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| **REGISTRATION REPORT**  **Part B**  Section 6  Mammalian Toxicology  Detailed summary of the risk assessment |
| Product code: SHA 148000 A  Product name: **METROPOLITAN**  Chemical active substance:  Metazachlor, 500 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| NATIONAL ASSESSMENT  (Authorization) |
| Applicant: XXXX  Submission date: October 2022  Evaluation date: July 2023  MS Finalisation date: October 2023 |

Version history

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| When | What |
| July 2023 | Version evaluated by zRMS PL |
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Table of Contents

[6 Mammalian Toxicology (KCP 7) 5](#_Toc148427707)

[6.1 Summary 5](#_Toc148427708)

[6.2 Toxicological Information on Active Substance(s) 6](#_Toc148427709)

[6.3 Toxicological Evaluation of Plant Protection Product 7](#_Toc148427710)

[6.4 Toxicological Evaluation of Groundwater Metabolites 8](#_Toc148427711)

[6.5 Dermal Absorption (KCP 7.3) 8](#_Toc148427712)

[6.5.1 Justification for proposed values – Metazachlor 9](#_Toc148427713)

[6.6 Exposure Assessment of Plant Protection Product (KCP 7.2) 9](#_Toc148427714)

[6.6.1 Selection of critical use(s) and justification 9](#_Toc148427715)

[6.6.2 Operator exposure (KCP 7.2.1) 10](#_Toc148427716)

[6.6.2.1 Estimation of operator exposure 10](#_Toc148427717)

[6.6.2.2 Measurement of operator exposure 11](#_Toc148427718)

[6.6.3 Worker exposure (KCP 7.2.3) 11](#_Toc148427719)

[6.6.3.1 Estimation of worker exposure 11](#_Toc148427720)

[6.6.3.2 Refinement of generic DFR value (KCP 7.2) 13](#_Toc148427721)

[6.6.3.3 Measurement of worker exposure 14](#_Toc148427722)

[6.6.4 Resident and bystander exposure (KCP 7.2.2) 14](#_Toc148427723)

[6.6.4.1 Estimation of resident and bystander exposure 14](#_Toc148427724)

[6.6.4.2 Measurement of resident and/or bystander exposure 16](#_Toc148427725)

[6.6.5 Combined exposure 16](#_Toc148427726)

[Appendix 1 Lists of data considered in support of the evaluation 17](#_Toc148427727)

[Appendix 2 Detailed evaluation of the studies relied upon 19](#_Toc148427728)

[A 2.1 Statement on bridging possibilities 19](#_Toc148427729)

[A 2.2 Acute oral toxicity (KCP 7.1.1) 19](#_Toc148427730)

[A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2) 20](#_Toc148427731)

[A 2.4 Acute inhalation toxicity (KCP 7.1.3) 21](#_Toc148427732)

[A 2.5 Skin irritation (KCP 7.1.4) 21](#_Toc148427733)

[A 2.6 Eye irritation (KCP 7.1.5) 21](#_Toc148427734)

[A 2.7 Skin sensitisation (KCP 7.1.6) 22](#_Toc148427735)

[A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7) 22](#_Toc148427736)

[A 2.9 Data on co-formulants (KCP 7.4) 22](#_Toc148427737)

[A 2.9.1 Material safety data sheet for each co-formulant 22](#_Toc148427738)

[A 2.9.2 Available toxicological data for each co-formulant 22](#_Toc148427739)

[A 2.10 Studies on dermal absorption (KCP 7.3) 22](#_Toc148427740)

[A 2.11 Other/Special Studies 23](#_Toc148427741)

[Appendix 3 Exposure calculations 24](#_Toc148427742)

[A 3.1 Operator exposure calculations (KCP 7.2.1.1) 24](#_Toc148427743)

[A 3.1.1 Calculations for Metazachlor 24](#_Toc148427744)

[A 3.2 Worker exposure calculations (KCP 7.2.3.1) 27](#_Toc148427745)

[A 3.2.1 Calculations for Metazachlor 28](#_Toc148427746)

[A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1) 29](#_Toc148427747)

[A 3.3.1 Calculations for Metazachlor 29](#_Toc148427748)

[Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1) 33](#_Toc148427749)

# Mammalian Toxicology (KCP 7)

## Summary

Table 6.1‑1: Information on SHA 148000 A / METROPOLITAN \*

|  |  |
| --- | --- |
| Product name and code | SHA 148000 A / METROPOLITAN |
| Formulation type | Suspension concentrate [Code: SC] |
| Active substance(s) (incl. content) | Metazachlor; 500 g/L |
| Function | Herbicide |
| Product already evaluated as the ‘representative formulation’ during the approval of the active substance(s) | No |
| Product previously evaluated in another MS according to Uniform Principles | Yes |

\* Information on the detailed composition of SHA 148000 A / METROPOLITAN can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1‑2: Justified proposals for classification and labelling for SHA 148000 A / METROPOLITAN according to Regulation (EC) No 1272/2008

|  |  |
| --- | --- |
| Hazard class(es), categories | Skin Sens. 1B ~~Skin Sens. 1~~, Carc.2 |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS07, GHS08 |
| Signal word | Warning |
| Hazard statement(s) | H317, H351 |
| Precautionary statement(s) | P201, P202, P261, P272, P280, P363, P302+P352, P308+P313, P333 + P313, P405, P501 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |

Table 6.1‑3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 148000 A / METROPOLITAN

|  | Result | PPE / Risk mitigation measures |
| --- | --- | --- |
| Operators | Acceptable | Work wear (arms, body and legs covered) M/L and A - winter and spring oilseed rape  Work wear (arms, body and legs covered) M/L and A + gloves M/L - cabbage, cauliflower |
| Workers | Acceptable | Inspection/irrigation activities  Work wear (arms, body and legs covered) – winter, spring oilseed rape,  cabbage, cauliflower  Harvesting activities  Work wear (arms, body and legs covered) + gloves - cabbage, cauliflower |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

No unacceptable risk for residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

No unacceptable risk for operators and workers was identified when the product is used as intended and provided that the PPE/ risk mitigation measures stated in Table 6.1‑3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders is presented in the following table.

