duration of aging** | |
| **60 d** | **300 d** |
| Metazachlor in aged soil methanol extracts (% TRR in soil samples at days 60&300) | 28 | 4.7 |
| Residues not extracted by methanol  (% TRR in soil samples at days 60&300) | 52 | 61.5 |
| Radioactivity in column segments  (% TRR in soil prior to leaching) | 39.9 | 41.0 |
| Radioactivity in percolate fractions  (% TRR in soil prior to leaching) | 54.5 | 51.51 |

### Lysimeter studies (KCP 9.1.2.2)

Table 8.5.9: Yearly mean concentration of metazachlor and metabolites in leachate in µg/L parent equivalents and % of applied radioactivity Lysimeter 45

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Metazachlor** | | **BH479-1** | | **BH479-4** | | **BH479-5** | | **NIR** | |
| **µg/L** | **%** | **µg/L** | **%** | **µg/L** | **%** | **µg/L** | **%** | **µg/L** | **%** |
| 1. year | Nd | Nd | Nd | Nd | 21.39 | 7.4 | Nd | Nd | 21.7 | 7.5 |
| 2. year | Nd | Nd | Nd | Nd | 6.33 | 4.1 | Nd | Nd | 15.5 | 10.0 |
| Mean µg/L  Sum % | Nd | Nd | Nd | Nd | 11.59 | 11.5 | Nd | Nd | 17.7 | 17.6 |

Table 8.5.10: Estimation of the contribution of the various components to the radioactive residues in two lysimeter leachates;(µg/L)

|  |  |  |
| --- | --- | --- |
| **Component** | **Leachate** | |
| **23.12.1991** | **08.01.1992** |
| Unidentified | 1.4 - 1.6 | 1.8 - 2.3 |
| BH479-12 | 0.4 - 3.6 | 0.8 - 3.3 |
| BH479-8 | 12.0 - 17.3 | 5.8 - 8.7 |
| BH479-4 | 8.9 - 9.6 | 3.3 - 3.4 |
| BH479-9 | 3.3 | 1.3 |
| BH479-11 | 0.8 - 2.4 | 1.5 - 2.5 |

Another lysimeter study in Germany is available. Experts considered this study as providing supportive information only.

### Field leaching studies (KCP 9.1.2.3)

Not available.

Not considered necessary, since lysimeter studies are available for the parent and metabolites.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Review Comments:**  The evaluation for metazachlor was conducted in accordance of EFSA Scientific Report (2008) 145, 1-132. Moreover, the data from evaluation of confirmatory data regarding the groundwater exposure (Technical Annex to Addendum – revised August 2016 and EFSA Peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data submitted– April 2017) provide new data concerning the concentrations of the metabolites 479M09, 479M11 and 479M12.  After comments by EFSA and MS, the RMS - UK revisited degradation rates for metabolites of metazachlor.  The groundwater modelling was repeated for winter and spring oil seed rape using both FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 for worst-case application scenario in dose rate of 1000 g a.s./ha.  The maximum PECGW values after application to oilseed rape (winter and spring) were summarised in the table below.   | Active substance / metabolite | Maximum PECGW value  [µg/L] | | --- | --- | | Metazachlor | < 0.001 | | BH479-4 (479M04) | < 10 | | BH479-8 (479M08) | < 15 | | BH479-9 (479M09) | < 2 | | BH479-11 (479M11) | < 2 | | BH479-12 (479M12) | |  | | --- | | < 10 (except Châteaudun, max 15.742 μg/L) | |   **Monitoring data**  In Technical Annex to Addendum the updated evaluation of assessment of concentration of metzachlor metabolites in ground water is present taking into account the monitoring results. Overall, the relevance and vulnerability of the monitoring sites in Germany in 4 sites were accepted. The quality of the data fulfils the criteria set out in the FOCUS guidance (2009) on groundwater monitoring.  Concentrations of metabolites in groundwater in the targeted monitoring (according to EFSA Journal 2017;15(6):4833) are summarised in table below.   | Metabolite (4 sites, 48 samples) | Maximum PECGW value  [µg/L] | | --- | --- | | BH479-4 (479M04) | 1.8 | | BH479-8 (479M08) | 6.76 | | BH479-9 (479M09) | < 0.05 | | BH479-11 (479M11) | < 0.05 | | BH479-12 (479M12) | 0.16 |   The monitoring data are not agreed between Member States and decision on their appropriateness as a higher tier risk assessment is still pending in the EU. Therefore, Member States are encouraged to make their own decision on relevance of German monitoring studies for their conditions and the use of groundwater monitoring as higher tier (hydrogeological data of targeted sites in France were classify as insufficient). |

## Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Table 8.6.1: Summary of degradation in water/sediment of metazachlor

| Metazachlor Distribution (max. sediment 10.87 – 19.76 % after 3-15 days) | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Water/sediment system | pH  water/  sed. | DegT50  whole syst.  (d) | DegT90 whole syst.  (d) | Kinetic, Fit | DissT50 water  (d) | DissT90 water  (d) | Kinetic, Fit | DissT50 sed.  (d) | Kinetic, Fit | Evaluated on EU level Reference |
| Millstream Pond (BASF) | 7.9/7.1 | 13.4 | 44.4\* | SFO (MCM) | 144 | 480 | SFO (MCM) | 3.0 | SFO (MCM) | y/EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| Swiss lake (BASF) | 6.7/5.5 | 23.0 | 76.5\* | SFO (MCM) | 133 | 443 | SFO (MCM) | 3.8 | SFO (MCM) |
| Schaephysen Pond (FSG) | 7.6/6.9 | 16.1 | 53.6\* | SFO (MCM) | 48.8 | 162 | SFO (MCM) | 5.9 | SFO (MCM) |
| Rückhaltebeck en river reservoir (FSG) | 7.1/7.0 | 27.8 | 92.4\* | SFO (MCM) | 384 | 1276 | SFO (MCM) | 6.8 | SFO (MCM) |
| Geometric mean (n=4) | | 19.3 |  |  | 137.6 |  |  | 4.6 |  |  |

\*Significant unextracted sediment residues formed

MCM = multi-compartment model

Table 8.6.2: Summary of observed metabolites

|  |  |  |
| --- | --- | --- |
| 479M04  Water/sediment system | Max. in water/sediment 8.41/2.79% after 121 d (Millstream Pond/ Swiss lake) | y/EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| 479M06  Water/sediment system | Max. in water/sediment 8.06/8.87% after 99 d (Millstream Pond/ Swiss lake) |

Table 8.6.3: Summary of degradation in water/sediment of 479M04

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 479M04 Distribution (max. water/sediment 8.41/ 2.79% after 121 days) | | | | | | | | | | |
| Water/sediment system | pH  water/  sed. | DegT50  whole syst.  (d) | DegT90 whole syst.  (d) | Kinetic, Fit | DissT50 water  (d) | DissT90 water  (d) | Kinetic, Fit | DissT50 sed.  (d) | Kinetic, Fit | Evaluated on EU level Reference |
| Millstream Pond@ (BASF) | 7.9/7.1 | - | - | - | -\* | -\* | - | - | - | y/EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| Swiss lake@ (BASF) | 6.7/5.5 | - | - | - | -\* | -\* | - | - | - |
| Schaephysen Pond (FSG) | 7.6/6.9 | - | - | - | -\* | -\* | - | - | - |
| Rückhaltebeck en river reservoir (FSG) | 7.1/7.0 | - | - | - | -\* | -\* | - | - | - |
| Geometric mean | | | - |  | \_ |  | - |  | - |  |

\*DT50/ DT90 values not calculated as concentrations still increasing at study termination.

