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| FINAL REGISTRATION REPORT  Part B  Section 9  Ecotoxicology  Detailed summary of the risk assessment |
| Product code: 054-01-05  Product name(s): Meso-Iodo OD-Life  Chemical active substance(s):  Mesosulfuron-methyl, 10 g/L  Iodosulfuron-methyl-sodium, 2 g/L  Safener: Mefenpyr-diethyl, 30 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland  Concerned Member State: Germany |
| CORE ASSESSMENT  (Article 34 Application) |
| Applicant: Life Scientific Ltd.  Submission date: November 2023  MS Finalisation date: 12.2023 ; 04.2024 |

Version history

|  |  |
| --- | --- |
| When | What |
| November 2023 | Following a request by IOS the applicant has provided a full dRR Part B9 |
| December 2023 | zRMs evaluated dRR submitted by Applicant |
| April 2024 | Final Report after commenting period |
|  |  |

**ZRMS Final Conclusion:**

All data referred to endpoints for iodosulfuron-methyl-sodium and mesosulfuron-methyl are in line EFSA conclusion (EFSA Journal 2016;14(4):4453 and EFSA Journal 2016;14(10): 4584 and are accepted by evaluator.

The proposed GAP of Meso-Iodo OD-Life is covered by the assessment contained in plant protected product of Atlantis 12 OD and is accepted for used in Meso-Iodo OD-Life.

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# Ecotoxicology (KCP 10)

This application is being submitted to support the registration of Meso-Iodo OD-Life, an oil dispersion (OD) formulation containing 10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl in Poland under Regulation (EC) 1107/2009. As the applicant also intends to register the product in Germany, they have been listed as a ‘concerned’ Member State (cMS). This evaluation is required subsequent to the inclusion of mesosulfuron-methyl on Annex I of Directive 91/414/EEC under Commission Directive 2003/119/EC on 1st April 2004. Mesosulfuron-methyl was renewed under Implementing Regulation (EU) 2017/755 on 1st July 2017. Iodosulfuron-methyl-sodium was included on Annex I of Directive 91/414/EEC under Commission Directive 2003/84/EC on 1st January 2004. Iodosulfuron-methyl-sodium was renewed under Implementing Regulation (EU) 2017/407 on 1st April 2017. Meso-Iodo OD-Life will be referred to as product 054-01-05 for the remainder of this document.

Product 054-01-05 is a professional use herbicide formulated as an oil dispersion containing 10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl. The product has not previously been evaluated in Poland according to Uniform Principles.

The sources of mesosulfuron-methyl (source 1 (20151195 PWSG), source 2 (20190977 PWSG)) and iodosulfuron-methyl-sodium (20150953 PWSG) have previously been assessed by the CTGB in the Netherlands and deemed technically equivalent to the Annex I reference source. The source of iodosulfuron-methyl-sodium was later assessed by the Central Institute for Supervising and Testing in Agriculture (UKZUZ 038555/2022) in the Czech Republic following Annex I renewal, where it was concluded that the source still met the specification listed in the renewal regulation. The results of each of these assessments were sent to Member States for commenting. Details of the evaluations are available on CIRCA BC.

As part of this application, Life Scientific Ltd. wishes to have the proposed formulation assessed for comparability to the Polish reference product Atlantis 12 OD (10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl, OD, authorisation number R-98/2009) of Bayer AG. The applicant considers product 054-01-05 to be comparable, if not identical to Atlantis 12 OD: details provided in Table 1.2-1 in the confidential dossier of this submission (Draft Registration Report – Part C). The uses and claims for which approval is being sought are the same as those already approved for Atlantis 12 OD in Poland.

Atlantis 12 OD (authorisation number R-98/2009) was first authorised on 14th August 2009 and re-registered on 24th August 2020. Given the 30-month data protection period for Atlantis 12 OD and the associated active substances, namely Mesosulfuron-methyl and Iodosulfuron-methyl-sodium, expired in February 2023, a new application is being submitted to apply for the authorisation of product 054-01-05 in Poland, whereby the applicant submits that it is scientifically valid to extrapolate data and information submitted by Bayer AG on Atlantis 12 OD and use it to evaluate product 054-01-05. This includes the data supporting uses that were applied for after the introduction of Regulation 1107 on 14th of June 2011. According to Paragraph 22 of Commission Notice - Technical Guidelines on Data Protection according to Regulation (EC) No. 1107/2009, 2019/C 229/01, new use data attracts 10 years protection from the date of first authorisation of that product in each Member State (not the date of authorisation of the new crop). Therefore, under Regulation 1107, new use data attracts zero data protection when the original 10-year data protection of the product has expired.

The ecotoxicity of the active substance iodosulfuron-methyl-sodium in the environment has been evaluated on EU level according to the Commission Regulation (EU) No. 1107/2009, full details are provided in the EU renewal assessment report and related documents and are summarised in the EFSA conclusion (EFSA Journal 2016;14(4):4453).

The ecotoxicity of the active substance mesosulfuron-methyl in the environment has been evaluated on EU level according to the Commission Regulation (EU) No. 1107/2009, full details are provided in the EU renewal assessment report and related documents and are summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584).

The ecotoxicity of the safener mefenpyr-diethylhave been reviewed in a work-sharing project of European competent authorities, in analogy to the procedures foreseen for active substances in Directive 91/414/EEC: France and Austria prepared an assessment report for this substance in the format of a Draft Assessment Report which was “peer-reviewed” (in an unscheduled procedure on voluntary basis) by all Member States in September 2011. The revised assessment report can be found on CIRCA (Archive individual substances – Mefenpyr-diethyl (safener)).

The remainder of this document is addressed by inclusion of out of protection data in the DAR/RAR for both iodosulfuron-methyl-sodium and mesosulfuron-methyl, and the Atlantis 12 OD re-registration report submitted by Bayer AG.

## Critical GAP and overall conclusions

Table 9.1‑1: Table of critical GAPs

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No. | Member state(s) | Crop and/or situation  (crop 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) | L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g a.s./ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max | Birds | Mammals | Aquatic organisms | Bees | Non-target arthropods | Soil organisms | Non-target plants |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | | | | | | | |
| 1 | DE | Winter soft wheat (TRZAW),  Winter rye (SECCW),  Winter triticale  (TTKWI) | F | Silky bent APESV | spraying | 11-25  Post-emergence, autumn | a) 1  b) 1 | -- | 0.6 L/ha | (a.s.1) 1.2 g as/ha  (a.s. 2) 6.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 2 | DE | Winter soft wheat (TRAZW),  Winter triticale (TTLWI) | F | Black twitch ALOMY,  Silky bent APESV  Annual meadowgrass POAAN,  Rough meadowgrass POATR,  Common chickweed STEME,  *Matricaria sp.* MATSS | spraying | 11-25  Post-emergence, autumn | a) 1  b) 1 | -- | 1.0 L/ha | (a.s.1) 2.0 g as/ha  (a.s. 2) 10.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 3 | DE | Winter soft wheat  (TRZAW) | F | Black twitch ALOMY,  Barren bromegrass BROST,  *Lolium sp.* LOLSS,  Annual dicotyledonous weeds TTTDS | spraying | 11-25  Post-emergence, autumn | a) 1  b) 1 | -- | 1.2 L/ha | (a.s. 1) 2.4 g as/ha  (a.s. 2) 12.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 4 | DE | Winter soft wheat (TRZAW),  Winter rye (SECCW),  Winter triticale  (TTKWI) | F | Silky bent APESV | spraying | 13-32, post-emergence, spring | a) 1  b) 1 | -- | 0.5 L/ha | (a.s. 1) 1.0 g as/ha  (a.s. 2) 5.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 5 | DE | Winter soft wheat (TRAZW),  Winter triticale (TTLWI) | F | Black twitch ALOMY,  Silky bent APESV,  Annual meadowgrass POAAN,  Rough meadowgrass POATR,  Common chickweed STEME,  *Matricaria sp.* MATSS | spraying | 13-32  Post-emergence, spring | a) 1  b) 1 | -- | 1.0 L/ha | (a.s. 1) 2.0 g as/ha  (a.s. 2) 10.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 6 | DE | Winter soft wheat  (TRAZW) | F | *Lolium sp.* LOLSS  Wild oat AVEFA | spraying | 13-30  Post-emergence, spring | a) 1  b) 1 | -- | 1.2 L/ha | (a.s. 1) 2.4 g as/ha  (a.s. 2) 12.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 7 | DE | Winter soft wheat (TRAZW) | F | Black twitch ALOMY,  Barren bromegrass BROST,  Annual dicotyledonous weeds TTTDS | spraying | 13-30  Post-emergence, spring | a) 1  b) 1 | -- | 1.5 L/ha | (a.s. 1) 3.0 g as/ha  (a.s. 2) 15.0 g as/ha | 200-400 L/ha | F\* |  | A | A | C | A | A | A | R |
| 8 | PL | Rye  (SECCW) | F | Corn chamomile ANTAR  Silky bent APESV  Volunteer oilseed rape BRSNN  Shepherd's purse CAPBP  Lamb's quarters CHEAL  Scentless mayweed MATIN  Field forget-me-not MYOAR  Corn poppy PAPRH  Yellow charlock SINAR  Common chickweed STEME  Field pennycress THLAR  Field pansy VIOAR  Veronica sp. VERSS | spraying | BBCH 21 - BBCH 31 | a) 1  b) 1 | -- | 0.45 L/ha | (a.s. 1) 0.9 g as/ha  (a.s. 2) 4.5 g as/ha | 200-300 L/ha | F\* |  | A | A | C | A | A | A | R |
| 9 | PL | Winter triticale  (TTLWI)  Winter wheat  (TRZAW) | F | Black twitch ALOMY  Corn chamomile ANTAR  Silky bent APESV  Wild oat AVEFA  Volunteer oilseed rape BRSNN  Barren bromegrass BROSE  Shepherd's purse CAPBP  Lamb's quarters CHEAL  Scentless mayweed MATIN  Field forget-me-not MYOAR  Corn poppy PAPRH  Yellow charlock SINAR  Common chickweed STEME  Field pennycress THLAR  Field pansy VIOAR  Veronica sp. VERSS | spraying | BBCH 21 –  BBCH 31 | a) 1  b) 1 | -- | 1.2 L/ha | (a.s. 1) 2.4 g as/ha  (a.s. 2) 12.0 g as/ha | 200-300 L/ha | F\* | Recommended dose for a single application: 0.45 - 1.2 l/ha. | A | A | C | A | A | A | R |

\* The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

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

Explanation for column 15 – 21 “Conclusion”

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

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Remarks  **table heading:** | (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  (b) Catalogue of pesticide formulation types and international coding system CropLife  International Technical Monograph n°2, 6th Edition Revised May 2008  (c) g/kg or g/l |  | (d) Select relevant  (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use. |
|  |  |  |  |
| Remarks  columns: | 1 Numeration necessary to allow references  2 Use official codes/nomenclatures of EU Member States  3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. |  | 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  8 The maximum number of application possible under practical conditions of use must be provided.  9 Minimum interval (in days) between applications of the same product  10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  13 PHI - minimum pre-harvest interval  14 Remarks may include: Extent of use/economic importance/restrictions |

### Overall conclusions

At the request of the zRMS, the applicant has provided a full dRR with the underlying out of protection data from the re-registration report of the comparable product Atlantis 12 OD (authorisation number R-98/2009).

This application is being submitted to register the product Meso-Iodo OD-Life (containing 10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl OD) in the central zone according to Article 34 of Regulation (EC) No. 1107/2009. It is requested that Poland act as zRMS for this application. As the applicant also intends to register the product in Germany, they have been listed as the ‘concerned’ Member State (cMS). Meso-Iodo OD-Life will be referred to as product 054-01-05 for the remainder of this document.

Product 054-01-05 is a professional use herbicide formulated as an oil dispersion containing 10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl. The product has not previously been evaluated in Poland according to Uniform Principles.

As part of this application, Life Scientific Ltd. wishes to have the proposed formulation assessed for comparability to the Polish reference product Atlantis 12 OD (10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl, OD, authorisation number R-98/2009) of Bayer AG. The applicant considers product 054-01-05 to be comparable, if not identical to Atlantis 12 OD (full details of the composition can be found in the dRR Part C). The uses and claims for which approval is being sought are the same as those already approved for Atlantis 12 OD. Therefore, the data presented in the renewal of Atlantis 12 OD can be utilised in order to support the authorisation of 054-01-05 in all areas of ecotoxicology except for the effect on bees (KCP 10.3.1). Formulation data to address the toxicity to bees was not presented as part of the renewal of Atlantis 12 OD. Consequently, in order to address the requirements of Regulation 284/2013 data on the toxicity of 054-01-05 to bees is presented as part of this application along with a risk assessment according to current guidance.

**ZRMS comments:**

Since report in dRR format is prepared by the Applicant, all remarks, comments, additional calculations and assessment done by the ZRMS **are included in the commenting boxes or highlighted in blue**.

All data referred to endpoints for iodosulfuron-methyl-sodium and mesosulfuron-methyl are in line EFSA conclusion (EFSA Journal 2016;14(4):4453 and EFSA Journal 2016;14(10): 4584 and are accepted by evaluator.

The proposed GAP of Meso-Iodo OD-Life is covered by the assessment contained in plant protected product of Atlantis 12 OD and is accepted for used in Meso-Iodo OD-Life.

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

The risk assessments for birds and mammals meet the trigger criteria at screening level, for all intended uses of product 054-01-05. No unacceptable risk resulted also from the assessment of exposure via drinking water, and for secondary poisoning via prey like fish and earthworms. The above assessments do not raise specific concern for other terrestrial vertebrate wildlife such as reptiles and amphibians.

No measures for exposure mitigation need to be taken into account for the protection of birds, mammals, and other terrestrial vertebrate wildlife.

**Evaluator comments:**

**Birds and mammals**

No data is provided in support of the application for authorization of **Meso-Iodo OD-Life**. The intended uses Product **Atlantis 12 OD** are within those considered acceptable for registration of **Meso-Iodo OD-Life.**

According to the Registration Report for Atlantis 12 OD the acute and long-term risk assessment for birds and mammals have been accepted. On the basis of performed calculations in **Atlantis 12 OD** report, acceptable acute and long-term risk to birds and mammals may be concluded from proposed uses of Meso-Iodo OD-Life. No additional risk assessment is required.

#### Effects on aquatic organisms (KCP 10.2)

Acceptable risk for all aquatic organisms other than macrophytes could be demonstrated in a screening level risk assessment (FOCUS Steps 1-2) for the active substances contained in the formulation, and their metabolites. Further assessment was provided for aquatic macrophytes considering FOCUS Step 3 and 4 values, along with proposed mitigation measures where necessary.

Mesosulfuron methyl

**Winter cereals, autumn use, 10 g a.s./ha**

There is an unacceptable risk for D4 (pond and stream) scenarios, D5 (stream) scenario with 20 meter vegetative buffer zone and further refinement is required. The R3 stream scenario can be resolved when a 20 meter high buffer zone is implemented; the R4 scenario can be resolved when a 10 meter low buffer zone is implemented

As the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and Member States should consider the relevance of these scenarios to their national conditions.

**Winter cereals, end of winter-spring use, 15 g a.s./ha**

The R3 stream scenario can be resolved when a 20 meter high buffer zone is implemented; the R4 scenario can be resolved when a 10 meter low buffer zone is implemented. As this refinement is Member State-specific, Member States should decide if this is acceptable according to their own national rules on mitigation. As the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions.

**Spring cereals (spring use on spring cereals / rate = 10 g/ha)**

No mitigation measures are required for all relevant scenarios for Central Zone countries.

Iodosulfuron-methyl-sodium

For use group B (end of winter to spring use on winter cereals / rate = 3 g/ha) and group C (spring use in winter cereals = 2 g/ha), no mitigation measures are required for scenarios relevant for Central Zone countries. However, for use group D (autumn use on winter cereals / rate = 2 g/ha) for R3 scenario the risk is acceptable when a 10 m vegetative buffer zone is implemented. Furthermore, as the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions.

Combined Toxicity

The combined risk assessment was provided for both the active substances and the metabolite AE F075736, based on max PECsw values. The overall conclusion was based on max PECsw values for use group B (end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM): The product can be safely applied with no precautionary measures required for exposure mitigation in all European regions other than those represented by drainage scenarios D1 and D2. In a Central Zone context, however, both of these scenarios are considered not representative. In case of R3, R4, R1 (stream) and D3 (ditch) scenarios the product can be safely when:

* For R3 and R4 scenarios a ~~20 meter high vegetative buffer~~ ~~zone~~ 20 meter wide buffer zone is implemented.
* For R1 (stream) and D3 ( ditch) a ~~10 meter low vegetative buffer zone~~ 10 meter wide buffer zone is implemented

**use group D (autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM**

In case of for R4 scenario the product can be safely applied when a 20 meter vegetative buffer zone is applied to surface water bodies For regions represented by scenario D3 and R1 scenarios no precautionary measures are required. However, risk assessments for drainage scenarios D1, D2, D4, D5, and D6 remained unresolved, as the drainage driven entry in these scenarios cannot be mitigated by the options considered in FOCUS Landscape & Mitigation. In a Central Zone context, however, scenarios D1, D2, and D6 are considered not representative.

The combined risk for aquatic organism assessment indicated for R3 scenario unresolved risk with a 20 meter vegetative buffer zone implemented Therefore, further refinement is required at MS level.

**use group C (spring use on cereals / rate = 2 g/ha IMS + 10 g/ha MSM ):**

The product can be safely applied with no precautionary measures required.

**Evaluator comments:**

**Aquatic organisms**

No data is provided in support of the application for authorization of **Meso-Iodo OD-Life**. The intended uses Product **Atlantis 12 OD** are within those considered acceptable for registration of **Meso-Iodo OD-Life.**

The intended uses in GAP for the formulation Atlantis 12 OD are considered acceptable for registration of for all proposed uses of Meso-Iodo OD-Life. The input parameters established in the EU review performed for iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453) and mesosulfuron-methyl summarized in the EFSA conclusion (EFSA Journal 2016;14(10): 4584) are accepted. All relevant metabolites were taken into consideration; PECSW and PECSED assessment was done in Step 1&2 and 3&4. Mitigation of spray drift and run-off was considered in Step 4 using the SWAN v 4.0.1 software. Runoff mitigation was used, based on the FOCUS Landscape and Mitigation guidance. A higher tier assessment was performed examining the exposure pattern at Step 3 and 4 for mesosulfuron-methyl using the EPAT Exposure Profile Analysis Tool. EPAT exposure pattern analysis of FOCUS multi-year calculations was used to define representative exposure patterns for those surface water scenarios where PECsw,max exceeded the regulatory acceptable concentration (RAC) at Step 3 in the standard FOCUS assessment. The PECSW values for active substances and its metabolites can be used for further risk assessment for aquatic organisms. Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using Focus models. Based on the risk assessment for Atlantis 12 OD, a safe use for in-tended uses for Meso-Iodo OD-Life could be identified, provided that appropriate risk mitigation measures are taken into account. The risk mitigation measures should be considered at MSs level. No additional risk assessment is required.

#### Effects on bees (KCP 10.3.1)

The acute risk to bees was demonstrated to be acceptable for all intended uses of product 054-01-05 based on assessments for the active substances, and the formulated product.

The chronic and larval risk was assessed by adapting the EPPO 2010 scheme. The calculated TER values were above the trigger of 1 indicating that the proposed uses of 054-01-05 pose an acceptable chronic risk to adult bees and to bee larval development.

Additionally, calculations were conducted in accordance with the recommendations of the EFSA bee GD (EFSA Journal 2013;11(7):3295). Acceptable risk to bees was indicated for all scenarios except for bees foraging on weeds in the treated field. However, as exceedance of calculated ETR value is negligible and no flowering weeds are expected in the field during the application of 054-01-05 it is considered that there is no risk to bees from use of the product.

An acceptable risk for bees exposed in accordance with the intended uses of 054-01-05 was demonstrated. No measures for exposure mitigation need to be taken into account for the protection of bees.

**Evaluator comments:**

The risk assessment for bees evaluated in Atlantis 12 OD cover all uses of Meso-Iodo OD-Life. However,

in response to data gaps in Atlantis 12 OD the new data was provided by Applicant (the chronic toxicity test for adult bees, the chronic test for larvae for formulation Meso-Iodo OD-Life). The studies were accepted by zRMS. The risk assessment based on new data was accepted by zRMS. The chronic and larval risk was assessed by adapting the EPPO 2010 scheme. The calculated TER values were above the trigger of 1 indicating that the proposed uses of Meso-Iodo OD-Life pose an acceptable chronic risk to adult bees and to bee larval development. Additionally, calculations were conducted in accordance with the recommendations of the EFSA bee GD (EFSA Journal 2013;11(7):3295). Acceptable risk to bees was indicated for all scenarios except for bees foraging on weeds in the treated field. However, as exceedance of calculated ETR value is negligible and no flowering weeds are expected in the field during the application of 054-01-05 it is considered that there is no risk to bees from use of the product.

The risk assessment for bees should be considered by MSs level.

#### Effects on arthropods other than bees (KCP 10.3.2)

The risk to arthropods other than bees is acceptable for all intended uses of product 054-01-05 based on the presented assessments for the in-field and the off-field exposure situations.

No measures for exposure mitigation need to be taken into account for the protection of arthropods other than bees.

**Evaluator comments:**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses in GAP for the formulation Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life. No unacceptable effects are anticipated on communities of terrestrial non-target arthropods due to the use of Meso-Iodo OD-Life according proposed use in GAP.

#### Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

No unacceptable risk to the soil meso- and macrofauna and to the soil microbial activity is concluded from the risk assessments presented, for all intended uses of the product 054-01-05.

No measures for exposure mitigation need to be taken into account for the protection of soil organisms.

**Evaluator comments:**

**Effect on non-target soil meso- and macrofauna**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.

The long-term risk assessment presented for earthworms and other soil non-target macro-organisms based On the endpoints from the studies performed on formulation of Atlantis 12 OD. The risk assessment is   
appropriate to be used for Meso-Iodo OD-Life. Use of Meso-Iodo OD-Life is not expected to pose risk to soil macro-organisms. No additional risk assessment is not required.

**Effects on soil microbial activity**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.

The risk assessment presented for micro-organisms on the endpoints from the studies performed on for-mulation of Atlantis 12 OD has been accepted for Meso-Iodo OD-Life. The risk assessment is appropriate to be used for Meso-Iodo OD-Life. According to the Registration Report for Atlantis 12 OD the risk assessment for microorganisms have been accepted. On the basis of performed calculations in Atlantis 12 OD report, acceptable risk assessment to microorganisms may be concluded from proposed uses of Meso-Iodo OD-Life. The risk to soil micro-organisms from uses of Meso-Iodo OD-Life is expected to be low. No additional risk assessment is not required.

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

Based on probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E) and 1.2 L prod/ha (use group F).
* a 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rates 1 x 1.0 L product/ha (use group G), and 1 x 0.6 L product/ha (use group H).
* No mitigation measures are needed for application rates 1 x 0.5 L product/ha (use group I), 1 x 0.45 L product/ha (use group J).

Based on deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* 10m or alternatively a 5 m buffer with 50 % drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E), 1.2 L product/ha (use group F) and 1 x 1.0 L product/ha (use group G) or non-buffer zone with 90 % drift reduction nozzles for application 1.5L/ha, 1.2 L/ha and 1.0 L/ha.
* 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application 1 x 0.6 L product/ha (use group H), 1 x 0.5 L product/ha (use group I) and 1 x 0.45 L product/ha (use group J)
* 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application 1 x 0.6 L product/ha (use group H), 1 x 0.5 L product/ha (use group I) and 1 x 0.45 L product/ha (use group J)

**Evaluator comments:**

**Effect on non-target terrestrial plants**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.The risk assessment for non-target plants based on the endpoints from the studies performed on formulation of Atlantis 12 OD. The risk assessment is appropriate to be used for Meso-Iodo OD-Life. Use of Meso-Iodo OD-Life is not expected to pose risk to non-target plants, when considering the appropriate mitigation measures. considering the appropriate mitigation measures.

**The risk assessment for non-target plants with considering the appropriate mitigation measures should be considered by MSs level.**

### Grouping of intended uses for risk assessment

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

**Table 9.1-2: Grouping of uses for assessment of 054-01-05**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Grouping according to use rate** | | | | |
| **Group** | **Intended uses** | **Relevant use parameters for grouping** | **Relevant parameter or value for sorting** | **Relevant for risk assessment areas** |
| A | Generic risk envelope covering all uses outlined in Table 9.1-1 # | Worst-case application rates:  10 g IMS/ha  15 g MSM/ha  BBCH <20 [no crop interception], year-round use. | Maximum application rates per a.s. (considered protective of all uses listed in Table 9.1-1) | Active substance based screening or Tier 1 level risk assessments for Birds / Mammals /  Aquatic Organisms /  Bees / Soil organisms. |
| B | Winter soft wheat  [e.g. use no. 7 in Table 9.1-1] | Application rate: 1.5 L product/ha,  [no crop interception] | Worst case use rate and BBCH for winter cereals - spring use | Active substance based assessments for aquatic macrophytes |
| C | Winter soft wheat, winter triticale  [e.g. use no. 5 in Table 9.1-1] | Application rate: 1.0 L/ product ha,  [no crop interception] | Worst case use rate and BBCH for spring use on crop type winter cereals. | Active substance based assessments for aquatic macrophytes |
| D | Winter soft wheat, winter triticale  [e.g. use no. 2 in Table 9.1-1] | Application rate: 1.0 L product/ha  [no crop interception] | Worst case use rate for autumn use on crop type winter cereals,  where FOCUSsw  methodology used | Active substance based assessments for aquatic  macrophytes |
| E | Winter soft wheat  [e.g. use no. 7 in Table 9.1-1] | Application rate:  1.5 L product/ha  BBCH 13-30 | Maximum application rate of product. | Formulation-based risk assessments for all areas |
| F | Winter triticale, winter wheat  [e.g. uses no. 3, 6 and 9] | Application rate:  1.2 L product/ha  BBCH 11-31 | Use rate. | Non-target terrestrial plants §) |
| G | Winter soft wheat,  Winter triticale  [e.g. use no. 2 in Table 9.1-1] | Application rate: 1.0 L product/ha  BBCH 11-25 | Use rate. | Non-target terrestrial plants §) |
| H | Winter soft wheat,  winter rye, winter triticale.  [e.g. use no. 1 in Table 9.1-1] | Application rate:  0.6 L product/ha  BBCH 11-25 | Use rate. | Non-target terrestrial plants §) |
| I | Winter soft wheat, winter rye, winter triticale  [e.g. use no 4 in Table 9.1-1] | Application rate:  0.5 L product/ha  BBCH 13-32 | Use rate. | Non-target terrestrial plant §) |
| J | Rye  [e.g. use no. 8 in Table 9.1-1] | Application rate:  0.45 L product/ha  BBCH 21-31 | Use rate. | Non-target terrestrial plants §) |

# ) In cases where the risk assessment is passed with a wide margin of safety already on screening or 1st tier level, exposure and risk characterisations for the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl are presented as a generic ‘risk envelope’ approach, which will cover all intended in Table 9.1. The European envelope rate considered for iodosulfuron-methyl-sodium is 10 g a.s./ha, for mesosulfuron-methyl is 15 g a.s./ha. Other crop or GAP dependent parameters relevant for the assessments are all set to the worst case (BBCH 00-39, 0 % crop interception, no tillage, application all year round). This risk envelope provides a simple and efficient tool to conservatively cover many areas of the risk assessment while being protective of every use listed in the GAP (Table 9.1-1).

§) to enable differentiated definition of mitigation setting adapted to the various intended product use rates

### Consideration of metabolites

A list of metabolites found in environmental compartments is provided below

Table 9.1‑3 Metabolites of iodosulfuron-methyl-sodium

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Metabolite** | **Molar mass** | **Chemical Structure** | **Maximum observed occurrence in compartments** | **Exposure assessment required due to** |
| AE F075736 | 381.4 |  | Soil: 88.5% (aerobic),  67.9% (anaerobic)  Water: 57.0%  Sediment: 15.9%  Water/sediment: 67.8% | PECsoil  PECgw  PECsw/sed |
| AE F145741 | 493.2 |  | Soil: 6.9% (aerobic)  Water: 7.0%  Sediment: 1.9%  Water/sediment: 8.7% | PECsoil  PECgw  PECsw/sed |
| AE F145740 | 493.2 |  | Soil: 8.7% (aerobic)  Water: 9.2%  Sediment: 3.5%  Water/sediment: 12.6% | PECsoil  PECgw  PECsw/sed |
| AE 0002166 | 397.4 |  | Soil: 20.0% (photolysis) Water: 25.1% (photolysis in natural water) | PECsoil  PECgw  PECsw/sed |
| AE F161778 | 367.3 |  | Soil: 14.5% (aerobic) Water/sediment: 2.6% | PECsoil  PECgw  PECsw/sed |
| BCS-  CW81253 | 343.3 |  | Soil: 35.1% (aerobic)  Water/sediment: 0.0001% | PECsoil  PECgw  PECsw/sed |
| AE 0000119 | 183.2 |  | Soil: 19.9% (aerobic)  Water: 17.7%  Sediment: 15.0%  Water/sediment: 24.9% | PECsoil  PECgw  PECsw/sed |
| AE F059411 | 140.2 |  | Soil: 40.9% (aerobic),  23.6% (anaerobic)  Water: 19.3%  Sediment: 8.3  Water/sediment: 27.5% | PECsoil  PECgw  PECsw/sed |
| AE 0014966 | 367.3 |  | Water: 11.8%  Sediment: 5.9%  Water/sediment: 15.5% | PECsw/sed |
| AE 0034855 | 169.1 |  | Water: 16.7%  Sediment: 10.7%  Water/sediment: 24.2% | PECsw/sed |
| AE 1234964 | 201.2 |  | Water: 6.8%  Sediment: 0.6%  Water/sediment: 7.4% | PECsw/sed |
| AE F159737 | 183.2 |  | Water: 6.1%  Sediment: 1.6%  Water/sediment: 7.8% | PECsw/sed |
| AE F154781 | 126.1 |  | Water: 8.7% (aerobic mineralisation in surface water) | PECsw/sed |

Table 9.1‑4 Metabolites of mesosulfuron-methyl

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Metabolite** | **Molar mass** | | **Chemical Structure** | **Maximum observed occurrence in compartments** | **Exposure assessment required due to** | |
| AE F154851    (mesosulfuron, mesosulfuron acid) | | 489.5 |  | Soil: 16.2% (aerobic) Water/sediment: 4.9% | | PECsoil  PECgw  PECsw/sed |
| AE F160459 | | 489.5 |  | Soil: 8.9% (aerobic), 25.9%  (anaerobic)  Water/sediment: 21.6% | | PECsoil  PECgw  PECsw/sed |
| AE F099095 | | 198.2 |  | Soil: 29.2% (aerobic) Water/sediment: 0.9% | | PECsoil  PECgw  PECsw/sed |
| AE F092944 | | 155.2 |  | Soil: 10.1% (aerobic) Water/sediment: 3.2% | | PECsoil  PECgw  PECsw/sed |
| AE F160460 | | 475.5 |  | Soil: 8.6% (aerobic) Water/sediment: 8.4% | | PECsoil  PECgw  PECsw/sed |
| AE F140584 | | 322.4 |  | Soil: 5.1% (aerobic) Water/sediment: 1.9% | | PECsoil  PECgw  PECsw/sed |
| AE F147447 | | 290.3 |  | Soil: 5.8% (aerobic), 6.5%  (anaerobic)  Water/sediment: 10.9% | | PECsoil  PECgw  PECsw/sed |
| BCS-CO60720 | | 407.4 |  | Water/sediment: 13.1% | | PECsw/sed |
| BCS-CV14885 | | 393.4 |  | Water/sediment: 22.0% | | PECsw/sed  PECgw |

Table 9.1‑5 Metabolites of mefenpyr-diethyl

| Metabolite | Chemical structure | Molar mass | Maximum observed occurrence in compartments | Risk assessment required? |
| --- | --- | --- | --- | --- |
| AE F113225 |  | 345.2 | Soil: 44.1%  Water/Sediment: 82.8% | Yes |
| AE F094270 |  | 271.11 | Soil: 72.2%  Water/Sediment: 62.4% | Yes |
| AE F109453 |  | 317.13 | Soil: not observed  Water/Sediment: 46.5% | Yes |
| AE F114952 |  | 345.2 | Soil: 11.5%  Water/Sediment:18.6% | Yes |
| AE 2211046  (M8) |  | 391.26 | Soil: 11% (photodegradation)  Water/Sediment: 41% (aqueous photolysis) | Yes |

## Effects on birds (KCP 10.1.1)

### Toxicity data

**Iodosulfuron-methyl-sodium**

Avian toxicity studies have been carried out with iodosulfuron-methyl-sodium. Full details of these studies are provided in the EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(4):4453.

**Mesosulfuron-methyl**

Avian toxicity studies have been carried out with mesosulfuron-methyl. Full details of these studies are provided in the EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584.

**054-01-05**

Possible risk to birds exposed to the formulated product 054-01-05 can be predicted on the basis of data for the individual active substances in a combined toxicity assessment. Therefore, no new toxicity data, from vertebrate studies with the formulation, is presented here.

In addition , it should be noted that, the results of the acute product study on mammals (LD50 > 5000 mg product/kg bw) on the representative formulation Atlantis 12 OD do not indicate increased toxicity of the formulation compared to the individual active substances. 054-01-05 is believed to be comparable to Atlantis 12 OD (please see dRR Part C for details of the composition).

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

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Bobwhite quail (*Colinus virginianus*)  Mallard duck  (*Anas platyrhynchos*) | Mesosulfuron-methyl | Oral Acute | LD50 > 2000 mg/kg bw | EFSA Journal 2016;14(10):4584 |
| Bobwhite quail (*Colinus virginianus*) | Mesosulfuron-methyl | Reproductive toxicity, 20 weeks | NOEL = 93 mg/kg bw/d | EFSA Journal 2016;14(10):4584 |
| Japanese quail (*Coturnix japonica*) | Iodosulfuron-methyl-sodium | Oral Acute | LD50 > 2000 mg/kg bw | EFSA Journal 2016;14(4):4453 |
| Bobwhite quail (*Colinus virginianus*) | Iodosulfuron-methyl-sodium | Dietary reproductive toxicity, 23 weeks | NOEL = 78 mg/kg bw/d | EFSA Journal 2016;14(4):4453 |
| Japanese quail (*Coturnix japonica*) | Mefenpyr-diethyl | Acute | NOLED\* > 20001)  LD50 = 3776 mg/kg bw | Mefenpyr-diethyl DAR, 2011 |
| Mallard duck (*Anas platyrhynchos*) | Mefenpyr-diethyl | Acute | NOLED\* > 20001)  LD50 = 3776 mg/kg bw | Mefenpyr-diethyl DAR, 2011 |
| Japanese quail (*Coturnix japonica*) | Mefenpyr-diethyl | Long-term | NO(A)EC = 1000 ppm  NO(A)EL = 106 mg/kg bw | Mefenpyr-diethyl DAR, 2011 |
| Japanese quail (*Coturnix japonica*) | Mefenpyr-diethyl | Long-term | LD50/10 = 377.6 mg/kg bw/d | Mefenpyr-diethyl DAR, 2011 |

\*NOLED = no observed lethal effect dose

1) 10 birds per group; no mortality during study. LD50 value extrapolated with a factor of 1.888

#### Justification for new endpoints

No deviation from the EU agreed endpoints.

### Risk assessment for spray applications

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

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

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

**Iodosulfuron-methyl-sodium**

For the active substance iodosulfuron-methyl-sodium – as the risk assessment is passed on screening level exposure and risk characterisation is presented as a generic ‘risk envelope’ approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which the mentioned compounds may be included.

Table 9.2‑2: Screening assessment of the acute and long-term/reproductive risk for birds of iodosulfuron-methyl-sodium due to the use of 054-01-05 in cereals.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A): cereals, maize, non-cropped area, BBCH 0-39 | | | | |
| Active substance/product | | Iodosulfuron-methyl-sodium | | | | |
| Application rate (g/ha) | | 1 x 10 | | | | |
| Acute toxicity (mg/kg bw) | | >2000 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals , maize\* | Small omnivorous bird1 | | 158.8 | 1.0 | 1.6 | >1250 |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals, maize\* | Small omnivorous bird | | 64.8 | 1.0 x 0.53 | 0.3 | 260 |

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

\*covers non-cropped areas

**Mesosulfuron-methyl**

For the active substance mesosulfuron-methyl – as the risk assessment is passed on screening level exposure and risk characterisation is presented as a generic ‘risk envelope’ approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which the mentioned compounds may be included.

Table 9.2‑3: Screening assessment of the acute and long-term/reproductive risk for birds of mesosulfuron-methyl due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A): winter & spring cereals, BBCH 10-39 | | | | |
| Active substance/product | | Mesosulfuron-methyl | | | | |
| Application rate (g/ha) | | 1 x 15 | | | | |
| Acute toxicity (mg/kg bw) | | >2000 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | Small omnivorous bird | | 158.8 | 1.0 | 2.4 | >833 |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | Small omnivorous bird | | 64.8 | 1.0 x 0.53 | 0.5 | 186 |

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

**Assessment of Combined Toxicity**

As requested by the Central Zone when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative toxicity risk assessment according to concentration addition is not needed if one of the following points applies:

* The risk assessment for all active substances in the product passes with a high margin of safety.
* One active substance clearly drives the risk assessment

These conditions are assessed following a step-wise approach. Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

**1st step: Margin of safety**

Condition: all TER values are > Trigger x n (n = number active substances in the mixture)

**2nd step: Risk per fraction**

Condition: One a.s. contributes to ≥ 90% of the predicted combined toxicity of the product

Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

1 1 1 1

*rpfa*.*s*.1 = /( + ...+ )

*TERa*.*s*.1 *TERa*.*s*.1 *TERa*.*s*.2 *TERa*.*s*.*i*

The estimation is based on TER values from the same refinement level to assure comparability.

**3rd step: TERMIX calculation**

Condition: The combined toxicity is acceptable if TERMIX ≥ 10 (acute) or 5 (long-term)

Assessment: The combined toxicity risk (TERMIX) with concentration-addition is estimated based on the following equation:

1 1 1

*TERmix* =1/( + ...+ )

*TERa*.*s*.1 *TERa*.*s*.2 *TERa*.*s*.*i*

As the notifier experienced differing preferences by national reviewers for one or the other step, results of all three steps are considered below:

Table 9.2‑4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of the formulation in cereals – combined toxicity

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A) | | | | | |
| Active substance/product | | mesosulfuron-methyl + iodosulfuron-methyl-sodium | | | | | |
| Application rate (g/ha) | | 1 x (10 g/ha + 15g/ha) | | | | | |
| Scenario/Generic focal species | IMS1) | | MSM1) | Trigger  a.s.1/a.s.2 | 1st step  All TER > trigger × n? | 2nd step  rpfMAX | 3rd step  TERmix |
| Acute/small omnivorous bird | >1250 | | >840 | 10/10 | Yes | not applicable#) | 502.51 |
| Long-term/small omnivorous bird | 260 | | 181 | 5/5 | Yes | not applicable#) | 107.52 |

1) Worst-case TER values as listed in point 9.2.2.1

# The rpf calculation is not meaningful if due to a risk envelope approach for one or more individual substances the ratio of the active substances in the assessed mixture differs from the ratio in the formulation.

In all cases the TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating no unacceptable risk from the use of the product.

**Mefenpyr-diethyl**

An assessment for the safener mefenpyr-diethyl has also been provided below as supplemental information. An application rate of 45g/ha has been considered in the risk assessment which is protective of all intended rates.

Table 9.2‑5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of the safener mefenpyr-diethyl in cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Winter & spring cereals | | | | |
| Active substance/product | | Mefenpyr-diethyl | | | | |
| Application rate (g/ha) | | 1 × 45 | | | | |
| Acute toxicity (mg/kg bw) | | 3776 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | Small omnivorous bird | | 158.8 | 1 | 7.15 | 528.4 |
| Reprod. toxicity (mg/kg bw/d) | | 106 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | Small omnivorous bird | | 64.8 | 0.53 | 1.55 | 68.6 |

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

**Conclusions**

Safe use of iodosulfuron-methyl-sodium, mesosulfuron methyl and mefenpyr-diethyl in cereals was confirmed for birds based on TERA and TERLT values for the active substances.

For the combined risk assessment in all cases the TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating an acceptable risk from the use of the product.

#### Higher-tier risk assessment

Not relevant.

#### Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf*. Appendix K of EFSA/2009/1438).

Leaf scenario

Since 054-01-05 is not a product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

**Iodosulfuron-methyl-sodium**

With a K(f)oc of 50.8, iodosulfuron-methyl-sodium belongs to the group of less sorptive substances.