Table 6.1‑4 Critical uses and overall conclusion of exposure assessment

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No.\* | Crops and situation (e.g. growth stage of crop) | F, Fn, Fpn G, Gn, Gpn or I \*\* | Application | | Application rate | | PHI (d) | Remarks:   (e.g. safener/synergist (L/ha))  critical gap for operator, worker, resident or bystander exposure based on [Exposure model] | Acceptability of exposure assessment | | | |
| Method / Kind  (incl. application technique \*\*\* | Max. number (min. interval between applications)  a) per use  b) per crop/ season | Max. application rate  kg as/ha   a) per use  b) per crop/ season | Water L/ha  min / max | Operator | Worker | Residents | Bystander |
| 1 | Winter and spring oilseed rape  (BBCH 00-09, BBCH 10-19) | F | Spraying, LCTM | a) 1  b) 1 | a) 0,75  b) 0,75 | 200-400 |  | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 | A | A | A | A |
| 2 | Cabbage, cauliflower  (BBCH 13-16, 7 days after planting) | F | Spraying, LCTM | a) 1  b) 1 | a) 1,0  b) 1,0 | 200-300 | - | R | R | A | A |

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

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

\*\*\* e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 “Acceptability of exposure assessment”

|  |  |
| --- | --- |
| A | Exposure acceptable without PPE / risk mitigation measures |
| R | Further refinement and/or risk mitigation measures required |
| N | Exposure not acceptable/ Evaluation not possible |

## Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2‑1.

Table 6.2‑1: Information on active substance(s)

|  | Metazachlor |
| --- | --- |
| Common Name | Metazachlor |
| CAS-No. | 67129-08-2 |
| Classification and proposed labelling | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | Hazard classes (s), categories: Skin Sens. 1B, Carc. 2,  Code(s) for hazard pictogram(s): GHS07, GHS08  Signal word: Warning  Hazard statement(s): H317, H351 |
| Additional C&L proposal | - |
| Agreed EU endpoints | |
| AOEL systemic | 0,2 mg/kg bw/d |
| Reference | EFSA Journal 2017;15(6):4833, conclusion on pesticides peer review |
| Conditions to take into account/critical areas of concern with regard to toxicology | |
| According to EFSA Journal 2017;15(6):4833, conclusion on pesticides peer review for Metazachlor | None |

## Toxicological Evaluation of Plant Protection Product

The assessment of all acute toxicological properties of SHA 148000 A / METROPOLITAN is derived from the classification of the active compound and co-formulants.

Justification for the proposed classification according to the Regulation (EC) No 1272/2008:

Full details of the calculation methodology, co-formulants and their volumes in the product can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Classification for SHA 148000 A / METROPOLITAN is calculated based on classification of active ingredient and co-formulants. Based on those calculations for formulation, SHA 148000 A / METROPOLITAN is classified as: Skin sensitisation, Category 1, Carcinogenicity, Category 2.

A summary of the toxicological evaluation for SHA 148000 A / METROPOLITAN is given in the following tables.

Table 6.3‑1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SHA 148000 A / METROPOLITAN

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of test, species, model system (Guideline) | Result | Acceptability | Classification  (acc. to the criteria in Reg. 1272/2008) | Reference |
| LD50 oral, rat | Not classified | Yes | None | Calculated |
| LD50 dermal, rat | Not classified | Yes | None | Calculated |
| LC50 inhalation, rat | Not classified | Yes | None | Calculated |
| Skin irritation | Not classified | Yes | None | Calculated |
| Eye irritation | Not classified | Yes | None | Calculated |
| Skin sensitisation | Sensitising | Yes | Skin Sens. 1B, H317 | Calculated |
| Supplementary studies for combinations of plant protection products | No data – not required |  |  |  |

Table 6.3‑2: Additional toxicological information relevant for classification/labelling of SHA 148000 A / METROPOLITAN

|  | Substance (concentration in product, % w/w) | Classification of the  substance  (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
| --- | --- | --- | --- | --- |
| Toxicological properties of active substance(s) (relevant for classification of product) | Metazachlor (50% (w/w)) | Skin Sens. 1B; H317,  Carc. 2; H351 | Reg. 1272/2008 | Skin Sens. 1B; H317, Carc. 2; H351 |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | - | - | - | - |
| Further toxicological information | No data – not required |  |  |  |

\*Please use concentration range or concentration limit (e.g. 1-10% or > 1%) as provided in MSDS.

\*\*Material safety data sheet by the applicant

## Toxicological Evaluation of Groundwater Metabolites

Metabolites (479M04, 479M08, 479M09, 479M11 and 479M12) of metazachlor were ~~either~~ predicted to occur in groundwater at levels above 0.1 ug/L. Metabolites 470M04, 470M08 and 479M12 were already evaluated in the DAR on metazachlor and found to be not of toxicological relevance whereas the metabolites 479M09 and 479M11 were evaluated in the DAR on metazachlor as toxicologically relevant based on structure similarity with the parent compound which is classified as Carc. Cat. 2 (H351 ~~H315~~) under CLP Regs 1272/2008. Therefore, these two metabolites should not exceed the groundwater above the parametric drinking water limit of 0.1 µg/L according to environmental exposure assessment. But it was seen through the FOCUS groundwater scenarios that these two toxicologically relevant metabolites were found to be more than 0.1 µg/L.

Therefore, please, refer to fate and behaviour sections dRR part B8 and dRR part B10 for all the details of the vulnerable groundwater situations and their refinements, as well as for results of toxicity studies for metabolites.

## Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 148000 A / METROPOLITAN are presented in the following table.

Table 6.5‑1: Dermal absorption rates for active substances in SHA 148000 A / METROPOLITAN

|  | Metazachlor | |
| --- | --- | --- |
|  | Value | Reference |
| Concentrate | 10% | EFSA Journal 2017;15(6):4873 |
| Dilution | 50% | EFSA Journal 2017;15(6):4873 |

### Justification for proposed values – Metazachlor

No data on dermal absorption for Metazachlor in SHA 148000 A / METROPOLITAN is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5‑2: Default dermal absorption rates for Metazachlor

|  | Value | Justification for value | Acceptability of justification |
| --- | --- | --- | --- |
| Concentrate | 10% | A default dermal absorption value of 10% may be applied for concentrated products that are water-based/dispersed. | Yes |
| Dilution | 50% | A default dermal absorption value of 50% may be applied for (in use) dilutions water-based/dispersed. | Yes |

## Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6‑1: Product information and toxicological reference values used for exposure assessment

|  |  |
| --- | --- |
| Product name and code | SHA 148000 A / METROPOLITAN |
| Formulation type | SC |
| Category | Herbicide |
| Active substance(s) (incl. content) | **Metazachlor**  500 g/L |
| AOEL systemic | 0,2 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | Concentrate: 10%  Dilution: 50% (Default) |

### Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1‑4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

There is only one intended GAP.