**@** Uncertain DT50/ DT90 values as partitioning rate constants in and out of sediment had low statistical significance

Table 8.6.4: Summary of degradation in water/sediment of 479M06

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 479M06 Distribution (max. water/sediment 8.06/8.87 % after 99 days) | | | | | | | | | | |
| Water/sediment system | pH  water/  sed. | DegT50  whole syst.  (d) | DegT90 whole syst.  (d) | Kinetic, Fit | DissT50 water  (d) | DissT90 water  (d) | Kinetic, Fit | DissT50 sed.  (d) | Kinetic, Fit | Evaluated on EU level Reference |
| Millstream Pond@ (BASF) | 7.9/7.1 | - | - | - | 45.4 | 150.8 | - | - | - | y/EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| Swiss lake@ (BASF) | 6.7/5.5 | - | - | - | 27.1 | 90.0 | - | - | - |
| Geometric mean | | | - |  | \_ |  | - |  | - |  |

**@** Uncertain DT50/ DT90 values as partitioning rate constants in and out of sediment had low statistical significance

## Predicted Environmental Concentrations in soil (PECsoil) (KCP 9.1.3)

|  |
| --- |
| **Review Comments:**  The PECsoil calculations for metazachlor and for formulation were provided by the Applicant and are considered acceptable. Nevertheless, due to the Applicant's error in the calculation of application rates for the metabolites, the PECs values are incorrect. Therefore, zRMS recalculated PECsoil;ini values for all metabolites (PECsoil;TWA are not required for ecotoxicological evalutaion). As the product will be applied ones every 3 years, soil accumulation of metabolites will not occur (based on available DT50 values).  The presented PECsoil values are suitable input parameters for ecotoxicological risk assessment. |

The PECsoil of metazachlor and relevant metabolites in soil has been assessed for winter and spring oilseed rape considering the highest application rate of 2 L product/ha (1000 g ai/ha) which covers all the intended uses and as a worst case approach no interception value is considered.

### Justification for new endpoints

The same endpoints as the EU agreed endpoints (EFSA 2008) and EFSA (2017) were used.

### Active substance(s) and relevant metabolite(s)

Table 8.7.1: Input parameters related to application for PECsoil calculations

|  |  |  |  |
| --- | --- | --- | --- |
| Use No. | 1\* | 2 | 3 |
| Crop | Oilseed rape | | Cabbage |
| Application rate (g as/ha) | 750 | | 1000 |
| Number of applications/interval | 1/- | | 1/- |
| Crop interception (%) | 0\* | 40 | 25 |
| Depth of soil layer (relevant for plateau concentration) (cm) | 20 | | |

**\*Worst case for PECsoil calculations**

Table 8.7.2: Input parameter for active substance(s) and relevant metabolite(s) for PECsoil calculation

| Compound | Molecular weight (g/mol) | Max. occurrence (%) | DT50  (days) | Value in accordance to EU endpoint y/n/  Reference |
| --- | --- | --- | --- | --- |
| metazachlor | 277.75 | - | 6.8 | EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| 479M08 | 323.4 | 21.6 | 116.4 |
| 479M04 | 273.3 | 16.2 | 56.4 |
| 479M11 | 305.4 | ~~6.8~~ 7.5 | 25.2 |
| 479M09 | ~~394.4~~ 349.4 | 5.3 | 16.9 |
| 479M12 | 303.2 | 8.29 | 85.2 |
| 479M06 | 243.3 | 18.49 | na\* |

**\*na = not available so only initial PEC calculated**

#### Metazachlor and its metabolites

Table 8.7.3: PECsoil for metazachlor on oilseed rape

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | 1.000 | - |
| Short term | 24h | 0.903 | 0.951 |
| 2d | 0.816 | 0.905 |
| 4d | 0.665 | 0.821 |
| Long term | 7d | 0.490 | 0.715 |
| 14d | 0.240 | 0.533 |
| 21d | 0.118 | 0.412 |
| 28d | 0.058 | 0.330 |
| 50d | 0.006 | 0.195 |
| 100d | 0.000 | 0.098 |
| Plateau concentration (20 cm)  after year - | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - |  |

PECsoil of metabolites

PECsoil values for the metabolites were determined as for the parent with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil as following:

Application ratemetabolite = (MWmetabolite/ MWparent) x (% maximum occurrence/100) x application rateparent

The corresponding application rates for each metabolite are summarized in the table below.

Table 8.7.4: Corrected application rates for the metabolites

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Metabolite** | **Application rate of the parent**  **(g/ha)** | **MWparent** | **MWmetabolite** | **Maximum occurrence in soil**  **(%)** | **Corrected application rate**  **(g/ha)** | |
| 479M08 | 750 as worst case | 277.75 | 323.4 | 21.6 | ~~139.1~~ | 188.63 |
| 479M04 | 273.3 | 16.2 | ~~123.5~~ | 119.55 |
| 479M11 | 305.4 | ~~6.8~~ 7.5 | ~~46.4~~ | 61.850 |
| 479M09 | ~~394.4~~ 349.4 | 5.3 | ~~27.99~~ | 50.004 |
| 479M12 | 303.2 | 8.29 | ~~56.96~~ | 67.872 |
| 479M06 | 243.3 | 18.49 | ~~158.3~~ | 121.475 |

The results of PECsoil calculations are presented in the tables below.

Table 8.7.5: PECsoil for 479M08 on oilseed rape\*

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | ~~0.185~~ 0.2515 | - |
| Short term | 24h | ~~0.184~~ | ~~0.185~~ |
| 2d | ~~0.183~~ | ~~0.184~~ |
| 4d | ~~0.181~~ | ~~0.184~~ |
| Long term | 7d | ~~0.178~~ | ~~0.182~~ |
| 14d | ~~0.171~~ | ~~0.178~~ |
| 21d | ~~0.164~~ | ~~0.174~~ |
| 28d | ~~0.157~~ | ~~0.171~~ |
| 50d | ~~0.138~~ | ~~0.160~~ |
| 100d | ~~0.102~~ | ~~0.140~~ |
| Plateau concentration (20 cm)  after year 3 | | ~~0.006~~ | ~~-~~ |
| PECaccumulation  (PECact +PECsoil plateau) | | ~~0.191~~ | ~~-~~ |

\*one application will occur every 3 years and soil accumulation of metabolites will not occur

Table 8.7.6: PECsoil for 479M04 on oilseed rape

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | ~~0.165~~ 0.1594 | ~~0.165~~ |
| Short term | 24h | ~~0.163~~ | ~~0.164~~ |
| 2d | ~~0.161~~ | ~~0.163~~ |
| 4d | ~~0.157~~ | ~~0.161~~ |
| Long term | 7d | ~~0.151~~ | ~~0.158~~ |
| 14d | ~~0.139~~ | ~~0.151~~ |
| 21d | ~~0.127~~ | ~~0.145~~ |
| 28d | ~~0.117~~ | ~~0.139~~ |
| 50d | ~~0.089~~ | ~~0.123~~ |
| 100d | ~~0.048~~ | ~~0.095~~ |
| Plateau concentration (20 cm)  after year - | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - | - |

Table 8.7.7: PECsoil for 479M11 on oilseed rape

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | ~~0.062~~ 0.0825 | ~~0.062~~ |
| Short term | 24h | ~~0.060~~ | ~~0.061~~ |
| 2d | ~~0.059~~ | ~~0.060~~ |
| 4d | ~~0.055~~ | ~~0.059~~ |
| Long term | 7d | ~~0.051~~ | ~~0.056~~ |
| 14d | ~~0.042~~ | ~~0.051~~ |
| 21d | ~~0.035~~ | ~~0.047~~ |
| 28d | ~~0.029~~ | ~~0.043~~ |
| 50d | ~~0.016~~ | ~~0.034~~ |
| 100d | ~~0.004~~ | ~~0.021~~ |
| Plateau concentration (20 cm)  after year - | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - |  |