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 10 |  |  |
| Acute toxicity (mg/kg bw) = | >2000 | quotient = | <0.01 |
| Reprod. toxicity (mg/kg bw/d) = | 78 | quotient = | 0.13 |

**Mesosulfuron-methyl**

With a K(f)oc of 64 L/kf, mesosulfuron-methyl belongs to the group of less sorptive substances.

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 15 |  |  |
| Acute toxicity (mg/kg bw) = | >2000 | quotient = | <0.01 |
| Reprod. toxicity (mg/kg bw/d) = | 93 | quotient = | 0.16 |

**Mefenpyr-diethyl**

With a K(f)oc of 614 ml/g mefenpyr-diethyl belongs to the group of more sorptive substances.

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 45 |  |  |
| Acute toxicity (mg/kg bw) = | 3776 | quotient = | 0.01 |
| Reprod. toxicity (mg/kg bw/d) = | 106 | quotient = | 0.42 |

Since the product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered taking onto account the proposed uses (cereals).

Evaluation of exposing for birds through the drinking water Puddle scenario for the active substances and the safener mefenpyr-diethyl solely, demonstrate that the acceptable risk for birds for the proposed use pattern in cereals.

#### Effects of secondary poisoning

**Iodosulfuron-methyl-sodium**

The log Pow of iodosulfuron-methyl-sodium (-0.70) and does not exceed the trigger value of 3. The log Pow of all iodosulfuron-methyl-sodium metabolites are below the trigger value of 3 as stated in the EFSA Journal 2016;14(4):4453. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

**Mesosulfuron-methyl**

The log Pow of mesosulfuron-methyl (-0.48) does not exceed the trigger value of 3. The log Pow values of the mesosulfuron-methyl metabolites are all below the trigger of 3 as EU agreed in EFSA Journal 2016;14(10):4584. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

**Mefenpyr-diethyl**

The log Pow of mefenpyr-diethyl amounts to 3.83 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations of mefenpyr-diethyl in soil.

Table 9.2‑6: Assessment of the risk for earthworm-eating birds due to exposure to mefenpyr-diethyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals

| Parameter | mefenpyr-diethyl | comments |
| --- | --- | --- |
| PECsoil (mg/kg soil) | 0.060 | See dRR Part B, Section 8 for Environmental Fate |
| log Pow / Pow | 3.83/6760.83 |  |
| Koc | 614 |  |
| foc | 0.02 | Default |
| BCFworm | 6.68 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.12 × Pow) / foc × Koc |
| PECworm | 0.40 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.42 | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) | 106 |  |
| TERlt | 252.1 | Acceptable |

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations of mefenpyr-diethyl in surface water.

Table 9.2‑7: Assessment of the risk for fish-eating birds due to exposure to mefenpyr-diethyl via bioaccumulation in fish (secondary poisoning) for the intended use in cereals

| Parameter | mefenpyr-diethyl | comments |
| --- | --- | --- |
| PECsw initial (mg/L) | 0.009 | See dRR Part B, Section 8 for Environmental Fate |
| BCFfish | 362 |  |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 3.26 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.52 | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) | 106 |  |
| TERlt | 204.6 | Acceptable |

TER values shown in bold fall below the relevant trigger.

#### Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

### Overall conclusions

**Iodosulfuron-methyl-sodium**

The acute and long-term risks of iodosulfuron-methyl-sodium to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For iodosulfuron-methyl-sodium, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log Pow values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

**Mesosulfuron-methyl**

The acute and long-term risks of mesosulfuron-methyl to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For mesosulfuron-methyl, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log Pow values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

**Mefenpyr-diethyl**

The acute and long-term risks of mefenpyr-diethyl to birds were assessed and an acceptable risk was demonstrated. As a log POW of mefenpyr-diethyl is > 3, risk assessment for effects due to secondary poisoning for birds exposed to this substance was provided. Both calculated TER met the trigger value of 5 indicating acceptable risk for earthworms-eating and fish-eating birds.

In conclusion, the risk for wild birds is acceptable for the use of 054-01-05 according to the intended use pattern.

**Evaluator comments:**

**Birds**

No data is provided in support of the application for authorization of **Meso-Iodo OD-Life**. The intended uses Product **Atlantis 12 OD** are within those considered acceptable for registration of **Meso-Iodo OD-Life.**

According to the Registration Report for Atlantis 12 OD the acute and long-term risk assessment for birds have been accepted. On the basis of performed calculations in **Atlantis 12 OD** report, acceptable acute and long-term risk to birds may be concluded from proposed uses of Meso-Iodo OD-Life. No additional risk assessment is required.

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

### Toxicity data

**Iodosulfuron-methyl-sodium**

Mammalian toxicity studies have been carried out with iodosulfuron-methyl-sodium. Full details of these studies are provided in the EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(4):4453.

**Mesosulfuron-methyl**

Mammalian toxicity studies have been carried out with mesosulfuron-methyl. Full details of these studies are provided in the EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584.

**054-01-05**

Possible risk to mammals exposed to the formulated product 054-01-05 can be predicted on the basis of data for the individual active substances in a combined toxicity assessment. Therefore, no new toxicity data, from vertebrate studies with the formulation, is presented here.

Effects on mammals of the representative formulation Atlantis 12 OD were evaluated as part of the EU assessment of the active substance mesosulfuron-methyl. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). It is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05

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

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Rat | Mesosulfuron-methyl | Oral Acute | LD50 > 5000 mg/kg bw | EFSA Journal 2016;14(10):4584 |
| Rat | Mesosulfuron-methyl | Dietary  Reproductive toxicity  Two-generation study | NOEL = 840 mg/kg bw | EFSA Journal 2016;14(10):4584 |
| Rat | Iodosulfuron-methyl-sodium | Oral Acute | LD50 = 2678 mg/kg bw | EFSA Journal 2016;14(4):4453 |
| Rat | Iodosulfuron-methyl-sodium | Combined chronic toxicity and oncogenicity study (2 years) | NOAEL =  2.96 (male) and 3.91 (female) mg/kg bw/day | EFSA Journal 2016;14(4):4453 |
| Rat | Mefenpyr-diethyl | Acute oral | LD50 > 5000 mg/kg b.w. 1)  NOAEL = 5000 mg/kg b.w. | Mefenpyr-diethyl  DAR, 2011 |
| Rat | Mefenpyr-diethyl | Multi-generations study (2-generation) | NOAEC = 1000 ppm  NOAEL = 88.8 mg/kg b.w./d | Mefenpyr-diethyl  DAR, 2011 |
| Rat | Mefenpyr-diethyl | Developmental study | NOAELmaternal = 200 mg/kg b.w./d  NOELfetal = 200 mg/kg b.w./d | Mefenpyr-diethyl  DAR, 2011 |
| Rabbit | Mefenpyr-diethyl | Developmental study | NOAELmaternal = 100 mg/kg b.w./d  NOELfetal = 100 mg/kg b.w./d | Anon, 1992,  Mefenpyr-diethyl  DAR |
| Rat | IMS+MSM+MPR OD 42 (2+10+30) | Oral Acute | LD50 > 5000 mg/kg bw | EFSA Journal  2016;14(10):4584 |

#### Justification for new endpoints

No deviation to EU agreed endpoints.

### Risk assessment for spray applications

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

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

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

**Iodosulfuron-methyl-sodium**

For the active substance iodosulfuron-methyl-sodium– as the risk assessment is passed on screening or 1st tier level - exposure and risk characterisation is presented as a generic ‘risk envelope’ approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which the mentioned compounds may be included.

Table 9.3‑2: Screening assessment of the acute and long-term/reproductive risk for mammals of Iodosulfuron-methyl-sodium due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A): cereals, maize, non-cropped area, BBCH 0-39 | | | | |
| Active substance/product | | Iodosulfuron-methyl-sodium | | | | |
| Application rate (g/ha) | | 1 x 10 | | | | |
| Acute toxicity (mg/kg bw) | | 2678 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals, maize | Small herbivorous airport | | 118.4 | 1.0 | 1.2 | 2232 |
| Reprod. toxicity (mg/kg bw/d) | | 2.96 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | Small herbivorous mammal | | 48.3 | 1.0 x 0.53 | 0.3 | 12.0 |

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

\*Covers grassland

**Mesosulfuron-methyl**

For the active substance mesosulfuron-methyl – as the risk assessment is passed on screening or 1st tier level - exposure and risk characterisation is presented as a generic ‘risk envelope’ approach: The risk assessment is based on worst case application rates which cover all intended European uses across different products in which the mentioned compounds may be included.

Table 9.3‑3: Screening assessment of the acute and long-term/reproductive risk for mammals of Mesosulfuron methyl due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A): winter & spring cereals, BBCH 10-39 | | | | |
| Active substance/product | | Mesosulfuron-methyl | | | | |
| Application rate (g/ha) | | 1 x 15 | | | | |
| Acute toxicity (mg/kg bw) | | >5000 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | Small herbivorous airport | | 118.4 | 1.0 | 1.78 | >2809 |
| Reprod. toxicity (mg/kg bw/d) | | 840 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | Small herbivorous mammal | | 48.3 | 1.0 x 0.53 | 0.40 | 2100 |

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

**Mammals - Assessment of combined toxicity**

As requested by the Central Zone when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative toxicity risk assessment according to concentration addition is not needed if one of the following points applies:

* The risk assessment for all active substances in the product passes with a high margin of safety
* One active substance clearly drives the risk assessment

These conditions are assessed following a step-wise approach. Note that for the calculation only the scenario with the lowest TER values was considered (most critical scenario). This safely covers all other scenarios.

**1st step: Margin of safety**

Condition: all TER values are > Trigger x n (n = number active substances in the mixture)

**2nd step: Risk per fraction**

Condition: One a.s. contributes to ≥ 90& of the predicted combined toxicity of the product.

Assessment: The contribution of each individual a.s. to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

1 1 1 1

*rpfa*.*s*.1 = /( + ...+ )

*TERa*.*s*.1 *TERa*.*s*.1 *TERa*.*s*.2 *TERa*.*s*.*i*

The estimation is based on TER values from the same refinement level to assure comparability.

**3rd step: TERMIX calculation**

Condition: The combined toxicity is acceptable if TERMIX ≥ 10 (acute) or 5 (long-term)

Assessment: The combined toxicity risk (TERMIX) with concentration-addition is estimated based on the following equation:

1 1 1

*TERmix* =1/( + ...+ )

*TERa*.*s*.1 *TERa*.*s*.2 *TERa*.*s*.*i*

As the notifier experienced differing preferences by national reviewers for one or the other step, results of all three steps are considered below:

Table 9.3‑4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of the formulation in cereals – combined toxicity

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Risk envelope approach (use group A) | | | | | |
| Active substance/product | | mesosulfuron-methyl + iodosulfuron-methyl-sodium | | | | | |
| Application rate (g/ha) | | 1 x (10 g/ha + 15g/ha) | | | | | |
| Scenario/Generic focal species | IMS1) | | MSM1) | Trigger  a.s.1/a.s.2 | 1st step  All TER > trigger×n? | 2nd step  rpfMAX | 3rd step  TERmix |
| Acute/small omnivorous bird | 2232 | | >2809 | 10/10 | Yes | not applicable#) | 1204.8 |
| Long-term/small omnivorous bird | 12 | | 2100 | 5/5 | Yes | not applicable#) | 12.43 |

1) Worst-case screening step TER values as listed in point 9.3.2.1

# The rpf calculation is not meaningful if due to a risk envelope approach for one or more individual substances the ratio of the active substances in the assessed mixture differs from the ratio in the formulation.

In the combined toxicity for acute/ small herbivorous mammal and for long-term/ small herbivorous mammal the TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating no unacceptable risk from the use of the product.

**Mefenpyr-diethyl**

An assessment for the safener mefenpyr-diethyl has been provided below as supplemental information. An application rate of 45g/ha has been considered in the risk assessment which is protective of all intended rates.

Table 9.3‑5: Screening assessment of the acute and long-term/reproductive risk for mammals due to the use of 054-01-05 in cereals - Mefenpyr-methyl

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | |
| Active substance/product | | Mefenpyr-methyl | | | | |
| Application rate (g/ha) | | 1 × 45 | | | | |
| Acute toxicity (mg/kg bw) | | > 5000 | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
| Cereals | Small herbivorous mammal | | 118.4 | 1 | 5.33 | > 938.4 |
| Reprod. toxicity (mg/kg bw/d) | | 88.8 | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
| Cereals | Small herbivorous mammal | | 48.3 | 0.53 | 1.15 | 77.1 |

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

**Conclusions**

Safe use of iodosulfuron-methyl-sodium, mesosulfuron methyl and mefenpyr-diethyl in cereals was confirmed for mammals based on TERA and TERLT values for the active substances.

For the combined risk assessment in all cases the TER values are ≥ Trigger × n (n = number of active substances in the mixture), indicating no unacceptable risk from the use of the product.

#### Higher-tier risk assessment

Not required.

#### Drinking water exposure

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

**Leaf scenario**

Since the product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

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

With a K(f)oc of 64 L/kf, mesosulfuron-methyl belongs to the group of less sorptive substances.

**Iodosulfuron-methyl-sodium**

With a K(f)oc of 50.8, iodosulfuron-methyl-sodium belongs to the group of less sorptive substances.

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 10 |  |  |
| Acute toxicity (mg/kg bw) = | 2678 | quotient = | 0.004 |
| Reprod. toxicity (mg/kg bw/d) = | 2.96 | quotient = | 3.34 |

**Mesosulfuron-methyl**

With a K(f)oc of 64 L/kg, mesosulfuron-methyl belongs to the group of less sorptive substances

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 15 |  |  |
| Acute toxicity (mg/kg bw) = | >5000 | quotient = | <0.01 |
| Reprod. toxicity (mg/kg bw/d) = | 840 | quotient = | 0.02 |

**Mefenpyr-diethyl**

With a K(f)oc of 614 ml/g mefenpyr-diethyl belongs to the group of more sorptive substances.

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = | 45 |  |  |
| Acute toxicity (mg/kg bw) = | >5000 | quotient = | <0.01 |
| Reprod. toxicity (mg/kg bw/d) = | 88.8 | quotient = | 0.51 |

Since the product is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered taking onto account the proposed uses (cereals).

Evaluation of exposing for birds through the drinking water Puddle scenario for the active substances and the safener mefenpyr-diethyl solely, demonstrate that the acceptable risk for mammals for the proposed use pattern in cereals.

#### Effects of secondary poisoning

**Iodosulfuron-methyl-sodium**

The log Pow of iodosulfuron-methyl-sodium (-0.70) does not exceed the trigger value of 3. The log Pow of all iodosulfuron-methyl-sodium metabolites are below the trigger value of 3 as stated in the EFSA Journal 2016;14(4):4453. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals a risk assessment for effects due to secondary poisoning is not required.

**Mesosulfuron-methyl**

The log Pow of mesosulfuron-methyl (-0.48) does not exceed the trigger value of 3. The log Pow values of the mesosulfuron-methyl metabolites are all below the trigger of 3 as stated in EFSA Journal 2016;14(10):4584. In accordance with the Guidance Document on Risk Assessment for Birds and Mammals, a risk assessment for effects due to secondary poisoning is not required.

**Mefenpyr-diethyl**

The log Pow of mefenpyr-diethyl amounts to 3.83 and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations of mefenpyr-diethyl in soil.

**Table 9.3‑6: Assessment of the risk for earthworm-eating mammals due to exposure to mefenpyr-diethyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in cereals**

| **Parameter** | **mefenpyr-diethyl** | **comments** |
| --- | --- | --- |
| PECsoil (mg/kg soil) | 0.060 | See dRR Part B, Section 8 for Environmental Fate |
| log Pow / Pow | 3.83 / 6760.83 |  |
| Koc | 614 |  |
| foc | 0.02 | Default |
| BCFworm | 6.68 | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.12 × Pow) / foc × Koc |
| PECworm | 0.40 | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) | 0.51 | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) | 88.8 |  |
| TERlt | 173.2 | Acceptable |

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations of mefenpyr-diethyl in surface water.

**Table 9.3‑7: Assessment of the risk for fish-eating mammals due to exposure to mefenpyr-diethyl via bioaccumulation in fish (secondary poisoning) for the intended use in cereals**

|  |  |  |
| --- | --- | --- |
| **Parameter** | **mefenpyr-diethyl** | **comments** |
| PECsw (mg/L) | 0.009 | See dRR Part B, Section 8 for Environmental Fate |
| BCFfish | 362 |  |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish | 3.26 | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) | 0.46 | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) | 88.8 |  |
| TERlt | 191.9 | Acceptable |

TER values shown in bold fall below the relevant trigger.

#### Biomagnification in terrestrial food chains

Not relevant.

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

Not relevant.

### Overall conclusions

**Iodosulfuron-methyl-sodium**

The acute and long-term risks of iodosulfuron-methyl-sodium to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For iodosulfuron-methyl-sodium, the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log Pow values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

**Mesosulfuron-methyl**

The acute and long-term risks of mesosulfuron-methyl to mammals were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies on the active substance and maximum residues occurring on food items following applications according to the proposed use pattern. For mesosulfuron-methyl the acute and long-term screening step TER values, calculated for the recommended scenario, were above the trigger value of 10 and 5, respectively, according to the proposed use pattern.

Furthermore, due to the k(f)oc and log Pow values, the risk assessment for exposure via drinking water from puddles and risk of secondary poisoning was not considered necessary.

**Mefenpyr-diethyl**

The acute and long-term risks of mefenpyr-diethyl to mammals were assessed and an acceptable risk was demonstrated. As a log POW of mefenpyr-diethyl is > 3, risk assessment for effects due to secondary poisoning for mammals exposed to this substance was provided. Both calculated TER met the trigger value of 5 indicating acceptable risk for earthworms-eating and fish-eating mammals.

In overall conclusion, the risk for wild mammals is acceptable for the use of 054-01-05 according to the intended use pattern.

**Evaluator comments:**

**Mammals**

No data is provided in support of the application for authorization of **Meso-Iodo OD-Life**. The intended uses Product **Atlantis 12 OD** are within those considered acceptable for registration of **Meso-Iodo OD-Life.**

According to the Registration Report for Atlantis 12 OD the acute and long-term risk assessment for mammals have been accepted. On the basis of performed calculations in **Atlantis 12 OD** report, acceptable acute and long-term risk to mammals may be concluded from proposed uses of Meso-Iodo OD-Life. No additional risk assessment is required.

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

The assessments on birds and terrestrial vertebrates other than birds presented in Sections 9.2 and 9.3 before do not raise particular concern for further terrestrial vertebrate wildlife such as reptiles and amphibians. Moreover, the ALS mode of action of all three active substances in the present formulation is well known to be highly specific for plants. Therefore, no testing on other vertebrate organisms is deemed necessary.

**Evaluator comments:** Agreed.

## Effects on aquatic organisms (KCP 10.2)

### Toxicity data

**Iodosulfuron-methyl-sodium**

Studies on the toxicity to aquatic organisms have been carried out with iodosulfuron-methyl-sodium and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report. Any additional data is referenced in Appendix 1 of this data.

The selection of studies and endpoints for the risk assessment for iodosulfuron-methyl-sodium is basically in line with the Results of the EU review process (EFSA Journal 2016;14(4):4453). However, in some cases clarity is missing regarding the endpoints which should be chosen for others than the “representative” formulation, or regarding endpoints which should be used when the new aquatic guidance document (EFSA Journal 2013;11(7):3290) is applied. In these cases, justifications for the selection are provided below.

For the provision of "further information to refine the risk to aquatic plants for iodosulfuron-methyl-sodium" (data gap acc. point 7 of EFSA conclusion), refined exposure type studies on the most sensitive macrophyte species *Lemna gibba* have been generated for the active substance and its metabolite AE F075736 after the EU review. The studies were presented as new data during the renewal of the reference product Atlantis 12 OD (authorisation number R-98/2009), and were used to establish refined risk assessments following options Tier 2C and Tier 3 of the EFSA Aquatic Guidance Document.

**Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – iodosulfuron-methyl-sodium and relevant metabolites**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Substance** | | | **Exposure System** | **Results** | | **Reference** |
| *Oncorhynchus mykiss* | Iodosulfuron-  methyl-sodium | | | 96 h, s | LC50 >100 mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Oncorhynchus mykiss* | Iodosulfuron-  methyl-sodium | | | 28 d, f | NOEC = 7.79 mg a.s./L mm | | EFSA Journal  2016;14(4):4453 |
| *Daphnia magna* | Iodosulfuron-  methyl-sodium | | | 48 h, s | EC50 >100 mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Daphnia magna* | Iodosulfuron-  methyl-sodium | | | 21 d, ss | NOEC = 7.9 mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | Iodosulfuron-  methyl-sodium | | | 96 h, s | ErC50 = 0.152  mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | Iodosulfuron-  methyl-sodium | | | 14 d semi static | 7 d EC50 = 0.00079 mg a.s./L nom  14 d EC= 0.00083 mg a.s./L nom 7 d **ErC50= 0.00134 mg a.s./L nom**    NOEC =0.0040  mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | Iodosulfuron-  methyl-sodium +  mefenpyr-diethyl  (formulated as OD) | | | 7 d static | frond number  7d ErC50=0.0084 mg product/L (nom)  **0.00074 mg a.s./L (nom**)    frond dry weight  7dErC50>0.100 mg product/L (nom)  >0.00882mg a.s./L  (nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | Iodosulfuron-  methyl-sodium | | | 7 d, ss | **ErC50 = 0.00108 mg a.s./L** nom 6 w ErC50=0.000679 mg a.s./L nom  NOEC = 0.0004 mg a.s./L nom *Frond area*  7 d ErC50 =  0.00112.s./L nom  6 w ErC50=0.000609 mg a.s./L nom  NOEC = 0.0004  mg a.s./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | Iodosulfuron-  methyl-sodium | | | Geomean approach (considering the three valid Lemna lab studies above) | **from endpoints (7d ErC50) of 1.34, 1.08 and 0.74 µg a.s./L-**  **geomean 7 d ErC50 = 1.02 µg a.s./L with AF of 10 (laboratory study)** | | |
| **If only a.s. studies are included: the geomean 7 d ErC50 of 1.34 and 1.08 would be 1.20 µg a.s./L .** | | |
| *Lemna gibba* | AE F075736 | | | 7 d, ss | ErC50 = 0.00057  mg met./L nom | | EFSA Journal  2016;14(4):4453; EFSA Journal 2015;13(1): |
| *Pseudokirchneriella subcapitata* | AE F145741 | | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal 2016;14(4):4453 |
| *Lemna gibba* | | AE F145741 | | 7 d, ss | ErC50 = 3.84 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | AE F145740 | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE F145740 | | 7 d, ss | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | AE 0002166 | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE 0002166 | | 7 d, ss | ErC50 = 0.0230 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | AE F161778 | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE F161778 | | 7 d, ss | ErC50 = 0.0281 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | BCS-CW81253 | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | BCS-CW81253 | | 7 d, ss | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE 0000119 | | 7 d, ss | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Daphnia magna* | | AE F059411 | | 48 h, s | LC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | AE F059411 | | 96 h, s | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE F059411 | | 7 d, ss | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE 0014966 | | 7 d, ss | ErC50 = 0.575 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE 0034855 | | 7 d, ss | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Oncorhynchus mykiss* | | AE 1234964 | | 96 h, s | LC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Daphnia magna* | | AE 1234964 | | 48 h, s | LC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE 1234964 | | 7 d, ss | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Oncorhynchus mykiss* | | AE F159737 | | 96 h, s | LC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Daphnia magna* | | AE F159737 | | 48 h, s | LC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE F159737 | | 7 d, ss | ErC50 >100 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Pseudokirchneriella subcapitata* | | AE F154781 | | 72 h, s | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| *Lemna gibba* | | AE F154781 | | 7 d, ss | ErC50 >10 mg met./L nom | | EFSA Journal  2016;14(4):4453 |
| Higher-tier studies | | | | | | | |
| *Lemna gibba* | | Iodosulfuron-  methyl-sodium | | Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d    Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d | | ErC50 = 0.00462 mg  a.s./L nom (frond area)      1st week ErC50 = 0.0272 mg a.s./L nom (frond area)    2nd week ErC50 =0.0159 mg a.s./L nom (frond area) | Kuhl, K.; 2016  [M-574865-01-1](dart://dart/edition?ed_no=M-574865-01-1) *New study; See justification.* |
| *Lemna gibba* | | AE F075736 | | Design 1: 2 peaks lasting 24h on day 0 and 3. Test duration 7 d | | ErC50 = 0.00203 mg  a.s./L nom (frond number) | Kuhl, K.; 2017  [M-600962-02-1](dart://dart/edition?ed_no=M-600962-02-1) *New study; See justification.* |
| *Lemna gibba* | | AE F075736 | | Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration 14 d | | 1st week ErC50 = 0.00585 mg a.s./L nom (frond area)    2nd week ErC50 =  0.00422 mg a.s./L nom  (frond area) | Kuhl, K., 2017  [M-600651-01-1](dart://dart/edition?ed_no=M-600651-01-1) *New study; See justification.* |
| **Higher-tier studies (micro- or mesocosm studies)** | | | | | | | |
| Higher-tier  Aquatic macrophytes  9 species | | | Iodosulfuron-methyl-sodium | 6 weeks, s | | NOEAEC = 0.00027 mg  a.s./L measured initial  NOEAEC = 0.00016 mg  a.s./L geomean  measured | EFSA Journal 2016;14(4):4453 |
| **Endpoints used for metabolites risk assessment in case that no test data are available** | | | | | | | |
| Fish acute  *Oncorhynchus mykiss* | | Metabolites of iodosulfuron-  methyl-sodium 1) | | 96 h, s | | LC50 >100 mg a.s./L nom | from parent compound - see justification for new endpoints |
| Fish prolonged  *Oncorhynchus mykiss* | | Metabolites of iodosulfuron-  methyl-sodium 2) | | 28 d, f | | NOEC = 7.79 mg a.s./L mm | from parent compound - see justification for new endpoints |
| Invertebrates acute  *Daphnia magna* | | Metabolites of iodosulfuron-  methyl-sodium 3) | | 48 h, s | | EC50 >100 mg a.s./L nom | from parent compound - see justification for new endpoints |
| Invertebr. prolonged  *Daphnia magna* | | Metabolites of iodosulfuron-  methyl-sodium 2) | | 21 d, ss | | NOEC = 7.9 mg a.s./L nom | from parent compound - see justification for new endpoints |
| Algae  *Pseudokirchneriella subcapitata* | | Metabolites of iodosulfuron-  methyl-sodium 4) | | 96 h, s | | ErC50 = 0.152  mg a.s./L nom | from parent compound - see justification for new endpoints |

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

1. AE F145741, AE F145740, AE 0002166, AE F161778, BCS-CW81253, AE 0000119, AE F059411, AE 0014966, AE 0034855, AE F154781
2. F145741, AE F145740, AE 0002166, AE F161778, BCS-CW81253, AE 0000119, AE F059411, AE 0014966, AE 0034855, AE 1234964, AE F159737, AE F154781
3. AE F145741, AE F145740, AE 0002166, AE F161778, BCS-CW81253, AE 0000119, AE 0014966, AE 0034855, AE F154781
4. AE 0000119, AE 0014966, AE 0034855, AE 1234964, AE F159737

**Mesosulfuron-methyl**

Studies on the toxicity to aquatic organisms have been carried out with mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents. Any additional data is referenced in Appendix 1 of this data. Presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584, if not otherwise stated.

The selection of studies and study-derived endpoints for the Tier 1 risk assessment is in line with the results of the EU review process, except for one new study submitted on metabolite BCS-CV14885 (during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009)), see justification provided below. In some cases, where surrogate RAC values for metabolites should be used according to the new aquatic guidance document (EFSA Journal 2013;11(7):3290) in the absence of a test, justifications on the derivation of these endpoints are provided.

**Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – mesosulfuron-methyl and relevant metabolites**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure**  **System** | **Results** | **Reference** |
| *Oncorhynchus mykiss Lepomis macrochirus*  *Cyprinodon variegates* | Mesosulfuron-methyl | 96 h, s | LC50 > 100 mg a.s./L nom | EFSA Journal  2016;14(10):4584 |
| *Oncorhynchus mykiss* | Mesosulfuron-methyl | 28 d (juvenile growth test), ss | NOEC = 32  mg a.s./L nom | EFSA Journal  2016;14(10):4584 |
| *Daphnia magna* | Mesosulfuron-methyl | 48 h, s | EC50 > 100 mg a.s./L nom | EFSA Journal  2016;14(10):4584 |
| *Daphnia magna* | Mesosulfuron-methyl | 21 d, ss | NOEC = 1.8  mg a.s./L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | Mesosulfuron-methyl | 72 h, s | ErC50 = 3.99 mg a.s./L mm 1) | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | Mesosulfuron-methyl | *Lemna gibba* | ErC50 = 0.001717 mg a.s./L(twa) | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | Mesosulfuron-methyl | 7 d, ss | ErC50 = 0.00129 mg a.s./L nom 2) | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | AE F154851 | 72 h, s | ErC50 = 38 mg/L mm | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | AE F154851 | 7 d, s | ErC50 = 0.11 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | AE F160459 | 72 h, s | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | AE F160459 | 7 d, s | ErC50 = 2.6 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Oncorhynchus mykiss* | AE F099095 | 96 h, s | LC50 > 70.7 mg/L nom | EFSA Journal  2016;14(10):4584\*\* |
| *Daphnia magna* | AE F099095 | 48 h, s | EC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584\*\* |
| *Pseudokirchneriella subcapitata* | AE F099095 | 72 h, s | ErC50 = 99.1 mg/L | EFSA Journal  2016;14(10):4584\*\*\* |
| *Lemna gibba* | AE F099095 | 7 d, s | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Oncorhynchus mykiss* | AE F092944 | 96 h, s | LC50 > 97 mg/L nom | EFSA Journal  2016;14(10):4584\* |
| *Daphnia magna* | AE F092944 | 48 h, s | EC50 = 223 mg/Lnom 3) | EFSA Journal  2016;14(10):4584\* |
| *Daphnia magna* | AE F092944 | 21 d, ss | NOEC = 24.9 mg/L mm | EFSA Journal  2016;14(10):4584\* |
| *Scenedesmus*  *subspicatus* | AE F092944 | 72 h, s | ErC50 > 100 mg/L | EFSA Journal  2016;14(10):4584\*\*\*\* |
| *Lemna gibba* | AE F092944 | 7 d, ss | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | AE F160460 | 7 d, ss | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | AE F140584 | 7 d, ss | ErC50 > 10 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | AE F147447 | 72 h, s | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | AE F147447 | 7 d, ss | ErC50 > 100 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | BCS-CO60720 | 72 h, s | ErC50 > 10 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella subcapitata* | BCS-CO60721 | 72 h, s | ErC50 > 10 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | BCS-CO60720 | 7 d, s | ErC50 > 11.8 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | BCS-CV14885 | 7 d, s | ErC50 = 0.00129 mg/L nom      ErC50 > 100 mg/L nom | generic surrogate value,  EFSA Journal  2016;14(10):4584    Kuhl, K.; 2017  [M-602447-01-1](dart://dart/edition?ed_no=M-602447-01-1) *New study; See justification.* |
| **Higher-tier studies** | | | | |
| *Lemna gibba* | Mesosulfuron-methyl | mimicking exposure of outdoor study  8 weeks | 7 -day ErC50  (frond area) = 0.00129 mg a.s./L nom 2)  7 -day ErC50  (frond number) =  0.00161  mg a.s./L nom 7-day NOErC = 0.00039 mg  a.s./L nom    8-week ErC50 = 0.00190  mg a.s./L nom  8-week NOErC  (frond area/number) = 0. 000388 mg a.s./L nom | EFSA Journal  2016;14(10):4584 |
| Aquatic macrophytes  (9 species)  *Elodea canadensis*  *Potamogeton pectinatus*  *Pontederia cordata*  *Nymphaea odorata*  *Cabomba caroliniana*  *Cerat. demersum*  *Glyceria maxima*  *Mentha aquatica*  *Myrio-*  *phyll.heterophyllum* | Mesosulfuron-methyl | outdoor growth inhibition, static  8 weeks | NOAEC  (shoot length/dry weight) = 0.00057 mg  a.s./Lmm | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | Mesosulfuron-methyl | Design 1: 2 peaks lasting 24h on day 0  and 3. Test duration  7 d    Design 2: 2 peaks lasting 24h on day 0 and 7. Test duration  14 d | ErC50 = 0.0109 mg a.s./L nom  (frond area)      1st week ErC50 > 0.100 mg a.s./L nom (frond area and frond  number)    2nd week ErC50 > 0.100 mg a.s./L nom (frond area and frond number) | Kuhl, K.; 2016 [M-577164-01-1](dart://dart/edition?ed_no=M-577164-01-1)  *New study; See justification.* |
| **Endpoints used for metabolites risk assessment in case that no test data are available** | | | | |

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

\* Refers to the EFSA conclusion on the peer review of the active substance flupyrsulfuron-methyl, EFSA Journal 2014;12(11):3881

\*\* Refers to the EFSA conclusion on the peer review of the active substance orthosulfamuron, EFSA Journal 2014;12(3):3353

\*\*\* Refers to the EFSA conclusion on the peer review of the active substance bensulfuron, EFSA Journal 2009;7(1):RN-178, 102 pp.

\*\*\*\* Refers to the EFSA conclusion on the peer review of the active substance flazasulfuron, EFSA Journal 2016; 14(8): 4575

1. Results of two studies on *Pseudokirchneriella subcapitata* are tabulated in the EFSA List of Endpoints, thereof the discrete numeric value of ErC50 = 3.99 mg a.s./L is deemed relevant for risk assessment, cf. clarification in RAR MCA Vol 3 B.9: introduction text of B.9.2.6 (page 44) and RMS comment on study KCA 8.2.6.1 /01 (page 46).
2. Results of several studies on aquatic plant are tabulated in the EFSA List of Endpoints, thereof the endpoint value for *Lemna gibba* 7 d ErC50 (frond area) = 1.29 μg/L is deemed relevant for Tier 1 risk assessment, cf. clarification in RAR MCA Vol 3 B.9: RMS comments on study KCA 8.2.7 /07 (page 74) and study KCA 8.2.7 /10 (page 82).
3. Results of two studies on *Daphnia magna* are tabulated in the EFSA List of Endpoints, thereof the discrete numeric value of EC50 = 223 mg/L is deemed relevant for risk assessment, as not in contradiction to the non-discrete value of EC50 > 100 mg/L resulting from the peer review of the active substance flupyrsulfuron-methyl, EFSA Journal 2014;12(11):3881.
4. AE F154851, AE F160459, AE F160460, AE F140584, BCS-CO60720, AE F147447, BCS-CV14885
5. AE F154851, AE F160459, AE F099095, AEF092944, AE F160460, AE F140584, AE F147447, BCS-CV14885, BCSCO60720
6. AE F154851, AE F160459, AE F099095, AE F160460, AE F140584, AE F147447, BCS-CV14885, BCS-CO60720

7) AE F160460, AE F140584, BCS-CV14885

Table 9.5‑3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Mefenpyr-diethyl and relevant metabolites

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| **Fish** | | | | |
| *Cyprinus carpio* | mefenpyr-diethyl | Acute 96 h (static) | **LC50 = 2.4 mg a.s./L nom** | Mefenpyr-diethyl DAR, 2011 |
| *Oncorhynchus mykiss* | mefenpyr-diethyl | Acute 96 h (static) | LC50 = 4.2 mg a.s./L nom |
| *Oncorhynchus mykiss* | mefenpyr-diethyl | JFG 28d (flow  through) | **NOEC = 0.100 mg a.s./L nom** |
| *Lepomis macrochirus* | AE F1132251) | Acute 96 h (static) | **LC50 > 100 mg/L nom** |
| *Oncorhynchus mykiss* | AE F1132251) | JFG 28d (flow  through) | **NOEC = 32 mg/L nom** |
| *Oncorhynchus mykiss* | AE F109453 | Acute 96 h (static) | **LC50 > 100 mg/L nom** |
| *Oncorhynchus mykiss* | AE F094270 | Acute 96 h (static) | LC50 > 100 mg/L nom |
| *Danio rerio* | AE F094270 | Acute 96 h (flow  through) | **LC50 > 72 mg/L nom** |
| *Danio rerio* | AE F094270 | EFS 8 d (flow through) | NOEC = 10 mg/L nom |
| *Danio rerio* | AE F094270 | 2-generation 206 d (flow through) | **NOEC = 3.2 mg/L nom** |
| *Cyprinus carpio* | AE F22110464) | Acute 96 h (static) | LC50 = 0.24 mg/L nom |
| *Oncorhynchus mykiss* | AE F22110464) | JFG 28d (flow  through) | NOEC = 0.01 mg/L nom |
| **Invertebrates** | | | | |
| *Daphnia magna* | mefenpyr-diethyl | Acute 48 h (static) | **EC50 = 5.500 mg a.s./L mm** | Mefenpyr-diethyl DAR, 2011 |
| *Daphnia magna* | mefenpyr-diethyl | Chronic 21d  (semi-static) | **NOEC = 0.320 mg a.s./L nom** |
| *Daphnia magna* | AE F1132251) | Acute 48 h (static) | **EC50 > 100 mg/L nom** |
| *Daphnia magna* | AE F1132251) | Chronic 21d (semi-static) | **NOEC = 3.2 mg/L nom** |
| *Daphnia magna* | AE F109453 | Acute 48 h (static) | **EC50 > 100 mg/L nom** |
| *Daphnia magna* | AE F094270 | Acute 48 h (static) | **EC50 > 60.3 mg/L mm** |
| *Daphnia magna* | AE F094270 | Chronic 21d (semi-static) | **NOEC = 32.0 mg/L nom** |
| *Chironomus riparius* | AE F094270 | Chronic 28d (static) | NOEC = 50.0 mg/L nom  (spiked water) |
| *Daphnia magna* | AE F22110464) | Acute 48 h (static) | EC50 = 0.55 mg/L mm |
| *Daphnia magna* | AE F22110464) | Chronic 21d (semi-static) | NOEC = 0.032 mg/L nom |
| **Algae** | | | | |
| *Pseudokirchneriella subcapitata* | mefenpyr-diethyl | 96 h growth test  (static) | EbC50 = 4.86 mg a.s./L mm  ErC50 = 10.71 mg a.s./L mm | Mefenpyr-diethyl DAR, 2011 |
| *Navicula pelliculosa* | mefenpyr-diethyl | 96 h growth test  (static) | EbC50 = 1.39 mg a.s./L mm  **ErC50 = 3.12 mg a.s./L mm** |
| *Pseudokirchneriella subcapitata* | AE F1132251) | 72 h growth test  (static) | EbC50 >100 mg/L nom  **ErC50 >100 mg/L nom** |
| *Pseudokirchneriella subcapitata* | AE F109453 | 96 h growth test  (static) | EbC50 = 41.9 mg/L nom2)  **ErC50 =41.9 mg/L nom2)** |
| *Pseudokirchneriella subcapitata* | AE F094270 | 96 h growth test  (static) | EbC50 = 30.8 mg/L nom3)  **ErC50 =42.0 mg/L nom3)** |
| *Navicula pelliculosa* | AE F22110464) | 72 h growth test  (static) | EbC50 = 0.139 mg a.s./L mm  ErC50 = 0.312 mg a.s./L mm |
| **Aquatic plants** | | | | |
| *Lemna gibba* | mefenpyr-diethyl | 7 d growth test  (static) | **EbC50 > 7.60 mg a.s./L mm**  ErC50 > 7.60 mg a.s./L mm | Mefenpyr-diethyl DAR, 2011 |
| *Lemna gibba* | AE F22110464) | 7 d growth test  (static) | EbC50 > 0.760 mg/L mm  ErC50 > 0.760 mg/L mm |

1) Also endpoint value of the isomeric metabolite AE F114952

2) Effects due to pH decrease, test item is dicarboxylic acid. In neutralised test medium the metabolite did not show any growth inhibition, resulting in EC50 values > 100 mg/L

3) Effects due to pH decrease, test item is carboxylic acid

4) This metabolite is considered, as a worst-case, 10 times more toxic than mefenpyr-diethyl.

**054-01-05**

Effects on aquatic organisms of the reference product Atlantis 12 OD (IMS+MSM+MPR OD 42 (2+10+30)) were evaluated as part of the EU assessment of the active substance mesosulfuron-methyl (representative formulation). Additionally, an assessment of the risk from both active substances and this reference product was performed during the renewal of Atlantis 12 OD (authorisation number R-98/2009).

054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). Consequently, no new studies are submitted with the formulation 054-01-05 and it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05.

As such, no new studies are submitted with this formulation and reference is made to the agreed endpoints reported in EFSA Journal 2016;14(10):4584, and RAR Volume 3 – B.9 (PPP) – ATLANTIS OD (revised version 2016-06).