### Operator exposure (KCP 7.2.1)

#### Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 148000 A / METROPOLITAN according to the critical use(s) is presented in Table 6.6‑2. The outcome of the estimation is presented in Table 6.6‑3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6‑2: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Winter and spring oilseed rape (max. 1,5 L product/ha)  Cabbage, cauliflower (max. 2,0 L product/ha) |
| Model(s) | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

Table 6.6‑3: Estimated operator exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Metazachlor | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops (winter and spring oilseed rape) | | | |
| Application rate | | 0,75 kg a.s./ha | |
| **Spray application** (AOEM**;** 75th percentile)  Body weight: 60 kg | Potential exposure | 0,2848 | 142 |
| Work wear (arms, body and legs covered) M/L and A | 0,1846 | 92 |
| Work wear (arms, body and legs covered) M/L and A + gloves M/L | 0.0534 | 26.7 |
| Tractor mounted boom spray application outdoors to low crops (cabbage, cauliflower) | | | |
| Application rate | | 1,0 kg a.s./ha | |
| **Spray application** (AOEM**;** 75th percentile)  Body weight: 60 kg | Potential exposure | 0,3601 | 180 |
| Work wear (arms, body and legs covered) M/L and A | 0.2348 | 117 |
| Work wear (arms, body and legs covered) M/L and A  + gloves M/L | 0,0710 | 36 |

**Conclusion**

According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable, using METROPOLITAN with tractor mounted spray application in winter and spring oilseed rape, without use of personal protective equipment.

According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable, using METROPOLITAN with tractor mounted spray application in cabbage and cauliflower, with use of adequate work clothing and gloves during mixing and loading.

**Implication for labelling:** P280: Wear protective gloves, protective clothing.

**zRMS**:

The potential exposure to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN of operator applying this product on winter and spring oilseed rape at maximal dose of 1.5 L product/ha (0,75 kg a.s./ha) or on cabbage/cauliflower at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM is well above AOEL of metazachlor.

The exposure to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN of operator wearing work wear covering arms, body and legs and applying this product on winter and spring oilseed rape at maximal dose of 1.5 L product/ha (0,75 kg a.s./ha) calculated with the EFSA AOEM amounted to 92% of AOEL, and in case operator is wearing additionally protective gloves during mixing/loading to 27% of AOEL.

The exposure to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN of operator wearing work wear covering arms, body and legs and applying this product on cabbage/cauliflower at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha) using tractor-mounted/trailed boom sprayer, calculated with the EFSA AOEM amounted to 117% of AOEL, and in case operator is wearing additionally protective gloves during mixing/loading to 36% of AOEL.

Summing up the application of product SHA 148000 A / METROPOLITAN does not pose an unacceptable risk to the health of operator during its intended use within good agricultural practice providing that operator is wearing work wear covering arms, body and legs during mixing/loading and application and protective gloves during mixing and loading.

#### Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

### Worker exposure (KCP 7.2.3)

#### Estimation of worker exposure

Table 6.6‑4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 148000 A / METROPOLITAN according to the critical use(s). Outcome of the estimation is presented in Table 6.6‑5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6‑4: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Winter and spring oilseed rape (max. 1 x 1,5 L product/ha)  Cabbage, cauliflower (max. 1 x 2,0 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

Table 6.6‑5: Estimated worker exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Metazachlor | |
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| **Winter and spring oilseed rape** | | | |
| Inspection, irrigation  Outdoor  Work rate: 2 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 0,75 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 12500 cm2/person/h | 0,4688 | 234 |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0,0525 | 26 |
| Work wear (arms, body and legs covered) and gloves  TC: not available for this assessment | \_ | \_ |
| **Cabbage, cauliflower** | | | |
| Inspection, irrigation  Outdoor  Work rate: 2 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 1,0 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 12500 cm2/person/h | 0,6250 | 313 |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0,0700 | 35 |
| Work wear (arms, body and legs covered) and gloves  TC: not available for this assessment | \_ | \_ |

|  |  |  |  |
| --- | --- | --- | --- |
| **Cabbage, cauliflower** | | | |
| Reaching, picking  Outdoor  Work rate: 8 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 1,0 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 5800 cm2/person/h | 1,1600 | 580 |
| Work wear (arms, body and legs covered)  TC: 2500 cm2/person/h | 0,5000 | 250 |
| Work wear (arms, body and legs covered) and gloves  TC: 580 cm2/person/h | 0,1160 | 58 |

**Conclusion**

According to the EFSA calculator, it can be concluded there is no unacceptable risk anticipated for the worker wearing adequate work clothing without gloves for inspection/irrigation activities for re-entering: winter, spring oilseed rape, cabbage and cauliflower treated with METROPOLITAN.

According to the EFSA calculator, it can be concluded there is no unacceptable risk anticipated for the worker wearing adequate work clothing and gloves for reaching, picking activities for re-entering cabbage and cauliflower treated with METROPOLITAN.

**zRMS**:

The exposure to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 2 hours for inspection a field of winter and spring oilseed rape treated with this product at maximal dose 1.5 L product/ha (0,75 kg a.s./ha) or a field of cabbage/cauliflower treated at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM is below AOEL of metazachlor, thus does not pose a systemic health risk.

The exposure to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN of worker not wearing PPE (gloves) but wearing a work clothing (long sleeved shirt, long trousers) and entering for 8 hours for reaching, picking a field of cabbage/cauliflower treated at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM is above AOEL of metazachlor, thus it does pose a systemic health risk, however in case a worker is wearing protective gloves an exposure is reduced to 58% of AOEL, thus a risk is acceptable.

Thus, it is concluded that the application of a product SHA 148000 A / METROPOLITAN does not pose an unacceptable risk to the health of worker due to its intended use within good agricultural practice providing that the worker is wearing a work clothing (long sleeved shirt, long trousers) during 2hrs inspection and a work clothing (long sleeved shirt, long trousers) and protective gloves during 8hrs reaching/ picking cabbage/cauliflower.

#### Refinement of generic DFR value (KCP 7.2)

Not required.

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 μg/cm2 (30 mg a.s./m2).

#### Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

### Resident and bystander exposure (KCP 7.2.2)

#### Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6‑6 shows the exposure model(s) used for estimation of resident and bystander exposure to Metazachlor. The outcome of the estimation is presented in Table 6.6-7 (longer term resident exposure). Detailed calculations are in Appendix 3.