Table 8.7.8: PECsoil for 479M09 on oilseed rape

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | ~~0.037~~ 0.0667 | - |
| Short term | 24h | ~~0.036~~ | ~~0.037~~ |
| 2d | ~~0.034~~ | ~~0.036~~ |
| 4d | ~~0.032~~ | ~~0.034~~ |
| Long term | 7d | ~~0.028~~ | ~~0.032~~ |
| 14d | ~~0.021~~ | ~~0.028~~ |
| 21d | ~~0.016~~ | ~~0.025~~ |
| 28d | ~~0.012~~ | ~~0.022~~ |
| 50d | ~~0.005~~ | ~~0.016~~ |
| 100d | ~~0.001~~ | ~~0.009~~ |
| Plateau concentration (20 cm)  after year - | | - | - |
| PECaccumulation  (PECact +PECsoil plateau) | | - |  |

Table 8.7.9: PECsoil for 479M12 on oilseed rape

|  |  |  |  |
| --- | --- | --- | --- |
| **PECsoil**  **(mg/kg)** | | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | | ~~0.076~~ 0.0905 | - |
| Short term | 24h | ~~0.075~~ | ~~0.076~~ |
| 2d | ~~0.075~~ | ~~0.075~~ |
| 4d | ~~0.074~~ | ~~0.075~~ |
| Long term | 7d | ~~0.072~~ | ~~0.074~~ |
| 14d | ~~0.068~~ | ~~0.072~~ |
| 21d | ~~0.064~~ | ~~0.070~~ |
| 28d | ~~0.060~~ | ~~0.068~~ |
| 50d | ~~0.051~~ | ~~0.062~~ |
| 100d | ~~0.034~~ | ~~0.052~~ |
| Plateau concentration (20 cm)  after year - | | ~~1.027~~ | - |
| PECaccumulation  (PECact +PECsoil plateau) | | ~~1.103~~ | - |

Table 8.7.10: PECsoil for 479M06 on oilseed rape

|  |  |  |
| --- | --- | --- |
| **PECsoil**  **(mg/kg)** | **Oilseed rape** | |
| **Single application** | |
| **Actual** | **TWA** |
| Initial | ~~0.211~~ 0.162 | - |

#### PECsoil of METROPOLITAN

Table 8.7.11: PECsoil for METROPOLITAN on oilseed rape

| Active substance /Preparation | Application rate (g/ha) | Interception (%) | PECact (mg/kg) |
| --- | --- | --- | --- |
| Metazachlor / METROPOLITAN | 1724.7\* | 0 | 2.300 |

**\*Based on a density of 1.1498 g/cm3**

## Predicted Environmental Concentrations in groundwater (PECgw) (KCP 9.2.4)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Review Comments:**  The evaluation for metazachlor was conducted in accordance of EFSA Scientific Report (2008) 145, 1-132. Moreover, the data from evaluation of confirmatory data regarding the groundwater exposure (Technical Annex to Addendum – revised August 2016 and EFSA Peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data submitted– April 2017) provide new data concerning the concentrations of the metabolites 479M09, 479M11 and 479M12 in groundwater, which were taken to consideration in the risk assessment.  After comments by EFSA and MS, the RMS - UK revisited degradation rates for metabolites of metazachlor.  In Technical Annex to Addendum is present updated evaluation of assessment of concentration of metzachlor metabolites in groundwater under consideration of monitoring results.  The groundwater modelling was repeated for winter and spring oil seed rape using both FOCUS PEARL 4.4.4 and FOCUS PELMO 4.4.3 for worst-case application scenario in dose rate of 1000 g a.s./ha.  The maximum PECGW values after application to oilseed rape (winter and spring) were summarised in the table below (data from Technical Annex to Addendum).   | Active substance / metabolite | Maximum PECGW value  [µg/L] | | --- | --- | | Metazachlor | < 0.001 | | BH479-4 (479M04) | < 10 | | BH479-8 (479M08) | < 15 | | BH479-9 (479M09) | < 2 | | BH479-11 (479M11) | < 2 | | BH479-12 (479M12) | |  | | --- | | < 10 (except Châteaudun, max 15.742 μg/L) | |   **Monitoring data**  Overall, the relevance and vulnerability of the monitoring sites in Germany in 4 sites were accepted. The quality of the data fulfils the criteria set out in the FOCUS guidance (2009) on groundwater monitoring.  Concentrations of metabolites in groundwater in the targeted monitoring (according to EFSA Journal 2017;15(6):4833) are summarised in table below.   | Metabolite (4 sites, 48 samples) | Maximum PECGW value  [µg/L] | | --- | --- | | BH479-4 (479M04) | 1.8 | | BH479-8 (479M08) | 6.76 | | BH479-9 (479M09) | < 0.05 | | BH479-11 (479M11) | < 0.05 | | BH479-12 (479M12) | 0.16 |   The monitoring data are not agreed between Member States and decision on their appropriateness as a higher tier risk assessment is still pending in the EU. Therefore, Member States are encouraged to make their own decision on relevance of German monitoring studies for their conditions and the use of groundwater monitoring as higher tier (hydrogeological data of targeted sites in France were classify as insufficient).  The PECGW calculations for metazachlor and its metabolites were provided by the Applicant and are considered acceptable. Due to the complexity of the assessment for groundwater due to leaching of metazachlor metabolites, the Tier 1 calculations (with PUF=0) were omitted.  The maximum PECGW values after application of METROPOLITAN to oilseed rape (winter and spring) and cabbage were summarised in the table below (data from Applicant’s calculations).   | Active substance / metabolite | Maximum PECGW value  [µg/L] | | --- | --- | | Metazachlor | < 0.001 (all) | | BH479-4 (479M04) | 4.70 (Hamburg, PEARL; winter OSR pre-emergence) | | BH479-8 (479M08) | 9.875 (Châteaudun, PEARL; winter OSR pre-emergence) | | BH479-9 (479M09) | 0.967 (Hamburg, PELMO; winter OSR pre-emergence) | | BH479-11 (479M11) | 0.959 (Piacenza, PELMO; winter OSR pre-emergence) | | BH479-12 (479M12) | < 10 except Châteaudun, PEARL; winter OSR pre-emergence max. 11.334 |   Based on the results of FOCUS groundwater calculations (application of product every third year) for metazachlor and higher tier refinement based on monitoring data for 479M09 and 479M11, which are of toxicological concern, do not exceed the regulatory trigger of 0.1 µg/L at 1 m depth in any of the scenarios.  Based on the results of FOCUS groundwater calculations (application of product every third year) the metabolites 479M04, 479M08 and 479M12 (except use in winter OSR pre-emergence), were found at concentrations above 0.1 µg/L but below 10 µg/L. The monitoring data submitted as part of the confirmatory data show that none of these metabolites is expected to exceed 10 µg/L in the most vulnerable soils where oilseed rape is grown. |

The PECGW values of metazachlor and its relevant metabolites was evaluated using FOCUS PEARL v5.5.5 and FOCUS PELMO v6.6.4 for all FOCUS groundwater scenarios parameterized for triennial single pre- / post-emergence application with use rates of 1000 and 750 g metazachlor /ha.

### Justification for new endpoints

The same endpoints as the EU agreed endpoints (EFSA 2017) were used.

### Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Table 8.8.1: Input parameters related to application for PECGW calculations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Use No. | 1 | | 2 | | 3 |
| BBCH growth stage | Pre-emergence  (BBCH=0-9) | | Post-emergence  (BBCH 10-19) | | (BBCH 13-16) |
| Crop | Winter Oilseed rape | Spring Oilseed rape | Winter Oilseed rape | Spring Oilseed rape | Cabbage |
| Application rate (g metazachlor /ha) | 750 | | | | 1000 |
| Number of applications/interval (d) | 1/- | | | | |
| Crop interception (%) | 0 | | 40 | | 25 |
| Frequency of application | triennial | | | | |
| Models used for calculation | FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4 | | | | |

Table 8.8.2: Application dates used for groundwater risk assessment

| Scenario | Application dates (absolute)\* | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| WOSR pre-emergence (BBCH 00) | WOSR post-emergence (BBCH 10) | SOSR Pre-emergence  (BBCH 00) | SOSR Postemergence (BBCH 10) | Cabbage 1st  (BBCH 13) | Cabbage 2nd  (BBCH 13) |
| Châteaudun | 30/08 | 08/09 | - | - | 03/05 | 12/08 |
| Hamburg | 25/08 | 03/09 | - | - | 03/05 | 12/08 |
| Jokioinen | - | - | 10/05 | 21/05 | 22/06 | - |
| Kremsmünster | 25/08 | 03/09 | - | - | 03/05 | 12/08 |
| Okehampton | 07/08 | 15/08 | 25/03 | 31/03 | - | - |
| Piacenza | 30/09 | 06/10 | - | - | - | - |
| Porto | 30/08 | 08/09 | 15/03 | 23/03 | 24/03 | 10/08 |
| Sevilla | - | - | - | - | 20/03 | 04/07 |
| Thivia | - | - | - | - | 30/08 | - |

**\* Application dates estimated with AppDate 3.06 (28 June 2019)**

#### Metazachlor and its metabolites

Table 8.8.3: Input parameters related to active substance metazachlor and metabolite(s) for PECgw calculations

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Compound** | **Metazachlor** | **479M04** | **479M08** | **479M09** | **479M11** | **479M12** | **Value in accordance with EU endpoint / Reference** |
| Molecular weight (g/mol) | 277.75 | 273.29 | 323.37 | 349.41 | 305.4 | 303.27 | “EFSA Confirmatory data, Metazachlor 2017;15(6):4833” |
| Water solubility (20ºC) (mg/L): | 450 | 1000 | | | | |
| Saturated vapour pressure (20ºC) (Pa): | 9.6 x 10-5 | 1 x 10-9 | | | | |
| DT50 in soil (d) | 6.8 (geomean DT50field, n=8) | 56.4 (geomean DT50field, n=3) | 116.4 (Maximum DT50field, n=3) | 16.9 (geomean from lab studies, n=3) | 25.2 (geomean from lab studies, n=4) | 85.2 (geomean from lab studies, n=3) |
| Kfoc / Kfom (mL/g) | 110/63.8 (median, n=29) | 9.1/5.3(median, n=11) | 10/5.8 (median, n=11) | 5.8/3.4 (arithmetic mean, n=3) | 20.5/11.9 (arithmetic mean, n=3) | 8.9/5.2 (arithmetic mean, n=3) |
| 1/n | 0.877 (median, n=29) | 1 (median, n=11) | 0.83 (median, n=11) | 0.897 (arithmetic mean, n=3) | 0.859 (arithmetic mean, n=3) | 0.963 (arithmetic mean, n=3) |
| Plant uptake factor | 0.5 | 0 | | | | |
| Formation fraction | - | 0.1 from parent | 0.112 from parent | 0.06 from parent | 0.143 from parent | 1.0 from 479 M04 |

Table 8.8.4: PECgw for active metazachlor and metabolite(s) on spring oilseed rape pre-emergence (with FOCUS PEARL v5.5.5 & PELMO v6.6.4) - Application rate 750 g a.i/ha (triennial)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Jokioinen | <0.001 | <0.001 | 3.829 | 3.725 | 6.478 | 6.264 | 0.294 | 0.357 | 0.140 | 0.177 | 5.775 | 5.550 |
| Okehampton | <0.001 | <0.001 | 2.023 | 2.057 | 3.844 | 3.949 | 0.170 | 0.232 | 0.257 | 0.327 | 2.962 | 2.759 |
| Porto | <0.001 | <0.001 | 1.149 | 1.301 | 2.616 | 2.759 | 0.058 | 0.093 | 0.073 | 0.168 | 2.282 | 2.141 |

Table 8.8.5: PECgw for active metazachlor and metabolite(s) on spring oilseed rape BBCH 10 (with FOCUS PEARL v5.5.5 & PELMO v6.6.4) - Application rate 750 g a.i/ha (triennial)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Jokioinen | <0.001 | <0.001 | 2.383 | 2.294 | 3.780 | 3.699 | 0.166 | 0.210 | 0.071 | 0.078 | 3.412 | 3.286 |
| Okehampton | <0.001 | <0.001 | 1.216 | 1.214 | 2.240 | 2.255 | 0.100 | 0.128 | 0.135 | 0.158 | 1.768 | 1.646 |
| Porto | <0.001 | <0.001 | 0.665 | 0.767 | 1.521 | 1.615 | 0.034 | 0.047 | 0.035 | 0.080 | 1.365 | 1.270 |

Table 8.8.6: PECgw for active metazachlor and metabolite(s) on winter oilseed rape pre-emergence (with FOCUS PEARL v5.5.5 & PELMO v6.6.4) - Application rate 750 g a.i/ha (triennial)

| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Châteaudun | <0.001 | <0.001 | 3.828 | 3.490 | 9.875 | 8.021 | 0.821 | 0.253 | 0.190 | 0.133 | 11.334 | 8.499 |
| Hamburg | <0.001 | <0.001 | 4.700 | 4.615 | 7.444 | 7.701 | 0.960 | 0.967 | 0.811 | 0.776 | 4.976 | 4.696 |
| Kremsmünster | <0.001 | <0.001 | 2.989 | 3.389 | 5.536 | 5.941 | 0.372 | 0.492 | 0.380 | 0.390 | 4.033 | 4.478 |
| Okehampton | <0.001 | <0.001 | 2.687 | 3.053 | 4.556 | 4.868 | 0.488 | 0.596 | 0.607 | 0.669 | 2.723 | 2.572 |
| Piacenza | <0.001 | <0.001 | 3.170 | 3.865 | 5.321 | 5780 | 0.653 | 0.927 | 0.761 | 0.959 | 3.496 | 3.639 |
| Porto | <0.001 | <0.001 | 2.767 | 2.662 | 5.013 | 4.656 | 0.524 | 0.542 | 0.563 | 0.627 | 3.011 | 2.667 |

Table 8.8.7: PECgw for active metazachlor and metabolite(s) on winter oilseed rape post-emergence (with FOCUS PEARL v5.5.5 & PELMO v6.6.4) - Application rate 750 g a.i/ha (triennial)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Châteaudun | <0.001 | <0.001 | 2.667 | 2.087 | 5.573 | 4.725 | 0.181 | 0.158 | 0.098 | 0.067 | 6.735 | 5.091 |
| Hamburg | <0.001 | <0.001 | 2.896 | 2.847 | 4.372 | 4.578 | 0.619 | 0.661 | 0.457 | 0.423 | 2.943 | 2.749 |
| Kremsmünster | <0.001 | <0.001 | 1.776 | 2.019 | 3.258 | 3.459 | 0.216 | 0.301 | 0.208 | 0.218 | 2.369 | 2.629 |
| Okehampton | <0.001 | <0.001 | 1.677 | 1.925 | 2.708 | 2.905 | 0.328 | 0.402 | 0.344 | 0.391 | 1.586 | 1.523 |
| Piacenza | <0.001 | <0.001 | 1.972 | 2.264 | 2.959 | 3.330 | 0.411 | 0.554 | 0.357 | 0.433 | 2.051 | 2.166 |
| Porto | <0.001 | <0.001 | 1.733 | 1.698 | 2.948 | 2.773 | 0.332 | 0.387 | 0.375 | 0.454 | 1.768 | 1.537 |