Table 9.5‑4: Endpoints and effect values relevant for the risk assessment for aquatic organisms – 054-01-05

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Oncorhynchus mykiss* | IMS+MSM+MPR OD  42 (2+10+30)\* | 96 h, s | LC50 = 8.83 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Daphnia magna* | IMS+MSM+MPR OD  42 (2+10+30)\* | 48 h, s | EC50 = 7.6 mg/L nom | EFSA Journal  2016;14(10):4584 |
| *Pseudokirchneriella* | IMS+MSM+MPR OD  42 (2+10+30)\* | 72 h, s | ErC50 = 6.71 mg/L  nom | EFSA Journal  2016;14(10):4584 |
| *Lemna gibba* | IMS+MSM+MPR OD  42 (2+10+30)\* | 7 d, s | ErC50 = 0.0884  mg a.s./L nom | EFSA Journal  2016;14(10):4584 |

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

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Justification for new endpoints

Growth-rate-related endpoints are proposed to be used in risk assessment for algae and macrophytes according to the EFSA aquatic guidance document (2013) and the EFSA (2015) Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology (EFSA supporting publication 2015:EN-924. 62 pp.).

**Iodosulfuron-methyl-sodium**

**Table 9.5-5: Justification for new endpoints\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Justification** |
| *Lemna gibba* | Iodosulfuron-methyl-sodium | Higher tier:  refined exposure test  Design 1:  2 peaks lasting 24h on day 0 and 3. Test duration 7 d  Design 2:  2 peaks lasting 24h on day 0 and 7. Test duration 14 d | New peak-exposure studies on *Lemna gibba* were performed with iodosulfuron-methyl sodium and its metabolite AE F075736 to support the refinement options presented in this dossier. The need for further information to address the risk to aquatic plants was stated in the EFSA conclusion on iodosulfuron-methyl sodium (EFSA Journal 2016;14(4):4453). |
| *Lemna gibba* | metabolite AE F075736 | Higher tier:  refined exposure test  Design 1:  2 peaks lasting 24h on day 0 and 3. Test duration 7 d  Design 2:  2 peaks lasting 24h on day 0 and 7. Test duration 14 d |  |

In the review process for Annex I Renewal three Lemna-studies have been reviewed, two with iodosulfuron-methyl-sodium active substance and one with the formulation IMS+MPR OD 400 (Hussar OD). The endpoints from these studies (as given in the EFSA conclusion report EFSA Journal 2016;14(4):4453) are listed in the table below.

**Table 9.5-6: Survey of results obtained from *Lemna*-growth inhibition tests conducted with iodosulfuron-methyl-sodium active substance and Hussar OD**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Test substance** | **Design** | **Endpoint** | **Concentration** |
| *Lemna gibba*  (duck weed) | Iodosulfuron-methyl-sodium | 14 d  (semi-static) | frond number  7d EC50  14d EC50    7d ErC50  NOEC | 0.00079 mg a.s./L (nom)  0.00083 mg a.s./L (nom)    0.00134 mg a.s./L (nom)  0.00040 mg a.s./L (nom) |
| *Lemna gibba*  (duck weed) | Iodosulfuron-methyl-sodium + metsulfuron-methyl | 6 weeks (semi-static) | frond number  7d ErC50  6w ErC50  NOEC  frond area  7d ErC50  6w ErC50  NOEC | 0.00108 mg a.s./L (nom)  0.000679 mg a.s./L (nom)  0.000400 mg a.s./L (nom)    0.00112 mg a.s./L (nom)  0.000609 mg a.s./L (nom)  0.000400 mg a.s./L (nom) |
| *Lemna gibba*  (duck weed) | Iodosulfuron-methyl-sodium + mefenpyr-diethyl  (formulated as  OD) | 7 d static | frond number  7d ErC50    biomass 7d ErC50 | 0.0084 mg product/L (nom)  0.00074 mg a.s./L (nom)    > 0.100 mg product/L (nom)  > 0.00882 mg a.s./L (nom) |

The first *Lemna* study with the active ingredient is a 14-day study conducted in 1997 by Christ & Ruff according to EPA Guideline 122-2. In this study, only frond number was determined on days 2, 5, 7, 9, 11 and 14. A second measurement variable like frond dry weight or frond area, which is mandatory according to OECD 221 (2006), had not been determined. Moreover, inhibition percentages were only calculated by using the absolute frond counts in the treatments compared to the control. The originally reported endpoints are biomass endpoints (7d EbC50 and 14d EbC50), i.e. endpoints are based on final frond numbers after 7 and 14 days, respectively. Nowadays a 7-day ErC50 based on growth rate inhibition is recommended to be used in the risk assessment for aquatic plants according to the EFSA AGD (2013). Therefore, during the review process for Annex I Renewal the RMS calculated the specific growth rate at day 7 and the corresponding ErC50 using non-linear regression and concluded a 7d ErC50 of 1.34 µg a.s./L.

The second study (Bruns 2013) was performed according to the currently valid guideline OECD 221 (2006) including two measurement variables, frond number and frond area. As the study was designed to mimic the exposure of a prolonged outdoor study, the total study duration was longer than what is specified in the guideline. This was done to obtain 6-week effect data for *Lemna* – a species that was not able to grow outdoors under pond study conditions. Beside the 6-week endpoints, effect data were calculated on a weekly basis. Thus, the first 7 days of this study are in accordance with the current guideline and can be considered as a fully valid study without restrictions. The obtained 7-day endpoints can be used in the risk assessment. The lowest ErC50 of 1.08 µg a.s./L is very close to, but slightly lower than the calculated ErC50 of 1.34 µg/L from the old study.

The third study was done with IMS+MPR OD 400, which was the representative formulation in the Annex I Renewal process of iodosulfuron-methyl-sodium (containing, beside iodosulfuron-methyl-sodium, the safener mefenpyr-diethyl). An ErC50 of 8.4 µg formulation/L was derived from the test results. This refers to 0.74 µg iodosulfuron a.s./L.

In their Conclusion on iodosulfuron (EFSA Journal 2016;14(4)) EFSA has performed the macrophyte risk assessment for the representative formulation Hussar OD with the endpoint from the formulation study only (instead of using an endpoint derived with the tech. a.s. as test substance). It is worth noting that the formulation has a very low content of iodosulfuron-methyl sodium (less than 9%), therefore the extrapolation of the toxicity of the whole mixture to the active substance only is less accurate than a test with the active substance itself. Consequently, for the aquatic macrophyte risk assessment for other mixture formulations containing additional active substances and/or other safeners this endpoint is neither considered appropriate due to the nature of the tested material, nor is it considered necessary for precaution to ensure a sufficient conservatism.

Overall, it is proposed that the new fully valid and according to current state of the science performed 7day *Lemna*-study supersedes the old 14-day study which was based on frond counts solely. Consequently the new 7-day ErC50 of 1.08 µg a.s./L is used in the tier 1 risk assessment for aquatic plants.

A multispecies outdoor growth inhibition study (Hoberg, 2011) together with the related 6-week *Lemna* test originally was conducted in order to obtain dose-response relationships (EC50 values) for species other than *Lemna* and using those endpoints to build a species sensitivity distribution (SSD), finally delivering an HC5 for the refined aquatic plant risk assessment.

The outdoor and large scale test design had been chosen as previous experiments had revealed that most macrophyte species do not perform well under lab conditions under lab conditions. Algal infestation, artificial illumination and slow growth even in the controls were the main issues.

The outdoor study was not designed as a mesocosm and not to deliver an overall NOEC. Spacing of test concentrations and numbers of replicates were chosen to cover a wide range of concentrations, instead of using narrow spacing and many replicates around the level of the expected NOEC. Therefore, the derivation of an NOEAEC (0.27 µg a.s./L) that has been done by EFSA and its use in the refined aquatic plant risk assessment with additional assessment factor is considered not appropriate by the notifier.

While EFSA concluded that the study results should not be used for a species sensitivity distribution (SSD) analysis and calculation of statistically valid HC5, the study nevertheless gives valuable information to compare the sensitivity of the different tested species within the test and relative to *Lemna*: The multispecies outdoor pond study had been started with ten species. *Glyceria maxima* were removed from the study on exposure day 29 due to generally poor health in all treated and control ponds. Thus, the evaluation was done with the remaining nine species. *Lemna* has been tested as the 10th species in the 6week laboratory study mentioned above. The studies led to a broad range of EC50-figures from 0.5 µg a.s./L (6 wk ErC50 (leaf dry weight) *Salvinia*) up to greater than 61 μg a.s./L. With regard to NOECs, *Salvinia*, *Potamogeton* and *Elodea* were most sensitive in the multispecies test design.

The sensitivity of *Salvinia*, *Potamogeton* and *Elodea* relative to *Lemna* is discussed below:

Which is the most sensitive species …

**… based on 6-week NOEC?**

The 6-week-*Lemna* test was conducted at iodosulfuron concentrations of 0.1, 0.2, 0.4, 0.8 and 1.6 µg a.s./L. The lowest concentrations of the outdoor growth inhibition study with macrophytes were 0.25,

0.63 and 1.6 µg a.s./L. A survey of NOECs and concentrations tested in both studies is given in Table

9.5-7.

Table 9.5-7 shows that the NOECs for all four species *Lemna*, *Salvinia*, *Elodea* and *Potamogeton* are very close and give no clear indication which species is the most sensitive to iodosulfuron:

For *Potamogeton*, a NOEC of 0.25 µg a.s./L was reported, while for *Lemna* the NOEC over the whole 6weeks period was 0.4 µg a.s./L. However, due to the nature of the NOEC endpoint, these figures do not show that *Potamogeton* is more sensitive to iodosulfuron-methyl-sodium than *Lemna*:

NOECs are defined as highest tested concentration where no effect was observed. They depend on the actually chosen test concentrations, and do not give information whether at slightly higher concentrations an effect would have occurred. The “highest possible NOEC”, meaning the highest concentration at which no effect would occur, would be somewhere between the NOEC and the next higher actually tested concentration.

For *Lemna* the next higher concentration in the test was 0.8 µg a.s./L. Thus, the “highest possible NOEC” would have been between 0.4 and 0.8 µg/L.

For *Potamogeton* the next higher test concentration where effects were observed was 0.63 µg a.s./L. Accordingly, with differently chosen test concentrations, in the range of 0.25 and 0.63 µg a.s./L both species could have shown the same sensitivity, or even reverse - *Lemna* more sensitive than *Potamogeton*.

**Table 9.5-7: Survey of 6-week-NOECs (in µg/L) for *Lemna* and the three most sensitive macrophyte species. The respective NOEC is printed in bold. Concentrations in brackets have not been included in the respective test.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Lemna*** | ***Salvinia*** | ***Elodea*** | ***Potamogeton*** |
| 0.1 | *(0.1)* | *(0.1)* | *(0.1)* |
| 0.2 | *(0.2)* | *(0.2)* | *(0.2)* |
| *(0.25)* | 0.25 | 0.25 | **0.25** |
| **0.4** | *(0.4)* | *(0.4)* | *(0.4)* |
| *(0.63)* | **0.63** | **0.63** | 0.63 |
| 0.8 | *(0.8)* | *(0.8)* | 0.8 |
| 1.6 | 1.6 | 1.6 | 1.6 |

Green cells (in black-white-presentation: medium grey): concentration included in respective test, but no effect.

Red cells (in black-white-presentation: dark grey): concentration included in respective test, significant effect.

White cells: concentration not included in respective test, concentration below NOEC. Yellow cells (in black-white-presentation: light grey): concentration not included in respective test, concentration above NOEC.

**… based on 6-weeks ErC50?**

The lowest ErC50 derived from the 6-week pond study for the macrophytes is 0.54 μ a.s./L, derived for *Salvinia* *minima*. This endpoint is only slightly lower than the 6-week ErC50 value derived for *Lemna gibba* (0.609 and 0.679 µg a.s./L, for frond area and frond no., respectively). The species with the next higher ErC50 value was *Elodea* with an ErC50 of 1.3 µg a.s./L. Obviously, *Lemna* is the second most sensitive species out of ten species tested in the two tests, with an endpoint very near to the most sensitive species *Salvinia* minima.

Considering that the *Salvinia* endpoint has an extreme control variability (CV = 79.4%), it seems not justified to put emphasis on the slight difference of 0.1 µg/L between *Salvinia* and *Lemna* and to consider one more sensitive than the other. The similarity of *Salvinia* and *Lemna* becomes even more obvious, when the 6-week ErC50 values together with their 95% confidence limits are compared:

In Figure 9.5-1 6-week- ErC50 values for the 4 sensitive species are shown, together with their 95% confidence limits. For *Lemna* confidence limits are in a very narrow range, while for the other species *Salvinia*, *Elodea* and *Potamogeton* wide ranges were found, all showing a complete overlap with the ErC50 confidence limits for *Lemna*.

This analysis visualizes that *Salvinia* and *Lemna* can be regarded equally sensitive to iodosulfuron-methyl-sodium.

A graph with green and red lines

Description automatically generated

**Figure 9.5-1: Lowest 6-week ErC50-figures for *Lemna* and the three most sensitive macrophyte species. The range of 95% confidence limits is given as green bars.**

**Conclusion**

Neither the comparison of 6-week-ErC50-figures nor the interpretation of NOEC-levels give a clear indication, that one of the species tested in the macrophyte pond study is more sensitive to iodosulfuron-methylsodium than *Lemna*. On the other hand, it is shown that *Lemna* is clearly at the left hand side of the species sensitivity distribution.

In conclusion, the macrophyte pond study in the risk assessment for the current formulation should be considered as supplemental information, which supports that *Lemna* is clearly among the most sensitive species to iodosulfuron, and that a risk assessment based on *Lemna* is fully protective also for other macrophyte species.

Therefore, and as for *Lemna* by far the most comprehensive and reliable data set is available, it is justified to base the aquatic macrophyte risk assessment for iodosulfuron-methyl-sodium on the Tier 1 endpoint derived with *Lemna*.

**Iodosulfuron-methyl-sodium metabolites, where no test data are available**

As the dossier for Renewal of approval for iodosulfuron-methyl-sodium had been submitted shortly before the implementation of the Aquatic Guidance Document (EFSA:3290 (2013), the complete risk assessment in the review process was done according to the “old” guidance SANCO/3268/2001-rev. 4 (final), 17 October 2002. Following this guidance, the risk assessment for metabolites where no test data were available was based on the endpoint of the parent compound, reduced by an additional safety factor of 10.

These “surrogate endpoints” used in the risk assessment were not listed as EU agreed toxicity endpoints for any metabolite in the “EFSA Conclusion on Iodosulfuron-methyl-sodium” (EFSA Journal 2016;14(4)), but just noted in the respective risk assessment tables.

The risk assessment for the present submission has to follow the requirements and approaches of the “new” Aquatic Guidance Document (EFSA:3290 (2013). Therefore, also the approach for metabolites where no test data are available and no EU agreed toxicity endpoint has been defined, is revised according to this guidance.

The approach for metabolite risk assessment refers to part 10.2.4 decision scheme of the Aquatic Guidance Document (EFSA:3290 (2013)). The decision scheme is followed step by step.

**Step 1:** none of the studies with the active substance is adequate for assessing the potential effect of the metabolites:  step 3.

**Step 3:** As mentioned in the Aquatic Guidance Document, toxophores for major classes of PPP have been identified ([[1]](#footnote-1)Sinclair, 2009), for sulfonylureas, it is:

A chemical structure with black letters and numbers

Description automatically generated

On this basis, it is considered that metabolites AE F075736, AE F145741, AE F145740, AE 0002166, AE F161778 and AE 0014966 still contain the toxophore (step 4). The other metabolites (BCS CW81253, AE 0000119, AE F059411, AE0034855, AE 1234964, AE F159737 and AE F154781) have lost it (step 6).

**Step 4**: Identify the species or taxonomic group determining the lowest tier 1 RACsw,ac for the active substance. Is the acute metabolite L(E)C50 > 10 times the a.s. L(E)C50 (on a molar basis)?

The active substance is not acutely toxic on fish and daphnia. Consequently it is proposed to use the macrophyte endpoint to compare the level of effects of the parent and the metabolites even though it is not considered as an acute endpoint.

This approach shows that only AE F075736 EC50 is NOT greater than 10 times the a.s. EC50 (on a molar basis).

AE F075736  **step 5**, i.e. risk assessment is performed with available data on macrophytes (*Lemna*) as the most sensitive organism. All other metabolites  **step 6**, i.e. risk assessment will address all taxonomic groups with parent endpoints when no study was performed with the metabolite.

**Iodosulfuron metabolite AE F075736: Refined risk assessment for aquatic macrophytes**

Metabolite AE F075736 of iodosulfuron-methyl-sodium is identical to the active substance metsulfuronmethyl. The approval of this active substance in accordance with Regulation (EC) No 1107/2009 has been renewed in Reg. (EU) 2016/139 of 2 Feb 2016.

According to EFSA Journal 2016;14(4):4453 (EFSA conclusion of iodosulfuron) 2 studies are available describing the toxicity of AE F075736 to aquatic macrophytes (*Lemna gibba*). The study with the lower endpoints (ErC50 = 0.57 µg/L; EbC50 = 0.365 µg/L) EFSA has used in the risk assessment.

No study with these endpoints is owned or submitted, while the figures are identical to those listed as critical endpoints in the metsulfuron-methyl EFSA conclusion (EFSA Journal 2015;13(1):3936). Therefore, it is concluded that EFSA considers the study delivering the critical endpoints agreed for metsulfuron-methyl also as relevant for AE F075736.

Based on this study, a refined risk assessment has been agreed and described by EFSA in the Conclusions of the evaluation (Chapter 5) of EFSA Journal 2015;13(1):3936 (metsulfuron-methyl):

*“The experts agreed on the use of the 7-day TWA PECsw as a risk assessment refinement.*

*Furthermore, considering that a set of additional studies was available on aquatic macrophytes and all the Results showed Lemna to be the most sensitive macrophyte among the tested species, the experts also agreed to apply a lower assessment factor for the risk assessment. Overall, the experts agreed to use the endpoint for Lemna gibba and to use the 7-day TWA in combination with an assessment factor of 5.”*

To conclude, it was proposed during the renewal of the reference product Atlantis 12 OD to use the ErC50 of 0.57 µg a.s./L (with an AF of 10) for the risk assessment of metabolite AE F075736. This endpoint is from the study listed in EFSA Journal 2016;14(4):4453 (EFSA conclusion of iodosulfuron) and EFSA Journal 2015;13(1):3936 (EFSA conclusion of metsulfuron-methyl) as the appropriate study to be used. Furthermore, being a growth rate endpoint, using the ErC50 for macrophytes is in line with the recommendations of the new aquatic guidance document (EFSA:3290 (2013)). If a refined risk assessment using the 7-day TWA PECsw is to be done, we follow the approach recommended in the EFSA Conclusion on metsulfuron of using the lower endpoint EbC50 of 0.365 µg a.s./L from the same study, in combination with an assessment factor of 5.

**Mesosulfuron-methyl**

**Table 9.5-8: Justification for new endpoints\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Justification** |
| *Lemna gibba* | BCS-CV14885 | 7 d, s | Metabolite BCS-CV14885 was agreed devoid of biological activity on aquatic plant based on extensive structure-activity relationship considerations (cf. RAR MCP Vol.3 B.9 (PPP), pages 18-23). Nevertheless, a simplistic risk assessment PECsw  FOCUS Step 2 vs. surrogate parent endpoint was adopted by EFSA to conclude "A low risk to aquatic organisms was identified for all pertinent surface water metabolites of mesosulfuron-methyl for all the representative uses."    Using this approach, the aquatic risk assessment is not passed for newer FOCUSsw model versions (v3.1 and higher), as model update led to change in PECsw of BCS-CV14885 now exceeding of the surrogate RAC value.    A *Lemna* 7d growth inhibition test on BCS-CV14885 was therefore performed to generate a measured endpoint in replace of the surrogate value, which is essential to pass the EFSA proposed numeric risk assessment. |
| *Lemna gibba* | Mesosulfuron-methyl | Higher tier:  refined exposure test  Design 1:  2 peaks lasting 24h  on day 0 and 3. Test duration 7 d  Design 2:  2 peaks lasting 24h on day 0 and 7. Test duration 14 d | New peak-exposure studies on *Lemna gibba* were performed with mesosulfuron to support the refinement options presented in this dossier. The need for further information to address the risk to aquatic plants was stated in the EFSA conclusion on mesosulfuron (EFSA Journal 2016;14(10):4584).\* |

**Mesosulfuron-methyl metabolites, where no test data are available**

As the dossier for Renewal of approval for mesosulfuron-methyl had been submitted shortly before the implementation of the Aquatic Guidance Document (EFSA:3290 (2013), the complete risk assessment in the review process was done according to the “old” guidance SANCO/3268/2001-rev. 4 (final), 17 October 2002. Following this guidance, the risk assessment for metabolites where no test data were available was based on the endpoint of the parent compound, reduced by an additional safety factor of 10.

These “surrogate endpoints” used in the risk assessment were not listed as EU agreed toxicity endpoints for any metabolite in the “EFSA Conclusion on Mesosulfuron-methyl” (EFSA Journal 2016;14(10)), but just noted in the respective risk assessment tables.

The risk assessment for the present submission has to follow the requirements and approaches of the “new” Aquatic Guidance Document (EFSA:3290 (2013). Therefore, also the approach for metabolites where no test data are available and no EU agreed toxicity endpoint has been defined, is revised according to this guidance.

The approach for metabolite risk assessment refers to part 10.2.4 decision scheme of the Aquatic Guidance Document (EFSA:3290 (2013)). The decision scheme is followed step by step.

**Step 1:** none of the studies with the active substance is adequate for assessing the potential effect of the metabolites:  step 3.

**Step 3:** As mentioned in the Aquatic Guidance Document, toxophores for major classes of PPP have been identified ([[2]](#footnote-2)Sinclair, 2009), for sulfonylureas, it is:

A chemical structure with black letters and numbers

Description automatically generated

On this basis, it is considered that metabolites AE F154851, AE F160459 and AE F160460 still contain the toxophore. The other metabolites (AE F099095, AE F092944, AE F140584, AE F147447, BCSCV14885 and BCS-CO60720) have lost it.

However, this basic assessment can be refined with information on the herbicidal activity and on the toxicity on the most sensitive aquatic organisms (macrophytes). The herbicidal activity tests performed with AE F154851, AE F160459, AE F160460, AE F099095, AE F092944, AE F140584 and AE F147447 (cf. RAR MCA Vol 3 B.9: RMS comment on page 180) and BCS-CV14885 (KCA 8.6.1 /02 and KCA 8.6.1 /03) showed that these metabolites have no activity or an activity 10 to 100 times lower than the active substance.

Moreover, AE F154851, the metabolite displaying the lowest ErC50 on macrophytes (0.11 mg/L) is 65 times less toxic to *Lemna* than the active substance.

Therefore, it can be concluded that all metabolites have lost the toxophore  step 6, i.e. risk assessment will address all taxonomic groups with parent endpoints when no study was performed with the metabolite

### Risk assessment

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

The relevant global maximum FOCUS Step 1, 2, 3 and PECSW for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the evaluation of the reference product Atlantis 12 OD the accepted refinement was based on risk mitigation measures with PECsw max STEP 1- 4 calculated by FOCUS program.

**Spray drift exposure assessment for the formulated product – 054-01-05**

As a first step of the assessment, a simple “spray-drift only”- assessment is presented for the formulated product, based on the measured endpoints for each organism group, and exposure being calculated based on Rautmann drift values:

**Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for IMS+MSM+MPR OD 42 (2+10+30) for each organism group based on Screening level (drift only) calculations for the use in cereals – 1.5 L prod./ha (Use group E)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Inverteb. acute** | **Algae** | **Aquatic macrophyte** |
| **Test species** | *Oncorhynchus mykiss* | *Daphnia magna* | *Pseudokirchneriella subcapitata* | *Lemna gibba* |
| **Endpoint** | LC50 | EC50 | ErC50 | ErC50 |
| **(µg/L)** |  | 8830 | 7600 | 6710 | 88.4 |
| **AF** | 100 | 100 | 10 | 10 |
| **RAC (µg/L)** | 88.3 | 76 | 671 | 8.84 |
| **Drift only** | **PEC gl-max (µg/L)** |  |  |  |  |
| **no buffer** |  |  |  |  |  |
| 0 % drift reduction | 13.85 | 0.16 | 0.18 | 0.02 | **1.57** |
| 50% drift reduction | 6.925 |  |  |  | 0.78 |
| **5 meters buffer** |  |  |  |  |  |
| 0 % drift reduction | 2.85 |  |  |  | 0.32 |

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

**Conclusion:** In a screening level risk assessment for 1.5 L product/ha (use group E), measures for drift exposure mitigation equivalent to a 5 m buffer zone or a use of 50% drift reducing spray equipment would be required to pass the risk assessment for aquatic macrophytes.

This simplistic screening conclusion is however subject to higher tiered assessments on the basis of the individual active substances, which allow for more detailed and sophisticated risk analysis and the consideration of further possible entry routes, presented in the subsequent sections here below

For less critical uses the screening level risk assessment would be passed without drift exposure mitigation. In case higher tier assessments on the basis of individual active substances are not considered to overrule the conclusion of this screening assessment, formulation risk assessment should be expanded for the lower use rates, to avoid unnecessarily severe mitigation measures for these less critical uses.

### MDR Calculation for the Formulated Product – 054-01-05

To check plausibility of the hypothesis that concentration-additive toxicity of the individual components applies for the present active substances and formulation, measured toxicity of the formulation on the most sensitive organism (driver of the risk assessment) is compared to the expected toxicity for this organism when predicted via concentration-addition (Finney calculation). This is performed using the MDR approach as defined in the EFSA Aquatic Guidance document (page 33):

**Table 9.5-10: Calculation of the acute mixed toxicity of 054-01-05 to *Lemna* according to Finney additivity assumption**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Iodosulfuron-methyl-sodium** | **Mesosulfuron-methyl** | **Formulation** | |
| Content within the product [%] as tested | 0.21 | 1.06 | - | - |
| **Effects on aquatic plants** | | | | |
| ErC50 [µg/L] | 0.74 | 1.29 | Expected | 0.0011 |
| Measured | 0.0884 |
|  |  |  | MDR  (Model deviation ratio) | 1.082 |

The MDR is 1.082 clearly falling into the threshold corridor between 0.2 and 5 defined in the Aquatic Guidance document as criterion for the conclusion of concentration additive toxicity behaviour of a formulation.

In consequence, any further risk assessment considerations and refinements can safely be made on the level of the individual active components. Where required, toxicity of a mixture (e.g. the formulation, or a combination of substances simultaneously present in a surface water body) can be described as the arithmetic sum of individual toxicity contributions (RQmix = ∑RQi).

This approach will be applied in all subsequent assessments.

### Screening Level: Risk Envelope Assessment Based on FOCUS Steps 1-2, all active substances and metabolites

In this step, the risk is assessed substance by substance including all metabolites which may potentially enter surface water, for all groups of organisms. The assessment considers all possible entry routes to surface water (drift, run-off, drainage), with exposure calculated on screening level (FOCUS Step 1-2) for the generic risk

envelope use pattern (use group A) covering all possible uses.

**Iodosulfuron-methyl-sodium and metabolites**

**Iodosulfuron-methyl-sodium**

In the risk assessment for aquatic macrophytes, the following endpoints for Lemna sp have been considered: ErC50 of 0.74 µg/L, NOEAEC of 0.27 µg/L, (imm.) and of 0.16 µg/L (geomm.), ErC50 of 1.2 µg/L, or 1.02 µg/L values (two last values - geometric mean values).

**Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  |  |  | | **Aquatic plants** |  |  |
| **Test species** |  |  | | ***Lemna gibba*** |  |  |
| **Endpoint** | **ErC50** | **NOEAEC**  **(Higher tier)** | | **NOEAEC**  **(Higher tier)** | **Geomean ErC50** | **Geomean ErC50** |
| **(µg/L)** |  | **0.74\*** | **0.27\*\*** | | **0.16\*\*** | **1.02\*\*\*** | **1.20\*\*\*** |
| **AF** | **10** | **3** | | **3** | **10** | **10** |
| **RAC**  **(µg/L)** | **0.074** | **0.09** | | **0.053** | **0.10** | **0.12** |
| **FOCUS**  **Scenario** | **PEC glmax**  **(µg/L)** |  |  | |  |  |  |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | |  | |  |  |  |
|  | 3.2832 | **44.37** | **36.48** |  | **61.94** | **32.83** | **27.36** |
| **Step 2 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | |  | |  |  |  |
| N-Europe | 0.6491 | **8.77** | **7.21** | | **12.24** | **6.49** | **5.40** |
| S-Europe | 0.5348 | **7.22** |  | |  |  |  |

\* the endpoint used in EU review report (2016). Study was done with IMS+MPR OD400, which was the representative formulation in the Annex I Renewal process of iodosulfuron-methyl-sodium \*\* A modified outdoor exposure study, this RAC is used in the final risk assessment ( EFSA Conclusion 2016)

\*\*\* Geomean approach

For aquatic plants PEC/RAC values are >1 at STEP 1-2 calculations and considering all toxicity endpoints, indicating an unacceptable risk for Lemna sp. Further refinement with consideration the PECsw values at STEP 3 calculations is needed.

**Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F075736 for macrophytes based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A)**

|  |  |  |
| --- | --- | --- |
| **Group** |  | **Aquatic plants** |
| **Test species** | ***Lemna gibba\**** |
| **Endpoint**  **(µg/L)** | ErC50 |
| 0.57 |
| **AF** | 10 |
| **RAC**  **(µg/L)** | 0.057 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | |
|  | 3.7303 | **65.44** |
| **Step 2 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | |
| N-Europe | 1.2631 | **22.15** |
| S-Europe | 1.0192 | **17.88** |

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

\*Note: according to EFSA aquatic guidance document, the risk assessment for metabolites with the toxophore of the parent substance has to be performed on the most sensitive organisms only (i.e. *Lemna* in this specific case)

**Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F145741 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | >10000 | 3840 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | 384 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.4920 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.001 |

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

**Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F145740 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | >10000 | >10000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | >1000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.6570 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

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

**Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE 0002166 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| **(µg/L)** | >100000 | 7790 | >100000 | 7900 | >10000 | 20.3 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | 2.03 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 1.1460 | < 0.001 | 0.001 | < 0.001 | 0.001 | < 0.001 | 0.564 |

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

**Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F161778 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
|  | >100000 | 7790 | >100000 | 7900 | >10000 | 28.1 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | 2.81 |
| **FOCUS Sce-**  **nario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | |  |  |  |
|  | 0.3821 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | 0.136 |

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

**Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite BCS-CW81253 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 >10000 |
| >100000 | 7790 | >100000 | 7900 | >10000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | >1000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.7188 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

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

**Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE 0000119 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | 152 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | 15.2 | >10000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.4549 | <0.001 | <0.001 | <0.001 | <0.001 | 0.030 | <0.001 |

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

**Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F059411 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC  7790 | EC50 | NOEC  7900 | ErC50 | ErC50 |
| >100000 | >100000 | >100000 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >10000 | >10000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.5756 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

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

**Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE 0014966 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | 152 | 575 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | 15.2 | 57.5 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.3684 | <0.001 | <0.001 | <0.001 | <0.001 | 0.024 | 0.006 |

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

**Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE 0034855 for each organism group based on FOCUS Step 1 calculations for the use 054-01-05 cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | 152 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | 15.2 | >10000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.2648 | <0.001 | <0.001 | <0.001 | <0.001 | 0.017 | <0.001 |

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

**Table 9.5-22: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE 1234964 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | 152 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | 15.2 | >10000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.0964 | <0.001 | <0.001 | <0.001 | <0.001 | 0.006 | <0.001 |

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

**Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F159737 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata a*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | 152 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | 15.2 | >10000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.0925 | <0.001 | <0.001 | <0.001 | <0.001 | 0.006 | <0.001 |

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

**Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F154781 for each organism group based on FOCUS Step 1 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic macrophyte** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 7790 | >100000 | 7900 | >10000 | >10000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 779 | >1000 | 790 | >1000 | >1000 |
| **FOCUS**  **Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 10 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.0710 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

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

**Mesosulfuron-methyl**

**Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for mesosulfuron-methyl for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 32000 | >100000 | 1800 | 3990 | 1.29 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | 399 | 0.129 |
| **FOCUS Sce-**  **nario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 4.7448 | 0.005 | 0.001 | 0.005 | 0.026 | 0.012 | **36.78** |
| **Step 2 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
| N-Europe | 2.3009 | - | - | - | - | - | **17.84** |
| S-Europe | 1.8652 | - | - | - | - | - | **14.46** |

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

As there is an unresolved risk to *Lemna gibba* from mesosulfuron-methyl at the proposed GAP, further consideration will be provided.

**Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F154851 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** | LC50 >100000 | NOEC | EC50 | NOEC | ErC50 | ErC50  110 |
| **(µg/L)** | 32000 | >100000 | 1800 | 38000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | 3800 | 11 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.9504 | <0.01 | 0.001 | <0.01 | 0.026 | <0.001 | 0.86 |

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

**Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F160459 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50  2600 |
| >100000 | 32000 | >100000 | 1800 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | >10000 | 260 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 1.4744 | <0.015 | 0.001 | <0.015 | 0.026 | <0.0015 | 0.006 |

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

**Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F099095 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50  >100000 |
| **(µg/L)** | >70700 | 32000 | >100000 | 1800 | 99100 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >707 | 3200 | >1000 | 180 | 9910 | >10000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.4104 | <0.001 | 0.001 | <0.001 | 0.026 | <0.001 | <0.001 |

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

**Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F092944 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Scenedesmus subspicatus*** | ***Lemna gibba*** |
| **Endpoint** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50  >100000 |
| **(µg/L)** | >97000 | 32000 | >100000 | 24900 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >970 | 3200 | >1000 | 2490 | >10000 | >10000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.1486 | <0.001 | 0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

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

**Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F160460 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** |  | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| **(µg/L)** |  | >100000 | 32000 | >100000 | 1800 | 3990 | >100000 |
| **AF** |  | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** |  | >1000 | 3200 | >1000 | 180 | 399 | >10000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | |  |  |  |  |
|  | 0.8008 | <0.01 | 0.001 | <0.01 | 0.026 | 0.012 | <0.001 |

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

**Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F140584 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| >100000 | 32000 | >100000 | 1800 | 3990 | >10000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | 399 | >1000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.2898 | <0.003 | 0.001 | <0.003 | 0.026 | 0.012 | <0.001 |

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

**Table 9.5-30: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite AE F147447 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| **(µg/L)** | >100000 | 32000 | >100000 | 1800 | >100000 | >100000 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | >10000 | >10000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.4868 | <0.001 | 0.001 | <0.001 | 0.026 | <0.001 | <0.001 |

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

**Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite BCS-CV14885 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** | |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** | |
| **Endpoint**  **(µg/L)** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 | ErC50 |
| >100000 | 32000 | >100000 | 1800 | >100000 | 1.29  [LoE surrogate endpoint] | >100000 [new measured endpoint] |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 | 10 |
| **RAC (µg/L)** | >1000 | 3200 | >1000 | 180 | >10000 | 0.129 | >10000 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | | |
|  | 1.0542 | <0.001 | 0.001 | <0.001 | 0.026 | <0.001 | **8.172** | <0.001 |
| **Step 2** | | | | | | | | |
| N-Europe | 0.5125 |  |  |  |  |  | **3.97** |  |
| S-Europe | 0.4145 |  |  |  |  |  | **3.21** |  |

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

**Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite BCS-CO60720 for each organism group based on FOCUS Steps 1, 2 calculations for the use of 054-01-05 in cereals (use group A).**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Fish acute** | **Fish prolonged** | **Inverteb. acute** | **Inverteb. prolonged** | **Algae** | **Aquatic plants** |
| **Test species** | ***Oncorhynchus mykiss*** | ***Oncorhynchus mykiss*** | ***Daphnia magna*** | ***Daphnia magna*** | ***Pseudokirchneriella subcapitata*** | ***Lemna gibba*** |
| **Endpoint** | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| **(µg/L)** | >100000 | 32000 | >100000 | 1800 | > 10000 | > 11800 |
| **AF** | 100 | 10 | 100 | 10 | 10 | 10 |
| **RAC (µg/L)** | > 1000 | 3200 | > 1000 | 180 | > 1000 | > 1180 |
| **FOCUS Scenario** | **PEC gl-max**  **(µg/L)** |  | | | | | |
| **Step 1 (risk envelope approach: 15 g/ha, year-round use, no crop interception)** | | | | | | | |
|  | 0.5446 | <0.005 | 0.001 | <0.005 | 0.026 | <0.001 | <0.001 |

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

**Combined risk assessment - Screening Level**

According to current requirements when a product contains more than one active substance, an additional assessment on combined toxicity risk has to be presented. It is considered that a quantitative assessment according to concentration addition is however not needed if one of the following points applies: - The risk assessment for all active substances in the product passes with a high margin of safety. - One active substance clearly drives the risk assessment.

These conditions are assessed following a step-wise approach. A detailed description of this approach is presented in a separate document (Gladbach, A., Ebeling, M., Weyers, A., 2016, [M-571377-02-1)](dart://dart/edition?ed_no=M-571377-02-1). The assessment is based on RQ values (risk quotient RQ = PEC/RAC). Note that RQ values which actually pass the risk assessment are used and if different mitigation measures result in an acceptable risk, the highest RQ value per individual substance is used.

**1st step: Margin of safety**

Condition: all RQ values are < 1/n (n = number active substances in the mixture).

**2nd step: Risk per fraction**

Condition: One active substance contributes to ≥ 90% of the predicted combined toxicity of the product.

Assessment: The contribution of each individual active substance to the combined toxicity (risk per fraction, rpf) is estimated based on the following equation:

The *rpfa*.*s*.1 = *RQa*..*s*.1 /(*RQa*.*s*.1 +*RQa*.*s*.2...+*RQa*..*s*.*i* ) estimation is based on RQ values from the same FOCUS Step to assure comparability.

**3rd step: RQMIX calculation**

Condition: The combined risk is acceptable when RQMIX  ≤ 1.

Assessment: The combined toxicity risk (RQMIX) with concentration-addition for aquatic organisms is estimated according to the following formula:

*RQmix* = A close up of text

Description automatically generated

**Table 9.5-33: Combined toxicity risk assessment for aquatic organisms – Screening Tier, FOCUS Step 1-2 for generic risk envelope (use group A)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Group** | | **Fish, acute** | **Fish, prolonged** | **Invertebrates, acute** | **Invertebrates, prolonged** | **Algae** | **Aquatic macrophytes** |
| **RQ values**1) | **MSM** | 0.005 | 0.001 | 0.005 | 0.026 | 0.012 | **17.842)** |
| **IMS** | < 0.003 | 0.004 | < 0.003 | 0.004 | 0.216 | **6.012)** |
| **AE F075736** | - | - | - | - | - | **22.152)** |
| **Trigger** | | 1 | 1 | 1 | 1 | 1 | 1 |
| **1/n** | | 0.50 | 0.50 | 0.50 | 0.50 | 0.50 | 0.33 |
| **1**st **step:**  **All RQ < 1/n** | | yes | yes | yes | yes | yes | Not profitable at screening level, as risk envelope assessment remained  unresolved for individual substances MSM, IMS, and AE F075736.  **Combined assessment for macrophytes is**  **therefore presented at**  **Tier 1, Tier 2, and Tier 3 for the accurate GAP below.** |
| **2**nd **step:**  **RPF**max | | Not needed | Not needed | Not needed | Not needed | Not needed |
| **3**rd **step:**  **RQ**mix | | Not needed | Not needed | Not needed | Not needed | Not needed |

MSM = mesosulfuron-methyl, IMS = iodosulfuron-methyl-sodium

1) Based on FOCUS step 1 calculations 2) Based on FOCUS Step 2 calculations

Combined toxicity risk is resolved for all aquatic organism groups other than macrophytes via a simple FOCUS Step 1-2 based screening level assessment for the generic risk envelope use pattern (use group A), covering all uses.

**Overall conclusion from Screening Level risk assessment:**

Assuming a highly conservative generic exposure situation (FOCUS Step 1-2 exposure simulations for risk envelope use pattern covering all uses, use group A), risk assessment including combination toxicity could be resolved for all groups of aquatic organisms other than macrophytes. Acceptable risk was also demonstrated for all biologically inactive metabolites (i.e. other than AE F075736), for all groups of organisms. Subsequent assessment steps will therefore concentrate on the biologically active components of relevance for this formulation, i.e. iodosulfuron-methyl-sodium, metabolite AE F075736, and mesosulfuron-methyl.

**Tier 1: Accurate GAP assessment based on FOCUS Step 3, all active substances and metabolite AE F075736**

In the following section the risk assessment will focus on macrophytes, as only for this group the risk was left unresolved after the FOCUS Step 1-2 based screening level assessments presented before. Tier 1 level risk assessment will start from FOCUS step 3 exposure calculations for the three critical GAP situations of use groups B-D covering all intended product uses of 054-01-05 in countries requiring FOCUSsw calculations.

The Tier 1 risk assessment will follow the recommendations of the EFSA Aquatic guidance document for chronic risk assessment, as found visualised in "Decision scheme B" on guidance page 15, and further outlined in the subsequent text of pages 15-16. In the chronic risk assessment, the RACsw is, in the first instance, compared with the PECsw;max, and under certain conditions with a PECsw;twa (the predicted time-weighted average (TWA) concentration in surface water). A decision scheme on when to use the PECsw;max or the PECsw;twa in the chronic RA is presented in the guidance and will be applied below to the components to be addressed.