Table 6.6‑6: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Winter and spring oilseed rape (max. 1 x 1,5 L product/ha)  Cabbage, cauliflower (max. 1 x 2,0 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874  calculator version: 30/03/2015 |

Table 6.6‑7: Estimated resident exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Metazachlor | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops (winter and spring oilseed rape)  Buffer zone: 2-3(m)  Drift reduction technology: no  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 0,75 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0,0504 | 25,18 |
| Vapour (75th perc.) | 0,0011 | 0,54 |
| Deposits (75th perc.) | 0,0061 | 3,03 |
| Re-entry (75th perc.) | 0,0633 | 31,64 |
| **Sum (mean)** | 0,0837 | 41,85 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0,0121 | 6,03 |
| Vapour (75th perc.) | 0,0002 | 0,12 |
| Deposits (75th perc.) | 0,0026 | 1,28 |
| Re-entry (75th perc.) | 0,0352 | 17,58 |
| **Sum (mean**) | 0,0359 | 17,93 |
| Tractor mounted boom spray application outdoors to low crops (cabbage and cauliflower)  Buffer zone: 2-3(m)  Drift reduction technology: no  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 1,0 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0,0671 | 33,57 |
| Vapour (75th perc.) | 0,0011 | 0,54 |
| Deposits (75th perc.) | 0,0081 | 4,05 |
| Re-entry (75th perc.) | 0,0844 | 42,19 |
| **Sum (mean)** | 0,1113 | 55,63 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0,0161 | 8,03 |
| Vapour (75th perc.) | 0,0002 | 0,12 |
| Deposits (75th perc.) | 0,0034 | 1,70 |
| Re-entry (75th perc.) | 0,0469 | 23,44 |
| **Sum (mean**) | 0,0477 | 23,87 |

**Conclusion**

According to the EFSA AOEM Model, it can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to METROPOLITAN.

**Implication for labelling:** None

**zRMS**:

The exposure estimation of residents (adult and child) to Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN applied on a field of winter and spring oilseed rape treated with this product at maximal dose 1.5 L product/ha (0,75 kg a.s./ha) or on a field of cabbage/cauliflower treated at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha) as foreseen in GAP, calculated with the EFSA AOEM demonstrates that such a exposure in both cases is well below AOEK, therefore the application of product SHA 148000 A / METROPOLITAN does not pose an unacceptable risk to the health of adult and child resident for its intended use within good agricultural practice.

No bystander acute exposure estimation for Metazachlor, an active substance of a product SHA 148000 A / METROPOLITAN) is required since no acute acceptable operator exposure value (AAOEL) has be set for any of this active substance. Therefore, as indicated in the EU guidance (SANTE-10832-2015 rev. 1.7; 24 January 2017), no unacceptable risk is expected for bystanders due to short-term single exposure to Metazachlor as a result of application of a product SHA 148000 A / METROPOLITAN with accordance with intended use within good agricultural practice.

Summing up an application of a product SHA 148000 A / METROPOLITAN on a field of winter and spring oilseed rape treated with this product at maximal dose 1.5 L product/ha or on a field of cabbage/cauliflower treated at maximal dose of 2.0 L product/ha (1.0 kg a.s./ha), using tractor-mounted/trailed boom sprayer in line with GAP does not pose an unacceptable health risk for residents and bystanders.

#### Measurement of resident and/or bystander exposure

Since the resident and/or bystander exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for Metazachlor will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

### Combined exposure

Not relevant. The product contains only one active substance.

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

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

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

No additional study submitted.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

1. Detailed evaluation of the studies relied upon
   1. Statement on bridging possibilities

Not relevant.

* 1. Acute oral toxicity (KCP 7.1.1)

|  |  |
| --- | --- |
| Comments of zRMS: | Calculation and conclusion provided by the applicant is acceptable. Metazachlor 50% SC/Metropolitan does not require classification for acute oral toxicity. |

The classification of Metazachlor 50% SC was performed by calculation. The assessment of all acute toxicological properties of Metazachlor 50% SC is derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Formulant** | **% of formulation** | **Acute Oral Toxicity** | **Acute Dermal Toxicity** | **Acute Inhalation Toxicity** | **Dermal Irritation** | **Ocular Irritation** | **Sensitising potential** |
| Metazachlor technical  (CAS: 67129-08-2) | **44.03** | >2000 mg/kg1) | >2000 mg/kg1) | >34.5 m/l/4 h | Not Irritating1) | Not Irritating1) | Skin Sens.1 H317 |
| Co-formulant 1 | **xxx** | >22000 mg/kg1) | >2000 mg/kg 1) | > 317042 m/l | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 2 | **xxx** | >5000 mg/kg1) | >2000 mg/kg1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 3 | **xxx** | 500 mg/kg2)  H302 | >2000 mg/kg1) | \* | Not Irritating1) | Eye Dam. 1, H318 | \* |
| Co-formulant 4 | **xxx** | \* | \* | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 5 | **xxx** | >2000 mg/kg1) | >2000 mg/kg1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |
| Co-formulant 6 | **xxx** | 500 mg/kg2)  H302 | \* | \* | Skin Corr. 1A, H314 | Eye Dam. 1, H318 | Skin Sens. 1  H317 |
| xxxxxxxxxxxx | xxx | 500 mg/kg2)  H302 | > 2000 mg/kg1) | \* | Skin Irrit. 2, H315 | Eye Dam. 1, H318 | Skin Sens. 1  H317 |
| xxxxxxxxxxxx | xxx | \* | \* | \* | Skin Corr. 1A, H314 | Eye Dam. 1, H318 | \* |
| Co-formulant 7 | **xxx** | > 2000 mg/kg1) | > 2000 mg/kg1) | \* | Not Irritating1) | Not Irritating1) | Not sensitising1) |

\* No Information / but in their MSDS are not classified acutely oral, dermal, inhalation toxic, not skin sensitising

1) As co-formulant is not classified

2) According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 4: H302.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

or

where:

Ci = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATEi = Acute Toxicity Estimate of ingredient i.

The acute oral toxicity classification for Metazachlor 50% SC is calculated:

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Metazachlor 50% SC can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

**Conclusion**

The acute oral toxicity of Metazachlor 50% SC was estimated to be > 2000 mg/kg.

Therefore, according to the Regulation EC No. 1272/2008, Metazachlor 50% SC is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Acute percutaneous (dermal) toxicity (KCP 7.1.2)

|  |  |
| --- | --- |
| Comments of zRMS: | Conclusion provided by the applicant is acceptable. Metazachlor 50% SC/Metropolitan does not require classification for acute dermal toxicity.  See part C |

Neither the active substance nor co-formulant in the Metazachlor 50% SC recipe classified as danger through dermal contact.