Table 8.8.8: PECgw for active metazachlor and metabolite(s) on Cabbage 1st – BBCH 13(with FOCUS PEARL v5.5.5, & PELMO v.6.6.4) - Application rate 1000 g a.i/ha (triennial)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Châteaudun | < 0.001 | < 0.001 | 2.231 | 1.921 | 5.159 | 4.847 | 0.095 | 0.079 | 0.112 | 0.089 | 4.789 | 4.613 |
| Hamburg | < 0.001 | < 0.001 | 3.167 | 2.740 | 5.850 | 5.601 | 0.294 | 0.186 | 0.294 | 0.226 | 4.657 | 4.560 |
| Jokioinen | < 0.001 | < 0.001 | 4.081 | 3.840 | 6.572 | 6.068 | 0.492 | 0.520 | 0.222 | 0.211 | 5.269 | 5.021 |
| Kremsmünster | < 0.001 | < 0.001 | 2.230 | 2.386 | 4.440 | 4.738 | 0.179 | 0.202 | 0.171 | 0.170 | 3.951 | 4.017 |
| Porto | < 0.001 | < 0.001 | 0.857 | 0.914 | 2.181 | 2.099 | 0.036 | 0.050 | 0.048 | 0.087 | 1.913 | 1.681 |
| Sevilla | < 0.001 | < 0.001 | 0.932 | 0.941 | 3.197 | 3.052 | 0.006 | 0.008 | 0.009 | 0.007 | 3.619 | 3.303 |
| Thivia | < 0.001 | < 0.001 | 2.981 | 2.596 | 6.015 | 5.126 | 0.210 | 0.192 | 0.264 | 0.214 | 4.596 | 4.182 |

Table 8.8.9: PECgw for active metazachlor and metabolite(s) on Cabbage 2nd – BBCH 13 (with FOCUS PEARL v5.5.5, & PELMO v.6.6.4) - Application rate 1000 g a.i/ha (triennial)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Scenario** | **80th Percentile PECgw at 1 m Soil Depth (mg/L)** | | | | | | | | | | | |
| **Metazachlor** | | **479M04** | | **479M08** | | **479M09** | | **479M11** | | **479M12** | |
| **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** | **PEARL** | **PELMO** |
| Châteaudun | < 0.001 | < 0.001 | 3.196 | 2.720 | 6.018 | 5.557 | 0.412 | 0.300 | 0.288 | 0.220 | 4.943 | 4.741 |
| Hamburg | < 0.001 | < 0.001 | 4.481 | 4.029 | 6.920 | 6.713 | 0.918 | 0.842 | 0.670 | 0.660 | 4.523 | 4.451 |
| Kemsmünster | < 0.001 | < 0.001 | 2.773 | 3.022 | 4.965 | 5.475 | 0.342 | 0.459 | 0.309 | 0.356 | 3.751 | 4.053 |
| Porto | < 0.001 | < 0.001 | 1.810 | 1.642 | 3.235 | 2.871 | 0.256 | 0.241 | 0.377 | 0.391 | 1.908 | 1.643 |
| Sevilla | < 0.001 | < 0.001 | 1.696 | 1.551 | 4.249 | 3.887 | 0.037 | 0.034 | 0.037 | 0.031 | 4.452 | 3.745 |

The FOCUS ground water model results shows that the metabolites of metazachlor are greater than 0.1 µg/L in all scenarios and for all crops. Hence the toxicological relevance of all the major metabolites is evaluated and explained in detail in section B.10 (Toxicological Relevance of ground water metabolites). The result shows that the metabolites 479M04, 479M08 and 479M12 are toxicologically irrelevant and the limit of these metabolites should be less than 10 µg/L, whereas the metabolites 479M09 and 479M11 are toxicologically relevant metabolites and their limit should not exceed 0.1 µg/L.

As a higher tier assessment ground water monitoring studies are done,one in Germany and one in France (9.6.3/1, Schneider M.,Penning H., 2011a).In both the field studies the weight of evidence indicates that neither 479M09 nor 479M11(toxicologically relevant metabolites) would normally be expected to leach into groundwater at concentrations greater than 0.1 μg/L and the toxicologically irrelevant metabolites(479M04, 479M08, 479M12**)** are less than 10 µg/L ((Drinking Water Directive for chlorinated aliphatic hydrocarbons).

## Predicted Environmental Concentrations in surface water (PECsw) (KCP 9.2.5)

|  |
| --- |
| **Review Comments:**  The PECsw calculations for metazachlor and its metabolites were provided by the Applicant and are considered acceptable.  For active substances and relevant metabolites PECSW calculations were performed with FOCUS STEPS 1-2 (active substances and metabolites) and FOCUS STEP 3 - 4 (metazachlor).  The formulation PECsw calculations were accepted.  The PECsw reported above can be used for the risk assessment for aquatic organisms. Please refer to section 9. |

### Justification for new endpoints

The same endpoints as the EU agreed endpoints (EFSA 2008) and EFSA (2017) were used.

### Metazachlor, relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9.1: Input parameters related to application for PECSW/SED calculations

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Plant protection product** | **METROPOLITAN** | | | | |
| **Use No.** | **1** | | **2** | | **3** |
| Crop | winter oil seed rape | spring oil seed rape | winter oil seed rape | spring oil seed rape | Vegetables leafy  (Cabbage, cauliflower)  BBCH 13 |
| Crop growth stage | 00 – 09  (pre-emergence) | | 10 – 19 | | 13 - 16 |
| Application rate (g a.s./ha) | 750 | | | | 1000 |
| Application window | Oct-Feb | March-May | Oct-Feb | March-May | June - Sep |
| Interception | No interception | | Minimal interception | | |
| CAM (Chemical application method) | 1 | | 2 | | |
| Soil depth (cm) | 4 | | | | |
| Models used for calculation | FOCUS Step 1 & 2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3 and SWAN v5.0.1 | | | | |

Table 8.9.2: FOCUS Step 3 Scenario related input parameters for PECsw/sed calculations for the application of METROPOLITAN

| Scenario | Application window used in modelling | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| WOSR  pre-emergence\* | WOSR  (BBCH 10)\*\* | SOSR  Pre-emergence\* | SOSR  (BBCH 10)\*\* | Vegetables leafy 1st (Cabbage, cauliflower)  BBCH 13\*\* | Vegetables leafy 2nd (Cabbage, cauliflower)  BBCH 13\*\* |
| D1 | - | - | 05/05 – 04/06 | 20/05 – 19/06 | - | - |
| D2 | 01/09 – 01/10 | 16/09 – 16/10 | - | - | - | - |
| D3 | 19/08 – 18/09 | 03/09 – 03/10 | 27/03 – 26/04 | 11/04 – 11/05 | 08/05 - 07/06 | 17/08 – 16/09 |
| D4 | 20/08 – 19/09 | 04/09 – 04/10 | 17/04 – 17/05 | 02/05 – 01/06 | 01/06/ - 01/07 | - |
| D5 | 06/09 – 06/10 | 21/09 – 21/10 | 01/03 – 31/03 | 16/03 – 15/04 | - | - |
| D6 | - | - | - | - | 30/08 – 29/09 | - |
| R1 | 21/08 – 20/09 | 05/09 – 05/10 | 27/03 – 26/04 | 11/04 – 11/05 | 03/05 – 02/06 | 12/08 – 11.09 |
| R2 | - | - | - | - | 24/03 - 23/04 | 10/08 – 09/09 |
| R3 | 21/09 – 21/10 | 06/10 – 05/11 | - | - | 20/03 – 19/04 | 04/07 – 03/08 |
| R4 | - | - | - | - | 20/03 – 19/04 | 04/07 – 03/08 |