**Iodosulfuron-methyl-sodium**

In the risk assessment for aquatic macrophytes, the following endpoints for Lemna sp were considered.: ErC50 of 0.74 µg/L, NOEAEC of 0.27 µg/L, (imm.) and of 0.16 µg/L (geom.), ErC50 of 1.2 µg/L, or 1.02 µg/L values (geometric mean).

The risk assessment for iodosulfuron-methyl-sodium, with consideration max PECsw STEP 3 values for all toxicity endpoints for Lemna sp.. is presented in the Tables below.

**Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium for aquatic macrophytes based on FOCUS Step 3 calculations for the use of 054-01-05 in cereals**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Group** |  | **Aquatic plants** | | | | |
| **Test species** | ***Lemna gibba*** | | | | |
| **Endpoint**  **µg/L** | **ErC50** | **NOEAEC (Higher tier)** | **NOEAEC (Higher tier)** | **Geomean ErC50** | **Geomean ErC50** |
| **0.74\*** | **0.27\*\*** | **0.16\*\*** | **1.02\*\*\*** | **1.20\*\*** |
| **AF** | **10** | **3** | **3** | **10** | **10** |
| **RAC** (**µg/L)** | **0.074** | **0.09** | **0.053** | **0.10** | **0.12** |
| **FOCUS**  **Scenario** | **PEC gl-max (µg/L)** |  | | | | |
| **use group B: end of winter to spring use on winter cereals / rate = 3 g/ha)** | | | | | | |
| D1/ditch | 0.0197 | 0.266 | 0.219 | 0.372 | 0.197 | 0.164 |
| D1/stream | 0.0165 | 0.223 | 0.183 | 0.311 | 0.165 | 0.138 |
| D2/ditch | 0.1540 | **2.081** | **1.711** | **2.906** | **1.540** | **1.283** |
| D2/stream | 0.09622 | **1.300** | **1.069** | **1.815** | 0.962 | 0.802 |
| D3/ditch | 0.0191 | 0.258 | 0.212 | 0.360 | 0.191 | 0.159 |
| D4/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| D4/stream | 0.0144 | 0.195 | 0.160 | 0.272 | 0.144 | 0.120 |
| D5/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| D5/stream | 0.0149 | 0.201 | 0.166 | 0.281 | 0.149 | 0.124 |
| D6/ditch | 0.0190 | 0.257 | 0.211 | 0.358 | 0.190 | 0.158 |
| R1/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| R1/stream | 0.0139 | 0.188 | 0.154 | 0.262 | 0.139 | 0.116 |
| R3/stream | 0.0428 | 0.578 | 0.476 | 0.808 | 0.428 | 0.357 |
| R4/stream | 0.0292 | 0.395 | 0.324 | 0.551 | 0.292 | 0.243 |
| **use group B: end of winter to spring use on winter cereals / rate = 3 g/ha)**  **-Refinement: exposure simulation based on field soil kinetics data** | | | | | | |
| D1/ditch | 0.0198 | 0.268 | 0.220 | 0.374 | 0.198 | 0.165 |
| D1/stream | 0.0165 | 0.223 | 0.183 | 0.311 | 0.165 | 0.138 |
| D2/ditch | 0.1788 | **2.416** | **1.987** | **3.374** | **1.788** | **1.490** |
| D2/stream | 0.1119 | **1.512** | **1.243** | **2.111** | 1.119 | 0.933 |
| D3/ditch | 0.0191 | 0.258 | 0.212 | 0.360 | 0.191 | 0.159 |
| D4/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| D4/stream | 0.0144 | 0.195 | 0.160 | 0.272 | 0.144 | 0.120 |
| D5/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| D5/stream | 0.0149 | 0.201 | 0.166 | 0.281 | 0.149 | 0.124 |
| D6/ditch | 0.0190 | 0.257 | 0.211 | 0.358 | 0.190 | 0.158 |
| R1/pond | 0.0007 | 0.009 | 0.008 | 0.013 | 0.007 | 0.006 |
| R1/stream | 0.0149 | 0.201 | 0.166 | 0.281 | 0.149 | 0.124 |
| R3/stream | 0.0453 | 0.612 | 0.503 | 0.855 | 0.453 | 0.378 |
| R4/stream | 0.0314 | 0.424 | 0.349 | 0.592 | 0.314 | 0.262 |
| **use group D: autumn use on winter cereals / rate = 2 g/ha\*)** | | | | | | |
| D1/ditch | 0.0897 | **1.212** | 0.997 | **1.692** | 0.897 | 0.748 |
| D1/stream | 0.0573 | 0.774 | 0.637 | **1.081** | 0.573 | 0.478 |
| D2/ditch | 0.0802 | **1.084** | 0.891 | **1.513** | 0.802 | 0.668 |
| D2/stream | 0.0503 | 0.680 | 0.559 | 0.949 | 0.503 | 0.419 |
| D3/ditch | 0.0128 | 0.173 | 0.142 | 0.242 | 0.128 | 0.107 |
| D4/pond | 0.0039 | 0.053 | 0.043 | 0.074 | 0.039 | 0.033 |
| D4/stream | 0.0103 | 0.139 | 0.114 | 0.194 | 0.103 | 0.086 |
| D5/pond | 0.0008 | 0.011 | 0.009 | 0.015 | 0.008 | 0.007 |
| D5/stream | 0.0117 | 0.158 | 0.130 | 0.221 | 0.117 | 0.098 |
| D6/ditch | 0.0127 | 0.172 | 0.141 | 0.240 | 0.127 | 0.106 |
| R1/pond | 0.0004 | 0.005 | 0.004 | 0.008 | 0.004 | 0.003 |
| R1/stream | 0.0107 | 0.145 | 0.119 | 0.202 | 0.107 | 0.089 |
| R3/stream | 0.0925 | **1.250** | **1.028** | **1.745** | 0.925 | 0.771 |
| R4/stream | 0.0242 | 0.327 | 0.269 | 0.457 | 0.242 | 0.202 |
| **use group C – FOCUS Step 3 (spring use on cereals / rate = 2 g/ha)** | | | | | | |
| D1/ditch | 0.0130 | 0.176 | 0.144 | 0.245 | 0.130 | 0.108 |
| D1/stream | 0.0102 | 0.138 | 0.113 | 0.192 | 0.102 | 0.085 |
| D3/ditch | 0.0128 | 0.173 | 0.142 | 0.242 | 0.128 | 0.107 |
| D4/pond | 0.0004 | 0.005 | 0.004 | 0.008 | 0.004 | 0.003 |
| D4/stream | 0.0103 | 0.139 | 0.114 | 0.194 | 0.103 | 0.086 |
| D5/pond | 0.0004 | 0.005 | 0.004 | 0.008 | 0.004 | 0.003 |
| D5/stream | 0.0100 | 0.135 | 0.111 | 0.189 | 0.100 | 0.083 |
| R4/stream | 0.0083 | 0.112 | 0.092 | 0.157 | 0.083 | 0.069 |

\* the endpoint used in EU review report (2016). Study was done with IMS+MPR OD400, which was the representative formulation in the Annex I Renewal process of iodosulfuron-methyl-sodium

\*\* A modified outdoor exposure study, this RAC is used in the final risk assessment

\*\*\* Geomean approach

# Autumn use in certain countries (NL, DE, UK) involves a higher intended dose rate of 1.2 L product/ha  2.4 g/ha iodosulfuron-methyl-sodium. Aquatic risk for this use situation will be addressed in the respective National Addenda documents, as national requirements request the use of country specific exposure models instead of the EU FOCUSsw procedure that is used in Core Assessment.

For three lowest toxicity endpoints : ErC50 of 0.74 µg/L, NOEAC of 0.16 µg/L and NOAEC of 0.27 µg/L, the acceptable risk cannot be demonstrated for Central Zone relevant scenarios, only in case of R3 stream scenario for winter cereals (use B, autumn use in winter cereals).

Step 4 values were calculated for all scenarios for completeness, however for D1 and D2 scenarios it is not possible to mitigate using FOCUS Step 4 as the main input is from drainage.

As such, only R3 scenario in the calculations are considered and therefore a risk assessment was provided for R3 scenario (winter cereals, autum use, 2 g a.s.ha) with consideration of PECsw STEP 4 values for Lemna sp

**Table 9.5-35.1: PECsw calculation and acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of 054-01-05 in cereals – Use: winter cereals, 1 × 2 g iodosulfuron methyl-sodium/ha, autumn use.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Winter cereals, autumn use,**  **2 g a.s./ha** | **Scenario** |  |  |  | |  |  | **PECsw / RAC RAC = 0.053 µg/L** | |  | |  |  |
|  |  | **PEC gl-max** | |  |  |  | | **PEC gl-max** | |  |  |
| Nozzle red. | **Vegetated strip (m)** | None | None | None | None | 10 m low\* | 20 m high\* | None | None | None | None | 10 m low\* | 20 m high\* |
| **No spray buffer**  **(m)** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** |
| None | **R3 Stream** | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.745283** | **1.745283** | **1.745283** | **1.745283** | 0.784906 | 0.409434 |
| 50 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.745283** | **1.745283** | **1.745283** | **1.745283** | 0.784906 | 0.409434 |
| 75 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.745283** | **1.745283** | **1.745283** | **1.745283** | 0.784906 | 0.409434 |
| 90 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.745283** | **1.745283** | **1.745283** | **1.745283** | 0.784906 | 0.409434 |

**Table 9.5-35.2: PECsw calculation and acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of 054-01-05 in cereals – Use: winter cereals, 1 × 2 g iodosulfuron methyl-sodium/ha, autumn use.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Winter cereals,**  **autumn use,**  **2 g a.s./ha** | | **Scenario** |  |  |  | |  |  | **PECsw / RAC RAC = 0.074 µg/L** | |  | |  |  |
|  |  | **PEC gl-ma** | | **x** |  |  | | **PEC gl-max** | |  |  |
| Nozzle red. | | **Vegetated strip (m)** | **None** | **None** | **None** | **None** | **10 m low\*** | **20 m high\*** | **None** | **None** | **None** | **None** | **10 m low\*** | **20 m high\*** |
|  | **No spray buffer (m)** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** |
| None | **R3 Stream** | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.250** | **1.250** | **1.250** | **1.250** | 0.562162 | 0.293243 |
| 50 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.250** | **1.250** | **1.250** | **1.250** | 0.562162 | 0.293243 |
| 75 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.250** | **1.250** | **1.250** | **1.250** | 0.562162 | 0.293243 |
| 90 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.250** | **1.250** | **1.250** | **1.250** | 0.562162 | 0.293243 |

**Table 9.5-35.3: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of IMS+MSM+MPR OD 42 (2+10+30) in cereals – Use: winter cereals, 1 × 2 g iodosulfuron-methyl-sodium/ha, autumn use.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Winter cereals,**  **autumn use,**  **2 g a.s./ha** | **Scenario** |  |  | | | |  | **PECsw / RAC RAC = 0.09µg/L** | |  | |  |  |
|  | **PEC gl-max** | | | |  |  | | **PEC gl-max** | |  |  |
| **Nozzle red.** | **Vegetated strip (m)** | **None** | **None** | **None** | **None** | **10 m low\*** | **20 m high\*** | **None** | **None** | **None** | **None** | **10 m low\*** | **20 m high\*** |
| **No spray buffer (m)** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** | **0 m** | **5 m** | **10 m** | **20 m** | **10 m** | **20 m** |
| None | **R3 Stream** | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.028** | **1.028** | **1.028** | **1.028** | 0.4622 | 0.2411 |
| 50 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.028** | **1.028** | **1.028** | **1.028** | 0.4622 | 0.2411 |
| 75 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.028** | **1.028** | **1.028** | **1.028** | 0.4622 | 0.2411 |
| 90 % | 0.0925 | 0.0925 | 0.0925 | 0.0925 | 0.0416 | 0.0217 | **1.028** | **1.028** | **1.028** | **1.028** | 0.4622 | 0.2411 |

**Conclusion:**

The acceptability of risk (PEC/RAC<1) for iodosulfuron-methyl-sodium based on FOCUS Step 4 calculations for R3 scenario for aquatic plants is considered, when at 10 m vegetative buffer zone will be applied in winter cereals for application rate 1x 2 g a.s./ha, autumn use.

It should be noted that consideration of a 10 and 20 meter vegetated buffer zone is member state specific and should be considered further by member states according to their own national rules on risk mitigation.

Furthermore, as the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions.

**Metabolite AE F075736 of Iodosulfuron-methyl-sodium**

This metabolite is also known as metsulfuron-methyl, another active substance having undergone EU review for Annex I inclusion. EFSA concluded[[3]](#footnote-3) that the PECtwa can be used for risk assessment, in combination with the EbC50 endpoint and a safety factor of 5. As this procedure has been previously EU agreed, no further applicability check according to AGD decision scheme is presented here.

**Risk Assessment:** In the following, therefore both, a risk assessment based on PECsw,max and a risk assessment based on PECsw, 7d-twa with associated RAC according EFSA will be shown side-by-side, as they are considered to represent alternative Tier 1 approaches applicable for metabolite AE F075736.

**Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for iodosulfuron-methyl-sodium metabolite AE F075736 for aquatic plants based on FOCUS Step 3 calculations for the use of 054-01-05 in cereals.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Group** |  | **Aquatic plants**  ***Lemna gibba***  ErC50 |  | **Aquatic plants1)** |
| **Test species** | ***Lemna gibba*** |
| **Endpoint** | EbC50 |
| **(µg/L)** |  | 0.57  10  0.057 |  | 0.365 |
| **AF** | 5 |
| **RAC (µg/L)** | 0.073 |
| **FOCUS Scenario** | **PEC gl-max (µg/L)** |  | **7-d PECtwa (µg/L)** |  |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g a.s./ha )** | | | |  |
| D1/ditch | 0.0348 | 0.611 | 0.0342 | 0.468 |
| D1/stream | 0.0282 | 0.495 | 0.0201 | 0.275 |
| D2/ditch | 0.1583 | **2.777** | 0.1122 | **1.537** |
| D2/stream | 0.1302 | **2.284** | 0.0697 | 0.955 |
| D3/ditch | 0.0053 | 0.093 | 0.0053 | 0.073 |
| D4/pond | 0.0123 | 0.216 | 0.0123 | 0.168 |
| D4/stream | 0.0065 | 0.114 | 0.0062 | 0.085 |
| **Group** |  | **Aquatic plants** |  | **Aquatic plants1)** |
| D5/pond | 0.0024 | 0.042 | 0.0024 | 0.033 |
| D5/stream | 0.0013 | 0.023 | 0.0011 | 0.015 |
| D6/ditch | 0.0010 | 0.018 | 0.0010 | 0.014 |
| R1/pond | 0.0003 | 0.005 | 0.0003 | 0.004 |
| R1/stream | 0.0071 | 0.125 | 0.0004 | 0.005 |
| R3/stream | 0.0133 | 0.233 | 0.0009 | 0.012 |
| R4/stream | 0.0111 | 0.195 | 0.0013 | 0.018 |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g/ha)**  **– Refinement: exposure simulation based on field soil kinetics data** | | | | |
| D1/ditch | 0.0156 | 0.274 | 0.0154 | 0.211 |
| D1/stream | 0.0134 | 0.235 | 0.0091 | 0.125 |
| D2/ditch | 0.0880 | **1.544** | 0.0618 | 0.847 |
| D2/stream | 0.0867 | **1.521** | 0.0442 | 0.605 |
| D3/ditch | 0.0002 | 0.004 | 0.0002 | 0.003 |
| D4/pond | 0.0006 | 0.011 | 0.0006 | 0.008 |
| D4/stream | 0.0003 | 0.005 | 0.0003 | 0.004 |
| D5/pond | 0.0002 | 0.004 | 0.0002 | 0.003 |
| D5/stream | 0.0002 | 0.004 | <0.0001 | <0.001 |
| D6/ditch | 0.0003 | 0.005 | 0.0003 | 0.004 |
| R1/pond | 0.0002 | 0.004 | 0.0002 | 0.003 |
| R1/stream | 0.0040 | 0.070 | 0.0002 | 0.003 |
| R3/stream | 0.0090 | 0.158 | 0.0006 | 0.008 |
| R4/stream | 0.0062 | 0.109 | 0.0007 | 0.010 |
| **Group** |  | **Aquatic plants** |  | **Aquatic plants1)** |
| **use group D – FOCUS Step 3**  **(autumn use on winter cereals / rate = 2 g a.s./ha )** | | |  |  |
| D1/ditch | 0.1625 | **2.851** | 0.1374 | **1.882** |
| D1/stream | 0.1095 | **1.921** | 0.0954 | **1.307** |
| D2/ditch | 0.1271 | **2.230** | 0.0826 | **1.132** |
| D2/stream | 0.0864 | **1.516** | 0.0525 | 0.719 |
| D3/ditch | 0.0140 | 0.246 | 0.0140 | 0.192 |
| D4/pond | 0.0460 | 0.807 | 0.0459 | 0.629 |
| D4/stream | 0.0365 | 0.640 | 0.0292 | 0.400 |
| D5/pond | 0.0360 | 0.632 | 0.0358 | 0.490 |
| D5/stream | 0.0220 | 0.386 | 0.0183 | 0.251 |
| D6/ditch | 0.0400 | 0.702 | 0.0141 | 0.193 |
| R1/pond | < 0.0001 | < 0.018 | < 0.0001 | < 0.014 |
| R1/stream | 0.0006 | 0.011 | < 0.0001 | < 0.014 |
| R3/stream | 0.0250 | 0.439 | 0.0019 | 0.026 |
| R4/stream | 0.0130 | 0.228 | 0.0011 | 0.015 |
| **use group C – FOCUS Step 3**  **(spring use on cereals / rate = 2 g/ha)** | | |  |  |
| D1/ditch | 0.0364 | 0.639 | 0.0349 | 0.478 |
| D1/stream | 0.0234 | 0.411 | 0.0213 | 0.292 |
| D3/ditch | 0.0046 | 0.081 | 0.0045 | 0.062 |
| D4/pond | 0.0089 | 0.156 | 0.0089 | 0.122 |
| D4/stream | 0.0046 | 0.081 | 0.0044 | 0.060 |
| D5/pond | 0.0017 | 0.030 | 0.0017 | 0.023 |
| **Group** |  | **Aquatic plants** |  | **Aquatic plants1)** |
| D5/stream | 0.0009 | 0.016 | 0.0008 | 0.011 |
| R4/stream | 0.0006 | 0.011 | < 0.0001 | < 0.014 |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in **bold** 1) according to EFSA conclusion; (EFSA Journal 2015;13(1):3936)

When the risk assessment is based on PECsw, max, one FOCUS scenario is left unresolved (i.e. D2 ditch/stream) for the intended end of winter application in winter cereals, or two scenarios (i.e. D1 ditch/stream and D2 ditch/stream) for the intended autumn use. Scenario D2 can be resolved for the end of winter application in winter cereals, when applying assessment parameters and procedures as are EU agreed for metsulfuron-methyl, i.e. based on 7d-TWA PECsw with a dedicated RAC value, and a refined exposure assessment based on field soil kinetics data.

As demonstrated in the exposure simulations (see Efate section), exposure in the D1 and D2 scenarios is driven by the entry route drainage. Drainage entry cannot be mitigated by the options considered in FOCUS Landscape & Mitigation. Therefore, no additional assessment based on FOCUS Step 4 is deemed necessary here, as it would not exert effect on the D1 and D2 exceedances[[4]](#footnote-4).

Overall, therefore for metabolite AE F075736 of iodosulfuron-methyl-sodium the risks are acceptable at Tier 1 level for all intended uses of the product in all European geoclimatic regions other than those represented by soil/climate scenario situations D1 and D2. Both of these scenarios are considered not representative in a Central Zone context.

A more in depth refined assessment of the potential risk for macrophytes posed by these scenario situations will be made in Section 9.5.2.7 of this document, as part of the Tier 3 level assessment.

**Mesosulfuron-methyl**

**Risk Assessment:** A risk assessment based on PECsw,max has been presented below.

**Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for mesosulfuron-methyl for aquatic macrophytes based on FOCUS Step 3 calculations for the use of 054-01-05 in cereals.**

|  |  |  |
| --- | --- | --- |
| **Group** |  | **Aquatic plants**  ***Lemna gibba***  ErC50 |
| **Test species** |
| **Endpoint** |
| **(µg/L)** |  | 1.29  10  0.129 |
| **AF** |
| **RAC (µg/L)** |
| **FOCUS Scenario** | **PEC gl-max (µg/L)** |  |
| **use group B – FOCUS Step 3 (end of winter to spring use on winter cereals / rate = 15 g/ha )** | | |
| D1/ditch | 0.2187 | **1.695** |
| D1/stream | 0.1410 | **1.093** |
| D2/ditch | 1.6040 | **12.434** |
| D2/stream | 1.0230 | **7.930** |
| D3/ditch | 0.0982 | 0.761 |
| D4/pond | 0.0412 | 0.319 |
| D4/stream | 0.0770 | 0.597 |
| D5/pond | 0.0198 | 0.153 |
| D5/stream | 0.0827 | 0.641 |
| D6/ditch | 0.1009 | 0.782 |
| R1/pond | 0.0063 | 0.049 |
| R1/stream | 0.1008 | 0.781 |
| R3/stream | 0.3099 | **2.402** |
| R4/stream | 0.2646 | **2.051** |
| **Group** |  | **Aquatic plants** |
| **use group D – FOCUS Step 3 (autumn use on winter cereals / rate = 10 g/ha# )** | | |
| D1/ditch | 1.3580 | **10.527** |
| D1/stream | 0.8475 | **6.570** |
| D2/ditch | 1.3980 | **10.837** |
| D2/stream | 0.8795 | **6.818** |
| D3/ditch | 0.0662 | 0.513 |
| D4/pond | 0.1414 | **1.096** |
| D4/stream | 0.1678 | **1.301** |
| D5/pond | 0.1018 | 0.789 |
| D5/stream | 0.1450 | **1.124** |
| D6/ditch | 0.3850 | **2.984** |
| R1/pond | 0.0022 | 0.017 |
| R1/stream | 0.0474 | 0.367 |
| R3/stream | 0.5158 | **3.998** |
| R4/stream | 0.2641 | **2.047** |
| **use group C – FOCUS Step 3 (spring use on cereals / rate = 10 g/ha)** | | |
| D1/ditch | 0.2085 | **1.616** |
| D1/stream | 0.1731 | **1.342** |
| D3/ditch | 0.0657 | 0.509 |
| D4/pond | 0.0288 | 0.223 |
| D4/stream | 0.0545 | 0.422 |
| D5/pond | 0.0118 | 0.091 |
| D5/stream | 0.0541 | 0.419 |
| **Group** |  | **Aquatic plants** |
| R4/stream | 0.0418 | 0.324 |

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

# Autumn use in certain countries (NL, DE, UK) involves a higher intended dose rate of 1.2 L product/ha  12 g/ha mesosulfuron-methyl. Aquatic risk for this use situation will be addressed in the respective National Addenda documents, as national requirements request the use of country specific exposure models instead of the EU FOCUSsw procedure that is used in Core Assessment.

When the risk assessment is based on PECsw, max, RQ values in excess of 1 are observed for several FOCUS scenarios: D1, D2, D4, D5, D6, R3, R4, depending on the use group considered.

As demonstrated in the exposure simulations (see Efate section), specifically those finally unresolved scenarios (D1 ditch, D2 ditch/stream for the end of winter use, D1 ditch/stream, D2 ditch/stream, D4 pond stream/stream for the autumn use, and D1 ditch for spring use) are driven by the entry route drainage.

**The following scenarios did not pass the trigger value of 5 for *Lemna gibba*:**

D1, D2, R3 and R4, for use group B (end of winter to spring use on winter cereals / rate = 15 g/ha )

D1, D2, D4, D5 (only stream), D6, R3 and R4, for use group D (autumn use on winter cereals / rate = 10 g/ha) - D1, for use group C (spring use on spring cereals / rate = 10 g/ha)

FOCUS Step 4 values were calculated for the failing scenarios; FOCUS Step 4 values were calculated for all scenarios for completeness, however for D1 and D2, D4 and D5, D6 scenarios it is not possible to mitigate using FOCUS Step 4 as the main input is from drainage.

Therefore, only the R scenarios (R3 and R4) and D4, D5 scenarios which are relevant for Central Zone have been considered in the risk assessment and presented below. The D4 and D5, D6 scenarios are not possible to mitigate using FOCUS Step 4 as the main input is from drainage. Therefore, they are included only for completeness.

**Table 9.5-38.1: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for mesosulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of 054-01-05 in cereals – Use: winter cereals, 1 × 15 g mesosulfuron-methyl /ha, end of winter use**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Winter**  **cereals, end of winter spring use,**  **15 g**  **a.s./ha** | **Scenario** |  | **PECsw STEP 4 –**  **mesosulfuron-methyl** | | | |  |  |  | **PECsw / RAC** RAC = 0.129 µg/L | |  |  |
|  | **PEC gl-max** | | | |  |  |  | **PEC gl-max** | |  |  |
| Nozzle red. | Vegetated strip (m) | None | None | None | None | 10 m low\* | 20 m high\* | None | None | None | None | 10 m low\* | 20 m high\* |
| No spray buffer  (m) | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m |
| None | R3  Stream | 0.3099 | 0.3099 | 0.3099 | 0.3099 | 0.1370 | 0.0710 | **2.402** | **2.402** | **2.402** | **2.402** | **1.062** | 0.550 |
| 50 % | 0.3099 | 0.3099 | 0.3099 | 0.3099 | 0.1370 | 0.0710 | **2.402** | **2.402** | **2.402** | **2.402** | **1.062** | 0.550 |
| 75 % | 0.3099 | 0.3099 | 0.3099 | 0.3099 | 0.1370 | 0.0710 | **2.402** | **2.402** | **2.402** | **2.402** | **1.062** | 0.550 |
| 90 % | 0.3099 | 0.3099 | 0.3099 | 0.3099 | 0.1370 | 0.0710 | **2.402** | **2.402** | **2.402** | **2.402** | **1.062** | 0.550 |
| None | R4  Stream | 0.2646 | 0.2646 | 0.2646 | 0.2646 | 0.1203 | 0.0631 | **2.051** | **2.051** | **2.051** | **2.051** | 0.933 | 0.489 |
| 50 % | 0.2646 | 0.2646 | 0.2646 | 0.2646 | 0.1203 | 0.0631 | **2.051** | **2.051** | **2.051** | **2.051** | 0.933 | 0.489 |
| 75 % | 0.2646 | 0.2646 | 0.2646 | 0.2646 | 0.1203 | 0.0631 | **2.051** | **2.051** | **2.051** | **2.051** | 0.933 | 0.489 |
| 90 % | 0.2646 | 0.2646 | 0.2646 | 0.2646 | 0.1203 | 0.0631 | **2.051** | **2.051** | **2.051** | **2.051** | 0.933 | 0.489 |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold \* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Therefore, the risk for a.s. is acceptable for R3 scenario when 20 meter vegetative buffer zone will be implemented. Therfore, the risk for a.s. is acceptable for R4 scenario when 10 meter vegetative buffer zone will be implemented.

Therefore, the risk for a.s. is acceptable for the R3 scenario when a 20 meter vegetative buffer zone is implemented.

Therefore, the risk for a.s. is acceptable for the R4 scenario when a 10 meter vegetative buffer zone is implemented.

**Table 9.5-38.2: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for mesosulfuron-methyl based on FOCUS Step 4 calculations and toxicity data for aquatic plants with mitigation of spray drift and run-off for the use of 054-01-05 in cereals – Use: winter cereals, 1 × 10 g mesosulfuron-methyl /ha, autumn use.**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Winter**  **cereals,**  **autumn use,**  **10 g**  **a.s./ha** | **Scenario** | **PECsw / RAC**  RAC = 0.129 µg/L | | | | | | | | | | | |
| **PEC gl-max** | | | | | | **PEC gl-max** | | | | | |
| Nozzle red. | Vegetated strip (m) | None | None | None | None | 10 m low\* | 20 m high\* | None | None | None | None | 10 m low\* | 20 m high\* |
| No spray buffer  (m) | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m | 0 m | 5 m | 10 m | 20 m | 10 m | 20 m |
| one | D4 Pond | 0.1414 | 0.1413 | 0.1411 | 0.1409 | 0.1411 | 0.1409 | **1.096** | **1.095** | **1.094** | **1.092** | **1.094** | **1.092** |
| 50 % | 0.1410 | 0.1409 | 0.1408 | 0.1407 | 0.1408 | 0.1407 | **1.093** | **1.092** | **1.091** | **1.091** | **1.091** | **1.091** |
| 75 % | 0.1408 | 0.1408 | 0.1407 | 0.1407 | 0.1407 | 0.1407 | **1.091** | **1.091** | **1.091** | **1.091** | **1.091** | **1.091** |
| 90 % | 0.1407 | 0.1406 | 0.1406 | 0.1406 | 0.1406 | 0.1406 | **1.091** | **1.090** | **1.090** | **1.090** | **1.090** | **1.090** |
| None | D4 Stream | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** |
| 50 % | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** |
| 75 % | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** |
| 90 % | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | 0.1678 | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** | **1.301** |
| None | D5 Stream | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** |
| 50 % | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** |
| 75 % | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | 0.1450 | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** | **1.124** |
| None | R3  Stream | 0.5158 | 0.5158 | 0.5158 | 0.5158 | 0.2319 | 0.1211 | **3.998** | **3.998** | **3.998** | **3.998** | **1.798** | 0.939 |
| 50 % | 0.5158 | 0.5158 | 0.5158 | 0.5158 | 0.2319 | 0.1211 | **3.998** | **3.998** | **3.998** | **3.998** | **1.798** | 0.939 |
| 75 % | 0.5158 | 0.5158 | 0.5158 | 0.5158 | 0.2319 | 0.1211 | **3.998** | **3.998** | **3.998** | **3.998** | **1.798** | 0.939 |
| 90 % | 0.5158 | 0.5158 | 0.5158 | 0.5158 | 0.2319 | 0.1211 | **3.998** | **3.998** | **3.998** | **3.998** | **1.798** | 0.939 |
| None | R4  Stream | 0.2641 | 0.2641 | 0.2641 | 0.2641 | 0.1192 | 0.0623 | **2.047** | **2.047** | **2.047** | **2.047** | 0.924 | 0.483 |
| 50 % | 0.2641 | 0.2641 | 0.2641 | 0.2641 | 0.1192 | 0.0623 | **2.047** | **2.047** | **2.047** | **2.047** | 0.924 | 0.483 |
| 75 % |  | 0.2641 | 0.2641 | 0.2641 | 0.2641 | 0.1192 | 0.0623 | **2.047** | **2.047** | **2.047** | **2.047** | 0.924 | 0.483 |
| 90 % | 0.2641 | 0.2641 | 0.2641 | 0.2641 | 0.1192 | 0.0623 | **2.047** | **2.047** | **2.047** | **2.047** | 0.924 | 0.483 |

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

\* low and high fractional reduction in the runoff and erosion through volume, mass and flux

Therefore, the risk is acceptable for the R3 scenario when a 20 meter vegetative buffer zone is implemented

Therefore, the risk is acceptable for the R4 scenario when a 10 meter vegetative buffer zone is implemented

There is an unacceptable risk for the scenarios D4, D5 (not relevant in the Central Zone)

Overall conclusion of risk mitigation measures using max PECsw STEP 4 calculations based on active substance - mesosulfuron methyl risk assessment.

Winter cereals, autumn use, 10 g a.s./ha

There is an unacceptable risk for the D4 ( pond and stream) scenarios, D5 ( stream) scenario with a 20 meter vegetative buffer zone. Therefore, further refinement is required.

The R3 stream scenario is resolved when a 20 metre high buffer zone is considered; the R4 scenario is resolved when a 10 metre low buffer zone is considered. (As this refinement is Member State-specific, Member States should decide if this is acceptable according to their own national rules on mitigation).

Furthermore, as the D scenarios are driven by drainage, there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions. These scenarios are not relevant for Poland and therefore have not been considered further.

Winter cereals, end of winter-spring use, 15 g a.s./ha

The R3 stream scenario is resolved when a 20 metre high buffer zone is considered; the R4 scenario is resolved when a 10 metre low buffer zone is considered. As this refinement is Member State-specific, Member States should decide if this is acceptable according to their own national rules on mitigation.

Furthermore, as the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions. These scenarios are not relevant for in Poland and therefore have not been considered further.

Spring cereals (spring use on spring cereals / rate = 10 g/ha)

No mitigation measures are required for all relevant scenarios for Central Zone countries.

Mefenpyr-diethyl and relevant metabolites

An assessment for the safener mefenpyr-diethyl has been provided as supplemental information. An application rate of 45g/ha has been considered in the generation of the PECsw values below. This rate is protective of the intended uses of 054-01-05.

Table 9.5‑39: Aquatic risk assessment for application of mefenpyr-diethyl to winter and spring cereals

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *C. carpio* | *O. mykiss* | *Daphnia magna* | *Daphnia magna* | *N. pelliculosa* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | 2 400 | 100 | 5 500 | 320 | 3 120 | >7 600 |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 24 | 10 | 55 | 32 | 312 | >760 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 8.69 | Yes | Yes | Yes | Yes | Yes | Yes |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-28 for FOCUS steps 1

Table 9.5‑40: Aquatic risk assessment for application of AE F113225 to winter and spring cereals

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *(L. macrochirus* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | >100 000 | 32 000 | >100 000 | 3 200 | >100 000 | >760\* |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | >1 000 | 3 200 | >1 000 | 320 | >10 000 | >76 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 15.68 | Yes | Yes | Yes | Yes | Yes | Yes |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-29 for FOCUS steps 1

\*Toxicity endpoint 10 times higher than the parent compound used

Table 9.5‑41: Aquatic risk assessment for application of AE F109453 to winter and spring cereals

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | >100 000 | 10\* | >100 000 | 32\* | 41 900 | >760\* |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | >1 000 | 1 | >1 000 | 3.2 | 4 190 | >76 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 6.01 | Yes | **No** | Yes | Yes | Yes | Yes |
| Step 2 |  |  |  |  |  |  | |
| NE Oct - Feb | 1.06 | Yes | **No\*\*** | Yes | Yes | Yes | Yes |
| NE Mar- May | 0.51 | Yes | Yes | Yes | Yes | Yes | Yes |
| NE Jun-Sep | 0.51 | Yes | Yes | Yes | Yes | Yes | Yes |
| SE Oct-Feb | 0.88 | Yes | Yes | Yes | Yes | Yes | Yes |
| SE Mar-May | 0.88 | Yes | Yes | Yes | Yes | Yes | Yes |
| SE Jun-Sep | 0.70 | Yes | Yes | Yes | Yes | Yes | Yes |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-29 for FOCUS steps 1 &2

\*Toxicity endpoint 10 times higher than the parent compound used

\*\* No further refinements were considered, as the toxicity value used in the determination of the RAC is derived as 10 × parent toxicity and the exceedance of the RAC for this scenario is negligible (PECsw of 1.06 µg/L vs. RAC of 1.0 µg/L). Moreover, it can be noted that mitigation measures issued from the risk assessment conducted for the active substances would also reduce PEC for this metabolite. Based on these evidence, overall risk is considered acceptable for this metabolite.

Table 9.5‑42: Aquatic risk assessment for application of AE F094270 to winter and spring cereals

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. Prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *D. rerio* | *D. rerio* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | >72 000 | 3 200 | >60 300 | 32 000 | 42 000 | >760\* |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | >720 | 320 | >603 | 3 200 | 4 200 | >76 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 12.05 | Yes | Yes | Yes | Yes | Yes | Yes |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-29 for FOCUS steps 1

\*Toxicity endpoint 10 times higher than the parent compound used

Table 9.5‑43: Aquatic risk assessment for application of AE F2211046 to winter and spring cereal

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | C. carpio | *O. mykiss* | *Daphnia magna* | *Daphnia magna* | *N. pelliculosa* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | 240\* | 10\* | 550\* | 32\* | 312\* | >760\* |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 2.4 | 1 | 5.5 | 3.2 | 31.2 | >76 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 0.63 | Yes | Yes | Yes | Yes | Yes | Yes |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-29 for FOCUS steps 1

\*Toxicity endpoint 10 times higher than the parent compound used

Table 9.5‑44: Aquatic risk assessment for application of AE F114952 to winter and spring cereal

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | **Higher plants** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | C. carpio | *O. mykiss* | *Daphnia magna* | *Daphnia magna* | *N. pelliculosa* | *Lemna gibba* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50 | ErC50 |
| (µg/L) |  | 240\* | 10\* | 550\* | 32\* | 312\* | >760\* |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 |
| RAC (µg/L) |  | 2.4 | 1 | 5.5 | 3.2 | 31.2 | >76 |
| FOCUS Scenario | PEC gl-max (µg/L) | **PEC less than RAC** | | | | | |
| Step 1 |  |  |  |  |  |  | |
|  | 4.19 | **No** | **No** | Yes | **No** | Yes | Yes |
| **Step 2** | | | | | | | |
| **NE Oct-Feb** | 1.25 | Yes | **No\*\*** | - | Yes | - | - |
| **NE Mar-May** | 0.54 | Yes | Yes | - | Yes | - | - |
| **NE Jun-Sep** | 0.54 | Yes | Yes | - | Yes | - | - |
| **SE Oct-Feb** | 1.01 | Yes | **No\*\*** | - | Yes | - | - |
| **SE Mar-May** | 1.01 | Yes | **No\*\*** | - | Yes | - | - |
| **SE Jun-Sep** | 0.77 | Yes | Yes | - | Yes | - | - |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; scenarios where the PECsw value is greater than the RAC are shown in **bold** above

PECsw taken from dRR part B section 8 Table 8.9-29 for FOCUS steps 1 & 2

\*Toxicity endpoint 10 times higher than the parent compound used

\*\* No further refinements were considered necessary, as the toxicity value used in the determination of the RAC is worst case, derived as 10 × parent toxicity and the exceedance of the RAC for this scenario is negligible in step 2 (PECsw of 1.01 to 1.25 µg/L vs. RAC of 1.0 µg/L).Moreover, it can be noted that mitigation measures issued from the risk assessment conducted for the active substances would also reduce PEC for this metabolite. Based on these evidence, overall risk is considered acceptable for this metabolite.

An acceptable risk to aquatic organisms, following exposure to mefenpyr-diethyl and its relevant metabolites, has been demonstrated at FOCUS steps 1 and 2 above. No further consideration is therefore necessary. For the metabolites AE F109453 and AE F114952, the PEC values for some Step 2 scenarios slightly exceeded the RAC (based on 10 × parent toxicity). However, these exceedances (PECsw of 1.01 µg/L to 1.25µg/L vs. RAC of 1.0 µg/L) were considered as negligible as the assessment is inherently conservative (based on x10 the toxicity of the parent). Moreover, it can be noted that mitigation measures issued from the risk assessment conducted for the active substances would also reduce the predicted environmental concentrations for these metabolites. Based on this evidence, the overall risk is considered acceptable for this metabolite and therefore no further modelling was carried out.

**Combined risk assessment - Tier 1 level**

A combined toxicity risk assessment of biologically active components is presented here below, considering Iodosulfuron-methyl-sodium, metabolite AE F075736, and Mesosulfuron-methyl via the methodology of concentration addition, i.e. calculation of RQmix based the above individual substance assessment results.

As before in the assessments on individual substance level both, a risk assessment based on PECsw,max and a risk assessment based on PECsw, 7d-twa will be shown side by-side, as these are considered justified alternative Tier 1 approaches with applicability for the present product demonstrated in details to fulfil respective AGD criteria.