According to the Regulation EC No. 1272/2008, Metazachlor 50% SC is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Acute inhalation toxicity (KCP 7.1.3)

|  |  |
| --- | --- |
| Comments of zRMS: | Conclusion provided by the applicant is acceptable. Metazachlor 50% SC/Metropolitan does not require classification for acute inhalation toxicity.  See part C |

Neither the active substance nor co-formulant in the Metazachlor 50% SC recipe are classified as danger through inhalation.

According to the Regulation EC No. 1272/2008, Metazachlor 50% SC is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Skin irritation (KCP 7.1.4)

|  |  |
| --- | --- |
| Comments of zRMS: | Calculation and conclusion provided by the applicant is acceptable. Metazachlor 50% SC/Metropolitan does not require classification for skin irritation.  See part C |

The product contains co-formulants:

Co-formulant 6: xxx% H315

Co-formulant 6: xxx% H314

Calculation method in Regulation No. 1272/2008: (10 × Skin Corrosive Category 1A) + Skin irritant Category 2:

(10 x xxx%) + xxx% = 0.1% < 10%

The sum of the corrosive and irritating ingredients of Metazachlor 50% SC is < 10% and below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

**Conclusion**

According to the Regulation EC No. 1272/2008, Metazachlor 50% SC is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Eye irritation (KCP 7.1.5)

|  |  |
| --- | --- |
| Comments of zRMS: | Calculation and conclusion provided by the applicant is acceptable. Metazachlor 50% SC/Metropolitan does not require classification for eye irritation.  See part C |

The product contains co-formulants:

Co-formulant 3: xxx% H318

Co-formulant 6: xxx% H318

Co-formulant 6: xxx% H318, H314

Calculation method in Regulation No. 1272/2008: Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1

xxx% + xxx% = 0.556% < 1%

The sum of the corrosive ingredients and ingredients seriously damaging to the eye of Metazachlor 50% SC is < 1% and below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

**Conclusion**

According to the Regulation EC No. 1272/2008, Metazachlor 50% SC is **not classified**. No signal word or hazard statement is required for this hazard.

* 1. Skin sensitisation (KCP 7.1.6)

|  |  |
| --- | --- |
| Comments of zRMS: | Calculation and conclusion provided by the applicant is acceptable, however since Metazachlor which is a main sensitising component, has harmonised classification Skin Sens. 1B, thus also entire formulation should have classification Skin Sens. 1B, H317  See part C |

The product contains > 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317). Under the GHS classification system this component does trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Metazachlor 50% SC is classified as Skin sensitisation, Category 1B (H317) with pictogram GHS07 and signal word “Warning”.

* 1. Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

* 1. Data on co-formulants (KCP 7.4)
     1. Material safety data sheet for each co-formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

* + 1. Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

* 1. Studies on dermal absorption (KCP 7.3)

|  |  |
| --- | --- |
| Comments of zRMS: | Using default values for dermal absorption according to EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 is acceptable |

According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 10% (concentrate) and 50% (diluted) of may be applied for products that are water-based/dispersed (c) or solid-formulated(d)

(c): Formulation types: soluble concentrate (SL), suspension concentrate (SC), flowable concentrate for seed treatment (FS), flowable (FL) (SC).

(d): Formulation types: wettable powder (WP), water-dispersible granules (WG/WDG), water-soluble granules (SG), water-soluble powder (SP), powder for dry seed treatment (DS).

* 1. Other/Special Studies

No new additional other/special studies.

1. Exposure calculations
   1. Operator exposure calculations (KCP 7.2.1.1)
      1. Calculations for Metazachlor

Table A 1: Input parameters considered for the estimation of operator exposure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Formulation type | SC | | Crop type | Winter and spring oilseed rape |
| Application rate (AR) | 0,75 | kg a.s./ha | Application method | Downward spraying |
| Area treated per day (A) | 50 | ha | Application equipment | Vehicle-mounted |
| Dermal absorption (DA) | 10 | % (concentr.) | Indoor/outdoor | Outdoor |
| 50 | % (dilution) | Closed cabin | No |
| Inhalation absorption (IA) | 100 | % | Drift reduction | No |
| Body weight (BW) | 60 | kg/person | Cultivation | Normal |
| AOEL | 0,2 | mg/kg bw/d | Water soluble bag | No |

Table A 2: Estimation of longer term operator exposure towards Metazachlor according to EFSA guidance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Potential | | With work wear + PPE/RPE | |
| Mixing and loading | | | | |
| Hands |  | | None | |
| Specific exposure value | 7908,5431920 | µg/person | 7908,5431920 | µg/person |
| **Systemic exposure** | **131,8090532** | **mg/kg bw/d** | **131,8090532** | **mg/kg bw/d** |
| Body |  | | Work wear | |
| Specific exposure value | 4557,8895729 | µg/person | 59,0424125 | µg/person |
| **Systemic exposure** | 75,9648262 | mg/kg bw/d | 0,9840402 | mg/kg bw/d |
| Head |  | | None | |
| Specific exposure value | 194,5634541 | µg/person | 194,5634541 | µg/person |
| **Systemic exposure** | 3,2427242 | mg/kg bw/d | 3,2427242 | mg/kg bw/d |
| Inhalation |  | | None | |
| Specific exposure value | 10,8850820 | µg/person | 10,8850820 | µg/person |
| **Systemic exposure** | 0,1814180 | mg/kg bw/d | 0,1814180 | mg/kg bw/d |
| Application | | | | |
| Hands |  | | None | |
| Specific exposure value | 2781,0633731 | µg/person | 2781,0633731 | µg/person |
| **Systemic exposure** | **46,3510562** | **mg/kg bw/d** | **46,3510562** | **mg/kg bw/d** |
| Body |  | | Work wear | |
| Specific exposure value | 1554,9875884 | µg/person | 42,6559334 | µg/person |
| **Systemic exposure** | **25,9164598** | **mg/kg bw/d** | **0,7109322** | **mg/kg bw/d** |
| Head |  | | None | |
| Specific exposure value | 73,4940408 | µg/person | 73,4940408 | µg/person |
| **Systemic exposure** | **1,2249007** | **mg/kg bw/d** | **1,2249007** | **mg/kg bw/d** |
| Inhalation |  | | None | |
| Specific exposure value | 6,3647455 | µg/person | 6,3647455 | µg/person |
| **Systemic exposure** | **0,1060791** | **mg/kg bw/d** | **0,1060791** | **mg/kg bw/d** |
| **Total** | | | | |
| Total systemic exposure | 0,2847965 | mg/kg bw/d | 0,1846102 | mg/kg bw/d |
| % of AOEL | 142,40 | % | 92,31 | % |