**\* Default values for preemergence use in oilseed rape crops in FOCUS SWASH v.5.3**

**\*\* Application dates according to AppDate 3.06 (28 June 2019)**

Table 8.9.3: Input parameters related to active substance metazachlor and metabolite(s) for PECsw/sed calculations STEP 1/2 and 3(/4)

| Compound | metazachlor | 479M04 | 479M08 | 479M09 | 479M11 | 479M12 | 479M06 | Value in accordance to EU endpoint y/n/  Reference |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Molecular weight (g/mol) | 277.7 | 273.3 | 323.4 | 349.4 | 305.4 | 303.2 | 243.3 | EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Saturated vapour pressure (Pa) | 9.6 x 10-5 | Not needed for Steps 1/2 | | | | | |
| Water solubility (mg/L) | 450 | 1000 | | | | | |
| Diffusion coefficient in water (m²/d) | 4.3 x 10-5 | Not needed for Steps 1/2 | | | | | | default |
| Diffusion coefficient in air (m²/d) | 0.43 | Not needed for Steps 1/2 | | | | | | default |
| Kfoc (mL/g) | 110 (median, n=29) | 9.1(median, n=11) | 10 (median, n=11) | 5.8 (arithmetic mean, n=3) | 20.5 (arithmetic mean, n=3) | 8.9 (arithmetic mean, n=3) | 54 (median, n=4) | EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| Freundlich Exponent  1/n | 0.877 (median, n=29) | Not needed for Steps 1/2 | | | | | |
| Plant Uptake | 0.5 | 0 | | | | | |
| Wash-Off factor from Crop (1/mm) | 0.05 (MACRO)  0.50 (PRZM) | Not needed for Steps 1/2 | | | | | | default |
| DT50,soil (d) | 62.3 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2, n =10) | 6.8  (geomean DT50field, n=8) | 56.4 (geomean DT50field, n=3) | 116.4 (Maximum DT50field, n=3) | 16.9 (geomean from lab studies, n=3) | 25.2 (geomean from lab studies, n=4) | 1000 (defult) | EFSA Confirmatory data, Metazachlor 2017;15(6):4833 |
| DT50,water (d) | 19.3 (geomean, n=4) | 1000 (default) | 1000 (default) | 1000 (default) | 1000 (default) | 1000 (default) | 35.1 (geomean, n=2) | EFSA Conclusion, Metazachlor (2008) 145, 1-132 |
| DT50,sed (d) | 1000 (default) | 1000 (default) | 1000 (default) | 1000  (default) | 1000  (default) | 1000  (default) | 1000  (default) |
| DT50,whole system (d) | 19.3 (geomean, n=4) | 1000 (default) | 1000 (default) | 1000 (default) | 1000 (default) | 1000 (default) | 35.1 (geomean, n=2) |
| Maximum occurrence observed (% molar basis with respect to the parent) | - | 16.2 | 21.6 | 5.3 | 7.5 | 8.29 | 0.01 |
| Formation fraction from parent (max % observed in lab studies, total system) | - | 13.3 | a0.01 | a0.01 | a0.01 | a0.01 | 16.45 |

a: not detected in sediment water systems or soil.

PECsw/sed

**Application rate 750 g a.i/ha**

Table 8.9.4: FOCUS Step 1, 2 and 3 PECsw and PECsed for metazachlor following single application of METROPOLITAN to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominant entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 224.92 | Runoff/drainage | 157.35 | 239.83 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 78.00 | Runoff/drainage | 56.75 | 83.51 |
| Southern Europe | Oct-Feb | 63.50 | Runoff/drainage | 46.17 | 69.56 |
| Step 3 | | | | | |
| D2 | ditch | 9.18 | Drainage | 2.95 | 5.88 |
| D2 | stream | 5.74 | Drainage | 1.73 | 3.99 |
| D3 | ditch | 4.81 | Drainage | 2.65 | 3.70 |
| D4 | pond | 0.19 | Drainage | 0.18 | 0.68 |
| D4 | stream | 4.11 | Drainage | 0.11 | 0.65 |
| D5 | pond | 0.17 | Drainage | 0.12 | 0.33 |
| D5 | stream | 4.44 | Drainage | 0.08 | 0.72 |
| R1 | pond | 0.16 | Runoff | 0.12 | 0.22 |
| R1 | stream | 3.14 | Runoff | 0.03 | 0.34 |
| R3 | stream | 5.22 | Runoff | 0.26 | 1.24 |

Table 8.9.5: FOCUS Step 1, 2 and 3 PECsw and PECsed for metazachlor following single application of METROPOLITAN to winter oilseed rape BBCH 10- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominant entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 224.92 | Runoff /drainage | 157.35 | 239.83 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 49.00 | Runoff /drainage | 35.59 | 53.62 |
| Southern Europe | Oct-Feb | 40.30 | Runoff /drainage | 29.24 | 44.06 |
| Step 3 | | | | | |
| D2 | ditch | 56.37 | Drainage | 18.78 | 26.99 |
| D2 | stream | 35.96 | Drainage | 10.83 | 16.40 |
| D3 | ditch | 4.77 | Drainage | 0.42 | 1.55 |
| D4 | pond | 0.40 | Drainage | 0.38 | 1.11 |
| D4 | stream | 4.11 | Drainage | 0.25 | 0.63 |
| D5 | pond | 0.17 | Drainage | 0.12 | 0.46 |
| D5 | stream | 4.43 | Drainage | 0.08 | 0.76 |
| R1 | pond | 0.16 | Run off | 0.12 | 0.24 |
| R1 | stream | 3.14 | Run off | 0.03 | 0.31 |
| R3 | stream | 15.75 | Run off | 0.74 | 3.97 |

Table 8.9.6: FOCUS Step 1, 2 and 3 PECsw and PECsed for metazachlor following single application of METROPOLITAN to spring oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominant entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 224.92 | Runoff/drainage | 157.35 | 239.83 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 78.00 | Runoff/drainage | 56.75 | 85.51 |
| Southern Europe | Oct-Feb | 63.50 | Runoff/drainage | 46.17 | 69.56 |
| Step 3 | | | | | |
| D1 | ditch | 4.87 | Drainage | 0.73 | 2.21 |
| D1 | stream | 3.88 | Drainage | 0.08 | 0.43 |
| D3 | ditch | 4.75 | Drainage | 0.23 | 1.17 |
| D4 | pond | 0.16 | Drainage | 0.13 | 0.27 |
| D4 | stream | 3.63 | Drainage | 0.01 | 0.12 |
| D5 | pond | 0.16 | Drainage | 0.14 | 0.27 |
| D5 | stream | 3.77 | Drainage | 0.01 | 0.09 |
| R1 | pond | 0.18 | Run off | 0.15 | 0.37 |
| R1 | stream | 3.13 | Run off | 0.07 | 0.54 |

Table 8.9.7: FOCUS Step 1, 2 and 3 PECsw and PECsed for metazachlor following single application of METROPOLITAN to spring oilseed rape BBCH 10- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominant entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 224.92 | Runoff /drainage | 157.35 | 239.83 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 49.00 | Runoff /drainage | 35.59 | 53.62 |
| Southern Europe | Oct-Feb | 40.30 | Runoff /drainage | 29.24 | 44.06 |
| Step 3 | | | | | |
| D1 | ditch | 4.90 | Drainage | 3.50 | 5.44 |
| D1 | stream | 4.21 | Drainage | 0.23 | 1.37 |
| D3 | ditch | 4.75 | Drainage | 0.23 | 1.17 |
| D4 | pond | 0.16 | Drainage | 0.12 | 0.23 |
| D4 | stream | 3.90 | Drainage | 0.02 | 0.22 |
| D5 | pond | 0.16 | Drainage | 0.13 | 0.26 |
| D5 | stream | 3.77 | Drainage | 0.01 | 0.09 |
| R1 | pond | 0.18 | Run off | 0.15 | 0.37 |
| R1 | stream | 3.13 | Run off | 0.07 | 0.54 |