**Table 9.5-45: Combined Risk Assessment – aquatic macrophytes, Tier 1**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | **RQ values based on EU endpoints** | | | | | | **RQMIX** |
|  | |  | |  | |  | |
| **Aquatic macrophytes** | | **IMS** | | **AE F075736** | | **MSM** | |  |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM )** | | | | | | | | |
| D1/ditch | | 2.429 | | 0.468 | | 1.695 | | **4.592** |
| D1/stream | | 1.591 | | 0.275 | | 1.093 | | **2.959** |
| D2/ditch | | 16.052 | | 1.537 | | 12.434 | | **30.023** |
| D2/stream | | 10.185 | | 0.955 | | 7.930 | | **19.07** |
| D3/ditch | | 1.092 | | 0.073 | | 0.761 | | **1.926** |
| D4/pond | | 0.496 | | 0.168 | | 0.319 | | 0.983 |
| D4/stream | | 0.877 | | 0.085 | | 0.597 | | **1.559** |
| D5/pond | | 0.195 | | 0.033 | | 0.153 | | 0.381 |
| D5/stream | | 0.857 | | 0.015 | | 0.641 | | **1.513** |
| D6/ditch | | 1.053 | | 0.014 | | 0.782 | | **1.849** |
| R1/pond | | 0.062 | | 0.004 | | 0.049 | | 0.115 |
| R1/stream | | 0.974 | | 0.005 | | 0.781 | | **1.76** |
| R3/stream | | 2.992 | | 0.012 | | 2.402 | | **5.406** |
| R4/stream | | 2.464 | | 0.018 | | 2.051 | | **4.533** |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g product/ha)**  **Refinement: exposure simulations for IMS and AE F075736 based on field soil kinetics data** | | | | |  | |  | |
| D1/ditch | 0.268 | | 0.211 | | 1.695 | | **2.174** | |
| D1/stream | 0.223 | | 0.125 | | 1.093 | | **1.441** | |
| D2/ditch | **2.416** | | 0.847 | | 12.434 | | **15.697** | |
| D2/stream | **1.512** | | 0.605 | | 7.93 | | **10.047** | |
| D3/ditch | 0.258 | | 0.003 | | 0.761 | | **1.022** | |
| D4/pond | 0.009 | | 0.008 | | 0.319 | | 0.336 | |
| D4/stream | 0.195 | | 0.004 | | 0.597 | | 0.796 | |
| D5/pond | 0.009 | | 0.003 | | 0.153 | | 0,165 | |
| D5/stream | 0.201 | | <0.001 | | 0.641 | | 0.843 | |
| D6/ditch | 0.257 | | 0.004 | | 0.782 | | **1.043** | |
| R1/pond | 0.009 | | 0.003 | | 0.049 | | 0.061 | |
| R1/stream | 0.201 | | 0.003 | | 0.781 | | 0.985 | |
| R3/stream | 0.612 | | 0.008 | | 2.402 | | **3.022** | |
| R4/stream | 0.424 | | 0.010 | | 2.051 | | **2.485** | |
| **use group D – FOCUS Step 3**  **(autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM )** | | | | |  | |  | |
| D1/ditch | **1.212** | | 1.882 | | 10.527 | | **13.621** | |
| D1/stream | 0.774 | | 1.307 | | 6.570 | | **8.651** | |
| D2/ditch | **1.084** | | 1.132 | | 10.837 | | **13.053** | |
| D2/stream | 0.68 | | 0.719 | | 6.818 | | **8.217** | |
| D3/ditch | 0.173 | | 0.192 | | 0.513 | | **0.878** | |
| D4/pond | 0.053 | | 0.629 | | 1.096 | | **1.778** | |
| D4/stream | 0.139 | | 0.400 | | 1.301 | | **1.840** | |
| D5/pond | 0.011 | | 0.490 | | 0.789 | | **1.290** | |
| D5/stream | 0.158 | | 0.251 | | 1.124 | | **1.533** | |
| D6/ditch | 0.172 | | 0.193 | | 2.984 | | **3.349** | |
| R1/pond | 0.005 | | 0.001 | | 0.017 | | 0.023 | |
| R1/stream | 0.145 | | 0.001 | | 0.367 | | 0.513 | |
| R3/stream | **1.25** | | 0.026 | | 3.998 | | **5.274** | |
| R4/stream | 0.327 | | 0.015 | | 2.047 | | **2.389** | |
| **use group C – FOCUS Step 3**  **(spring use on spring cereals / rate = 2 g/ha IMS + 10 g/ha MSM )** | | | | |  | |  | |
| D1/ditch | **2.27** | | 2.27 | | 2.27 | | **2.27** | |
| D1/stream | 1.772 | | 1.772 | | 1.772 | | **1.772** | |
| D3/ditch | **0.744** | | 0.744 | | 0.744 | | 0.744 | |
| D4/pond | 0.35 | | 0.35 | | 0.35 | | 0.35 | |
| D4/stream | 0.621 | | 0.621 | | 0.621 | | 0.621 | |
| D5/pond | 0.005 | | 0.023 | | 0.091 | | 0.119 | |
| D5/stream | 0.135 | | 0.011 | | 0.419 | | 0.565 | |
| R4/stream | 0.112 | | 0.001 | | 0.324 | | 0.437 | |

MSM = mesosulfuron-methyl, ISM = iodosulfuron-methyl-sodium

**Table 9.5-46-1: Combined toxicity assessment – aquatic macrophytes for R3 and R4 scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **RQ values based on EU endpoints** | | | **RQmix** |
| **Aquatic macrophytes** | **IMS** | **AE F075736** | **MSM** |
| **use group B (end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15g/ha MSM)** | | | | |
| R3/stream | 0.255\*\*\* | 0.012\* | 0.550\*\* | 0.817 |
| R4/stream | 0.179\*\*\* | 0.018\* | 0.489\*\* | 0.686 |
| **use group D (autumn use on winter cereals / rate = 2 g/ha IMS + 10g/ha MSM)** | | | | |
| R3/stream | 0.29324\*\* | 0.026\* | 0.939\*\* | **1.258** |
| R4/stream | 0.1472\*\* | 0.015\* | 0.483\*\* | 0.645 |

MSM = mesosulfuron-methyl, ISM = iodosulfuron-methyl-sodium

\*Step 3

\*\* 20m vegetative buffer strip

\*\*\* 10m vegetative buffer strip

**Conclusion**

The combined toxicity for R3 and R4 scenarios for application of end of winter to spring use on winter cereals /rate = 3g /ha IMS + 15 g/ha MSM is considered acceptable when a 20m vegetative buffer zone is implemented. The risk assessment for the combined toxicity for the R3 scenario for application in autumn rate of 2g/ha IMS + 10g/ha MSM does not pass the trigger value of 1. Therefore, this scenario and further refinement should be considered by Member States at National Level.

The combined toxicity for the R4 scenario for applications in autumn rate of 2g/ha IMS + 10g/ha MSM is considered acceptable a 20m high vegetative buffer zone is implemented.

The assessment of the combined chronic risk from the active substances and metabolite- AE F075736, taking into account in the calculations of RQ the following RAC values: RAC=0.074 µg/L for IMS, RAC-0.057 µg/L for AE F075736 and RAC - 0.129 µg/L for MSM and max PECsw values calculated with FOCUS STEP 3-4, is also provided

**Table 9.5-46-2: Combined toxicity assessment – aquatic macrophytes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Aquatic macrophytes** | **RQ values based on EU endpoints** | | | **RQmix** |
| **IMS** | **AE F075736** | **MSM** |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM )** | | | | |
| D1/ditch | 0.266 | 0.611 | 1.695 | **2.572** |
| D1/stream | 0.223 | 0.495 | 1.093 | **1.811** |
| D2/ditch | 2.081 | 2.777 | 12.434 | **17.292** |
| D2/stream | 1.3 | 2.284 | 7.930 | **11.514** |
| D3/ditch | 0.258 | 0.093 | 0.761 | **1.112** |
| D4/pond | 0.009 | 0.216 | 0.319 | 0.544 |
| D4/stream | 0.195 | 0.114 | 0.597 | 0.906 |
| D5/pond | 0.009 | 0.042 | 0.153 | 0.204 |
| D5/stream | 0.201 | 0.023 | 0.641 | 0.865 |
| D6/ditch | 0.257 | 0.018 | 0.782 | **1.057** |
| R1/pond | 0.009 | 0.005 | 0.049 | 0.063 |
| R1/stream | 0.188 | 0.125 | 0.781 | **1.094** |
| R3/stream | 0.578 | 0.233 | 2.402 | **3.213** |
| R4/stream | 0.395 | 0.195 | 2.051 | **2.641** |
| **use group B – FOCUS Step 3**  **(end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM )**  **Refinement: exposure simulations for IMS and AE F075736 based on field soil kinetics data** | | | | |
| D1/ditch | 0.268 | 0.274 | 1.695 | **2.237** |
| D1/stream | 0.223 | 0.235 | 1.093 | **1.551** |
| D2/ditch | **2.416** | 1.544 | 12.434 | **16.394** |
| D2/stream | **1.512** | 1.521 | 7.93 | **10.963** |
| D3/ditch | 0.258 | 0.004 | 0.761 | **1.023** |
| D4/pond | 0.009 | 0.011 | 0.319 | 0.339 |
| D4/stream | 0.195 | 0.005 | 0.597 | 0.797 |
| D5/pond | 0.009 | 0.004 | 0.153 | 0.166 |
| D5/stream | 0.201 | 0.004 | 0.641 | 0.846 |
| D6/ditch | 0.257 | 0.005 | 0.782 | **1.044** |
| R1/pond | 0.009 | 0.004 | 0.049 | 0.062 |
| R1/stream | 0.201 | 0.07 | 0.781 | **1.052** |
| R3/stream | 0.612 | 0.158 | 2.402 | **3.172** |
| R4/stream | 0.424 | 0.109 | 2.051 | **2.584** |
| **use group D – FOCUS Step 3 (autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM)** | | | | |
| D1/ditch | **1.212** | 2.851 | 10.527 | **14.590** |
| D1/stream | 0.774 | 1.921 | 6.570 | **9.265** |
| D2/ditch | **1.084** | 2.23 | 10.837 | **14.151** |
| D2/stream | 0.68 | 1.516 | 6.818 | **9.014** |
| D3/ditch | 0.173 | 0.246 | 0.513 | 0.932 |
| D4/pond | 0.053 | 0.807 | 1.096 | **1.956** |
| D4/stream | 0.139 | 0.64 | 1.301 | **2.080** |
| D5/pond | 0.011 | 0.632 | 0.789 | **1.432** |
| D5/stream | 0.158 | 0.386 | 1.124 | **1.668** |
| D6/ditch | 0.172 | 0.702 | 2.984 | **3.858** |
| R1/pond | 0.005 | 0.018 | 0.017 | 0.040 |
| R1/stream | 0.145 | 0.011 | 0.367 | 0.523 |
| R3/stream | **1.25** | 0.439 | 3.998 | **5.687** |
| R4/stream | 0.327 | 0.228 | 2.047 | **2.602** |
| **use group C – FOCUS Step 3 (spring use on cereals / rate = 2 g/ha IMS + 10 g/ha MSM)** | | | | |
| D1/ditch | 0.176 | 0.639 | 1.616 | **2.431** |
| D1/stream | 0.138 | 0.411 | 1.342 | **1.891** |
| D3/ditch | 0.173 | 0.081 | 0.509 | 0.763 |
| D4/pond | 0.005 | 0.156 | 0.223 | 0.384 |
| D4/stream | 0.139 | 0.081 | 0.422 | 0.642 |
| D5/pond | 0.005 | 0.03 | 0.091 | 0.126 |
| D5/stream | 0.135 | 0.016 | 0.419 | 0.57 |
| R4/stream | 0.112 | 0.011 | 0.324 | 0.447 |

MSM =mesosulfuron-methyl, IMS = iodosulfuron-methyl-sodium

For the metabolite AE F075736 (= metsulfuron-methyl). The ErC50 value with an AF of 10 was considered

**Table 9.5-46-3: Combined toxicity assessment – aquatic macrophytes with consideration STEP 3-4 PECsw values**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **RQ values based on EU endpoints** | | | | **RQMIX** |
|  |  |  |  |  |
| **Aquatic macrophytes** | **IMS** |  | **AE F075736** | **MSM** |  |
| **use group B**  **(end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM )** | | |  |  |  |
| R3/stream | 0.255\*\*\* |  | 0.104\*\*\* | 0.550\*\* | 0.909 |
| R4/stream | 0.179\*\*\* |  | 0.088\*\*\* | 0.489\*\* | 0.756 |
| R1 stream | 0.077\*\*\* |  | 0.125  0.007 1 | 0.322\*\*\* | 0.524 |
| D3 ditch | 0.035\*\*\* |  | 0.093  0.004 1 | 0.1325\*\*\* | 0.2605 |
| **use group D**  **(autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM )** | | |  |  |  |
| R3/stream | 0.29324\*\* |  | 0.104\*\* | 0.939\*\* | **1.33** |
| R4/stream | 0.1472\*\* |  | 0.104\*\*\* | 0.483\*\* | 0.7342 |

MSM = mesosulfuron-methyl, IMS = iodosulfuron-methyl-sodium STEP 3

\*\* 20 meter vegetative buffer strip

\*\*\* 10 meter vegetative buffer strip

1 value with refined DT50

**Conclusion**

The combined toxicity for R3 and R4 scenarios for application of end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM is considered acceptable when 20 meter vegetative buffer zone is implemented.

The combined toxicity for R1 (stream) and D3 scenarios for application of end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM is considered acceptable when low 10 meter vegetative buffer zone is implemented.

The risk assessment for combined toxicity for R3 scenario for application in autumn rate of 2 g /ha IMS + 10 g /ha MSM does not pass the trigger value of 1. The combined toxicity for R3 scenario, should be therefore to be refine further by Member States at national level.

The combined toxicity for R4 scenario for application in autumn rate of 2 g /ha IMS + 10 g /ha MSM is considered acceptable when 20 high vegetative buffer zone is implemented.

**Overall conclusion with consideration the combined risk assessment for the active substances and metabolite AE F075736, with max. PECsw values**

**use group B (end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM ):**

The product can be safely applied with no precautionary measures required for exposure mitigation in all European regions other than those represented by drainage scenarios D1 and D2. In a Central Zone context, however, both of these scenarios are considered not representative. In case of R3 , R4, R 1 ( stream) and D3 scenarios the product can be safely applied when:

* For R3 and R4 scenarios 20 meter high vegetative buffer zone should be applied
* For R1 (stream) and D3 (ditch) 10 meter low vegetative buffer zone should be applied

**use group D (autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM ):**

In case of for R4 scenario the product can be safely applied when 20 meter vegetative buffer zone is applied to surface water bodies For regions represented by scenario D3 and R1 scenarios no precautionary measures are required.

However, risk assessments for drainage scenarios D1, D2, D4, D5, and D6 remained unresolved, as the drainage driven entry in these scenarios cannot be mitigated by the options considered in FOCUS Landscape & Mitigation. a Central Zone context, however, scenarios D1, D2, and D6 are considered not representative.

The combined risk for aquatic organism assessment indicated for R3 scenario unresolved the risk with 20 meter vegetative buffer zone implemented. Therefore, further refinement should be considered at MS level.

**use group C (spring use on spring cereals / rate = 2 g/ha IMS + 10 g/ha MSM ):**

The product can be safely applied with no precautionary measures required for exposure mitigation in all European regions other than those represented by drainage scenario D1. Regions represented by scenario D1 are all located in the Northern zone, while the scenario is of no relevance for countries in the Central Zone.

Further consideration of the combined toxicity should be considered by Member States at national level, as it is related to what exposure scenarios are considered relevant to their Member State and hence the likely co-occurrence of the active substance and metabolites together in either run off or drain flow.

### Overall conclusions

Acceptable risk for all aquatic organisms other than macrophytes could be demonstrated in a screening level risk assessment (FOCUS Steps 1-2) for the active substances contained in the formulation, and their metabolites. Further assessment was provided for aquatic macrophytes considering FOCUS Step 3 and 4 values, along with proposed mitigation measures where necessary.

Mesosulfuron methyl

**Winter cereals, autumn use, 10 g a.s./ha**

There is an unacceptable risk for D4 ( pond and stream) scenarios, D5 ( stream) scenario with 20 meter vegetative buffer zone and further refinement is required. The R3 stream scenario can be resolved when a 20 meter high buffer zone is implemented; the R4 scenario can be resolved when a 10 meter low buffer zone is implemented

As the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and Member States should consider the relevance of these scenarios to their national conditions.

**Winter cereals, end of winter-spring use, 15 g a.s./ha**

The R3 stream scenario can be resolved when a 20 meter high buffer zone is implemented; the R4 scenario can be resolved when a 10 meter low buffer zone is implemented. As this refinement is Member State-specific, Member States should decide if this is acceptable according to their own national rules on mitigation. As the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions.

**Spring cereals (spring use on spring cereals / rate = 10 g/ha)**

No mitigation measures are required for all relevant scenarios for Central Zone countries.

Iodosulfuron-methyl-sodium

For use group B (end of winter to spring use on winter cereals / rate = 3 g/ha) and group C (spring use in cereals -= 2 g/ha), no mitigation measures are required for scenarios relevant for Central Zone countries. However, for use group D (autumn use on winter cereals / rate = 2 g/ha) for R3 scenario the risk is acceptable when a 10 m vegetative buffer zone is implemented. Furthermore, as the D scenarios are driven by drainage there is no mitigation by FOCUS Step 4 and member states should consider the relevance of these scenarios to their national conditions.

Combined Toxicity

The combined risk assessment was provided for both the active substances and the metabolite AE F075736, based on max PECsw values. The overall conclusion was based on max PECsw values for use group B (end of winter to spring use on winter cereals / rate = 3 g/ha IMS + 15 g/ha MSM): The product can be safely applied with no precautionary measures required for exposure mitigation in all European regions other than those represented by drainage scenarios D1 and D2. In a Central Zone context, however, both of these scenarios are considered not representative. In case of R3, R4, R1 (stream) and D3 (ditch) scenarios the product can be safely when:

* For R3 and R4 scenarios a ~~20 meter high vegetative buffer zone~~ 20 meter wide buffer zone is implemented.
* For R1 (stream) and D3 (ditch) a ~~10 meter low vegetative buffer zone~~ 10 meter wide buffer zone is implemented

**use group D (autumn use on winter cereals / rate = 2 g/ha IMS + 10 g/ha MSM**

In case of for R4 scenario the product can be safely applied when a 20 meter vegetative buffer zone is applied to surface water bodies For regions represented by scenario D3 and R1 scenarios no precautionary measures are required. However, risk assessments for drainage scenarios D1, D2, D4, D5, and D6 remained unresolved, as the drainage driven entry in these scenarios cannot be mitigated by the options considered in FOCUS Landscape & Mitigation. In a Central Zone context, however, scenarios D1, D2, and D6 are considered not representative.

The combined risk for aquatic organism assessment indicated for R3 scenario unresolved risk with a 20 meter vegetative buffer zone implemented Therefore, further refinement is required at MS level.

**use group C (spring use on cereals / rate = 2 g/ha IMS + 10 g/ha MSM ):**

The product can be safely applied with no precautionary measures required.

**Evaluator comments:**

**Aquatic organisms**

No data is provided in support of the application for authorization of **Meso-Iodo OD-Life**. The intended uses Product **Atlantis 12 OD** are within those considered acceptable for registration of **Meso-Iodo OD-Life.**

The intended uses in GAP for the formulation Atlantis 12 OD are considered acceptable for registration of for all proposed uses of Meso-Iodo OD-Life. The input parameters established in the EU review performed for iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453) and mesosulfuron-methyl summarized in the EFSA conclusion (EFSA Journal 2016;14(10): 4584) are accepted. All relevant metabolites were taken into consideration; PECSW and PECSED assessment was done in Step 1&2 and 3&4. Mitigation of spray drift and run-off was considered in Step 4 using the SWAN v 4.0.1 software. Runoff mitigation was used, based on the FOCUS Landscape and Mitigation guidance. A higher tier assessment was performed examining the exposure pattern at Step 3 and 4 for mesosulfuron-methyl using the EPAT Exposure Profile Analysis Tool. EPAT exposure pattern analysis of FOCUS multi-year calculations was used to define representative exposure patterns for those surface water scenarios where PECsw,max exceeded the regulatory acceptable concentration (RAC) at Step 3 in the standard FOCUS assessment. The PECSW values for active substances and its metabolites can be used for further risk assessment for aquatic organisms. Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using Focus models. Based on the risk assessment for Atlantis 12 OD, a safe use for in-tended uses for Meso-Iodo OD-Life could be identified, provided that appropriate risk mitigation measures are taken into account. The risk mitigation measures should be considered at MSs level. No additional risk assessment is required.

**April 2024 Updated after commenting period**

Level of protection reached for primary producers

The endpoint ErC50 is selected in this Core Assessment but there are some uncertainties regarding the level of protection reached for primary producers. This is indicated for macrophytes in the aquatic Guidance Document (EFSA Journal 2013;11(7):3290) that recommends: “... a proper calibration between different tiers (higher and lower tier data) for macrophytes should be performed in the future”. Such calibration should be extended to algae. Until available relevant information on the level of protection reached is considered at EU level, it is recommended to address this uncertainty at Member State level in the National Addendum if considered necessary, although it would be highly appreciated to have a harmonised approach in the central zone.

## Effects on bees (KCP 10.3.1)

### Toxicity data

**Iodosulfuron-methyl-sodium**

Studies on the toxicity to bees have been carried out with iodosulfuron-methyl-sodium. Full details of these studies are provided in the corresponding document of the EU draft assessment report where the study references can be found; presented agreed endpoints were taken from EFSA Journal 2016;14(4):4453

Table 9.6‑1: Endpoints and effect values relevant for the risk assessment for bees – iodosulfuron-methyl-sodium

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| **Laboratory tests** | | | | |
| *Apis mellifera* | Iodosulfuron-methyl-sodium, techn. | Acute, oral | LD50 > 70 µg a.s./bee | EFSA Journal  2016;14(4):4453 |
| *Apis mellifera* | Iodosulfuron-methyl-sodium, techn. | Acute, contact | LD50 > 131 µg a.s./bee | EFSA Journal  2016;14(4):4453 |
| *Apis mellifera* | Iodosulfuron-methyl-sodium, techn. | Acute, oral | LD50 > 107.6 µg a.s./bee | EFSA Journal  2016;14(4):4453 |
| *Apis mellifera* | Iodosulfuron-methyl-sodium, techn. | Acute, contact | LD50 > 100 µg a.s./bee | EFSA Journal  2016;14(4):4453 |
| *Apis mellifera* | Iodosulfuron-methyl-sodium, techn. | 10-day chronic, oral | LDD50 > 4.4 µg a.s./bee/d NOEDD ≥ 4.4 µg a.s./bee/d | EFSA Journal  2016;14(4):4453 |
| **Higher-tier studies (tunnel test, field studies)** | | | | |
| *Apis mellifera* | Iodosulfuron-methyl-sodium (formulated as Iodosulfuron-methyl-sodium + Mefenpyr diethyl OD 400  (100+300)) | Semi-field honey bee  brood study (acc. to OECD No. 75; forced exposure conditions) in *Phacelia*; application during full-bloom and bees actively foraging;  4 d exposure 18 days observation | No adverse effects on mortality, flight intensity, behaviour, brood development (brood termination rate, brood index, compensation index) as well as on colony vitality at maximum application rate 10 g iodosulfuron-methyl-sodium/ha | EFSA Journal  2016;14(4):4453 |

**Mesosulfuron-methyl**

Studies on the toxicity to bees have been carried out with mesosulfuron-methyl. Full details of these studies are provided in the EU Renewal Assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584.

Table 9.6‑2: Endpoints and effect values relevant for the risk assessment for bees – mesosulfuron-methyl

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Apis mellifera* | Mesosulfuron-methyl | Acute, oral | LD50 > 105.6 µg a.s./bee | EFSA Journal  2016;14(10):4584 |
| *Apis mellifera* | Mesosulfuron-methyl | Acute contact | LD50 > 100 µg a.s./bee | EFSA Journal  2016;14(10):4584 |
| *Apis mellifera* | Mesosulfuron-methyl | 10-day chronic, oral | LC50 > 120 mg a.s./kg food, equivalent to  LDD50 > 4.85 μg a.s./bee/d \* | EFSA Journal  2016;14(10):4584 |
| **Higher-tier studies (tunnel test, field studies)** | | | | |
| *Apis mellifera* | Mesosulfuron-methyl  (formulated as  Mesosulfuron-methyl WG) | Semi-field honey bee brood study (acc. to OECD No. 75; forced exposure conditions) in *Phacelia*; application during full-bloom and bees actively foraging | No adverse effects on mortality of adult bees and brood, flight intensity, behaviour, brood development (brood termination rate, brood index, compensation index) and colony vitality at 15 g mesosulfuron-methyl/ha | EFSA Journal  2016;14(10):4584 |

\* There was no mortality at the LDD50.

**054-01-05**

Effects on bees of 054-01-05 were not evaluated as part of the EU assessment of mesosulfuron-methyl, iodosulfuron-methyl-sodium or mefenpyr-diethyl. An assessment of the risk from the active substances was performed during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009). However, no assessment was performed to address the risk from the formulated product and contrary to Regulation 284/2013 no data was submitted for Atlantis 12 OD on the chronic toxicity and sub-lethal effects on larvae. As such, new data is now presented on the acute contact, acute oral, chronic and larval toxicity of the formulation. These studies were conducted with Altesse Pro, which is identical to 054-01-05, and are summarised in Appendix 2 of this document.

An assessment addressing the risk of the formulation to bees according to the EFSA bee GD (EFSA Journal 2013;11(7):3295) is presented as part of this application. Additionally, evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and by adapting the EPPO 2010 scheme.

Table 9.6‑3: Endpoints and effect values relevant for the risk assessment for bees – formulation

| **Species** | **Substance** | **Exposure**  **System** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| *Apis mellifera* | 054-01-05 (Altesse Pro) 1) | Oral | LD50 (72h, 96h) = 529.8 μg 054-01-05/bee = 6.36 μg total a.s./bee | Wilkins, S. (2020a) |
| *Apis mellifera* | 054-01-05 (Altesse Pro) 1) | Contact | LD50 (48h, 72h, 96h) = 249.5 μg 054-01-05/bee = 2.99 μg total a.s./bee | Wilkins, S. (2020a) |
| *Apis mellifera* | 054-01-05 (Altesse Pro) 1) | Chronic, 10-day | NOEDD = 79.8 µg 054-01-05/bee/day = 0.96 μg total a.s./bee/day  LDD50 = 100.8 µg 054-01-05/bee/day = 1.21 μg total a.s./bee/day | Wilkins, S. (2020b) |
| *Apis mellifera* | 054-01-05 (Altesse Pro) 1) | Bee brood development (22 day) | NOED = 49.28 µg 054-01-05/larva = 0.59 μg total a.s./larva  LD50 = 152.3 µg 054-01-05/larva = 1.83 μg total a.s./bee | Wilkins, S. (2020c) |
| **Higher-tier studies (tunnel test, field studies)** | | | | |
| None | | | | |

1) 054-01-05 is an oil dispersion formulation containing 10 g/L mesosulfuron-methyl, 2 g/L iodosulfuron-methyl-sodium and 30 g/L mefenpyr-diethyl. 054-01-05 was considered by CRD as comparable to Bayer’s product Hatra which has been authorised in UK under MAPP Number 16190 (COP 2017/00207). The applicant believes that Hatra is identical to Bayer’s product Atlantis 12 OD which has been authorised in Poland (authorisation number R-98/2009).

#### Justification for new endpoints

EU agreed endpoints are used in the risk assessment for both active substances (mesosulfuron-methyl and iodosulfuron-methyl-sodium)

Both available for mefenpyr-diethyl toxicity studies on bees (acute oral and contact) were considered in the EU DAR as not valid. Thus, no toxicity values of mefenpyr-diethyl for bees are available however, this is not considered to be a critical data gap as mefenpyr-diethyl is a safener which is included in the preparation and its toxicity is addressed by the toxicity studies available for the formulations.

New endpoints are provided for contact and oral acute toxicity as well as chronic adult and larval toxicity for the formulated product. These studies are required according to Regulation (EC) No. 284/2013. Data on the toxicity of the formulation to bees were not provided during the authorisation or renewal of the reference product, Atlantis 12 OD, and as such it is necessary to provide them as part of this application.

### Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002) and by adapting the EPPO 2010 scheme. Additionally, the evaluation of the risk for honeybees was performed in accordance with the EFSA bee GD (EFSA Journal 2013;11(7):3295). For completeness both assessments have been included in this submission. Assessment was provided for the formulation only and an assessment is not presented for the active substances. In order to address the risk of the active substances to bees please refer to the assessment for bees presented in the registration report for the reference product, Atlantis 12 OD (authorisation number R-98/2009).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment has been conducted at the highest proposed application rate for winter cereals in order to cover the risk from the product from all of the proposed uses.

#### Hazard quotients for bees

Table 9.6‑4: First-tier assessment of the risk for bees due to the use of 054-01-05 in cereals

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | | **Risk envelope approach (use group A):**  **Cereals (BBCH 12-39), [maize (BBCH 12-18), non-cropped area]** | | |
| Active substance | | Iodosulfuron-methyl-sodium | | |
| Application rate (g/ha) | | 1 × 10 (risk envelope approach) | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity | >107.6 | | 10 | <0.1 |
| Contact toxicity | >100.0 | | <0.1 |
| Intended use | | **Risk envelope approach (use group A):**  **Cereals (winter and spring), BBCH 10-39** | | |
| Active substance | | Mesosulfuron-methyl | | |
| Application rate (g/ha) | | 1 × 15 (risk envelope appraoch) | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity | >105.6 | | 15 | <0.14 |
| Contact toxicity | >100.0 | | <0.15 |
| Intended use | | Winter and spring wheat, winter and spring durum wheat, rye, spelt and triticale | | |
| Product | | 054-01-05 | | |
| Application rate (L product/ha) | | 1 × 1.5 | | |
| Test design | LD50 (lab.)  (µg product/bee) | | Single application rate  (mL product/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity | 529.8 | | 1500 | 2.83 |
| Contact toxicity | 250.0 | | 6.00 |

QHO, QHC: Hazard quotients for oral and contact exposure. QH values shown in bold breach the relevant trigger.

The results of the first-tier risk assessment demonstrate an acceptable acute risk to bees from the proposed use of 054-01-05 in cereals.

**Risk assessment conducted in accordance with EPPO (2010):**

Chronic adult and larval honeybee studies have been conducted with formulation according to the data requirements under 1107/2009. The endpoints from these studies have been assessed by adapting the EPPO 2010 scheme.

**Larval assessment:**

The risk to larvae can be assessed by carrying out a worst-case risk assessment through the calculation of a TER value, as set out in the EPPO 2010 scheme (point 5 on the scheme).

A worst-case of potential exposure via residues in pollen / nectar can be estimated based on the default worst-case residue of 1 mg a.s./kg proposed in the EPPO 2010 scheme, which is based on a database of measured values from aerial plant parts as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption, in order to estimate the exposure. Worst-case data from Rortais *et al*., 2005[[5]](#footnote-5) as proposed in the EPPO scheme have been used to estimate the consumption by bee larvae:

Worst-case: drone larvae consuming 98.2 mg sugar in 6.5 days (= 15.1 mg sugar /day).

Assuming a mean sugar content of 40% in nectar: (98.2 \* 2.5)/6.5 = **37.8 mg nectar/larva/day**

Thus, considering residues of 1 mg a.s./kg x consumption of 37.8 mg nectar/larva/day:

Total exposure ETE = 0.0378 µg a.s./larva/day

This can be compared to the lowest formulation larval NOED of 0.59 µg total a.s./larva or 0.15 µg total a.s./larva/day (data for 054-01-05)

TER = NOEDD (µg a.s./larva/day)/ ETE (µg a.s./larva/day) = 0.15 /0.0378 = 3.9

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honeybees. TER value of 3.9 that the proposed uses of 054-01-05 pose an acceptable risk to bee larval development.

**April 2024 Updated after commenting period**

According to the DE comment the used default residue values of 1 mg a.s./kg in the chronic risk assessment was recommended in EPPO 2010 scheme to be used for first-tier risk assessment for soil and seed treatments ( “This value is deduced from a compilation of the data generated in various plant species treated with systemic insecticides and the consequent residue concentrations measured in all types of plant parts (leaves, fruit, green parts, inflorescence, whole plant, grain) at the period as close as possible to blossom, as well as residues measured in nectar and pollen.”) and is not applicable for spray applications. The use of realistic residues in pollen and nectar would result in a more realistic calculation of the TER. However, the proposed uses for Meso-Iodo OD-Life are wheat, rye, and triticale which are all listed as non-melliferous in Appendix II of SANTE/11956/2016 rev. 9 and therefore residues in honey are not expected with the intended uses of Meso-Iodo OD-Life. As a result, no residue trials in honey are required following the decision-making scheme in the guideline. In our opinion the use of realistic residues in pollen and nectar - are not necessary in this case. On the other hand, the chronic risk assessment based on chronic studies for bees (adult and larvae) should be performed in line with the EFSA 2013 guideline during the transition period. The chronic risk assessment was performed in EPPO 2010 scheme only as additionally source of information. **Final decision should be taken into account at MSs level.**

**Adult chronic assessment:**

The EPPO 2010 scheme does not recommend a chronic assessment for adults for foliar spray applications. However, the EPPO scheme proposes an approach for a refined assessment for seed coatings/soil treatments (point 7 on the scheme). This approach can therefore be adapted to provide a worst-case assessment for foliar sprays.

A worst-case of potential exposure via residues in pollen / nectar can be estimated as before based on the default worst-case value of 1 mg a.s./kg proposed in the EPPO 2010 scheme (see Note 6 as defined above).

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst-case data from Rortais *et al*., 2005 as proposed in the EPPO 2010 scheme have been used to estimate the consumption by bee foragers:

Worst case: forager consuming 898.8 mg sugar during 7 days (= 128 mg sugar /day).

Assuming 40% sugar content of nectar: (898.8 \* 2.5)/7 = 321 mg nectar/day

Thus considering residues of 1 mg a.s./kg sugar x consumption of 321 mg nectar/bee/day

Total exposure ETE = 0.32 µg a.s./bee/day

This can be compared to the lowest formulation adult NOEDD of 0.96 µg a.s./bee/day (data for 054-01-05).

TER = NOEDD (µg a.s./bee/day)/ ETE (µg a.s./bee/day) = 0.96/0.32 = 3.0

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the risk to honeybees. A TER value of 3 indicates that the proposed uses of 054-01-05 pose an acceptable chronic risk to adult bees.

**Risk assessment in accordance with the recommendations of the EFSA bee GD (EFSA Journal 2013;11(7):3295):**

Application rate of 18 g total a.s./ha was considered in the risk assessment.

**Table 9.6‑5: Screening and first-tier assessment of the risk for bees due to the use of 054-01-05 in winter cereals and spring cereals - contact and oral dietary exposure**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Species** | **Formulation** | **Scenario** | **Risk quotient** | **Endpoint** | **HQ/ETR** | **Trigger** |
| **Screening level assessment** | | | | | | |
| *Apis mellifera* | 054-01-05 | Not relevant | ETRacute adult oral | LD50 = 6.36 µg total a.s./bee | 0.02 | 0.2 |
| *Apis mellifera* | 054-01-05 | Not relevant | HQcontact | LD50 = 2.99 µg total a.s./bee | 6.0 | 42 |
| *Apis mellifera* | 054-01-05 | Not relevant | ETRchronic adult oral | LDD50 = 1.21 µg total a.s./bee/day | **0.113** | 0.03 |
| *Apis mellifera* | 054-01-05 | Not relevant | ETRlarvae | NOED = 0.59 µg total a.s./larva/developmental period | 0.13 | 0.2 |
| **Tier 1 level assessment – Cereals BBCH 12-32 at 18 g total a.s./ha x 1 application** | | | | | | |
| *Apis mellifera* | 054-01-05 | Treated crop | ETRchronic adult oral | LDD50 = 1.21 µg total a.s./bee/day | 0.010 | 0.03 |
| *Apis mellifera* | 054-01-05 | Weeds | **0.031** |
| *Apis mellifera* | 054-01-05 | Field margin | 0.000 |
| *Apis mellifera* | 054-01-05 | Adjacent crop | 0.000 |
| *Apis mellifera* | 054-01-05 | Next crop | 0.006 |

Values shown in bold fall below the relevant trigger

Acceptable risk to bees was indicated for all scenarios except for bees foraging on weeds in the treated field. However, as exceedance of calculated ETR value is negligible and 054-01-05 is intended for application to grasses and annual broad-leaved weeds early in the growing season during a time when flowering of weeds would not be expected.

An assessment of exposure via residues in surface water has been presented in Table 9.6-6 below. The surface water PECs used in the calculations were taken from the Step 1 calculated values in the registration report for Atlantis 12 OD (authorisation number R-98/2009).

**Table 9.6‑6: Screening assessment of the risk for bees due to the use of 054-01-05 in cereals - exposure to residues in surface water**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Formulation** | **Risk quotient** | **Endpoint** | **HQ/ETR** | **Trigger** |
| **Risk assessment from exposure to residues in surface water (FOCUS Step 1 PECsw for mesosulfuron-methyl of 4.74 µg a.s./L + for iodosulfuron-methyl-sodium 3.28 µg a.s./L = 0.00802 mg total a.s./L)** | | | | | |
| *Apis mellifera* | 054-01-05 | ETRacute adult oral | LD50 = 6.36 µg total a.s./bee | 0.00 | 0.2 |
| *Apis mellifera* | 054-01-05 | ETRchronic adult oral | LDD50 = 1.21 µg total a.s./bee/day | 0.000 | 0.03 |
| *Apis mellifera* | 054-01-05 | ETRlarvae | NOED = 0.59 µg total a.s./larva/developmental period | 0.00 | 0.2 |

No significant risk to bees via exposure to residues in surface water is predicted.

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

Not relevant.

### Effects on bumble bees

There are no testing requirements for any bee other than the honey bee within the current implemented Regulation (EC) No. 1107/2009. The following studies on bumble bees are presented as additional information.

**Iodosulfuron-methyl-sodium**

A study on the toxicity to bumble bees has been carried out with iodosulfuron-methyl-sodium. Full details are provided in the EU Renewal Assessment Report and related documents. The findings indicate that bumble bees are not more sensitive to iodosulfuron-methyl-sodium compared to honey bees.

**Table 9.6-7: Endpoints and effect values for bumble bees – iodosulfuron-sodium-methyl**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Bombus*  *terrestris* | Iodosulfuron-methyl-sodium,  technical | Contact | LD50 > 100 µg a.s./bee | EFSA Scientific  Report, 2016;14(4):4453 |

**Mesosulfuron-methyl**

A study on the toxicity to bumble bees has been carried out with mesosulfuron-methyl. Full details are provided in the EU Renewal Assessment Report and related documents. The findings indicate that bumble bees are not more sensitive to mesosulfuron-methyl compared to honey bees.

**Table 9.6-8: Endpoints and effect values for bumble bees – mesosulfuron-methyl**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Bombus*  *terrestris* | Mesosulfuron-methyl (formulated as Mesosulfuron-methyl WG 75) | Contact | LD50 > 100 µg a.s./bee | EFSA Scientific  Report, 2016;14(10):4584 |

No further assessment or consideration is currently required.

### Effects on solitary bees

Not required.

### Overall conclusions

The formulation endpoints for 054-01-05 give low QH values, well below the trigger value of 50.

The chronic and larval risk was assessed by adapting the EPPO 2010 scheme. The calculated TER values were above the trigger of 1 indicating that the proposed uses of 054-01-05 pose an acceptable chronic risk to adult bees and to bee larval development.

Additionally, calculations were conducted in accordance with the recommendations of the EFSA bee GD (EFSA Journal 2013;11(7):3295). Acceptable risk to bees was indicated for all scenarios except for bees foraging on weeds in the treated field. However, as exceedance of calculated ETR value is negligible and no flowering weeds are expected in the field during the application of 054-01-05 it is considered that there is no risk to bees from use of the product.

An acceptable risk for bees exposed in accordance with the intended uses of 054-01-05 was demonstrated.

**Evaluator comments:**

The risk assessment for bees evaluated in Atlantis 12 OD cover all uses of Meso-Iodo OD-Life. However,

in response to data gaps in Atlantis 12 OD the new data was provided by Applicant (the chronic toxicity test for adult bees, the chronic test for larvae for formulation Meso-Iodo OD-Life). The studies were accepted by zRMS. The risk assessment based on new data was accepted by zRMS. The chronic and larval risk was assessed by adapting the EPPO 2010 scheme. The calculated TER values were above the trigger of 1 indicating that the proposed uses of Meso-Iodo OD-Life pose an acceptable chronic risk to adult bees and to bee larval development. Additionally, calculations were conducted in accordance with the recommendations of the EFSA bee GD (EFSA Journal 2013;11(7):3295). Acceptable risk to bees was indicated for all scenarios except for bees foraging on weeds in the treated field. However, as exceedance of calculated ETR value is negligible (**0.031**) and no flowering weeds are expected in the field during the application of 054-01-05 it is considered that there is no risk to bees from use of the product.

**The risk assessment for bees should be considered by MSs level.**

## Effects on arthropods other than bees (KCP 10.3.2)

### Toxicity data

An assessment of the risk from the active substances and representative formulation (Atlantis 12 OD) was performed during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009). 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). Consequently, no new studies are submitted with the formulation 054-01-05 and it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05.