Table A 3: Input parameters considered for the estimation of operator exposure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Formulation type | SC | | Crop type | Cabbage, cauliflower |
| Application rate (AR) | 1,0 | kg a.s./ha | Application method | Downward spraying |
| Area treated per day (A) | 50 | ha | Application equipment | Vehicle-mounted |
| Dermal absorption (DA) | 10 | % (concentr.) | Indoor/outdoor | Outdoor |
| 50 | % (dilution) | Closed cabin | No |
| Inhalation absorption (IA) | 100 | % | Drift reduction | No |
| Body weight (BW) | 60 | kg/person | Cultivation | Normal |
| AOEL | 0,2 | mg/kg bw/d | Water soluble bag | No |

Table A 4: Estimation of longer term operator exposure towards Metazachlor according to EFSA guidance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Potential | | With work wear + PPE/RPE | |
| Mixing and loading | | | | |
| Hands |  | | Protective gloves | |
| Specific exposure value | 9869,1120188 | µg/person | 43,9304444 | µg/person |
| **Systemic exposure** | **164,4852003** | **mg/kg bw/d** | **0,7321741** | **mg/kg bw/d** |
| Body |  | | Work wear | |
| Specific exposure value | 5579,3934101 | µg/person | 76,1914156 | µg/person |
| **Systemic exposure** | 92,9898902 | mg/kg bw/d | 1,2698569 | mg/kg bw/d |
| Head |  | | None | |
| Specific exposure value | 259,4179388 | µg/person | 259,4179388 | µg/person |
| **Systemic exposure** | 4,3236323 | mg/kg bw/d | 4,3236323 | mg/kg bw/d |
| Inhalation |  | | None | |
| Specific exposure value | 11,8580554 | µg/person | 11,8580554 | µg/person |
| **Systemic exposure** | 0,1976343 | mg/kg bw/d | 0,1976343 | mg/kg bw/d |
| Application | | | | |
| Hands |  | | None | |
| Specific exposure value | 3708,0844975 | µg/person | 3708,0844975 | µg/person |
| **Systemic exposure** | **61,8014083** | **mg/kg bw/d** | **61,8014083** | **mg/kg bw/d** |
| Body |  | | Work wear | |
| Specific exposure value | 2073,3167845 | µg/person | 56,8745779 | µg/person |
| **Systemic exposure** | **34,5552797** | **mg/kg bw/d** | **0,9479096** | **mg/kg bw/d** |
| Head |  | | None | |
| Specific exposure value | 97,9920543 | µg/person | 97,9920543 | µg/person |
| **Systemic exposure** | **1,6332009** | **mg/kg bw/d** | **1,6332009** | **mg/kg bw/d** |
| Inhalation |  | | None | |
| Specific exposure value | 7,3514897 | µg/person | 7,3514897 | µg/person |
| **Systemic exposure** | **0,1225248** | **mg/kg bw/d** | **0,1225248** | **mg/kg bw/d** |
| **Total** | | | | |
| Total systemic exposure | 0,3601088 | mg/kg bw/d | 0,0710283 | mg/kg bw/d |
| % of AOEL | 180,05 | % | 35,51 | % |

zRMS estimation of operator exposure applying product Metropolitan on winter and spring oilseed rape at dose of 0.75 kg a.s./ha



ZRMS estimation of operator exposure applying product Metropolitan on cabbage at dose of 1kg a.s./ha



* 1. Worker exposure calculations (KCP 7.2.3.1)
     1. Calculations for Metazachlor

Table A 5: Input parameters considered for the estimation of worker exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use(s) | Winter and spring oilseed rape, inspection, irrigation, outdoor | | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s./ha |
| Application rate (AR) | 0,75 | kg a.s./ha | Dermal absorption (DA) | 50 | % (worst case) |
| Number of applications (NA) | 1 |  | Inhalation absorption (IA) | 100 | % |
| Interval between applications | 365 | days | Work rate per day (WR) | 2 | h/d |
| Half-life of active substance | 30 | days | TC dermal (potential) | 12500 | cm2/h |
| Multiple application factor (MAF) | 1,0 |  | TC dermal (work wear) | 1400 | cm2/h |
| Body weight (BW) | 60 | kg/person | TC dermal (work wear, gloves) | - | cm2/h |
| AOEL | 0,2 | mg/kg bw/d | Task specific factor inhalation | - | ha/h x 10-3 |

Table A 6: Estimation of longer term worker exposure towards Metazachlor according to EFSA guidance

|  | Potential | | With work wear | | With work wear and gloves | |
| --- | --- | --- | --- | --- | --- | --- |
| Worker (re-entry): Dermal exposure after application | | | | | | |
| (DFR x TC x WR x AR x MAF x DA) / BW | | | | | | |
| Systemic exposure | 0,4687500 | mg/kg bw/d | 0,0525000 | mg/kg bw/d | - | mg/kg bw/d |
| % of AOEL | 234,38 | % | 26,25 | % | - | % |

Table A 7: Input parameters considered for the estimation of worker exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use(s) | Cabbage, cauliflower, inspection, irrigation, outdoor | | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s./ha |
| Application rate (AR) | 1,0 | kg a.s./ha | Dermal absorption (DA) | 50 | % (worst case) |
| Number of applications (NA) | 1 |  | Inhalation absorption (IA) | 100 | % |
| Interval between applications | 365 | days | Work rate per day (WR) | 2 | h/d |
| Half-life of active substance | 30 | days | TC dermal (potential) | 12500 | cm2/h |
| Multiple application factor (MAF) | 1,0 |  | TC dermal (work wear) | 1400 | cm2/h |
| Body weight (BW) | 60 | kg/person | TC dermal (work wear, gloves) | - | cm2/h |
| AOEL | 0,2 | mg/kg bw/d | Task specific factor inhalation | - | ha/h x 10-3 |

Table A 8: Estimation of longer term worker exposure towards Metazachlor according to EFSA guidance

|  | Potential | | With work wear | | With work wear and gloves | |
| --- | --- | --- | --- | --- | --- | --- |
| Worker (re-entry): Dermal exposure after application | | | | | | |
| (DFR x TC x WR x AR x MAF x DA) / BW | | | | | | |
| Systemic exposure | 0,6250000 | mg/kg bw/d | 0,0700000 | mg/kg bw/d | - | mg/kg bw/d |
| % of AOEL | 312,50 | % | 35,00 | % | - | % |