Table 8.9.4: FOCUS Step 1, 2 and 3 PECsw and PECsed for metazachlor following single application of Metazachlor 50 % SC to Cabbage (vegetable leafy) BBCH 13- Application rate 1000 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominant entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 224.92 | Runoff/drainage | 157.35 | 239.83 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 47.20 | Runoff/drainage | 34.28 | 51.65 |
| Southern Europe | Oct-Feb | 68.05 | Runoff/drainage | 49.49 | 74.57 |
| Step 3 | | | | | |
| D3 1st | ditch | 6.482 | Drainage | 0.490 | 2.281 |
| D3 2nd | ditch | 6.569 | Drainage | 0.609 | 2.943 |
| D4 | pond | 3.573 | Drainage | 3.452 | 10.78 |
| D4 | stream | 5.470 | Drainage | 2.352 | 6.362 |
| R1 1st | pond | 0.436 | Runoff | 0.355 | 0.732 |
| R1 2nd | pond | 0.612 | Runoff | 0.463 | 0.968 |
| R1 1st | stream | 6.812 | Runoff | 0.240 | 1.535 |
| R1 2nd | stream | 8.216 | Runoff | 0.336 | 2.199 |
| R2 1st | stream | 11.03 | Runoff | 0.486 | 2.327 |
| R2 2nd | stream | 6.195 | Runoff | 0.429 | 1.963 |
| R3 1st | stream | 11.86 | Runoff | 0.565 | 3.430 |
| R3 2nd | stream | 32.18 | Runoff | 2.036 | 8.608 |
| R4 1st | stream | 33.41 | Runoff | 1.264 | 8.281 |
| R4 2nd | stream | 33.42 | Runoff | 1.569 | 7.976 |

FOCUS Step 4

**Application rate of 750 g a.i/ha**

Table 8.9.9: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to winter oilseed rape pre-emergence according to the south EU zone GAP according to surface water Step 4- Application rate 750 g a.i/ha

| PECsw (µg/L) | Scenario | STEP 4 metazachlor | | |
| --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | None | 10 | 20 |
| No spray buffer (m) | 5 | 10 | 20 |
| None | D2 ditch | 9.184 | - | - |
| D2 stream | 5.736 | - | - |
| D3 ditch | 1.303 | - | - |
| D4 stream | 1.502 | - | - |
| D5 stream | 1.620 | - | - |
| R1 stream | 1.148 | - | - |
| R3 Stream | 5.222 | 2.377 | 1.246 |

Table 8.9.10: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to winter oilseed rape BBCH 10 according to the south EU zone GAP according to surface water Step 4- Application rate 750 g a.i/ha

| PECsw (µg/L) | Scenario | STEP 4 metazachlor | | |
| --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | None | 10 | 20 |
| No spray buffer (m) | 5 | 10 | 20 |
| None | D2 ditch | 56.37 | - | - |
| D2 stream | 35.96 | - | - |
| D3 ditch | 1.294 | - | - |
| D4 stream | 1.502 | - | - |
| D5 stream | 1.620 | - | - |
| R1 stream | 1.148 | - | - |
| R3 stream | 15.75 | 7.169 | 3.758 |

Table 8.9.11: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to winter oilseed rape BBCH 10 according to the south EU zone GAP according to surface water Step 4- Application rate 750 g a.i/ha (VFSmod)

| PECsw (µg/L) | Scenario | VFSMOD  STEP 4 metazachlor | | |
| --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 5 | 10 | 15 |
| No spray buffer (m) | 5 | 10 | 15 |
| None | R3 stream | 6.461 | 4.027 | 0.582 |

Table 8.9.12: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to spring oilseed rape pre-emergence according to the south EU zone GAP according to surface water Step 4- Application rate 750 g a.i/ha

| PECsw (µg/L) | Scenario | STEP 4 metazachlor | |
| --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | None | 5\* |
| No spray buffer (m) | 5 | 5\* |
| None | D1 ditch | 1.383 | - |
| D1 stream | 1.453 | - |
| D3 ditch | 1.288 | - |
| D4 stream | 1.325 | - |
| D5 stream | 1.376 | - |
| R1 stream | 2.218 | 1.446 |

**\*0.4 was used for used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).**

Table 8.9.13: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to spring oilseed rape post emergence according to the south EU zone GAP according to surface water Step 4- Application rate 750 g a.i/ha

| PECsw (µg/L) | Scenario | STEP 4 metazachlor | |
| --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | None | 5\* |
| No spray buffer (m) | 5 | 5\* |
| None | D1 ditch | 1.394 | **-** |
| None | D1 stream | 1.538 | **-** |
| None | D3 ditch | 1.288 | - |
| None | D4 stream | 1.423 | - |
| None | D5 stream | 1.379 | - |
| None | R1 stream | 2.218 | 1.446 |

**\*0.4 was used for used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).**

Table 8.9.14: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to Cabbage BBCH 13 according to the south EU zone GAP according to surface water Step 4- Application rate 1000 g a.i/ha

| PECsw (µg/L) | Scenario | STEP 4 metazachlor | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | None | | 5\* | 10 | 15\*\* | 20 |
| No spray buffer (m) | 5 | 10 | 5 | 10 | 15 | 20 |
| None | D3 stream 1st | 1.860 | 1.052 | - | - | - | - |
| D3 ditch 2nd | 1.943 | 1.135 | - | - | - | - |
| D6 stream | 7.567 | - | - | - | - | - |
| R1 stream 1st | 6.812 | - | 4.436 | 3.090 | 2.370 | 1.617 |
| R1 stream 2nd | 8.216 | - | 5.360 | 3.737 | 2.868 | 1.958 |
| R2 stream 1st | 11.03 | - | 7.107 | 4.916 | 3.757 | 2.554 |
| R2 stream 2nd | 6.195 | - | 4.009 | 2.780 | 2.129 | 1.449 |
| R3 stream 1st | 11.86 | - | 7.754 | 5.412 | 4.157 | 2.839 |
| R3 stream 2nd | 32.18 | - | 21.03 | 14.67 | 11.27 | 7.692 |
| R4 stream 1st | 33.41 | - | 21.79 | 15.20 | 11.66 | 7.962 |
| R4 stream 2nd | 32.42 | - | 21.14 | 14.74 | 11.31 | 7.713 |

**\*0.4 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were used for strip vegetative simulation, according to the Austrian Environmental Agency AGES.**

**\*\*0.7 and 09 for Fractional reduction in run-off volume and flux and Fractional reduction in erosion mass and flux were respectively**

Table 8.9.15: Global maximum PECsw values for metazachlor, following single application of METROPOLITAN to Cabbage BBCH 13 according to the south EU zone GAP according to surface water Step 4- Application rate 1000 g a.i/ha (VFSmod)

| PECsw (µg/L) | Scenario | VFSMOD  STEP 4 metazachlor | | |
| --- | --- | --- | --- | --- |
| Nozzle  reduction | Vegetative strip (m) | 5 | 10 | 15 |
| No spray buffer (m) | 5 | 10 | 15 |
| None | R1 stream 1st | 1.510 | - | - |
| 50% | - | - | - |
| None | R1 stream 2nd | 1.532 | - | - |
| 50% | - | - | - |
| None | R2 stream 1st | 2.021 | 1.072 | - |
| 50% | 1.011 | - | - |
| None | R2 stream 2nd | 2.053 | 1.089 | - |
| 50% | 1.027 | - | - |
| None | R3 stream 1st | 4.828 | 3.023 | 0.777 |
| 50% | 4.828 | - | - |
| None | R3 stream 2nd | 6.874 | 1.145 | - |
| 50% | 6.874 | - | - |
| None | R4 stream 1st | 1.529 | - | - |
| 50% | - | - | - |
| None | R4 stream 2nd | 1.523 | - | - |
| 50% | - | - | - |