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

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Typhlodromus pyri*  (protonymphs) | IMS+MSM+MPR  OD 42 (2+10+30)\* | Laboratory test glass plates (2D) | LR50 > 1500 mL/ha | EFSA Scientific Report, 2016;14(10):4584 |
| *Aphidius rhopalosiphi*  (adults) | IMS+MSM+MPR \*  OD 42 (2+10+30) | Laboratory test glass plates (2D) | LR50 = 877.3 mL/ha | EFSA Scientific Report, 2016;14(10):4584 |
| *Aphidius rhopalosiphi*  (adults) | IMS+MSM+MPR \*  OD 42 (2+10+30) | Extended laboratory test  barley plants (3D) | LR50 > 1500 mL/ha | EFSA Scientific Report, 2016;14(10):4584 |
| *Chrysoperla carnea*  (larvae) | IMS+MSM+MPR\*  OD 42 (2+10+30) | Extended laboratory test  maize leaves (2D) | LR50 > 1500 mL/ha | EFSA Scientific Report, 2016;14(10):4584 |
| Field or semi-field tests | | | | |
|  | | | | |

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Justification for new endpoints

Not relevant.

### Risk assessment

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

#### Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group E (1.5L product/ha) also covers the risk for non-target arthropods from all other intended use groups (see 9.1.2).

Table 9.7‑2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of 054-01-05 in cereals

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | | Cereals | | |
| Active substance/product | | 054-01-05+ | | |
| Application rate (L/ha) | | 1 x 1.5 | | |
| MAF | | 1 | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | PERin‑field  (g/ha) | HQin-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* | >1500 | | 1500 | <1.0 |
| *Aphidius rhopalosiphi* | 877.3 | | 1.7 |

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

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

+Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group E (1 x 1.5L product/ha) also covers the risk for non-target arthropods from all other intended use groups (see 9.1.2).

Table 9.7‑3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals | | | | |
| Active substance/product | | 054-01-05+ | | | | |
| Application rate (L/ha) | | 1 x 1.5 | | | | |
| MAF | | 1 | | | | |
| vdf | | 5 (2D) / 1 (3D) | | | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | CF | HQoff-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* | >1500 | | 2.77 | 83.1 | 10 | <0.0277 |
| *Aphidius rhopalosiphi* | 877.3 | | 0.948 |

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

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

+Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Additional higher-tier risk assessment

Not relevant.

#### Risk mitigation measures

No risk mitigation needed.

### Overall conclusions

It can be concluded that no unacceptable risk to non-target arthropods in the in-field and the off-field is to be expected from the use of 054-01-05 according to the intended use pattern.

**Evaluator comments:**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses in GAP for the formulation Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life. No unacceptable effects are anticipated on communities of terrestrial non-target arthropods due to the use of Meso-Iodo OD-Life according proposed use in GAP.

The VDF of 10 was also considered in off-field risk assessment for non-target arthropods by zRMS as the use of VDF of 5 is in conflict with the noted ESCORT 2 guidance. Some Member states require the use of VDF 10 in off-field risk assessment.

**First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of Meso-Iodo-Life in cereals**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Intended use** | | Cereals | | | | |
| **Active substance/product** | | Meso-Iodo OD-Life | | | | |
| **Application rate (L/ha)** | | 1 x 1.5 | | | | |
| **MAF** | | 1 | | | | |
| **vdf** | | 10 (2D) / 1 (3D) | | | | |
| **Test species**  **Tier I** | **LR50 (lab.)**  **(g/ha)** | | **Drift rate** | **PERoff‑field**  **(g/ha)** | **CF** | **HQoff-field**  **criterion: HQ ≤ 2** |
| *Typhlodromus pyri* | >1500 | | 2.77 | 41.55 | 10 | <0.0277 |
| *Aphidius rhopalosiphi* | 877.3 | | 0.0474 |

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

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

+Data for Atlantis 12 OD. Meso-Iodo OD-Life is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

The risk from the formulation Meso-Iodo OD-Life indicating an acceptable in–field and off-fiel risk as the HQ values are < 2.

The risk assessment for non-target arthropods other than bees should be considered by MSs level.

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

### Toxicity data

An assessment of the risk from the active substances and representative formulation (IMS+MSM+MPR OD 42 (2+10+30) was performed during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009). 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). Consequently, no new studies are submitted with the formulation 054-01-05 and it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05.

**Iodosulfuron-methyl-sodium**

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with iodosulfuron-methyl-sodium and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2016;14(4):4453.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Eisenia fetida* | Iodosulfuron-methyl-sodium | Mixed into substrate  56 d, chronic  10 % peat content | EC10 = 7 mg a.s./kg dw | EFSA Journal  2016;14(4):4453 |
| *Folsomia candida* | Iodosulfuron-methyl-sodium | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 316 mg  a.s./kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | Iodosulfuron-methyl-sodium | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 1000  a.s./kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE F075736 | Mixed into substrate  56 d, chronic  10 % peat content | EC10 (estimated) =  0.7 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Folsomia candida* | AE F075736 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 9.86 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE F075736 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 9.86 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE F145741 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 94.4 mg /kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE F145741 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE F145740 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 97.5 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE F145740 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 97.5 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE 0002166 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 95.0 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE 0002166 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 95.2 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | BCS-CW81253 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 99.0 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Folsomia candida* | BCS-CW81253 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 99.0 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | BCS-CW81253 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 99.0 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE 0000119 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 97.8 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Folsomia candida* | AE 0000119 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 97.8 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE 0000119 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 97.8 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Eisenia fetida* | AE F059411 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 30 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Folsomia candida* | AE F059411 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 99.7 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| *Hypoaspis aculeifer* | AE F059411 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 98.7 mg/kg dw | EFSA Journal  2016;14(4):4453 |
| **Field studies** | | | | |
|  | | | | |
| **Litter bag test** | | | | |
|  | | | | |

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

**Mesosulfuron-methyl**

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Eisenia fetida* | Mesosulfuron-methyl | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 125 mg a.s./kg dws | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | Mesosulfuron-methyl | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 1000 mg  a.s./kg dws | EFSA Journal  2016;14(10):4584 |
| *Hypoaspis aculeifer* | Mesosulfuron-methyl | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 1000 mg  a.s./kg dws | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | AE F154851 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F160459 | Mixed into substrate  56 d, chronic  5 % peat content | NOEC = 90 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | AE F160459 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F099095 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 100 mg p.m./kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F092944 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 10 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | AE F092944 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg/kg dws1) | EFSA Journal  2016;14(10):45841) |
| *Hypoaspis aculeifer* | AE F092944 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F160460 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 100 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F140584 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 117 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Eisenia fetida* | AE F147447 | Mixed into substrate 56 d, chronic  5 % peat content | NOEC = 90 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | AE F147447 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg/kg dws | EFSA Journal  2016;14(10):4584 |
| **Endpoints used for metabolites risk assessment in case that no EU agreed test data are available** | | | | |
| *Eisenia fetida* | AE F154851 | Mixed into substrate  56 d, chronic  10 % peat content | NOEC = 12.5 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F154851 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F160459 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Folsomia candida* | AE F099095 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F099095 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Folsomia candida* | AE F160460 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F160460 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Folsomia candida* | AE F140584 | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F140584 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |
| *Hypoaspis aculeifer* | AE F147447 | Mixed into substrate  14 d, chronic  5 % peat content | NOEC = 100 mg  a.s./kg dws2) | from parent compound - see EFSA Journal 2016;14(10):4584 |

1) Results of two studies on *Folsomia candida* are tabulated in the EFSA List of Endpoints, thereof the value of NOEC = 100 mg/kg dws is deemed relevant for risk assessment, since not in contradiction to the value of NOEC = 50 mg/kg dws resulting from the peer review of the active substance flupyrsulfuron-methyl, EFSA (EFSA Journal 2014;12(11):3881). 2) assuming the metabolite is 10 times more toxic than the parent

Table 9.8‑3: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) – mefenpyr-diethyl and relevant metabolites

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Eisenia fetida* | Mefenpyr-diethyl | Mixed with soil / 10 % peat,  14 day, Acute | LC50 > 1 000 mg a.s./kg dw soil | Mefenpyr-diethyl DAR, 2011 |
| *Eisenia fetida* | AE F113225 | Mixed with soil / 10 % peat,  14 day, Acute | LC50 > 1 000 mg a.s./kg dw soil | Mefenpyr-diethyl DAR, 2011 |
| *Eisenia fetida* | AE F094270 | Mixed with soil / 10 % peat,  14 day, Acute | LC50 > 1 000 mg a.s./kg dw soil | Mefenpyr-diethyl DAR, 2011 |
| *Eisenia fetida* | AE F094270 | Mixed with soil / 10 % peat,  56 day, Chronic | NOEC = 100 mg /kg dw soil | Mefenpyr-diethyl DAR, 2011 |
| *Eisenia fetida* | AE F2211046 | Mixed with soil / 10 % peat,  14 day, Acute | LC50 > 100\* mg a.s./kg dw soil | EFSA Journal 2016;14(10):4584 |
| Field studies | | | | |
| None | | | | |
| Litter bag test | | | | |
| None | | | | |

\* metabolite considered 10 times more toxic than mefenpyr-diethyl (no study available)

**Table 9.8-4: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) – 054-01-05**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Exposure System** | **Results** | **Reference** |
| *Eisenia fetida* | IMS+MSM+MPR OD 42  (2+10+30)\* | Mixed into substrate  56 d chronic  10 % peat content | EC10 = 60 mg/kg  soil | EFSA Journal  2016;14(10):4584 |
| *Folsomia candida* | IMS+MSM+MPR OD 42  (2+10+30)\* | Mixed into substrate  28 d, chronic  5 % peat content | NOEC = 17 mg/kg  soil | EFSA Journal  2016;14(10):4584 |
| *Hypoaspis aculeifer* | IMS+MSM+MPR OD 42  (2+10+30)\* | Mixed into substrate  14 d, chronic  5 % peat content | EC10 = 297 mg/kg  soil | EFSA Journal  2016;14(10):4584 |

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Justification for new endpoints

No deviation from the EU agreed endpoints.

Based on the available acute toxicity data it can be assumed that mefenpyr-diethyl and its soil metabolites have a low toxicity for earthworms and at the exception of the metabolite AE F094270, their persistence is low. A long-term endpoint for the metabolite AE F094270 for earthworms is available and it was used in the risk assessment.

### Risk assessment

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

#### First-tier risk assessment

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered where relevant.

**Iodosulfuron-methyl-sodium**

For the active substance iodosulfuron-methyl-sodium (and metabolites) risk assessments are passed without any refinement, even if worst case PECsoil values are considered. Therefore, to further simplify the assessment, PECsoil for these compounds is calculated in an additional “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception). The resulting PECsoil calculations may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

**Table 9.8-5: First-tier assessment of the chronic risk of iodosulfuron-methyl-sodium for earthworms due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals, maize, non-cropped area, 10 g a.s./ha, BBCH 00-39 | | |
| **Chronic effects on earthworms** | | | |
| **Product/active substance** | **NOEC / EC10 (mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| Iodosulfuron-methyl-sodium | 7 | 0.013 | 538 |
| AE F075736 | 0.7 | 0.009 | 78 |
| AE F145741 | 94.4 | <0.001 | 94400 |
| AE F145740 | 97.5 | 0.001 | 97500 |
| AE 0002166 | 95.0 | 0.001 | 95000 |
| BCS-CW81253 | 99.0 | 0.003 | 33000 |
| AE 0000119 | 97.8 | 0.001 | 97800 |
| AE F059411 | 30 | 0.002 | 15000 |

**Table 9.8-6: First-tier assessment of the chronic risk of iodosulfuron-methyl-sodium for other non-target soil organisms (meso- and macrofauna) due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals, maize, non-cropped area, 10 g a.s./ha, BBCH 00-39 | | |
| **Chronic effects on other soil macro- and mesofauna** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| Iodosulfuron-methyl-sodium (*F. candida*) | 316 | 0.013 | 24308 |
| AE F075736 (*F. candida*) | 9.86 | 0.009 | 1096 |
| BCS-CW81253  (*F. candida*) | 99.0 | 0.003 | 33000 |
| AE 0000119 (*F. candida*) | 97.8 | 0.001 | 97800 |
| AE F059411 (*F. candida*) | 99.7 | 0.002 | 49850 |
| Iodosulfuron-methyl-sodium (*H. aculeifer*) | 1000 | 0.013 | 76923 |
| AE F075736  (*H. aculeifer*) | 9.86 | 0.009 | 1096 |
| AE F145741  (*H. aculeifer*) | 100 | <0.001 | 100000 |
| AE F145740  (*H. aculeifer*) | 97.5 | 0.001 | 97500 |
| AE 0002166  (*H. aculeifer*) | 95.2 | 0.001 | 95200 |
| BCS-CW81253  (*H. aculeifer*) | 99.0 | 0.003 | 33000 |
| AE 0000119  (*H. aculeifer*) | 97.8 | 0.001 | 97800 |
| AE F059411  (*H. aculeifer*) | 98.7 | 0.002 | 49350 |

**Mesosulfuron-methyl**

For the active substance mesosulfuron-methyl (and metabolites) risk assessments are passed without any refinement, even if worst case PECsoil values are considered. Therefore, to further simplify the assessment, PECsoil for these compounds is calculated in an additional “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception).

The resulting PECsoil calculations may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

**Table 9.8-7: First-tier assessments of the acute and chronic risk of mesosulfuron-methyl for earthworms due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals (winter and spring), 15 g a.s./ha, no crop interception | | |
| **Chronic effects on earthworms** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| Mesosulfuron-methyl | 125 | 0.022 | 5682 |
| AE F154851 | 12.5\* | 0.004 | 3125 |
| AE F160459 | 90 | 0.002 | 45000 |
| AE F099095 | 100 | 0.003 | 33333 |
| AE F092944 | 10 | <0.001 | >10000 |
| AE F160460 | 100 | 0.002 | 50000 |
| AE F140584 | 117 | <0.001 | >117000 |
| AE F147447 | 90 | <0.001 | >90000 |

TER values shown in bold fall below the relevant trigger.

\*assuming it is 10 times more toxic than the parent

**Table 9.8-8: First-tier assessments of the acute and chronic risk of mesosulfuron-methyl for other non-target soil organisms (meso- and macrofauna) due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals (winter and spring), 15 g a.s./ha, no crop interception | | |
| **Chronic effects on other soil macro- and mesofauna** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| Mesosulfuron-methyl (*F. candida*) | 1000 | 0.022 | 45455 |
| AE F154851 (*F. candida*) | 100 | 0.004 | 25000 |
| AE F160459 (*F. candida*) | 100 | 0.002 | 50000 |
| AE F099095 (*F. candida*) | 100\* | 0.003 | 3333 |
| AE F092944 (*F. candida*) | 100 | < 0.001 | >100000 |
| AE F160460 (*F. candida*) | 100\* | 0.002 | 50000 |
| AE F140584 (*F. candida*) | 100\* | <0.001 | >100000 |
| AE F147447 (*F. candida*) | 100 | < 0.001 | >100000 |
| Mesosulfuron-methyl (*H. aculeifer*) | 1000 | 0.022 | 45455 |
| AE F154851  (*H. aculeifer*) | 100\* | 0.004 | 25000 |
| AE F160459  (*H. aculeifer*) | 100\* | 0.002 | 50000 |
| AE F099095  (*H. aculeifer*) | 100\* | 0.003 | 33333 |
| AE F092944  (*H. aculeifer*) | 100 | < 0.001 | >100000 |
| AE F160460  (*H. aculeifer*) | 100\* | 0.002 | 50000 |
| AE F140584  (*H. aculeifer*) | 100\* | <0.001 | >100000 |
| AE F147447  (*H. aculeifer*) | 100\* | <0.001 | >100000 |

TER values shown in bold fall below the relevant trigger.

\*assuming it is 10 times more toxic than the parent

**Mefenpyr-diethyl**

An assessment for the safener mefenpyr-diethyl has been provided as supplemental information. A worst-case application rate of 45g/ha has been considered in the risk assessment below, which is protective of all proposed uses.

**Table 9.8‑9: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of 054-01-05 in winter and spring cereals**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Winter and spring cereals | | |
| **Chronic effects on earthworms** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| AE F094270 (metabolite of mefenpyr-diethyl) | 100 | 0.070 (accumulation) | 1428 |
| Mefenpyr-diethyl | 500.0 | 0.060 (initial) | >8333 |
| AE F113225 | 1000.0 | 0.024 (initial) | >41000 |
| AE F094270 | 500.0 | 0.070 (accumulation) | 7142 |
| AE 2211046 | 50.0 | 0.007 (initial) | 7142 |

**054-01-05**

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group E (1 x 1.5L product/ha) also covers the risk for non-target soil organisms (meso- and macrofauna) from all other intended use groups (see 9.1.2).

**Table 9.8-10: First-tier assessment of the acute and chronic risk of 054-01-05 for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use in cereals (use group E)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | **Cereals (winter), 1.5 L/ha, no crop interception** | | |
| **Acute effects on earthworms** | | | |
| Not required according to Regulation (EC) 1107/2009 | | | |
| **Chronic effects on earthworms** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| IMS+MSM+MPR OD 42 (2+10+30) \* | 60 | 2 | 30 |
| **Chronic effects on other soil macro- and mesofauna** | | | |
| **Product/active substance** | **NOEC**  **(mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **TERlt**  **(criterion TER ≥ 5)** |
| IMS+MSM+MPR OD 42 (2+10+30)  (*F. candida*) \* | 17 | 2 | 8.5 |
| IMS+MSM+MPR OD 42 (2+10+30)  (*H. aculeifer*) \* | 297 | 2 | 148.5 |

TER values shown in bold fall below the relevant trigger.

\* Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Higher-tier risk assessment

Not relevant.

### Overall conclusions

The acute and/or long-term risk of the active substances and their relevant metabolites and of the formulated product was assessed, based on maximum PECsoil. All TER values for earthworms and other soil macro-organisms are greater than the relevant triggers indicating acceptable for the use of 054-01-05 in cereals.

**Evaluator comments:**

**Effect on non-target soil meso- and macrofauna**

The calculations PECs evaluated for GAP of Atlantis 42 OD cover all uses proposed in GAP for Meso-Iodo OD-Life. The PECs calculations of Atlantis 12 OD were been accepted for max. rate application of iodosulfuron-methyl-sodium 10 g as/ha and 15 g a.s./ha of mesosulfuron-methyl. The input parameters used in calculations PECs were established in the EU reviews: Iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453) and Mesosulfuron-methyl summarised in the EFSA conclusion (EFSA Journal 2016;14(10): 4584). The results max PEC soil of the active substances and their metabolites were used for the ecotoxicological risk assessment.

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.

The long-term risk assessment presented for earthworms and other soil non-target macro-organisms based On the endpoints from the studies performed on formulation of Atlantis 12 OD. The risk assessment is   
appropriate to be used for Meso-Iodo OD-Life. Use of Meso-Iodo OD-Life is not expected to pose risk to soil macro-organisms. No additional risk assessment is not required.

## Effects on soil microbial activity (KCP 10.5)

### Toxicity data

**Iodosulfuron-methyl-sodium**

Studies on effects soil microorganisms have been carried out with iodosulfuron-methyl-sodium and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents; presented agreed endpoints were taken from EFSA Journal 2016;14(4):4453, if not otherwise stated.

**Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms – iodosulfuron-methyl-sodium**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Endpoint** | **Substance** | **Exposure**  **System** | **Results** | **Reference** |
| N-mineralisation | Iodosulfuron-  methyl-sodium | 28 d, aerobic soil type | No unacceptable effects on N  transformations at 0.067 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | *AE F075736 (as formulated product 20DP submitted for active substance metsulfuron-methyl)* | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.04 mg/kg soil dw | EFSA Journal 2016;14(4):4453 endpoint taken from: Sanco 7593/VI/97  final from  14 AUG 2000 |
| N-mineralisation | AE F145741 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.063 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | AE F145740 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.063 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | AE 0002166 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0,053 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | AE F161778 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.049 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | BCS-CW81253 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.043 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | AE 0000119 | 28 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.4 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |
| N-mineralisation | AE F059411 | 42 d, aerobic soil type | No unacceptable  effects on N  transformations at 0.204 mg/kg soil dw | EFSA Journal  2016;14(4):4453 |

soil dw = soil dry weight

**Mesosulfuron-methyl**

Studies on effects on soil microorganisms have been carried out with mesosulfuron-methyl and its relevant metabolites. Full details of these studies are provided in the EU Renewal Assessment Report and related documents, presented agreed endpoints were taken from EFSA Journal 2016;14(10):4584.

**Table 9.9-2: Endpoints and effect values relevant for the risk assessment for soil microorganisms – mesosulfuron-methyl**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Endpoint** | **Substance** | **Exposure**  **System** | **Results** | **Reference** |
| N-mineralisation | Mesosulfuron-  methyl | 28 d, aerobic silty sand and loamy  silt | No unacceptable  effects on N  transformations at 0.1 mg/kg d.w. soil | EFSA Journal  2016;14(10):4584 |
| N-mineralisation | AE F154851 | 28 d, aerobic sandy loam | No unacceptable  effects on N  transformations at 0.1 mg/kg d.w. soil | EFSA Journal  2016;14(10):4584 |
| N-mineralisation | AE F160459 | 42 d, aerobic sandy loam | No unacceptable  effects on N  transformations at 0.1 mg/kg d.w. soil | EFSA Journal  2016;14(10):4584 |
| N-mineralisation | AE F099095 | 28 d, aerobic sandy loam | No unacceptable  effects on N  transformations at 0.1 mg/kg d.w. soil | EFSA Journal  2016;14(10):4584 |
| N-mineralisation | AE F092944 | 28 d, aerobic loamy sand | No unacceptable  effects on N  transformations at 0.137 mg/kg d.w.  soil\* | EFSA Journal  2016;14(10):4584 |
| N-mineralisation | AE F147447 | 28 d, aerobic loamy sand | No unacceptable  effects on N  transformations at 0.057 mg/kg d.w.  soil | EFSA Journal  2016;14(10):4584 |

d.w. soil = dry weight soil

\* ) Results of two studies on N-mineralisation are tabulated in the EFSA List of Endpoints, thereof the value of "< 25 % effect at day 28 at 0.137 mg/kg d.w.soil" is deemed relevant for risk assessment, since not in contradiction to the value of "<25% effect at day 28 at 0.06 mg/kg d.w.soil" resulting from the peer review of the active substance flazasulfuron (EFSA Journal 2016;14(8):4575).

**054-01-05**

An assessment of the risk from the active substances and representative formulation (IMS+MSM+MPR OD 42 (2+10+30) was performed during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009). 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). Consequently, no new studies are submitted with the formulation 054-01-05 and it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05

**Table 9.9-3: Endpoints and effect values relevant for the risk assessment for soil microorganisms with 054-01-05**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Endpoint** | **Substance** | **Exposure**  **System** | **Results** | **Reference** |
| N-mineralisation | IMS+MSM+MPR OD  42 (2+10+30) \* | 42 d, aerobic silty sand | No adverse effect at  7.5 L prod./ha =  10 µL prod. /kg soil  dw | EFSA Journal  2016;14(10):4584 |

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

#### Justification for new endpoints

No deviation from the EU agreed endpoints.

No toxicity values on soil microbial activity for mefenpyr-diethyl and its soil metabolites AE F113225 and AE F2211046 are available. This is not considered to be a critical data gap as mefenpyr-diethyl is a safener which is included in the preparation and its toxicity is addressed by the toxicity studies available for the preparation.

### Risk assessment

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

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

**Iodosulfuron-methyl-sodium**

For the active substance iodosulfuron–methyl-sodium (and metabolites) risk assessments are passed without any refinement, even if worst case PECsoil values are considered. Therefore, to further simplify the assessment, PECsoil for these compounds is calculated in an additional “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception). The resulting PECsoil calculations may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

**Table 9.9-4: Assessment of the risk of iodosulfuron-methyl-sodium for effects on soil microorganisms due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals, maize, non-cropped area, 10 g a.s./ha, BBCH 00-39 | | |
| **N-mineralisation** |  | | |
| **Product/active substance** | **Max. conc. with effects ≤ 25 % (mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **Risk acceptable?** |
| Iodosulfuron-methyl-sodium | 0.067 (at 28 d) | A black background with a black square  Description automatically generated with medium confidence0.013  0.009 | yes |
| AE F075736 | 0.04 (at 28 d) | yes |
| AE F145741 | 0.063 (at 28 d) | yes |
| AE F145740 | 0.063 (at 28 d) | yes |
| AE 0002166 | 0.053 (at 28 d) | yes |
| AE F161778 | 0.049 (at 28 d) | yes |
| BCS-CW81253 | 0.043 (at 28 d) | yes |
| AE 0000119 | 0.4 (at 28 d) | yes |
| AE F059411 | 0.204 (at 42 d) | yes |

dw = dry weight

**Mesosulfuron-methyl**

For the active substance mesosulfuron-methyl (and metabolites) risk assessments are passed without any refinement, even if worst case PECsoil values are considered. Therefore, to further simplify the assessment, PECsoil for these compounds is calculated in an additional “risk envelope approach”, addressing the maximum registered application rate and overall worst case exposure situation (no tillage, no crop interception).

The resulting PECsoil calculations may overestimate the actual exposure due to use of the present product, and thus further increase the conservatism of the Tier 1 risk assessments.

**Table 9.9-5: Assessment of the risk for effects of mesosulfuron-methyl effects on soil micro-organisms due to the use of 054-01-05 in cereals (use group A)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | Risk envelope approach:  Cereals (winter and spring), 15 g a.s./ha, BBCH 10-39 | | |
| **N-mineralisation** |  | | |
| **Product/active substance** | **Max. conc. with effects ≤ 25 % (mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **Risk acceptable?** |
| Mesosulfuron-methyl | 0.1 (at 28 d) | A black background with a black square  Description automatically generated with medium confidence0.022  0.004  0.002  0.003 | yes |
| AE F154851 | 0.1 (at 28 d) | yes |
| AE F160459 | 0.1 (at 42 d) | yes |
| AE F099095 | 0.1 (at 28 d) | yes |
| AE F092944 | 0.137 (at 28 d) | yes |
| AE F147447 | 0.057 (at 28 d) | yes |

dw = dry weight

**054-01-05**

**Table 9.9-6: Assessment of the risk for effects of 054-01-05 on soil micro-organisms due to the use in cereals (use group E)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Intended use** | **Cereals (winter), 1.5 L/ha, no crop interception** | |  |
| **N-mineralisation** |  | |  |
| **Product/active substance** | **Max. conc. with effects ≤ 25 % (mg/kg dw)** | **PECsoil**  **(mg/kg dw)** | **Risk acceptable?** |
| IMS+MSM+MPR OD  42 (2+10+30) \* | 10\* (at 42 d) | 2 | yes |

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

### Overall conclusions

The risk of the active substances, their relevant metabolites, and of the formulated product was assessed based on maximum PECsoil, and indicated acceptable for the use of 054-01-05 in cereals.

**Evaluator comments:**

**Effects on soil microbial activity**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.

The risk assessment presented for micro-organisms on the endpoints from the studies performed on for-mulation of Atlantis 12 OD has been accepted for Meso-Iodo OD-Life. The risk assessment is appropriate to be used for Meso-Iodo OD-Life. According to the Registration Report for Atlantis 12 OD the risk assessment for microorganisms have been accepted. On the basis of performed calculations in Atlantis 12 OD report, acceptable risk assessment to microorganisms may be concluded from proposed uses of Meso-Iodo OD-Life. The risk to soil micro-organisms from uses of Meso-Iodo OD-Life is expected to be low. No additional risk assessment is not required.

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

### Toxicity data

Effects on non-target soil meso and macrofauna of 054-01-05 were not evaluated as part of the EU assessment of mesosulfuron-methyl, iodosulfuron-methyl-sodium or mefenpyr-diethyl.

An assessment of the risk from the active substances and representative formulation (IMS+MSM+MPR OD 42 (2+10+30) was performed during the renewal of the reference product, Atlantis 12 OD (authorisation number R-98/2009). 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition). Consequently no new studies are submitted with the formulation 054-01-05 and it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05

**Table 9.10-1: Assessment of the risk of iodosulfuron-methyl-sodium for effects on soil microorganisms due to the use of 054-01-05 in cereals (use group A)**

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Beta vulgaris.* d 1)  *Brassica napus.* d 2)  *Cucumis sativus* d 3)  *Glycine max* d 4) | IMS+MSM+  MPR OD 42  (2+10+30+ | 21 d Seedling emergence,  Tier 2 | 1. ER50 shoot dry weight = 155 mL product/ha 2. ER50 shoot dry weight = 229 mL product/ha 3. ER50 shoot dry weight = 327 mL product/ha   ER50 shoot dry weight > 375 mL product/ha | RAR Volume 3 –  B.9 (PPP) – ATLANTIS OD  [all values]    EFSA Journal  2016;14(10):4584  [critical values |
| *Helianthus annuus* d 5)  *Raphanus sativus* d 6)  *Lycopersicon esculentum* d 7)  *Allium cepa* m 8)  *Avena sativa* m 9)  *Zea mays* m 10) | 1. ER50 shoot dry weight = 98 mL product/ha 2. ER50 shoot dry weight = 136 mL product/ha 3. ER50 shoot dry weight = 326 mL product/ha 4. **ER50 emergence = 64 mL product/ha** 5. ER50 shoot dry weight = 760 mL product/ha 6. ER50 shoot dry weight = 631 mL product/ha |
| **HR5 shoot dry weight = 54.9 mL product/ha (**calculated with ETX 2.0, unbound figures with values that are shown to be > have been omitted from the calculation)\* |
| *Beta vulgaris.* d 1)  *Brassica napus.* d 2)  *Cucumis sativus* d 3)  *Glycine max* d 4)  *Helianthus annuus* d 5)  *Raphanus sativus* d 6)  *Lycopersicon esculentum* d 7)  *Allium cepa* m 8)  *Avena sativa* m 9)  *Zea mays* m 10) | 21 d Vegetative vigour, Tier 2 | 1. ER50 shoot dry weight = 144 mL product/ha 2. ER50 shoot dry weight = 56 mL product/ha 3. ER50 shoot dry weight > 0.188 mL product/ha 4. ER50 shoot dry weight = 136 mL product/ha 5. **ER50 shoot dry weight = 27 mL product/ha** 6. ER50 shoot dry weight = 38 mL product/ha 7. ER50 shoot dry weight = 36 mL product/ha 8. ER50 shoot dry weight > 188 mL product/ha 9. ER50 shoot dry weight = 287 mL product/ha 10. ER50 shoot dry weight = 385 mL product/ha |
| **HR5 shoot dry weight = 16 mL product/ha** (calculated with ETX 2.0, unbound figures with values that are shown to be > have been omitted from the calculation) |  |

m: monocotyledonous; d: dicotyledonous

\* SSD calculation was done with ER50 values based on shoot dry weight except for onion (Allium cepa) where the ER50 based on emergence was used. These endpoints represent the lowest endpoint for each tested species. An SSD calculation only based on shoot dry weight values resulted in a higher HR5 of 72 ml product/ha and is therefore regarded less conservative.

+Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition).

In order to be able to apply the species sensitivity distribution (SSD) approach for calculation of an HR5, it is required to show that log-normal distribution fits the data adequately. The data sets of both - the seedling emergence study and the vegetative vigour study - meet the criteria of normality (see figure below):

|  |  |
| --- | --- |
| **seedling emergence data** | **vegetative vigour data** |
| A graph showing the number of data  Description automatically generated with medium confidence | A graph showing the number of data  Description automatically generated with medium confidence |
| A screenshot of a computer  Description automatically generated | A screenshot of a computer  Description automatically generated |

**Figure 9.10-1: SSD graphs and results from Anderson-Darling tests for normality of ER50-figures from the seedling emergence test (left) and vegetative vigour test (right).**

#### Justification for new endpoints

Not relevant

### Risk assessment

#### Tier-1 risk assessment (based screening data)

Not relevant.

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

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

The quantitative risk assessment presented here follows a step-wise approach: First step is a **deterministic risk assessment** based on the lowest endpoints of the Tier-2 greenhouse studies. Second step is a **probabilistic risk assessment** based on the HR5 which is derived from the species sensitivity distribution (SSD) analysis of the various species tested in the Tier-2 greenhouse studies

**Deterministic Approach**

According to the Terrestrial Guidance Document, the risk to non-target plants is evaluated by comparing the lowest ER50 with the calculated Predicted Environmental Rates (PERoff-field) from spray-drift exposure. A trigger of 5 is considered appropriate if at least six plant species have been tested.

Table 9.10‑2: Assessment of the risk for non-target plants due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals, 1 x 1.5L/ha (use group E) | | | |
| Active substance/product | | 054-01-05\* | | | |
| Application rate (mL/ha) | | 1 x 1500 | | | |
| MAF | | 1 (single application) | | | |
| Test species | ER50  (mL/ha) | | Drift rate (%) | PERoff‑field  (mL/ha) | TER  criterion: TER ≥ 5 |
| *Allium cepa -*  seedling emergence | 64.0 | | 2.77 | 41.55 | **1.54** |
| *Helianthus annuus* - vegetative vigour | 27.0 | | 2.77 | 41.55 | **0.65** |
| Intended use | | | Cereals, 1 x 0.45L/ha (use group J) | | | |
| Active substance/product | | | 054-01-05 | | | |
| Application rate (mL/ha) | | | 1 x 450 | | | |
| MAF | | | 1 (single application) | | | |
| Test species | | ER50  (mL/ha) | | Drift rate (%) | PERoff‑field  (mL/ha) | TER  criterion: TER ≥ 5 |
| *Allium cepa -*  seedling emergence | | 64.0 | | 2.77 | 12.47 | 5.13 |
| *Helianthus annuus* - vegetative vigour | | 27.0 | | 2.77 | 12.47 | **2.16** |

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

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

The trigger is not met for both, seedling emergence and vegetative vigour, for the highest application rate intended for the product, and it is also failed for vegetative vigour for the lowest rate. As the next step, a probabilistic assessment is therefore provided below.

**Probabilistic Approach**

According to the Guidance Document on Terrestrial Ecotoxicology, the probabilistic method makes use of the species sensitivity distribution (SSD) in order to calculate an HR5. The HR5 is the concentration below which less than 5% of the species will be harmed above the ER50 level and can be calculated from the data sets of ER50 growth inhibition levels. If the HR5 is below the highest predicted exposure level, the risk for terrestrial plants is deemed to be acceptable. The EU guidance document for terrestrial ecotoxicology states: ”*If the ED50 for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable. ~~Thus, the HC5 itself (TER =1) can be regarded to be protective.”~~*

A probabilistic approach is considered more suitable than the deterministic one to achieve the environmental protection goal, since sensitivity data of several species are taken into account. However, it is applicable only if data of at least 6 species are available, and requires that log-normal or another defined type of distribution of the data has been shown to fit the data adequately. The HR5 in the present risk assessment was calculated using the ETX2.1 program.

For the representative product IMS+MSM+MPR OD 42, applicability criteria for the probabilistic approach are met as has been shown previously in Section 9.10.1 including SSD graph analysis, and this conclusion has been EU agreed in EFSA Journal 2016;14(10):4584, and RAR Volume 3 – B.9 (PPP) – ATLANTIS OD (revised version 2016-06). As 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition) it is requested that the zRMS refers to the data presented in the renewal of Atlantis 12 OD in order to support the authorisation of 054-01-05.

Table 9.10‑3: Probabilistic assessment of the risk for non-target plants due to the use of 054-01-05 in cereals

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | | Cereals, 1 x 1.5L/ha (use group E) | | | |
| Active substance/product | | 054-01-05+ | | | |
| Application rate (mL/ha) | | 1 x 1500 | | | |
| MAF | | 1 (single application) | | | |
| Test species | **HR5**  (mL/ha) | | Drift rate (%) | PERoff‑field  (mL/ha) | TER  criterion: TER ≥ 1\* |
| HR5  seedling emergence | 54.9 | | 2.77 | 41.55 | 1.32 |
| HR5  vegetative vigour | 16.0 | | 2.77 | 41.55 | **0.39** |
| Intended use | | | Cereals, 1 x 0.45L/ha (use group J) | | | |
| Active substance/product | | | 054-01-05+ | | | |
| Application rate (mL/ha) | | | 1 x 450 | | | |
| MAF | | | 1 (single application) | | | |
| Test species | | **HR5**  (mL/ha) | | Drift rate (%) | PERoff‑field  (mL/ha) | TER  criterion: TER ≥ 1\* |
| HR5  seedling emergence | | 54.9 | | 2.77 | 12.47 | 4.40 |
| HR5  vegetative vigour | | 16.0 | | 2.77 | 12.47 | 1.28 |

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

\* TER ≥ 1 for probabilistic risk assessment based on HR5

+Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

For the highest intended rate, the trigger is met for seedling emergence, however it has not been reached for vegetative vigour. Accordingly, further analysis is required and will be presented, considering possible options for exposure mitigation, focused on vegetative vigour. The lowest rate is passed for both, seedlings emergence and vegetative vigour and therefore does not require any further analysis or consideration.

#### Higher-tier risk assessment

No semi-field or field studies have been provided.

#### Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the lowest HR5 (vegetative vigour) and ER50 value (vegetative vigour) as well as typical mitigation measures (no-spray buffer zones of 5, 10, 15, 20 or 30 m ; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following tables.

Table 9.10‑4: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 154-05-01 in cereals: Use group E.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.5 L prod./ha (use group E)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 1500 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 41.55 | 20.78 | 10.39 | 4.16 |
| 5 m | 0.57 | 8.55 | 4.28 | 2.14 | 0.86 |
| 10 m | 0.29 | 4.35 | 2.18 | 1.09 | 0.44 |
| 15 | 0.20 | 3.00 | 1.50 | 0.75 | 0.30 |
| 20 | 0.15 | 2.25 | 1.13 | 0.56 | 0.23 |
| 30 | 0.10 | 1.50 | 0.75 | 0.38 | 0.15 |
| **Toxicity value** | | **TER** | | |  |
| **ER50=27 mL prod./ha (vegetative vigour test)** | | **criterion: TER ≥ 5** | | |  |
| no buffer | | **0.65** | **1.30** | 2.60 | 6.50 |
| 5 m | | 3.16 | 6.32 | 12.63 | 31.58 |
| 10 m | | 6.21 | 12.441 | 24.83 | 62.07 |
| 15 m | | 9.00 | 18.00 | 36.00 | 90.00 |
| 20 m | | 12.00 | 24.00 | 48.00 | 120.00 |
| 30 m | | 18.00 | 36.00 | 72.00 | 180.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑5: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 054-01-05 in cereals: Use group F.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.2 L prod./ha (use group F)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 1200 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 33.24 | 16.62 | 8.31 | 3.32 |
| 5 m | 0.57 | 6.84 | 3.42 | 1.71 | 0.68 |
| 10 m | 0.29 | 3.48 | 1.74 | 0.87 | 0.35 |
| 15 m | 0.20 | 2.40 | 1.20 | 0.60 | 0.24 |
| 20 m | 0.15 | 1.80 | 0.90 | 0.45 | 0.18 |
| 30 m | 0.10 | 1.20 | 0.60 | 0.30 | 0.12 |
| **Toxicity value** | | **TER** | | |  |
| **27 mL prod./ha (vegetative vigour test)** | | **criterion: TER ≥ 5** | | |  |
| no buffer | | **0.81** | **1.62** | 3.25 | 8.12 |
| 5 m | | 3.95 | 7.89 | 15.79 | 39.47 |
| 10 m | | 7.76 | 15.52 | 31.03 | 77.59 |
| 15 m | | 11.25 | 22.50 | 45.00 | 112.50 |
| 20 m | | 15.00 | 30.00 | 60.00 | 150.00 |
| 30 m | | 22.50 | 45.00 | 90.00 | 225.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑6: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 054-01-05 in cereals: Use group G.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.0 L prod./ha (use group G)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 1000 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red.**  **(mL/ha)** | **PERoff-field**  **75 % drift red.**  **(mL/ha)** | **PERoff-field**  **90 % drift red.**  **(mL/ha)** |
| no buffer | 2.77 | 27.70 | 13.85 | 6.93 | 2.77 |
| 5 m | 0.57 | 5.70 | 2.85 | 1.43 | 0.57 |
| 10 m | 0.29 | 2.90 | 1.45 | 0.73 | 0.29 |
| 15 m | 0.20 | 2.00 | 1.00 | 0.50 | 0.20 |
| 20 m | 0.15 | 1.50 | 0.75 | 0.38 | 0.15 |
| 30 m | 0.10 | 1.00 | 0.50 | 0.25 | 0.10 |
| **Toxicity value** | | **TER** | | |  |
| **ER5 = 27mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 5** | | |  |
| no buffer | | **0.97** | **1.95** | 3.90 | 9.75 |
| 5 m | | 4.74 | 9.47 | 18.95 | 47.37 |
| 10 m | | 9.31 | 18.62 | 37.24 | 93.10 |
| 15 m | | 13.50 | 27.00 | 54.00 | 135.00 |
| 20 m | | 18.0 | 36.0 | 72.0 | 180.0 |
| 30 m | | 27.00 | 54.00 | 108.00 | 270.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑7: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 054-01-05 in cereals: use group H

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 0.6 L prod./ha (use group H)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 600 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 16.62 | 8.31 | 4.16 | 1.66 |
| 5 m | 0.57 | 3.42 | 1.71 | 0.86 | 0.34 |
| 10 m | 0.29 | 1.74 | 0.87 | 0.44 | 0.17 |
| 15 m | 0.20 | 1.20 | 0.60 | 0.30 | 0.12 |
| 20 m | 0.15 | 0.90 | 0.45 | 0.23 | 0.09 |
| 30 m | 0.10 | 0.60 | 0.30 | 0.15 | 0.06 |
| **Toxicity value** | | **TER** | | |  |
| **ER5 = 27 mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 5** | | |  |
| no buffer | | **1.62** | **3.25** | 6.50 | 16.25 |
| 5 m | | 7.89 | 15.79 | 31.58 | 78.95 |
| 10 m | | 15.52 | 31.03 | 62.07 | 155.17 |
| 15 m | | 22.50 | 45.00 | 90.00 | 225.0 |
| 20 m | | 30.00 | 60.00 | 120.00 | 300.00 |
| 30 m | | 45.00 | 90.00 | 180.00 | 450.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑8: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 054-01-05 in cereals: use group I.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 0.5 L prod./ha (use group I)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 500 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 13.85 | 6.93 | 3.46 | 1.39 |
| 5 m | 0.57 | 2.85 | 1.43 | 0.71 | 0.29 |
| 10 m | 0.29 | 1.45 | 0.73 | 0.36 | 0.15 |
| 15 m | 0.20 | 1 | 0.50 | 0.25 | 0.10 |
| 20 m | 0.15 | 0.75 | 0.38 | 0.19 | 0.08 |
| 30 m | 0.10 | 0.50 | 0.25 | 0.13 | 0.05 |
| **Toxicity value** | | **TER** | | |  |
| **ER5 = 27mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 5** | | |  |
| no buffer | | **1.95** | **3.90** | 7.80 | 19.49 |
| 5 m | | 9.47 | 18.95 | 37.24 | 94.74 |
| 10 m | | 18.62 | 37.24 | 74.48 | 186.21 |
| 15 m | | 27 | 54 | 108 | 270 |
| 20 m | | 36 | 72 | 144 | 360 |
| 30 m | | 54.00 | 108.00 | 216.00 | 540.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑9: Deterministic risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) for the use of 054-01-05 in cereals: use group J

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 0.45 L prod./ha (use group J)** | | |  |
| **Active substance/product** | | 054-01-05\* | | |  |
| **Application rate (mL/ha)** | | 1 × 450 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 12.47 | 6.23 | 3.12 | 1.25 |
| 5 m | 0.57 | 2.57 | 1.28 | 0.64 | 0.26 |
| 10 m | 0.29 | 1.31 | 0.65 | 0.33 | 0.13 |
| 15 m | 0.20 | 0.90 | 0.45 | 0.23 | 0.09 |
| 20 m | 0.15 | 0.68 | 0.34 | 0.17 | 0.07 |
| 30 m | 0.10 | 0.45 | 0.23 | 0.11 | 0.05 |
| Toxicity value | | **TER** | |  |  |
| **ER5 = 27mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 5** | |  |  |
| no buffer | | 2.17 | 4.33 | 8.66 | 21.66 |
| 5 m | | 10.53 | 21.05 | 42.11 | 105.26 |
| 10 m | | 20.69 | 41.38 | 82.76 | 206.90 |
| 15 m | | 30.00 | 60.00 | 120.00 | 300.00 |
| 20 m | | 40.00 | 80.00 | 160.00 | 400.00 |
| 30 m | | 60.00 | 120.00 | 240.00 | 600.00 |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

\*Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

The deterministic risk assessment is based on the lowest ER50 value of 27 ml product/ha from the vegetative vigour test as the worst case scenario. According to Central Zone harmonised position made by MSs in Dessau (Sep., 2018) the risk assessment was done with consideration of max 30 meter buffer zones to non-crop area. It is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* 10m or alternatively a 5 m buffer with 50 % drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E), 1.2 L product/ha (use group F) and 1 x 1.0 L product/ha (use group G) or non-buffer zone with 90 % drift reduction nozzles for application 1.5L/ha, 1.2 L/ha and 1.0 L/ha.
* 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application 1 x 0.6 L product/ha (use group H), 1 x 0.5 L product/ha (use group I) and 1 x 0.45 L product/ha (use group J).