Table A 9: Input parameters considered for the estimation of worker exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use(s) | Cabbage, cauliflower, reaching, picking, outdoor | | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s./ha |
| Application rate (AR) | 1,0 | kg a.s./ha | Dermal absorption (DA) | 50 | % (worst case) |
| Number of applications (NA) | 1 |  | Inhalation absorption (IA) | 100 | % |
| Interval between applications | 365 | days | Work rate per day (WR) | 8 | h/d |
| Half-life of active substance | 30 | days | TC dermal (potential) | 5800 | cm2/h |
| Multiple application factor (MAF) | 1,0 |  | TC dermal (work wear) | 2500 | cm2/h |
| Body weight (BW) | 60 | kg/person | TC dermal (work wear, gloves) | 580 | cm2/h |
| AOEL | 0,2 | mg/kg bw/d | Task specific factor inhalation | - | ha/h x 10-3 |

Table A 10: Estimation of longer term worker exposure towards Metazachlor according to EFSA guidance

|  | Potential | | With work wear | | With work wear and gloves | |
| --- | --- | --- | --- | --- | --- | --- |
| Worker (re-entry): Dermal exposure after application | | | | | | |
| (DFR x TC x WR x AR x MAF x DA) / BW | | | | | | |
| Systemic exposure | 1,1600000 | mg/kg bw/d | 0,5000000 | mg/kg bw/d | 0,1160000 | mg/kg bw/d |
| % of AOEL | 580,00 | % | 250,00 | % | 58,00 | % |

* 1. Resident and bystander exposure calculations (KCP 7.2.2.1)
     1. Calculations for Metazachlor

Table A 11: Input parameters considered for the estimation of longer term resident exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use(s) | Winter and spring oilseed rape, downward spraying | | Drift reduction (DR) |  | % |
| Application rate (AR) | 0,75 | kg a.s./ha | Transfer coefficient surface deposits (TC) | 7300 | cm2/h (adult) |
| 2600 | cm2/h (child) |
| Minimum water volume (V) | 200 | L/ha | Drift on surface (D) - 75th perc. | 5,60 | % |
| Buffer strip | 2-3 | m | Drift on surface (D) - mean | 4,10 | % |
| Number of applications (NA) | 1 |  | Turf Transferable Residues (TTR) | 5 | % |
| Interval between applications | 365 | days | Exposure duration dermal (HD) | 2 | h |
| Half-life of active substance | 30 | days | Exposure duration inhal. (HI) | 24 | h |
| Multiple application factor (MAF) | 1,0 |  | Exposure duration entry into treated crops (HE) | 0.25 | h |
| Body weight (BW) | 60 | kg/person (adults) | Airborne Concentration of Vapour (VC) | 0,001 | mg/m3 |
| 10 | kg/person (children) |
| Dermal absorption (DA) | 50 | % ('worst case') | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s. |
| Inhalation absorption (IA) | 100 | % | Light clothing adjustment factor (CF) | 18 | % |
| Oral absorption (OA) | 100 | % | Saliva Extraction Factor (SE) | 50 | % |
| AOEL | 0,2 | mg/kg bw/d | Surface Area of Hands (SA) | 20 | cm2 |
| Spray drift dermal (SD) - 75th perc. | 0.47 | mL spray dilution (adult) | Frequency of Hand to Mouth (Freq) | 20 | events/h |
| 0.327 | mL spray dilution (child) |
| Spray drift inhal. (SI) - 75th perc. | 0.00010 | mL spray dilution (adult) | Dislodgeable residues object to mouth (DROM) | 20 | % |
| 0.00022 | mL spray dilution (child) |
| Spray drift dermal (SD) - mean | 0.22318 | mL spray dilution (adult) | Ingestion Rate for Mouthing of Grass (IgR) | 25 | cm2/d |
| 0.18 | mL spray dilution (child) |
| Spray drift inhal. (SD) - mean | 0.00009 | mL spray dilution (adult) | TC entry into treated crops - 75th perc. | 7500 | cm2/h (adult) |
| 0.00017 | mL spray dilution (child) | 2250 | cm2/h (child) |
| Inhalation rate (IR) | 16.57 | m3/d (adult) | TC entry into treated crops - mean: | 5980 | cm2/h (adult) |
| 8.31 | m3/d (child) | 1794 | cm2/h (child) |

Table A 12: Estimation of longer term resident exposure towards Metazachlor according to EFSA guidance

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adult | | | Child | | | | | | |
| Spray drift (75th perc.) | | | | | | | | | |
| (SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW | | | | | | | | | |
| **Systemic exposure** | **0,0120500** | **mg/kg bw/d** | **Systemic exposure** | | **0,0503588** | **mg/kg bw/d** | | | |
| % of AOEL: | 6,03 | % | % of AOEL: | | 25,18 | % | | | |
| Vapour (75th perc.) | | | | | | | | | |
| (VC x IR x IA) / BW | | | | | | | | | |
| **Systemic exposure** | **0,0002300** | **mg/kg bw/d** | **Systemic exposure** | | **0,0010700** | **mg/kg bw/d** | | | |
| % of AOEL: | 0,12 | % | % of AOEL: | | 0,54 | % | | | |
| Surface deposits (75th perc.) | | | | | | | | | |
| Dermal | | | | | | | | | |
| AR x MAF x D x TTR x TC x HD x DA / BW | | | | | | | | | |
| **Systemic exposure** | **0,0025550** | **mg/kg bw/d** | **Systemic exposure** | | **0,0054600** | **mg/kg bw/d** | | | |
| Hand to mouth | | | | | | | | | |
| AR x MAF x D x TTR x SE x SA x Freq x HD x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | | **0,0003990** | **mg/kg bw/d** | | | |
| Object to mouth | | | | | | | | | |
| AR x MAF x D x DROM x IgR x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | | **0,0002100** | **mg/kg bw/d** | | | |
| **Total** | | | | | | | | | |
| **Systemic exposure** | **0,0025550** | **mg/kg bw/d** | **Systemic exposure** | | **0,0060690** | **mg/kg bw/d** | | | |
| % of AOEL: | 1,28 | % | % of AOEL: | | 3,03 | % | | | |
| Entry into treated crops (75th perc.) | | | | | | | | | |
| Dermal | | | | | | | | | |
| AR x MAF x TC x HD x DFR x DA / BW | | | | | | | | | |
| **Systemic exposure** | **0,0351563** | **mg/kg bw/d** | **Systemic exposure** | | **0,0632813** | **mg/kg bw/d** | | | |
| Hand to mouth | | | | | | | | | |
| AR x MAF x 100% x TTR x x SE x SA x Freq x HD x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | |  | **mg/kg bw/d** | | | |
| Object to mouth | | | | | | | | | |
| AR x MAF x 100% x DROM x IgR x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | |  | **mg/kg bw/d** | | | |
| **Total** | | | | | | | | | |
| **Systemic exposure** | **0,0351563** | **mg/kg bw/d** | **Systemic exposure** | | **0,0632813** | **mg/kg bw/d** | | | |
| % of AOEL: | 17,58 | % | % of AOEL: | | 31,64 | % | | | |
| **All pathways (mean)** | | | | | | | | | |
| **Systemic exposure** | | | **0,0358565** | **mg/kg bw/d** | **Systemic exposure** | | | **0,0837084** | **mg/kg bw/d** |
| % of AOEL: | 17,93 | % | % of AOEL: | | | 41,85 | % | | |