Metabolite(s) of metazachlor-

**The worst case for metabolites is winter oilseed rape pre-emergence at 750 g a.i/ha**

Table 8.9.16: FOCUS Step 1, 2 PECsw and PECsed for 479M04 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 72.36 | Runoff /drainage | 71.83 | 6.58 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 29.33 | Runoff /drainage | 29.11 | 2.67 |
| Southern Europe | Oct-Feb | 23.74 | Runoff /drainage | 23.56 | 2.16 |

Table 8.9.17: FOCUS Step 1, 2 PECsw and PECsed for 479M08 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 62.09 | Runoff /drainage | 61.64 | 6.21 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 29.56 | Runoff /drainage | 29.34 | 2.96 |
| Southern Europe | Oct-Feb | 23.64 | Runoff /drainage | 23.47 | 2.36 |

Table 8.9.18: FOCUS Step 1, 2 PECsw and PECsed for 479M09 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 16.58 | Runoff /drainage | 16.46 | 0.96 |
| Step 2> | | | | | |
| Northern Europe | Oct-Feb | 8.09 | Runoff /drainage | 8.03 | 0.47 |
| Southern Europe | Oct-Feb | 6.47 | Runoff /drainage | 6.43 | 0.38 |

Table 8.9.19: FOCUS Step 1, 2 PECsw and PECsed for 479M11 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 18.24 | Runoff /drainage | 18.10 | 3.66 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 7.74 | Runoff /drainage | 7.68 | 1.55 |
| Southern Europe | Oct-Feb | 6.19 | Runoff /drainage | 6.15 | 1.24 |

Table 8.9.20: FOCUS Step 1, 2 PECsw and PECsed for 479M12 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 22.39 | Runoff /drainage | 22.23 | 1.99 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 10.03 | Runoff /drainage | 9.96 | 0.89 |
| Southern Europe | Oct-Feb | 8.02 | Runoff /drainage | 7.97 | 0.71 |

Table 8.9.21: FOCUS Step 1, 2 PECsw and PECsed for 479M06 following single application to winter oilseed rape pre-emergence- Application rate 750 g a.i/ha

| Scenario  FOCUS | Waterbody | Max PECsw  (μg/L) | Dominat entry route | 21 d- PECsw,twa  (µg/L) | Max PECsed (μg/kg) |
| --- | --- | --- | --- | --- | --- |
| Step 1 | --- | 0.04 | Runoff /drainage | 0.04 | 0.02 |
| Step 2 | | | | | |
| Northern Europe | Oct-Feb | 0.02 | Runoff /drainage | 0.02 | 0.01 |
| Southern Europe | Oct-Feb | 0.02 | Runoff /drainage | 0.01 | 0.01 |

#### PECsw/sed of METROPOLITAN

The PECSW for METROPOLITAN was calculated using the following equation:



The application of METROPOLITAN is 1.5 and 2 L/ha, corresponding to 1724.7 and 2300 g fp/ha (taking into account a density of 1.1498 g/cm3) for oilseed rape and cabbage respectively. The depth of the static water body was assumed to be 30 cm. The resulting maximum instantaneous PECSW value is presented in the table 8.9-22 and 8.9-23.

Table 8.9‑22: PECsw for METROPOLITAN following single application to oilseed rape

| Crop | Distance  (m) | Drift\*  (%) | Max PECsw (μg/L) | Nozzles reduction (%) | | |
| --- | --- | --- | --- | --- | --- | --- |
| 50 | 75 | 90 |
| Oilseed rape | 1 | 1.9274 | 11.081 | 5.540 | 2.770 | 1.108 |
| 5 | 0.5224 | 3.003 | 1.502 | 0.751 | 0.300 |
| 10 | 0.2771 | 1.593 | 0.797 | 0.398 | - |
| 14 | 0.2020 | 1.161 | 0.581 | 0.290 | - |
| 20 | 0.1440 | 0.828 | 0.414 | - | - |

**\*Drift values from FOCUS Drift Calculator v1.1**

Table 8.9‑23: PECsw for METROPOLITAN following single application to cabbage

| Crop | Distance  (m) | Drift\*  (%) | Max PECsw (μg/L) | Nozzles reduction (%) | | |
| --- | --- | --- | --- | --- | --- | --- |
| 50 | 75 | 90 |
| Cabbage | 1 | 1.9274 | 14.777 | 7.389 | 3.694 | 1.478 |
| 5 | 0.5224 | 4.005 | 2.003 | 1.001 | 0.401 |
| 10 | 0.2771 | 2.124 | 1.062 | 0.531 | 0.212 |
| 14 | 0.2020 | 1.549 | 0.775 | 0.387 | - |
| 20 | 0.1440 | 1.104 | 0.552 | 0.276 | - |

**\*Drift values from FOCUS Drift Calculator v1.1**

The PECsed for METROPOLITAN was calculated using the following equation:



The application METROPOLITAN is is 1.5 L/ha, corresponding to 1724.7 and 2300 g fp/ha (taking into account a density of 1.1498 g/cm3) for oilseed rape and cabbage respectively. The maximum percentage of Metazachlor in the sediment is 19.76%, but the percentage in the formulated product is 50%, thus the actual percentage in sediment is 19.76 x 0.5 = 9.88. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm3. The resulting maximum instantaneous PECsed value is presented in the table 8.9-24.

Table 8.9‑24: PECsed for METROPOLITAN following single application to oilseed rape

| Crop | Distance  (m) | Drift\*  (%) | % in sediment | Max PECsed (µg/kg) (based on maximum occurrence) |
| --- | --- | --- | --- | --- |
| Oilseed rape | 1 | 1.9274 | 9.88 | 5.053 |
| Cabbage | 6.738 |

**\*Drift values from FOCUS Drift Calculator v1.1**

## Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

|  |
| --- |
| **Review Comments:**  The data on atmospheric degradation and behaviour in air for metazachlor provided by the Applicant are considered acceptable. |

Table 8.10.1: Summary of atmospheric degradation and behaviour of Metazachlor

|  |  |
| --- | --- |
| Compound | metazachlor |
| Direct photolysis in air | Not studied - no data requested |
| Quantum yield of direct phototransformation | No study conducted |
| Photochemical oxidative degradation in air | DT50 (h): <19 h derived by the Atkinson model  OH (12h) concentration assumed =5x105 OH radicals/ cm3 |
| Volatilisation | Vapour pressure (Pa): 9.5x10-5  Henry's Law Constant (Pa.m3/mol): 5.9x10-5  from plant surfaces: 1.6% in a 24 hour period  from soil surfaces: 4% loss to trapped volatiles within 24 hours |
| Metabolites | none |

The vapour pressure at 20 °C of the active substance metazachlor is between 10‑5 and 10‑4 Pa. Hence the active substance metazachlor is regarded as semi volatile (volatilisation only from plant surfaces).

Losses from plant surfaces were also measured with these being 10% loss to trapped volatiles within 24 hours under controlled conditions from bush bean leaves but only 1.6% of that applied not being recovered from oilseed rape leaves after 24 hours in the field. The small proportion of metazachlor that is lost to the upper atmosphere is expected to degrade relatively rapidly, it having an Atkinson calculated tropospheric photochemical oxidative photochemical (indirect reaction with OH radicals) degradation half-life of 6.5 hours (more recent functional group information) assuming a hydroxyl radical concentration of 5x105 radicals/ cm3. (Note this half-life is marginally conservative as a higher hydroxyl radical concentration of 1.5x106 radicals/cm3 is more usually assumed in calculations). Metazachlor would therefore be unlikely to be subject to long range aerial transport.

Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance metazachlor due to volatilization with subsequent deposition should not be considered.

1. Lists of data considered in support of the evaluation

Detailed evaluation of the new Annex II studies

Additional information provided by the applicant (e.g. detailed modelling data)