Table A 13: Input parameters considered for the estimation of longer term resident exposure

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use(s) | Cabbage, cauliflower, downward spraying | | Drift reduction (DR) |  | % |
| Application rate (AR) | 1,0 | kg a.s./ha | Transfer coefficient surface deposits (TC) | 7300 | cm2/h (adult) |
| 2600 | cm2/h (child) |
| Minimum water volume (V) | 200 | L/ha | Drift on surface (D) - 75th perc. | 5,60 | % |
| Buffer strip | 2-3 | m | Drift on surface (D) - mean | 4,10 | % |
| Number of applications (NA) | 1 |  | Turf Transferable Residues (TTR) | 5 | % |
| Interval between applications | 365 | days | Exposure duration dermal (HD) | 2 | h |
| Half-life of active substance | 30 | days | Exposure duration inhal. (HI) | 24 | h |
| Multiple application factor (MAF) | 1,0 |  | Exposure duration entry into treated crops (HE) | 0.25 | h |
| Body weight (BW) | 60 | kg/person (adults) | Airborne Concentration of Vapour (VC) | 0,001 | mg/m3 |
| 10 | kg/person (children) |
| Dermal absorption (DA) | 50 | % ('worst case') | Dislodgeable foliar residue (DFR) | 3 | µg/cm2/kg a.s. |
| Inhalation absorption (IA) | 100 | % | Light clothing adjustment factor (CF) | 18 | % |
| Oral absorption (OA) | 100 | % | Saliva Extraction Factor (SE) | 50 | % |
| AOEL | 0,2 | mg/kg bw/d | Surface Area of Hands (SA) | 20 | cm2 |
| Spray drift dermal (SD) - 75th perc. | 0.47 | mL spray dilution (adult) | Frequency of Hand to Mouth (Freq) | 20 | events/h |
| 0.327 | mL spray dilution (child) |
| Spray drift inhal. (SI) - 75th perc. | 0.00010 | mL spray dilution (adult) | Dislodgeable residues object to mouth (DROM) | 20 | % |
| 0.00022 | mL spray dilution (child) |
| Spray drift dermal (SD) - mean | 0.22318 | mL spray dilution (adult) | Ingestion Rate for Mouthing of Grass (IgR) | 25 | cm2/d |
| 0.18 | mL spray dilution (child) |
| Spray drift inhal. (SD) - mean | 0.00009 | mL spray dilution (adult) | TC entry into treated crops - 75th perc. | 7500 | cm2/h (adult) |
| 0.00017 | mL spray dilution (child) | 2250 | cm2/h (child) |
| Inhalation rate (IR) | 16.57 | m3/d (adult) | TC entry into treated crops - mean: | 5980 | cm2/h (adult) |
| 8.31 | m3/d (child) | 1794 | cm2/h (child) |

Table A 14: Estimation of longer term resident exposure towards Metazachlor according to EFSA guidance

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adult | | | Child | | | | | | |
| Spray drift (75th perc.) | | | | | | | | | |
| (SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW | | | | | | | | | |
| **Systemic exposure** | **0,0160667** | **mg/kg bw/d** | **Systemic exposure** | | **0,0671450** | **mg/kg bw/d** | | | |
| % of AOEL: | 8,03 | % | % of AOEL: | | 33,57 | % | | | |
| Vapour (75th perc.) | | | | | | | | | |
| (VC x IR x IA) / BW | | | | | | | | | |
| **Systemic exposure** | **0,0002300** | **mg/kg bw/d** | **Systemic exposure** | | **0,0010700** | **mg/kg bw/d** | | | |
| % of AOEL: | 0,12 | % | % of AOEL: | | 0,54 | % | | | |
| Surface deposits (75th perc.) | | | | | | | | | |
| Dermal | | | | | | | | | |
| AR x MAF x D x TTR x TC x HD x DA / BW | | | | | | | | | |
| **Systemic exposure** | **0,0034067** | **mg/kg bw/d** | **Systemic exposure** | | **0,0072800** | **mg/kg bw/d** | | | |
| Hand to mouth | | | | | | | | | |
| AR x MAF x D x TTR x SE x SA x Freq x HD x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | | **0,0005320** | **mg/kg bw/d** | | | |
| Object to mouth | | | | | | | | | |
| AR x MAF x D x DROM x IgR x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | | **0,0002800** | **mg/kg bw/d** | | | |
| **Total** | | | | | | | | | |
| **Systemic exposure** | **0,0034067** | **mg/kg bw/d** | **Systemic exposure** | | **0,0080920** | **mg/kg bw/d** | | | |
| % of AOEL: | 1,70 | % | % of AOEL: | | 4,05 | % | | | |
| Entry into treated crops (75th perc.) | | | | | | | | | |
| Dermal | | | | | | | | | |
| AR x MAF x TC x HD x DFR x DA / BW | | | | | | | | | |
| **Systemic exposure** | **0,0468750** | **mg/kg bw/d** | **Systemic exposure** | | **0,0843750** | **mg/kg bw/d** | | | |
| Hand to mouth | | | | | | | | | |
| AR x MAF x 100% x TTR x x SE x SA x Freq x HD x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | |  | **mg/kg bw/d** | | | |
| Object to mouth | | | | | | | | | |
| AR x MAF x 100% x DROM x IgR x OA / BW | | | | | | | | | |
|  |  |  | **Systemic exposure** | |  | **mg/kg bw/d** | | | |
| **Total** | | | | | | | | | |
| **Systemic exposure** | **0,0468750** | **mg/kg bw/d** | **Systemic exposure** | | **0,0843750** | **mg/kg bw/d** | | | |
| % of AOEL: | 23,44 | % | % of AOEL: | | 42,19 | % | | | |
| **All pathways (mean)** | | | | | | | | | |
| **Systemic exposure** | | | **0,0477320** | **mg/kg bw/d** | **Systemic exposure** | | | **0,1112545** | **mg/kg bw/d** |
| % of AOEL: | 23,87 | % | % of AOEL: | | | 55,63 | % | | |

1. Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Not relevant.