Table 9.10‑10: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR5 - for the use of 054-01-05 in cereals: Use group E

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.5 L prod./ha (use group E)** | | |  |
| **Active substance/product** | | 054-01-05+ | | |  |
| **Application rate (mL/ha)** | | 1 × 1500 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 41.55 | 20.78 | 10.39 | 4.16 |
| 5 m | 0.57 | 8.55 | 4.28 | 2.14 | 0.86 |
| 10 m | 0.29 | 4.35 | 2.18 | 1.09 | 0.44 |
| **Toxicity value** | | **TER** | | |  |
| **HR5 = 16 mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 1**  **criterion: TER ≥ 5\*** | | |  |
| no buffer | | **0.39** | **0.77** | 1.54 | 3.85 |
| 5 m | | 1.87 | 3.74 | 7.49\* | 18.71\* |
| 10 m | | 3.68 | 7.36\* | 14.71\* | 36.78\* |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger of 1.

\*TER>5

+ Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑11: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR5 - for the use of 054-01-05 in cereals: Use group F

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.2 L prod./ha (use group F)** | | |  |
| **Active substance/product** | | 054-01-05+ | | |  |
| **Application rate (mL/ha)** | | 1 × 1200 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 33.24 | 16.62 | 8.31 | 3.32 |
| 5 m | 0.57 | 6.84 | 3.42 | 1.71 | 0.68 |
| 10 m | 0.29 | 3.48 | 1.74 | 0.87 | 0.35 |
| **Toxicity value** | | **TER** | | |  |
| **HR5 = 16 mL prod./ha (vegetative vigour)** | | **criterion: TER ≥ 1**  **criterion: TER ≥ 5\*** | | |  |
| no buffer | | **0.48** | **0.96** | 1.93 | 4.81 |
| 5 m | | 2.34 | 4.68 | 9.36\* | 23.39\* |
| 10 m | | 4.60 | 9.20\* | 18.39\* | 45.98\* |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger of 1.

\*TER>5

+ Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑12: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR5 - for the use of 054-01-05 in cereals: Use group G

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 1.0 L prod./ha (use group G)** | | |  |
| **Active substance/product** | | 054-01-05+ | | |  |
| **Application rate (mL/ha)** | | 1 × 1000 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 27.70 | 13.85 | 6.93 | 2.77 |
| 5 m | 0.57 | 5.70 | 2.85 | 1.43 | 0.57 |
| 10 m | 0.29 | 2.90 | 1.45 | 0.73 | 0.29 |
| **Toxicity value** | | **TER** | | |  |
| HR5 = 16 mL prod./ha (vegetative vigour) | | **criterion: TER ≥ 1**  **criterion: TER ≥ 5\*** | | |  |
| no buffer | | **0.58** | 1.16 | 2.31 | 5.78\* |
| 5 m | | 2.81 | 5.61\* | 11.23\* | 28.07\* |
| 10 m | | 5.52\* | 11.03\* | 22.07\* | 55.17\* |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger of 1.

\*TER>5

+ Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑13: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR5 - for the use of 054-01-05 in cereals: Use group H

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 0.6 L prod./ha (use group H)** | | |  |
| **Active substance/product** | | 054-01-05+ | | |  |
| **Application rate (mL/ha)** | | 1 × 600 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 16.62 | 8.31 | 4.16 | 1.66 |
| 5 m | 0.57 | 3.42 | 1.71 | 0.86 | 0.34 |
| 10 m | 0.29 | 1.74 | 0.87 | 0.44 | 0.17 |
| **Toxicity value** | | **TER** | | |  |
| HR5 = 16 mL prod./ha (vegetative vigour) | | **criterion: TER ≥ 1**  **criterion: TER ≥ 5\*** | | |  |
| no buffer | | **0.96** | 1.93 | 3.85 | 9.63\* |
| 5 m | | 4.68 | 9.36\* | 18.71\* | 46.78\* |
| 10 m | | 9.20\* | 18.39\* | 36.78\* | 91.95\* |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger of 1.

\*TER>5

+ Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

Table 9.10‑14: Risk assessment for non-target terrestrial plants considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles) based on the lowest HR5 - for the use of 054-01-05 in cereals: Use group I (covering use group J)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Intended use** | | **Cereals, 1 x 0.5 L prod./ha (use group I)** | | |  |
| **Active substance/product** | | 054-01-05+ | | |  |
| **Application rate (mL/ha)** | | 1 × 500 | | |  |
| **MAF** | | 1.0 | | |  |
| **Buffer strip (m)** | **Drift rate (%)** | **PERoff-field (mL/ha)** | **PERoff-field**  **50 % drift red. (mL/ha)** | **PERoff-field**  **75 % drift red. (mL/ha)** | **PERoff-field**  **90 % drift red. (mL/ha)** |
| no buffer | 2.77 | 13.85 | 6.93 | 3.46 | 1.39 |
| 5 m | 0.57 | 2.85 | 1.43 | 0.71 | 0.29 |
| 10 m | 0.29 | 1.45 | 0.73 | 0.36 | 0.15 |
| **Toxicity value** | | **TER** | | |  |
| HR5 = 16 mL prod./ha (vegetative vigour) | | **criterion: TER ≥ 1**  **criterion: TER ≥ 5\*** | | |  |
| no buffer | | 1.16 | 2.31 | 4.62 | 11.55\* |
| 5 m | | 5.61\* | 11.23\* | 22.46\* | 56.14\* |
| 10 m | | 11.03\* | 22.07\* | 44.14\* | 110.34\* |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger of 1.

\*TER>5

+ Data for Atlantis 12 OD. 054-01-05 is believed to be comparable to Atlantis 12 OD in all areas of the assessment (refer to dRR Part C for details of the composition

As requested by Poland, a trigger value of 1 has been considered in the probabilistic risk assessments above, however it is noted that this is not a Central Zone harmonised position and other member states may consider the use of a different trigger value at National Registration.

It is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E) and 1.2 L prod/ha (use group F).
* a 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rates 1 x 1.0 L product/ha (use group G), and 1 x 0.6 L product/ha (use group H).
* No mitigation measures are needed for application rates 1 x 0.5 L product/ha (use group I), 1 x 0.45 L product/ha (use group J).

### Overall conclusions

Based on probabilistic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E) and 1.2 L prod/ha (use group F).
* a 5 m buffer zone, or alternatively 50% drift reducing spray nozzles for application rates 1 x 1.0 L product/ha (use group G), and 1 x 0.6 L product/ha (use group H).
* No mitigation measures are needed for application rates 1 x 0.5 L product/ha (use group I), 1 x 0.45 L product/ha (use group J).

Based on deterministic risk assessment it is concluded that the use of the product will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* 10m or alternatively a 5 m buffer with 50 % drift reducing spray nozzles for application rates 1 x 1.5 L product/ha (use group E), 1.2 L product/ha (use group F) and 1 x 1.0 L product/ha (use group G) or non-buffer zone with 90 % drift reduction nozzles for application 1.5L/ha, 1.2 L/ha and 1.0 L/ha.
* 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application 1 x 0.6 L product/ha (use group H), 1 x 0.5 L product/ha (use group I) and 1 x 0.45 L product/ha (use group J).

**Evaluator comments:**

**Effect on non-target terrestrial plants**

No data is provided in support of the application for authorization of Meso-Iodo OD-Life. The intended uses Product Atlantis 12 OD are within those considered acceptable for registration of Meso-Iodo OD-Life.The risk assessment for non-target plants based on the endpoints from the studies performed on formulation of Atlantis 12 OD. The risk assessment is appropriate to be used for Meso-Iodo OD-Life. Use of Meso-Iodo OD-Life is not expected to pose risk to non-target plants, when considering the appropriate mitigation measures. considering the appropriate mitigation measures.

**~~The risk assessment for non-target plants with considering the appropriate mitigation measures should be considered by MSs level.~~**

**The risk assessment for non-target plants with considering the appropriate mitigation measures should be chosen by MSs considering their national conditions.**

**April 2024 Updated after commenting period.**

*According to the DE comment: Please note that Member states agreed in the 4th central zone harmonisation meeting in September 2018 to report all effects and endpoints, including visual phytotoxic effects, in the study summary and in the core assessment. In addition, it is stated in EFSA Supporting P publication 2019:EN-1673 that phytotoxicity effects should be reported in the study summary and the ER50 based on visual injury/phytotoxicity should be calculated and considered for use in risk assessment. Therefore, please calculate and report ER50 values for visual phytotoxic effects for all vegetative vigour and seedling emergence tests used for risk assessment and subsequently consider them in risk assessment, if relevant. Please note that the refinement of the risk assessment using a probabilistic approach (SSD) based on biomass does not cover relevant effects on visual phytotoxicity”.*

**zRMS comment:** The risk assessment for non-target plants based on the endpoints from the studies performed on formulation of Atlantis 12 OD. The risk assessment is appropriate to be used for Meso-Iodo OD-Life. Use of Meso-Iodo OD-Life is not expected to pose risk to non-target plants, when considering the appropriate mitigation measures considering the appropriate mitigation measures. In reference to phytotoxicity effects observed in the studies it should be noted that, in the case of Atlantis OD appropriate to be used for Meso-Iodo OD-Life, the highest phytotoxicity effects were assessed for radish in the vegetative vigour study. For this species, 44% phytotoxicity was rated for the rate of 23 ml prod./ha. The lowest ER50 for Atlantis OD is 27 ml prod./ha for sunflower shoot dry weight in the vegetative vigour test. Accordingly, an ER50 for phytotoxicity would be in the same range as the lowest ER50 for the vegetative endpoints. Due to the reasons mentioned above we agree that, the ER50 for vegetative endpoints should be chosen over a subjective ER50 for phytotoxicity.

**The risk assessment for non-target plants with considering the appropriate mitigation measures should be chosen by MSs considering their national conditions.**

*According to the DE comment*: Please note that DE does not support the use of an AF of 1 in a risk assessment based on species sensitivity distributions (SSD) when there are doubts about its reliability or representativeness or when the derived HR5 is not protective. According to the terrestrial guidance document (SANCO/10329/2002), a probabilistic risk assessment based on HR5 values from an SSD is assumed to be protective if this method is applicable based on the underlying data. Requirements for the derivation of a reliable HR5 (from SSD) were presented on CZHW 2022. Please provide the data to conclude on the reliability of the SSD-HR5 derived for the use in the NTTP risk assessment.

Looking at table 9.10-1, at least the requirement for the range of ER50 used to construct the SSD is not met in this case. The ranges for seedling emergence (64 -760 mL product / ha) and vegetative viguor (27 – 385 mL product / ha) clearly outrange the criterium of “range of ER50 are within a factor of 100”. Therefore, please dismiss the SSD approach in the core assessment and use instead the deterministic approach to address the low protectivity of the SSD outcome. In our opinion a not-reliable HR5 used in combination with an assessment factor of 1 result in a low protection level, which will not be acceptable for national authorization in Germany when Meso-Iodo OD-Life is used according to the GAP.

**zRMS comment:** zRMS-PL is of the opinion that TER criterion in the probabilistic approach should be considered at MSs level.The risk mitigation measures for Meso-Iodo OD-Life with HR50 value of 16 ml product/ha (the worst case) and trigger of 5 are provided below (deterministic risk assessment):

• a 5 m buffer zone with 75% drift reducing spray nozzles or alternatively 10 m buffer zone with 50% drift reducing spray nozzels for application rates 1 x 1.5 L product/ha (use group E) and 1.2 L prod/ha (use group F)

• a 5 m buffer zone with 50% drift reducing spray nozzles for application rates 1 x 1.0 L product/ha (use group G), 1 x 0.9 L product/ha (use group H) and 1 x 0.6 L prod/ha (use group I) or no buffer zone with 90% drift reduction nozzels or alternatively 10 meter buffer zone

• a 5 meter buffer zone or no buffer zone with 90% drift reduction nozzels for application 0.5 L/ha.

**The risk assessment for non-target plants with considering the appropriate mitigation measures should be chosen by MSs considering their national conditions.**

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

No further information is available or considered to be necessary.

## Monitoring data (KCP 10.8)

No further information is available or considered to be necessary.

## Classification and Labelling

The classification and labelling proposed for 054-01-05 is in line with that proposed for the reference product Atlantis 12 OD. The applicant considers product 054-01-05 to be comparable, if not identical, to the reference product Atlantis 12 OD (authorisation number R-98/2009) of Bayer AG. Therefore, the applicant requests identical classification to that of Atlantis 12 OD. Please refer to Part B9 Section 9.13 ‘Ecotoxicological Evaluation of Plant Protection Product’ of the Atlantis 12 OD re-registration report submitted by Bayer AG for further information

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 ecotoxicological data is proposed for the preparation:

|  |  |
| --- | --- |
| Hazard class(es), categories | Aquatic Acute: Category 1  Aquatic Chronic: Category 1 |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS 09 |
| Signal word | Warning |
| Hazard statement(s) | H400  H410 |
| Precautionary statement(s) | P273  P391 – Collect spillage  P501 – Dispose of contents/container in accordance with local regulation |
| Additional labelling phrases | To avoid risks to human health and the environment, comply with the instructions for use. [EUH401] |
| Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads. [SP1] |

**Evaluator comments:** Agreed.

1. Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company) GLP or GEP status Published or not** | **Vertebrate study**  **Y/N** | **Owner** |
| --- | --- | --- | --- | --- | --- |
| KCP 10.3.1.1/01 | Wilkins, S. | 2020a | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: Acute contact and oral toxicity to adult worker honeybees (Apis mellifera L.)  Report No.: FR/001918-06  GLP  Unpublished | N | Life Scientific Ltd. |
| KCP 10.3.1.2/01 | Wilkins, S. | 2020b | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: 10 Day chronic oral toxicity test (repeated dose) for adult honey bees (*Apis mellifera* L.)  Report No.: FR/001918-10  GLP  Unpublished | N | Life Scientific Ltd. |
| KCP 10.3.1.3/01 | Wilkins, S. | 2020c | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: In vitro 22 day toxicity test - repeated exposure to larval stage honeybees (*Apis mellifera* L.)  Report No.: FR/001918-11  GLP  Unpublished | N | Life Scientific Ltd. |
| KCP 10.2 / 01 | Sinclair, C. J. | 2009 | Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products  Publisher: unknown  Journal: unknown  Year: 2009  Report No.: [M-551653-01-1](dart://dart/edition?ed_no=M-551653-01-1)  GLP/GEP: n.a.  published | No | published |
| KCP 10.2.1 / 01 | Kuhl, K. | 2017 | Amendment no. 1 to final report - *Lemna gibba* G3 - Growth inhibition test with BCS-CV14885 under static conditions - Limit test  Report No.: EBMM0006, Edition Number: [M-602447-02-1](dart://dart/edition?ed_no=M-602447-02-1)  Bayer AG, Crop Science Division, Monheim, Germany  …amended: 2017-11-14  GLP/GEP: Yes  unpublished | No | Bayer |
| KCP 10.2.1 / 02 | Kuhl, K. | 2016 | *Lemna gibba* G3 - Growth inhibition test with mesosulfuron-methyl tech. (BCS-AK65185) under peak exposure conditions  Report No.: EBMMN160, Edition Number: [M-577164-01-1](dart://dart/edition?ed_no=M-577164-01-1)  Bayer CropScience AG, Monheim, Germany  GLP/GEP: Yes  unpublished | No | Bayer |
| KCP 10.2.1 / 03 | Kuhl K. | 2016 | *Lemna gibba* G3 - Growth inhibition test with iodosulfuron-methyl-sodium TC (BCS-BB66887) under peak exposure conditions  Report No.: EBIMN158, Edition Number: [M-574865-01-1](dart://dart/edition?ed_no=M-574865-01-1)  Bayer CropScience AG, Monheim, Germany  GLP/GEP: Yes  unpublished | No | Bayer |
| KCP 10.2.1 / 04 | Kuhl, K. | 2017 | Amendment no. 1: Lemna gibba G3 - Growth inhibition test with metsulfuron-methyl (AE F075736) under peak exposure conditions (peaks on day 0 and 3) Report No.: EBIM0007, Edition Number: [M-600962-02-1](dart://dart/edition?ed_no=M-600962-02-1)  Bayer AG, Crop Science Division, Monheim, Germany  …amended: 2017-10-27  GLP/GEP: Yes  unpublished | No | Bayer |
| KCP 10.2.1 / 05 | Kuhl, K. | 2017 | *Lemna gibba* G3 - Growth inhibition test with metsulfuron-methyl (AE F075736) under peak exposure conditions (peaks on day 0 and 7)  Report No.: EBIM0008, Edition Number: [M-600651-01-1](dart://dart/edition?ed_no=M-600651-01-1)  Bayer AG, Crop Science Division, Monheim, Germany  GLP/GEP: Yes  unpublished | No | Bayer |
| KCP 10.2.3 / 01 | Isemer-Kellner, R.; Heine, S. | 2017 | Justification for the use of time-weighted average concentrations in the chronic risk assessment for iodosulfuron-methyl-sodium and aquatic plants  Report No.: [M-607957-01-1](dart://dart/edition?ed_no=M-607957-01-1)  Bayer AG, Crop Science Division, Monheim, Germany GLP/GEP: n.a.  unpublished | No | Bayer |
| KCP 10.2.3 / 02 | Sowig, P.;  Herno, V.; Heine, S. | 2017 | Justification for the use of time-weighted average concentrations in the chronic risk assessment for mesosulfuron-methyl and aquatic plants  Report No.: [M-602786-01-1](dart://dart/edition?ed_no=M-602786-01-1) Bayer AG, Germany GLP/GEP: n.a.  unpublished | No | Bayer |

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

**Active data**

Please note that all data mentioned as part of DAR, RAR, or EFSA journals are considered as relied on.

**Iodosulfuron-methyl-sodium**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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** |
| KCA 8.1.1.1 /01 | Ebert, E. | 1996 | Acute oral toxicity in the male and female Japanese quail (*Coturnix japonica*) Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A57013,  Report includes Trial Nos.: 95.0517  Edition Number: [M-140780-01-1](dart://dart/edition?ed_no=M-140780-01-1)  EPA MRID No.: 45109026  Date: 1996-05-23  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.1.1.1 /02 | Ebert, E. | 1998 | Bobwhite quail acute oral toxicity test AE F115008 substance, technical Code: AE F115008 00 1C89 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C000842,  Report includes Trial Nos.: 98.0360  Edition Number: [M-181334-01-1](dart://dart/edition?ed_no=M-181334-01-1)  EPA MRID No.: 45109027  Date: 1998-08-03  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.1.1.1 /03 | Ebert, E. | 1997 | Acute oral toxicity in the male and female mallard duck (*Anas platyrhynchos*) Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A58728,  Report includes Trial Nos.: 96.0599  Edition Number: [M-142450-01-1](dart://dart/edition?ed_no=M-142450-01-1)  Date: 1997-02-13  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.1.1.3 /01 | Ebert, E. | 1998 | Bobwhite quail 6-week dietary reproduction study - Limit-Test Hoe 115008 substance technical  Code: Hoe 115008 00 ZC89 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C000807, Report includes Trial Nos.: 98.0011  Edition Number: [M-181277-01-1](dart://dart/edition?ed_no=M-181277-01-1)  EPA MRID No.: 45109033  Date: 1998-11-17  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.1.1.3 /02 | Sabbert, T. | 2004 | Effect of technical Iodosulfuron methyl sodium on northern bobwhite reproduction  Bayer CropScience LP, Kansas City, MO, USA  Bayer CropScience,  Report No.: EBIMX013,  Report includes Trial Nos.: IM741701  Edition Number: [M-242537-01-1](dart://dart/edition?ed_no=M-242537-01-1)  EPA MRID No.: 46431803  Date: 2004-12-21  GLP/GEP: yes  unpublished | Y | Bayer Crop  Science |
| KCA 8.1.1.3 /03 | Frey, L. T.; Beavers, J. B.; Jaber, M. | 1999 | Mallard duck dietary reproduction toxicity study AE F115008 substance technical Code: AE F115008 00 1C89 0001  Wildlife International, Ltd., Easton, MD, USA  Bayer CropScience,  Report No.: C005102,  Edition Number: [M-191367-01-1](dart://dart/edition?ed_no=M-191367-01-1)  EPA MRID No.: 45109034  Date: 1999-08-17  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /01 | Heusel, R. | 1998 | Acute toxicity to rainbow trout (*Oncorhynchus mykiss*) AE F115008 substance, technical Code:  AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59423,  Edition Number: [M-143096-01-1](dart://dart/edition?ed_no=M-143096-01-1)  EPA MRID No.: 45109035  Date: 1998-02-03  GLP/GEP: yes  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /02 | Heusel, R. | 1998 | Acute toxicity to bluegill sunfish (*Lepomis macrochirus*) AE F115008 substance, technical Code:  AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59422,  Edition Number: [M-143095-01-1](dart://dart/edition?ed_no=M-143095-01-1)  EPA MRID No.: 45109101  Date: 1998-02-03  GLP/GEP: yes  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /03 | Stachura, B. J.; Ruff, D. F. | 2000 | 96 hour acute toxicity to the sheepshead minnow, *Cyprinodon variegatus*, in a static renewal system:  AE F115008 technical 89.6% w/w: AE F115008 00 1C89 0001  Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA  Bayer CropScience,  Report No.: B002715,  Report includes Trial Nos.: BY99W509  BY99W509A  Edition Number: [M-238449-02-1](dart://dart/edition?ed_no=M-238449-02-1)  Date: 2000-01-14  ...Amended: 2000-02-28  GLP/GEP: yes  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /04 | Grade, R.; Wydra, V. | 2006 | Acute toxicity of MKH 6561-sulfonamide acid to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test - limit test  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 30183230,  Edition Number: [M-278097-01-1](dart://dart/edition?ed_no=M-278097-01-1)  Date: 2006-09-25  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /05 | Grade, R.; Wydra, V. | 2006 | Acute toxicity of MKH 6561-saccharine to rainbow trout (*Oncorhynchus mykiss*) in a 96-hour static test - limit test  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 30193230,  Edition Number: [M-278099-01-1](dart://dart/edition?ed_no=M-278099-01-1)  Date: 2006-09-25  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.2.1 /01 | Heusel, R.; Gosch, H. | 1998 | Effects on juvenile growth of rainbow trout (*Oncorhynchus mykiss*) in a 28 days flow-through study  AE F115008 substance, technical Code: AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59424,  Edition Number: [M-143097-01-1](dart://dart/edition?ed_no=M-143097-01-1)  EPA MRID No.: 45109102  Date: 1998-04-29  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.2.1 /02 | Kern, M.; Lam, C. | 2004 | Early life stage toxicity of AE F115008 Iodosulfuron-methyl-sodium technical to the fathead minnow  (*Pimephales promelas*) under flow-through conditions  Bayer CropScience LP, Kansas City, MO, USA  Bayer CropScience,  Report No.: 201022,  Edition Number: [M-240261-01-1](dart://dart/edition?ed_no=M-240261-01-1)  EPA MRID No.: 46431804  Date: 2004-10-14  GLP/GEP: no  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.4.1 /01 | Heusel, R. | 1998 | Acute toxicity to *Daphnia magna* (waterflea) AE F115008 substance, technical Code: AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59425,  Edition Number: [M-143098-01-1](dart://dart/edition?ed_no=M-143098-01-1)  EPA MRID No.: 45109103  Date: 1998-03-26  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.4.1 /02 | Heusel, R.; Weller, O.; Gosch, H. | 1998 | Acute toxicity to *Daphnia magna* (waterflea) AE F059411 substance, technical Metabolite of AE  F115008 Code: AE F059411 00 1C99 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: C000840,  Edition Number: [M-181330-01-1](dart://dart/edition?ed_no=M-181330-01-1)  Date: 1998-10-07  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.4.1 /03 | Grade, R.; Wydra, V. | 2006 | Acute toxicity of MKH 6561-sulfonamide acid to *Daphnia magna* in a 48-hour immobilization test IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 30182220,  Edition Number: [M-278971-01-1](dart://dart/edition?ed_no=M-278971-01-1)  Date: 2006-10-16  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.4.1 /04 | Grade, R.; Wydra, V. | 2006 | Acute toxicity of MKH 6561-saccharine to *Daphnia magna* in a 48-hour immobilization test  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 30192220,  Edition Number: [M-278973-01-1](dart://dart/edition?ed_no=M-278973-01-1)  Date: 2006-10-16  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.4.2 /01 | Stachura, B. J.; Ruff, D. F. | 2000 | 96 hour acute toxicity to the Mysid shrimp, *Mysidopsis bahia*, in a static renewal system: AE  F115008 technical 89.6 percent w/w: AE F115008 00 1C89 0001  Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA  Bayer CropScience,  Report No.: B002713,  Edition Number: [M-238447-02-1](dart://dart/edition?ed_no=M-238447-02-1)  Date: 2000-01-14  ...Amended: 2000-02-28  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.5.1 /01 | Heusel, R.; Gosch, H. | 1998 | Effects on growth and reproduction of *Daphnia magna* AE F115008 substance, technical Code: AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59426,  Edition Number: [M-143099-01-1](dart://dart/edition?ed_no=M-143099-01-1)  EPA MRID No.: 45109104  Date: 1998-08-12  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /01 | Heusel, R. | 1998 | Algal growth inhibition (*Pseudokirchneriella subcapitata*) AE F115008 substance, technical Code:  AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59421,  Edition Number: [M-143094-01-1](dart://dart/edition?ed_no=M-143094-01-1)  EPA MRID No.: 45109105  Date: 1998-01-28  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 | Hermes, H.; Wydra, V. | 2015 | Iodosulfuron-methyl-sodium, technical: Toxicity to *Navicula pelliculosa* in an Algal Growth Inhibition Test.  Bayer CropScience,  Report No.: EBIMN165,  Edition Number: [M-532054-01-1](dart://dart/edition?ed_no=M-532054-01-1)  Date: 2015-xx-xx  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /04 | Kuhl, K. | 2013 | *Pseudokirchneriella subcapitata* - Growth inhibition test with BCS-AU71532 - limit test Bayer CropScience,  Report No.: E 201 4592-3,  Edition Number: [M-470687-01-1](dart://dart/edition?ed_no=M-470687-01-1)  Date: 2013-11-07  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /05 | Hoffmann, K. | 2013 | *Pseudokirchneriella subcapitata* growth inhibition test with BCS-AU71533 - limit test Bayer CropScience,  Report No.: EBIMN062,  Edition Number: [M-465388-01-1](dart://dart/edition?ed_no=M-465388-01-1)  Date: 2013-09-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /06 | Bruns, E. | 2013 | *Pseudokirchneriella subcapitata* - Growth inhibition test with BCS-AW35544 - limit test Bayer CropScience,  Report No.: E 201 4589-9,  Edition Number: [M-470669-01-1](dart://dart/edition?ed_no=M-470669-01-1)  Date: 2013-11-04  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /07 | Hoffmann, K. | 2013 | *Pseudokirchneriella subcapitata* - Growth inhibition test with BCS-AU85549 - limit test Bayer CropScience,  Report No.: EBIML036,  Edition Number: [M-468872-01-1](dart://dart/edition?ed_no=M-468872-01-1)  Date: 2013-09-27  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /08 | Hoffmann, K. | 2013 | *Pseudokirchneriella subcapitata* - Growth inhibition test with BCS-CW81253 - Limit test Bayer CropScience,  Report No.: EBIMN061,  Edition Number: [M-465389-01-1](dart://dart/edition?ed_no=M-465389-01-1)  Date: 2013-09-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /02 | Heusel, R.; Weller, O.; Gosch, H. | 1998 | Algal growth inhibition (*Pseudokirchneriella subcapitata*) AE F059411 substance, technical Metabolite of AE F115008 Code: AE F059411 00 1C99 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: C000867,  Edition Number: [M-181379-01-1](dart://dart/edition?ed_no=M-181379-01-1)  EPA MRID No.: 45109110  Date: 1998-10-09  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.6.1 /14 | Bruns, E. | 2013 | *Pseudokirchneriella subcapitata* - Growth inhibition test with AE F154781 - limit test Bayer CropScience,  Report No.: EBIMN105,  Edition Number: [M-476160-01-1](dart://dart/edition?ed_no=M-476160-01-1)  Date: 2013-11-08  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /01 | Christ, M. T.; Ruff, D. F. | 1997 | Toxicity to duckweed (*Lemna gibba*), in a static system AE F115008 technical 87.4% w/w Code:  AE F115008 00 1C89 0001  AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA  Bayer CropScience,  Report No.: A57770,  Report includes Trial Nos.: 501BY  Edition Number: [M-141441-02-1](dart://dart/edition?ed_no=M-141441-02-1)  EPA MRID No.: 45109111  Date: 1997-10-15  ...Amended: 1998-01-19  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /05 | Sowig, P. | 2014 | Iodosulfuron-methyl-sodium rationale for the replacement of the old 14-day Lemna growth inhibition study (Christ & Ruff 1997; M-141441-02) with the 7-day endpoints from the Lemna study (Bruns 2013; [M-469584-01-1)](dart://dart/edition?ed_no=M-469584-01-1)  Bayer CropScience,  Report No.: [M-479697-01-1,](dart://dart/edition?ed_no=M-479697-01-1)  Edition Number: [M-479697-01-1](dart://dart/edition?ed_no=M-479697-01-1)  Date: 2014-03-11  GLP/GEP: n.a.,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /07 | Bruns, E. | 2013 | *Lemna gibba* G3 - Prolonged growth inhibition test with iodosulfuron-methyl-sodium (AE F115008) with stepwise decreasing concentrations and metsulfuron-methyl (AE F075736) with stepwise in-  creasing concentrations over a 6 week test duration - Amendment 1 to report –  Bayer CropScience,  Report No.: E 412 3763 - 6,  Edition Number: [M-469584-02-1](dart://dart/edition?ed_no=M-469584-02-1)  Date: 2013-11-05  ...Amended: 2015-03-04  GLP/GEP: no,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /08 | Banman, C. S.; Matlock, D.; Lam, C. V. | 2012 | Toxicity of Iodosulfuron-methyl-sodium technical to the aquatic macrophyte, *Myriophyllum spicatum*  Bayer CropScience LP, Stilwell, KS, USA  Bayer CropScience,  Report No.: EBIML032,  Edition Number: [M-431705-01-1](dart://dart/edition?ed_no=M-431705-01-1)  Date: 2012-05-21  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /06 | Hoberg, J.R. | 2011 | Outdoor growth inhibition and recovery of aquatic plants exposed to iodosulfuron-methyl-sodium  WG50  Smithers Viscient, Wareham, MA, USA  Bayer CropScience,  Report No.: 13798.6259,  Edition Number: [M-407716-01-1](dart://dart/edition?ed_no=M-407716-01-1)  Date: 2011-05-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /03 | Sowig, P.; Weller, O. | 1998 | Duckweed (*Lemna gibba* G3) growth inhibition test AE F075736 (metsulfuron-methyl) metabolite of  AE F115008 substance, technical Code: AE F075736 00 1C92 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: C001314,  Edition Number: [M-182336-01-1](dart://dart/edition?ed_no=M-182336-01-1)  EPA MRID No.: 45109112  Date: 1998-11-16  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /09 | Sowig, P.; Gosch, H. | 2001 | Duckweed (*Lemna gibba* G3) growth inhibition test with recovery phase Metsulfuron-methyl substance, pure (metabolite of AE F115008) Code: AE F075736 00 1B98 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C015669,  Edition Number: [M-200947-01-1](dart://dart/edition?ed_no=M-200947-01-1)  Date: 2001-09-28  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /10 | Bruns, E. | 2013 | *Lemna gibba* G3 - Growth inhibition test with AE F145741 (metabolite of iodosulfuron-methylsodium) under static conditions  Bayer CropScience,  Report No.: EBIML041,  Edition Number: [M-462128-01-1](dart://dart/edition?ed_no=M-462128-01-1)  Date: 2013-08-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /11 | Hoffmann, K. | 2013 | *Lemna gibba* G3 - Growth inhibition test with BCS-AU71533 (metabolite of iodosulfuron-methyl sodium) under static conditions  Bayer CropScience,  Report No.: EBIMN063,  Edition Number: [M-462121-02-1](dart://dart/edition?ed_no=M-462121-02-1)  Date: 2013-07-31  ...Amended: 2013-09-09  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /12 | Sowig, P. | 2002 | Duckweed (*Lemna gibba* G3) growth inhibition test AE 0002166 (metabolite of AE F115008) substance, technical Code: AE 0002166 00 1C92 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C018083,  Edition Number: [M-205481-01-1](dart://dart/edition?ed_no=M-205481-01-1)  Date: 2002-05-08  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /13 | Sowig, P. | 2001 | Duckweed (*Lemna gibba* G3) growth inhibition test AE F161778 (metabolite of AE F115008) substance, technical 93.7 percent Code: AE F151778 00 1C94 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C008628,  Edition Number: [M-197639-01-1](dart://dart/edition?ed_no=M-197639-01-1)  Date: 2001-12-11  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /14 | Hoffmann, K. | 2013 | *Lemna gibba* G3 - Growth inhibition test with BCS-CW81253 (metabolite of iodosulfuron-methylsodium) under static conditions  Bayer CropScience,  Report No.: EBIMN060,  Edition Number: [M-462125-01-1](dart://dart/edition?ed_no=M-462125-01-1)  Date: 2013-07-30  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /15 | Sowig, P. | 2002 | Duckweed (*Lemna gibba* G3) growth inhibition test AE 0000119 (metabolite of AE F115008) substance, pure Code: AE 0000119 00 1B98 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C020878,  Edition Number: [M-210320-01-1](dart://dart/edition?ed_no=M-210320-01-1)  Date: 2002-05-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /02 | Sowig, P.; Weller, O. | 1998 | Duckweed (*Lemna gibba* G3) growth inhibition test AE F059411 metabolite of AE F115008 substance, technical Code: AE F059411 00 1C99 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: C000745,  Edition Number: [M-181177-01-1](dart://dart/edition?ed_no=M-181177-01-1)  EPA MRID No.: 45109113  Date: 1998-10-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /16 | Sowig, P. | 2002 | Duckweed (*Lemna gibba* G3) growth inhibition test AE F059411 substance, pure (metabolite of AE F115008) Code: AE F059411 00 1B99 0002  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C017092,  Edition Number: [M-203638-01-1](dart://dart/edition?ed_no=M-203638-01-1)  Date: 2002-06-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /17 | Sowig, P. | 2002 | Duckweed (*Lemna gibba* G3) growth inhibition test AE 0014966 (metabolite of iodosulfuron AE F115008) substance, technical Code: AE 0014966 00 1B98 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C003832,  Edition Number: [M-186853-01-1](dart://dart/edition?ed_no=M-186853-01-1)  Date: 2002-03-06  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /18 | Sowig, P. | 2002 | Duckweed (*Lemna gibba* G3) growth inhibition test AE 0034855 (metabolite of AE F115008) substance, pure Code: AE 0034855 00 1B99 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C020876,  Edition Number: [M-210318-01-1](dart://dart/edition?ed_no=M-210318-01-1)  Date: 2002-06-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /19 | Grade, R. | 2006 | Toxicity of MKH 6561-Sulfonamide Acid to the aquatic plant *Lemna gibba* in a growth inhibition test  IBACON GmbH, Rossdorf, Germany BCS,  Report No.: 30184240,  Edition Number: [M-281240-01-1](dart://dart/edition?ed_no=M-281240-01-1)  Date: 2006-10-26  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /20 | Grade, R. | 2006 | Toxicity of MKH 6561-Saccharine to the aquatic plant *Lemna gibba* in a growth inhibition test  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 30194240,  Edition Number: [M-281250-01-1](dart://dart/edition?ed_no=M-281250-01-1)  Date: 2006-11-01  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /21 | Hoffmann, K. | 2013 | *Lemna gibba* G3 - Growth inhibition test with AE F154781 (metabolite of iodosulfuron-methyl-  sodium) under static conditions Bayer CropScience,  Report No.: E 412 4513 - 0,  Edition Number: [M-470494-01-1](dart://dart/edition?ed_no=M-470494-01-1)  Date: 2013-10-25  GLP/GEP: yes,  unpublished | N | Bayer Crop-  Science |
| KCA 8.2.7/22 | Rosenkrantz, R.T.; Cedergreen, N.; Baun, A.; Kusk, K.O. | 2013 | Influence of pH, light cycle, and temperature on ecotoxicity of four sulfonylurea herbicides towards *Lemna gibba.*  Journal: Ecotoxicology,  Volume:22,  Issue:1,  Pages:33-41,  Year:2013,  Report No.: [M-469998-01-1,](dart://dart/edition?ed_no=M-469998-01-1)  Edition Number: [M-469998-01-1](dart://dart/edition?ed_no=M-469998-01-1)  GLP/GEP: no,  published | N | Literature data |
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| KCA 8.3.1.1.1 /01 | Waltersdorfer, A. | 1996 | Oral toxicity (LD50) to honey bees (*Apis mellifera* L.) Code: Hoe 115008 00 ZC89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A58108,  Edition Number: [M-141821-01-1](dart://dart/edition?ed_no=M-141821-01-1)  EPA MRID No.: 45109114  Date: 1996-11-28  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.1.2 /01 | Waltersdorfer, A. | 1996 | Contact toxicity (LD50) to honey bees (Apis mellifera L.) Code: Hoe 115008 00 ZC89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A57512,  Edition Number: [M-141225-01-1](dart://dart/edition?ed_no=M-141225-01-1)  EPA MRID No.: 45109115  Date: 1996-09-24  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.1 /01 | Schmitzer, S. | 2004 | Effects of iodosulfuron-methyl-sodium tech. (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 73071035,  Edition Number: [M-436273-01-1](dart://dart/edition?ed_no=M-436273-01-1)  Date: 2004-08-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.1 /02 | Kling, A. | 2014 | Iodosulfuron-methyl sodium (tech.): Acute contact toxicity to the bumble bee, *Bombus terrestris* L.  under laboratory conditions  eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: S13-01780,  Edition Number: [M-477331-01-1](dart://dart/edition?ed_no=M-477331-01-1)  Date: 2014-02-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.2 /01 | Kling, A. | 2014 | Iodosulfuron-methyl sodium (tech.) - Assessment of chronic effects to the honeybee, *Apis mellifera*  L., in a 10 days continuous laboratory feeding limit test  Eurofins Agroscience Services EcoChem GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience,  Report No.: S13-00142,  Edition Number: [M-479396-01-1](dart://dart/edition?ed_no=M-479396-01-1)  Date: 2014-03-07  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.3 /01 | Jeker, L. | 2013 | Iodosulfuron-methyl-sodium WG 10 - A honeybee brood feeding study to evaluate potential effects on brood development and mortality of the honeybee, *Apis mellifera* L. (Hymenoptera: Apidae) Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland  Bayer CropScience,  Report No.: 20110173,  Edition Number: [M-465335-01-1](dart://dart/edition?ed_no=M-465335-01-1)  Date: 2013-07-15  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.3.1.3 /02 | Schmitzer, S. | 2014 | Iodosulfuron-methyl-sodium + mefenpyr-diethyl OD 400 (100+300 g/L): Effects on honey bee brood (*Apis mellifera* L.) under semi-field conditions - Tunnel test  BACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 79081033,  Edition Number: [M-477913-01-1](dart://dart/edition?ed_no=M-477913-01-1)  Date: 2014-02-24  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /02 | Scheffczyk, A.; Moser, T. | 2010 | Iodosulfuron-methyl-sodium: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test  ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: 10P29RR,  Edition Number: [M-397577-01-1](dart://dart/edition?ed_no=M-397577-01-1)  Date: 2010-12-13  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /01 | Sowig, P. | 1998 | Effects on growth and reproduction of earthworms (*Eisenia fetida*) AE F075736 (metsulfuron-methyl) metabolite of AE F115008 substance technical Code: AE F075736 00 1C92 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Report No.: C001315,  Edition Number: [M-182339-01-1](dart://dart/edition?ed_no=M-182339-01-1)  EPA MRID No.: 45109124  Date: 1998-11-11  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /03 | Witte, B. | 2013 | Iodosulfuron-methyl-sodium- AE F145741: Effects on reproduction and growth of earthworms *Eisenia fetida* in artificial soil  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 82101022,  Edition Number: [M-457891-01-1](dart://dart/edition?ed_no=M-457891-01-1)  Date: 2013-06-12  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /04 | Witte, B. | 2013 | Iodosulfuron-methyl-sodium- AE F145740: Effects on reproduction and growth of earthworms *Eisenia fetida* in artificial soil  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 82091022,  Edition Number: [M-457334-01-1](dart://dart/edition?ed_no=M-457334-01-1)  Date: 2013-06-07  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /05 | Witte, B. | 2013 | Iodosulfuron-methyl-sodium- AE 0002166: Effects on reproduction and growth of earthworms *Eisenia fetida* in artificial soil  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 82111022,  Edition Number: [M-457338-01-1](dart://dart/edition?ed_no=M-457338-01-1)  Date: 2013-06-12  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /06 | Friedrich, S. | 2013 | Iodosulfuron-methyl-sodium-des-iodo-carbamoyl-guanidine (BCS-CW81253): Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 091 S,  Edition Number: [M-462824-01-1](dart://dart/edition?ed_no=M-462824-01-1)  Date: 2013-08-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /07 | Leicher, T. | 2011 | BCS-AA10579-urea (AE 0000119): Effects on survival, growth and reproduction on the earthworm *Eisenia fetida* tested in artificial soil with 10% peat- limit test  Bayer CropScience,  Report No.: LRT-RG-R-104/11,  Edition Number: [M-404685-01-1](dart://dart/edition?ed_no=M-404685-01-1)  Date: 2011-03-29  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.1 /08 | Leicher, T. | 2011 | Aminotriazine (AE F059411): Effects on survival, growth and reproduction on the earthworm *Eisenia* *fetida* tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: LRT-RG-R-100/11,  Edition Number: [M-410930-01-1](dart://dart/edition?ed_no=M-410930-01-1)  Date: 2011-06-30  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /01 | Kratz, M. A. | 2012 | Iodosulfuron-methyl-sodium a.s. (BCS-BB66887): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: kra-HR-70/12,  Edition Number: [M-438590-01-1](dart://dart/edition?ed_no=M-438590-01-1)  Date: 2012-09-04  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /02 | Frommholz, U. | 2012 | Iodosulfuron-methyl-sodium a.s. (BCS-BB66887): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil  Bayer CropScience,  Report No.: FRM-Coll-140/12,  Edition Number: [M-438498-01-1](dart://dart/edition?ed_no=M-438498-01-1)  Date: 2012-09-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /03 | Kratz, M. A. | 2013 | AE F075736 (BCS-AC12303): Influence on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: kra-HR-93/13,  Edition Number: [M-465338-01-1](dart://dart/edition?ed_no=M-465338-01-1)  Date: 2013-08-22  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /04 | Frommholz, U. | 2013 | AE F075736 (BCS-AC12303): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil  Bayer CropScience,  Report No.: FRM-Coll-163/13,  Edition Number: [M-464404-01-1](dart://dart/edition?ed_no=M-464404-01-1)  Date: 2013-08-29  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /05 | Kratz, M. A. | 2013 | Iodosulfuron-methyl-sodium-AE F145741 (BCS-AU71532): Influence on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: kra-HR-85/13,  Edition Number: [M-462732-01-1](dart://dart/edition?ed_no=M-462732-01-1)  Date: 2013-08-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /06 | Kratz, M. A. | 2013 | Iodosulfuron-methyl-sodium-AE F145740 (BCS-AU71533): Influence on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: kra-HR-84/13,  Edition Number: [M-459885-01-1](dart://dart/edition?ed_no=M-459885-01-1)  Date: 2013-07-05  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /07 | Larnaudie Lopez, M. I. | 2013 | AE 0002166 (BCS-AW35544): Influence on mortality and reproduction of the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: LAR-HR-94/13,  Edition Number: [M-470489-01-1](dart://dart/edition?ed_no=M-470489-01-1)  Date: 2013-10-25  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /08 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-des-iodo-carbamoyl-guanidine (BCS-CW81253): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer*  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: [M-453497-01-1,](dart://dart/edition?ed_no=M-453497-01-1)  Edition Number: [M-453497-01-1](dart://dart/edition?ed_no=M-453497-01-1)  Date: 2013-04-29  GLP/GEP: no,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /09 | Friedrich, S. | 2013 | Iodosulfuron-methyl-sodium-des-iodo-carbamoyl-guanidine (BCS-CW81253): Effects on the reproduction of the collembolan *Folsomia candida*  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 089 S,  Edition Number: [M-462821-01-1](dart://dart/edition?ed_no=M-462821-01-1)  Date: 2013-08-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /10 | Klug, T. | 2010 | IN-A4098: Effect on reproduction of the predatory mite *Hypoaspis* (Geolaelaps) *aculeifer* Canestrini (Acari: Laelapidae) in artificial soil  Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany  TF- BCS-DuPont-Syngenta, Report No.: S10-00288,  Report includes Trial Nos.: S10-00288-L1\_NLHa  Edition Number: [M-452258-01-1](dart://dart/edition?ed_no=M-452258-01-1)  Date: 2010-06-24  GLP/GEP: yes,  unpublished | N | TF- BCS DuPont Syngenta |
| KCA 8.4.2.1 /11 | Frommholz, U. | 2011 | BCS-AA10579-aminotriazine (BCS-AA40997, AE F059411): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil  Bayer CropScience,  Report No.: FRM-Coll-110/11,  Edition Number: [M-400027-01-1](dart://dart/edition?ed_no=M-400027-01-1)  Date: 2011-01-20  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /12 | Kratz, M.-A. | 2010 | BCS-AA10579-urea (BCS-AB56501): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil with 5 % peat  Bayer CropScience,  Report No.: KRA-HR-33/10,  Edition Number: [M-386844-01-1](dart://dart/edition?ed_no=M-386844-01-1)  Date: 2010-07-26  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.4.2.1 /13 | Frommholz, U. | 2010 | BCS-AA10579-urea (BCS-AB56501): Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil.  Bayer CropScience,  Report No.: FRM-COLL-93/10,  Edition Number: [M-384229-01-1](dart://dart/edition?ed_no=M-384229-01-1)  Date: 2010-06-29  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /01 | Heusel, R. | 1996 | Effects on soil microbial activity (nitrogen turn-over) AE F115008 substance, technical Code: AE F115008 00 1C89 0001  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A58058,  Edition Number: [M-141782-01-1](dart://dart/edition?ed_no=M-141782-01-1)  EPA MRID No.: 45109125  Date: 1996-12-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /02 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-AE F145741 (BCS-AU71532): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 024 N,  Edition Number: [M-457273-01-1](dart://dart/edition?ed_no=M-457273-01-1)  Date: 2013-06-11  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /03 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-AE F145740 (BCS-AU71533): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 025 N,  Edition Number: [M-457344-01-1](dart://dart/edition?ed_no=M-457344-01-1)  Date: 2013-06-18  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /04 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-AE 0002166 (BCS-AW35544): Effects on the activity of soil microflora (Nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 026 N,  Edition Number: [M-464391-01-1](dart://dart/edition?ed_no=M-464391-01-1)  Date: 2013-09-11  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /05 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-AE F161778 (BCS-AU85549): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 027 N,  Edition Number: [M-464817-01-1](dart://dart/edition?ed_no=M-464817-01-1)  Date: 2013-09-11  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /06 | Schulz, L. | 2013 | Iodosulfuron-methyl-sodium-des-iodo-carbamoyl-guanidine (BCS-CW81253): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 028 N,  Edition Number: [M-459899-01-1](dart://dart/edition?ed_no=M-459899-01-1)  Date: 2013-06-26  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /07 | Schulz, L. | 2010 | BCS-AA10579-urea (BCS-AB56501): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 10 10 48 048 N,  Edition Number: [M-395864-01-1](dart://dart/edition?ed_no=M-395864-01-1)  Date: 2010-11-24  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5 /08 | Reis, K. H. | 2003 | IN-A4098: Assessment of the effects on soil microflora  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: Dupont-12117,  Edition Number: [M-448838-01-1](dart://dart/edition?ed_no=M-448838-01-1)  Date: 2003-07-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.6.1 /01 | Bieringer, H. | 1998 | Efficacy of the herbicide iodosulfuron-methyl-sodium (AE F115008) on higher plant species as ap-  plied under greenhouse conditions  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C001486,  Edition Number: [M-182753-01-1](dart://dart/edition?ed_no=M-182753-01-1)  EPA MRID No.: 45109133  Date: 1998-11-18  GLP/GEP: no,  unpublished  ...also filed: KCA 3.3 /01 | N | Bayer Crop-  Science |
| KCA 6.6.2 /04 | Thuerwaechter, F | 1998 | Selectivity thresholds for AE F115008 in various crops- ED10 values in soil  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C001481,  Edition Number: [M-182740-01-1](dart://dart/edition?ed_no=M-182740-01-1)  Date: 1998-10-15  GLP/GEP: no,  unpublished | N | Bayer Crop  Science |
| KCA 8.6.2 /01 | Kleiner, R. | 1999 | Acute phytotoxicity to non-target terrestrial plants following the OECD Guideline 208 (proposal  1998) and US EPA OPPTS 850.4250 vegetative vigour, Tier II (public draft 1996) Code: AE F115008 02 WG20 B002  BioChem agrar GmbH, Cunnersdorf, Germany  Bayer CropScience,  Report No.: C006692,  Edition Number: [M-194440-01-1](dart://dart/edition?ed_no=M-194440-01-1)  Date: 1999-12-16  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.6.2 | Teixeira, D. | 2000 | Determination of Effects on Vegetative Vigor of Ten Plant Species.  Bayer CropScience,  Report No.: B002811,  Edition Number: [M-238538-01-1](dart://dart/edition?ed_no=M-238538-01-1)  Date: 2000-xx-xx  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.8 /02 | Reinhardt, J. | 1996 | Respiration inhibition to activated sludge of AE F115008 substance, technical  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A58107,  Edition Number: [M-141820-01-1](dart://dart/edition?ed_no=M-141820-01-1)  EPA MRID No.: 45109136  Date: 1996-12-10  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.8 /03 | Reinhardt, J. | 1996 | Inhibitory effect of water constituents on bacteria (Pseudomonas cell multiplication inhibition test) Hoe 115008 substance, technical  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A57292,  Edition Number: [M-141031-01-1](dart://dart/edition?ed_no=M-141031-01-1)  EPA MRID No.: 45109137  Date: 1996-08-15  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |

**Mesosulfuron-methyl**

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| --- | --- | --- | --- | --- | --- |
| **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** |
| KCA 8.2.1 /03 | Abedi, J.; Stachura, B.; Young, B. | 2001 | 96 Hour acute toxicity to the sheepshead minnow, *Cyprinodon variegatus*, in a static system AE F130060 technical 95.7 percent w/w  Aventis CropScience USA LP, RTP, NC, USA  Bayer CropScience,  Report No.: B003157,  Edition Number: [M-238810-01-1](dart://dart/edition?ed_no=M-238810-01-1)  EPA MRID No.: 45386301  Date: 2001-02-16  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA 8.2.1 /04 | Heusel, R. | 1993 | Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Oncorhynchus mykiss* (Rainbow trout) in a Static-Acute Toxicity Test (method OECD)  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A50396,  Edition Number: [M-131422-01-1](dart://dart/edition?ed_no=M-131422-01-1)  Date: 1993-04-13  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA  8.2.2.1 /01 | xxxxxx | 2003 | xxxxxxxxxxxxxxxxx  Edition Number: [M-241475-01-1](dart://dart/edition?ed_no=M-241475-01-1)  Date: 2003-10-20  GLP/GEP: yes,  unpublished | Y | Bayer Crop  Science |
| KCA  8.2.4.1 /02 | Heusel, R. | 1993 | Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Daphnia magna* (waterflea) in a Static -Acute Toxicity Test (method OECD)  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A50353,  Edition Number: [M-131382-01-1](dart://dart/edition?ed_no=M-131382-01-1)  Date: 1993-04-13  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.4.2 /01 | Abedi, J.; Stachura, B.; Young, B. | 2001 | 96 Hour Acute Toxicity to the Mysid Shrimp, *Mysidopsis bahia*, in a Static System AE F130060 Technical 95.7% w/w  Aventis CropScience USA LP, RTP, NC, USA  Bayer CropScience,  Report No.: B003158,  Edition Number: [M-238811-01-1](dart://dart/edition?ed_no=M-238811-01-1)  EPA MRID No.: 45386303  Date: 2001-02-16  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /04 | Dorgerloh, M. | 2005 | *Pseudokirchneriella subcapitata* - growth inhibition test with AE F154851 00 1B96 0001  Bayer CropScience,  Report No.: EBMMX093,  Edition Number: [M-255087-01-1](dart://dart/edition?ed_no=M-255087-01-1)  Date: 2005-07-26  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /05 | Dorgerloh, M. | 2005 | *Pseudokirchneriella subcapitata* - growth inhibition test with AE F099095 00 1B99 0001  Bayer CropScience,  Report No.: EBMMX092,  Edition Number: [M-254084-01-1](dart://dart/edition?ed_no=M-254084-01-1)  Date: 2005-07-08  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /06 | Heusel, R. | 1993 | Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to *Scenedesmus subspicatus* (Green alga) in a Growth Inhibition Test (method OECD)  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A50395,  Edition Number: [M-131421-01-1](dart://dart/edition?ed_no=M-131421-01-1)  Date: 1993-04-13  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /07 | Bruns, E. | 2011 | *Pseudokirchneriella subcapitata* growth inhibition test with BCS-CO60720 - limit test  Bayer CropScience,  Report No.: EBMML012,  Edition Number: [M-414950-01-1](dart://dart/edition?ed_no=M-414950-01-1)  Date: 2011-10-07  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /08 | Bruns, E. | 2011 | *Pseudokirchneriella subcapitata* growth inhibition test with BCS-CO60721 - limit test  Bayer CropScience,  Report No.: EBMML013,  Edition Number: [M-415112-01-1](dart://dart/edition?ed_no=M-415112-01-1)  Date: 2011-10-06  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.1 /09 | Kuhl, K. | 2015 | *Pseudokirchneriella subcapitata* growth inhibition test with mesosulfuron-methyl (tech.)  Bayer CropScience,  Report No.: EBMMN130,  Edition Number: M-516540-01  Date: 2015-04-15  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.2 /02 | Abedi, J.; Christ, M.; Young, B. | 2001 | Effect to *Anabaena flosaquae* (Blue-Green Alga) in a Growth Inhibition Test, AE F130060 Technical, 95.7% w/w  Aventis CropScience USA LP, RTP, NC, USA  Bayer CropScience,  Report No.: B003222,  Edition Number: [M-238869-01-1](dart://dart/edition?ed_no=M-238869-01-1)  EPA MRID No.: 45386315  Date: 2001-03-23  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.2.6.2 /03 | Young, B. M.;  Abedi, J. | 2001 | Effect to *Skeletonema costatum* (Marine Diatom) in a Growth Inhibition Test AE F130060 Technical  95.7% w/w  Aventis CropScience USA LP, RTP, NC, USA  Bayer CropScience,  Report No.: B003156,  Edition Number: [M-238809-01-1](dart://dart/edition?ed_no=M-238809-01-1)  EPA MRID No.: 45386314  Date: 2001-02-16  GLP/GEP: yes,  unpublished | N | Bayer Crop-  Science |
| KCA 8.2.7 /07 | Sowig, P.; Gosch, H. | 2002 | Duckweed (*Lemna gibba* G3) - Growth inhibition test with recovery phase AE F130060 substance, pure Code: AE F130060 00 1B98 0002  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C018852,  Edition Number: [M-206814-01-1](dart://dart/edition?ed_no=M-206814-01-1)  Date: 2002-02-19  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /08 | Hoberg, J. | 2009 | Outdoor growth inhibition of aquatic plants exposed to Mesosulfuron-methyl  Springborn Smithers Laboratories, Wareham, MA, USA  Bayer CropScience,  Report No.: 13798.6220,  Edition Number: [M-329474-01-1](dart://dart/edition?ed_no=M-329474-01-1)  Date: 2009-02-17  GLP/GEP: yes, unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /09 | Bruns, E. | 2013 | *Lemna gibba* G3 - Prolonged growth inhibition test with mesosulfuron-methyl (AE F130060) with stepwise decreasing concentrations over an 8 week test duration  Bayer CropScience,  Report No.: EBMML017,  Edition Number: [M-445139-01-1](dart://dart/edition?ed_no=M-445139-01-1)  Date: 2013-01-09  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.2.7 /11 | Dorgerloh, M. | 2005 | *Lemna gibba* G3, growth inhibition test with AE F154851 under static conditions, (code: AE F154851 00 1B96 0001)  Bayer CropScience,  Report No.: EBMMX090,  Edition Number: [M-255283-01-1](dart://dart/edition?ed_no=M-255283-01-1)  Date: 2005-07-28  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.2.7 /12 | Dorgerloh, M. | 2005 | *Lemna gibba* G3 - growth inhibition test with AE F099095 under static conditions (Code: AE F099095 00 1B99 0001)  Bayer CropScience,  Report No.: EBMMX091,  Edition Number: [M-254496-01-1](dart://dart/edition?ed_no=M-254496-01-1)  Date: 2005-07-14  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.2.7 /13 | Sowig, P.; Weller, O. | 2000 | Duckweed (*Lemna gibba* G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1C99 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C003865,  Edition Number: [M-186916-01-1](dart://dart/edition?ed_no=M-186916-01-1)  Date: 2000-11-03  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.2.7 /14 | Bruns, E. | 2013 | *Lemna gibba* G3 - Growth inhibition test with BCS-AU66443 (AE F 140584) under semi static conditions Bayer CropScience,  Report No.: EBMMN119,  Edition Number: [M-486658-01-1](dart://dart/edition?ed_no=M-486658-01-1)  Date: 2013-10-29  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.2.7 /15 | Bruns, E. | 2013 | *Lemna gibba* G3 - Growth inhibition test with BCS-CO60720 under static conditions Bayer CropScience,  Report No.: EBMML010,  Edition Number: [M-449110-01-1](dart://dart/edition?ed_no=M-449110-01-1)  Date: 2013-02-20  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.2.7 /16 | Bruns, E. | 2013 | *Lemna gibba* G3 - Growth inhibition test with BCS-CO60721 under static conditions Bayer CropScience,  Report No.: EBMML011,  Edition Number: [M-445154-01-1](dart://dart/edition?ed_no=M-445154-01-1)  Date: 2013-01-23  GLP/GEP: yes  unpublished | N | Bayer Crop Science |
| KCA 8.2.8 /01 | Dionne, E. | 2000 | AE F130060 00 1C96 0004 - Acute Toxicity to Eastern Oysters (*Crassostrea virginica*) Under Flow Through Conditions  Springborn Laboratories, Inc. (SLS), USA  Bayer CropScience,  Report No.: B003104,  Edition Number: [M-238739-02-1](dart://dart/edition?ed_no=M-238739-02-1)  EPA MRID No.: 45386302  Date: 2000-11-30  ...Amended: 2000-12-07  GLP/GEP: yes  unpublished | N | Bayer Crop Science |
| KCA  8.3.1.1 /01 | Schmitzer, S. | 2012 | Effects of mesosulfuron-methyl tech. (Acute contact and oral) o honey bees (*Apis mellifera* L.) in the laboratory  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 72941035,  Edition Number: [M-433998-01-1](dart://dart/edition?ed_no=M-433998-01-1)  Date: 2012-06-22  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.3.1.1 /02 | Vergé, E. | 2014 | Mesosulfuron-methyl WG 75 W: Acute contact toxicity to the bumble bee, *Bombus terrestris* L. under laboratory conditions  Eurofins Agroscience Services,Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: S13-01778,  Edition Number: [M-485279-01-1](dart://dart/edition?ed_no=M-485279-01-1)  Date: 2014-02-04  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.3.1.2 /01 | Kling, A. | 2014 | Mesosulfuron-methyl (tech.) - Assessment of chronic effects to the honeybee, *Apis mellifera* L., in a 10 days continuous laboratory feeding limit test  Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany  Bayer CropScience,  Report No.: S13-00143,  Edition Number: [M-485655-01-1](dart://dart/edition?ed_no=M-485655-01-1)  Date: 2014-05-02  GLP/GEP: yes,  unpublished | N | Bayer CropScience |
| KCA  8.3.1.3 /01 | Jeker, L. | 2013 | Mesosulfuron-methyl WG 75 - A honeybee brood feeding study to evaluate potential effects on brood development and mortality of the honeybee, *Apis mellifera* L. (Hymenoptera: Apidae)  Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland Bayer CropScience,  Report No.: 20110174,  Edition Number: [M-465325-01-1](dart://dart/edition?ed_no=M-465325-01-1)  Date: 2013-07-15  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA  8.3.1.3 /03 | Taenzler, V. | 2015 | Mesosulfuron-methyl WG 75 W: Effects on honey bee brood (*Apis mellifera* L.) under semi-field conditions - Tunnel test  IBACON GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 87431033,  Edition Number: [M-510267-01-1](dart://dart/edition?ed_no=M-510267-01-1)  Date: 2015-02-09  GLP/GEP: yes,  unpublished  ...also filed: Ecotox /02 | N | Bayer Crop Science |
| KCA 8.4.1 /02 | Scheffczyk, A.; Moster, T. | 2010 | Mesosulfuron-methyl - Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: 10P30RR,  Edition Number: [M-392544-01-1](dart://dart/edition?ed_no=M-392544-01-1)  Date: 2010-10-15  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /03 | Moser, T.; Scheffczyk, A. | 2012 | AE F154851: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: 11P33RR,  Edition Number: [M-425013-01-1](dart://dart/edition?ed_no=M-425013-01-1)  Date: 2012-02-16  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /04 | Moser, T.; Scheffczyk, A. | 2012 | AE F160459: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: 11P32RR,  Edition Number: [M-429097-01-1](dart://dart/edition?ed_no=M-429097-01-1)  Date: 2012-04-04  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /05 | Kratz, M. A. | 2013 | AE F099095 (BCS-AB40283): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil  Bayer CropScience,  Report No.: kra/Rg-R-158/13,  Edition Number: [M-473217-01-1](dart://dart/edition?ed_no=M-473217-01-1)  Date: 2013-12-19  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /06 | Kratz, M. A. | 2013 | AE F092944 (BCS-AA25052): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil  Bayer CropScience,  Report No.: kra/Rg-R-147/13,  Edition Number: [M-461051-01-1](dart://dart/edition?ed_no=M-461051-01-1)  Date: 2013-07-31  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /07 | Kratz, M. A. | 2013 | Mesosulfuron-methyl-AE F160460: Effects on survival, growth and reproduction of the earthworm *Eisenia* *fetida* tested in artificial soil  Bayer CropScience,  Report No.: kra/Rg-R-156/13,  Edition Number: [M-468911-01-1](dart://dart/edition?ed_no=M-468911-01-1)  Date: 2013-10-18  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /08 | Kratz, M. A. | 2013 | Mesosulfuron-methyl-AE F140584 (BCS-AU66443): Effects on survival, growth and reproduction of the earthworm *Eisenia fetida* tested in artificial soil  Bayer CropScience,  Report No.: kra/Rg-R-155/13,  Edition Number: [M-468921-01-1](dart://dart/edition?ed_no=M-468921-01-1)  Date: 2013-10-21  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA 8.4.1 /09 | Moser, T.; Scheffczyk, A. | 2012 | AE F147447: Reproduction toxicity to the earthworm *Eisenia fetida* in an artificial soil test ECT Oekotoxikologie GmbH, Floersheim, Germany  Bayer CropScience,  Report No.: 11P34RR,  Edition Number: [M-428651-01-1](dart://dart/edition?ed_no=M-428651-01-1)  Date: 2012-04-04  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA  8.4.2.1 /01 | Kratz, M.A. | 2012 | Mesosulfuron-methyl (AE F130060): Influence on mortality and reproduction on the soil mite species *Hypoaspis aculeifer* tested in artificial soil  Bayer CropScience,  Report No.: KRA-HR-67/12,  Edition Number: [M-429376-01-1](dart://dart/edition?ed_no=M-429376-01-1)  Date: 2012-04-02  GLP/GEP: yes,  unpublished | N | Bayer Crop Science |
| KCA  8.4.2.1 /02 | Frommholz, U. | 2012 | Mesosulfuron-methyl (AE F130060) a.s.: Influence on the reproduction of the collembolan species *Folsomia candida* tested in artificial soil  Bayer CropScience,  Report No.: FRM-COLL-138/12,  Edition Number: [M-426538-01-1](dart://dart/edition?ed_no=M-426538-01-1)  Date: 2012-03-06  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.4.2.1 /03 | Friedrich, S. | 2013 | Mesosulfuron-methyl-AE F154851 (BCS-AU80405): Effects on the reproduction of the collembolan *Folsomia candida*  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 104 S,  Edition Number: [M-462785-01-1](dart://dart/edition?ed_no=M-462785-01-1)  Date: 2013-08-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.4.2.1 /04 | Friedrich, S. | 2013 | Mesosulfuron-methyl-AE F160459 (BCS-AU84907): Effects on the reproduction of the collembolan *Folsomia candida*  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 103 S,  Edition Number: [M-462786-01-1](dart://dart/edition?ed_no=M-462786-01-1)  Date: 2013-08-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.4.2.1 /05 | Schulz, L. | 2013 | AE F092944 (BCS-AA25052): Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience,  Report No.: 13 10 48 044 S,  Edition Number: [M-454043-01-1](dart://dart/edition?ed_no=M-454043-01-1)  Date: 2013-05-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.4.2.1 /06 | Friedrich, S. | 2013 | AE F092944 (BCS-AA25052): Effects on the reproduction of the collembolan *Folsomia candida*  BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 045 S,  Edition Number: [M-451142-01-1](dart://dart/edition?ed_no=M-451142-01-1)  Date: 2013-03-28  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA  8.4.2.1 /07 | Friedrich, S. | 2013 | Mesosulfuron-methyl-AE F147447 (BCS-AU73625): Effects on the reproduction of the collembolan *Folsomia candida*  BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 105 S,  Edition Number: [M-462782-01-1](dart://dart/edition?ed_no=M-462782-01-1)  Date: 2013-08-14  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5  /09 | Schulz, L. | 2013 | AE F092944 (BCS-AA25052): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem agrar GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 018 N,  Edition Number: [M-453511-01-1](dart://dart/edition?ed_no=M-453511-01-1)  Date: 2013-05-02  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.5  /10 | Schulz, L. | 2013 | Mesosulfuron-methyl-AE F147447 (BCS-AU73625): Effects on the activity of soil microflora (nitrogen transformation test)  BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany  Bayer CropScience,  Report No.: 13 10 48 076 N,  Edition Number: [M-460668-01-1](dart://dart/edition?ed_no=M-460668-01-1)  Date: 2013-07-05  GLP/GEP: yes,  unpublished | N | Bayer Crop  Science |
| KCA 8.6.1 /02 | Noeding, S. | 2013 | Evaluation of the pre-emergence biological activity of mesosulfuron and its metabolite BCS-CV 14885  Bayer CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: FFS135005,  Edition Number: [M-460393-01-1](dart://dart/edition?ed_no=M-460393-01-1)  Date: 2013-03-06  GLP/GEP: no,  unpublished | N | Bayer Crop  Science |
| KCA 8.6.1 /03 | Noeding, S. | 2013 | Evaluation of the post-emergence biological activity of mesosulfuron and its metabolite BCS-CV 14885 Bayer CropScience,  Report No.: FFS135004,  Edition Number: [M-460647-01-1](dart://dart/edition?ed_no=M-460647-01-1)  Date: 2013-03-06  GLP/GEP: no,  unpublished | N | Bayer Crop  Science |

**Mefenpyr-diethyl**

| **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** |
| --- | --- | --- | --- | --- | --- |
| KCA 8.1.1.1/06 | xxx | 1991a | Hoe 107892; SUBSTANCE, TECHNICAL (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Mallard duck (*Anas platyrhynchos*)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.1.1.1/07 | xxx | 1992 | Hoe 107892; substance, technical (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Japanese quail (*Coturnix coturnix japonica*)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.1.1.3/07 | xxx | 1991b | Hoe 107892; substance, technical;  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.1.1.3/08 | xxx | 1991c | Hoe 107892; SUBSTANCE, TECHNICAL  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/11 | xxx | 1991e | Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to *Oncorhynchus mykiss* (Rainbow trout) in a Static-Acute Toxicity Test (method OECD)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/12 | xxx | 1992b | Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to *Cyprinus carpio* (Mirror carp) in a Static-Acute Toxicity Test (method OECD)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/13 | xxx | 2002 | Acute toxicity to *Lepomis macrochirus* (bluegill sunfish) AE F113225; substance, technical (Metabolite of AE F107892) Code: AE F113225 00 1C92 0001  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/14 | xxx | 1999b | Acute toxicity to *Oncorhynchus mykiss* (Rainbow trout) AE F109453 (metabolite of mefenpyr-diethyl AE F107892)  substance, xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/15 | xxx | 1997 | AE F094270 Substance, technical Metabolite of AE F107892 Code: AE F094270 00 1C99 0003 Acute toxicity to rainbow trout (*Oncorhynchus mykiss*)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.1/16 | xxx | 2005 | Zebra fish (*Danio rerio*) acute toxicity test - dynamic conditions AE F094270  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.2.1/05 | xxx | 1994b | Hoe 107892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to *Oncorhynchus mykiss* (Rainbow trout) in a 28-days Juvenile Growth Test under Flow-Through Conditions  xxx  Unpublished | Y | Bayer |
| KCA 8.2.2.1/06 | xxx | 2004 | Rainbow trout (*Oncorhynchus mykiss*), Juvenile growth test (OECD 215), flow-through conditions AE F113225, substance xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.2.1/07 | xxx | 2005b | Zebra fish (*Danio rerio*) toxicity test on embryo and sac-fry stages - dynamic conditions AE F094270, substance technical  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.2.2/01 | xxx | 2005c | Zebra fish (*Danio rerio*) two-generation test - dynamic conditions AE F094270, substance technical  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.2.3/01 | xxx | 1995 | Code: Hoe 107892 00 ZE99 0003 Hoe 107892 (dichlorophenyl-14C) Flow-through Bioaccumulation and Metabolism Study with Bluegill Sunfish (*Lepomis macrochirus*)  xxx  GLP  Unpublished | Y | Bayer |
| KCA 8.2.4.1/09 | Heusel, R. | 1993 | AE F107892 substance technical Code: AE F107892 00 1C97 0001 Acute toxicity to *Daphnia magna* (Waterflea)  Report No.: A58156  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.4.1/10 | Sowig P., Gosch H. | 2002a | Acute toxicity to *Daphnia magna* (waterflea) AE F113225; substance, technical (Metabolite of AE F107892) Code: AE F113225 00 1C92 0001  Report No.: C014740  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.4.1/11 | Sowig P., Weller, O., Gosch H. | 1999 | Acute toxicity to *Daphnia magna* (Waterflea) AE F109453 substance, technical Code: AE F109453 00 1C96 0001  Report No.: C003086  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.4.1/12 | Heusel, R. | 1997a | AE F094270 Substance, technical Metabolite of AE F107892 Code: AE F094270 00 1C99 0003 Acute toxicity to *Daphnia magna* (Waterflea)  Report No.: A59055  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.5.1/04 | Heusel, R. | 1994 | Hoe 907892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to *Daphnia magna* (Waterflea) in a 21-day Reproduction Test (method OECD)  Report No.: A59055  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.5.1/05 | Schafers, C. | 2004a | *Daphnia magna*, Reproduction test (OECD 211) Semi-static conditions AE F113225, substance pure Code: AE F113225 00 1C97 0001  Report No. C046107  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.5.1/06 | Schafers, C. | 2004b | *Daphnia magna*, Reproduction test (OECD 211), Semi-static conditions AE F094270, substance technical Code: AE F094270 00 1C99 0004  Report No. C046108  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.5.4/01 | Dogerloh, M. | 2004 | *Chironomus riparius* 28-day Chronic Toxicity Test with Mefenpyr-diethyl-metabolite (AE F094270) in a Water-Sediment System using Spiked Water  Report No. C045893  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/20 | Scheerbaum, D. | 1998 | Mefenpyr-diethyl (Draft lSO), substance, technical Code: AE F107892 00 1 C97 0001 Alga, Growth Inhibition Test (*Pseudokirchneriella subcapitata*, 96 [h])  Report No. C000738  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/21 | Sowig, P., Weller, O. | 1999 | Algal growth inhibition - *Navicula pelliculosa* Mefenpyr-diethyl (draft ISO) substance, technical Code: AE F107892 00 1C97 0001  Report No. C001644  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/22 | Sowig, P., Gosch, H. | 2002b | Algal growth inhibition - *Pseudokirchneriella subcapitata* AE F113225; substance, technical Code: AE F113225 00 1C92 0001  Report No. C015166  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/23 | Sowig, P., Gosch, H., Weller, O. | 1999 | Algal growth inhibition - *Pseudokirchneriella subcapitata* AE F109453 (Metabolite of the safener AE F107892) substance, technical Code: AE F109453 00 1C96 0001  Report No. C002636  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/24 | Heusel, R. | 1997b | AE F094270 Substance, technical Metabolite of AE F107892 Code: AE F094270 00 1C99 0003 Algal growth inhibition - *Pseudokirchneriella subcapitata*  Report No. A59218  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.6.1/25 | Heusel, R. | 1991b | Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to *Scenedesmus subspicatus* (Green alga) in a Growth Inhibition Test (method OECD)  Report No. CE91/046  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.2.7/34 | Sowig, P. | 1998 | Duckweed (*Lemna gibba* G3) growth inhibition test Mefenpyr-diethyl (draft ISO) substance, technical Code: AE F107892 00 1C97 0001  Report No.: C001664  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.3.1.1.1/04 | Bock, K. | 1991a | Hoe 107892; substance, technical (Hoe 107892 00 ZC94 0001) Investigating the oral toxicity to the honey bee *Apis mellifera* L.  Report No.: CW91/075  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.3.1.1.2/04 | Bock, K. | 1992b | Hoe 107892; substance, technical (Hoe 107892 00 ZC94 0001) Investigating the contact toxicity to the honey bee *Apis mellifera* L.  Report No.: CW91/076  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.4/01 | Heusel, R. | 1991c | Hoe 107892; substance, technical (Hoe 207892 00 ZC94 0001) Effect to *Eisenia fetida* (Earthworm) in a 14 day Artificial Soil Test (method OECD)  Report No.: A46760  Mefenpyr-diethyl RAR  GLP  Unpublished | N | Bayer |
| KCA 8.4/02 | Friedrich, S. | 2004a | Mefenpyr-diethyl-monocarboxylic acid (AE F113225): Acute toxicity to the earthworm *Eisenia fetida* in artificial soil Mefenpyr-diethyl-monocarboxylic acid (AE F113225)  Report No.: C045217  Mefenpyr-diethyl RAR  GLP  Unpublished | N | Bayer |
| KCA 8.4/03 | Friedrich, S. | 2004b | AE F094270: Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil  Report No.: C045810  Mefenpyr-diethyl RAR  GLP  Unpublished | N | Bayer |
| KCA 8.4/04 | Sowig, P., Gosch, H. | 1999 | Acute toxicity to earthworms (*Eisenia fetida*) AE F094270 (metabolite of the safener AE F107892) substance, pure Code: AE F094270 00 1B99 0002  Report No. C005428  Mefenpyr-diethyl RAR  GLP  Unpublished | N | Bayer |
| KCA 8.5/17 | Schultz, L. | 2006 | Effects of AE F094270 (Metabolite of AE F107892) on the activity of soil microflora (Nitrogen transformation test)  Report No.: 061048123N  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.6.2 | Pallett, K.& Gosch, H. | 2005a | Evidence of the absence of herbicidal activity Comparative Tier 1 testing on seedling emergence and growth of nine species of non target terrestrial plants Mefenpyr-diethyl (AE F107892) Test items: Blank formulation (AE F046360 24 EW00 A3)  Report No. C046797  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |
| KCA 8.6.2 | Pallett, K.& Gosch, H. | 2005b | Evidence of the absence of herbicidal activity Comparative Tier 1 testing on the vegetative vigour of ten species of non target terrestrial plants Mefenpyr-diethyl (AE F107892) Test items: Blank formulation (AE F046360 24 EW00 A309)  Report No. C046797  Mefenpyr-diethyl DAR  GLP  Unpublished | N | Bayer |

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 new studies

All relevant studies (except three new bee studies provided as part of this submission – KCP 10.3.1.1, KCP 10.3.1.2 and KCP 10.3.1.3) have previously been evaluated in the dRR Part B9 for the reference product Atlantis 12 OD (authorisation number R-98/2009) of Bayer AG. Therefore, the applicant requests that the zRMS please refer to Appendix 2 – Detailed Evaluation of New Studies, Part B9 ‘Ecotoxicological Evaluation of Plant Protection Product’ of the Atlantis 12 OD re-registration report submitted by Bayer AG for the detailed summaries of these studies which have already been evaluated.

* 1. KCP 10.1 Effects on birds and other terrestrial vertebrates
     1. KCP 10.1.1 Effects on birds
        1. KCP 10.1.1.1 Acute oral toxicity
        2. KCP 10.1.1.2 Higher tier data on birds
     2. KCP 10.1.2 Effects on terrestrial vertebrates other than birds
        1. KCP 10.1.2.1 Acute oral toxicity to mammals
        2. KCP 10.1.2.2 Higher tier data on mammals
     3. KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)
  2. KCP 10.2 Effects on aquatic organisms
     1. KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes
     2. KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms
     3. KCP 10.2.3 Further testing on aquatic organisms
  3. KCP 10.3 Effects on arthropods
     1. KCP 10.3.1 Effects on bees
        1. KCP 10.3.1.1 Acute toxicity to bees

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | The study is considered as valid. This study was evaluated according to OECD 213 and OECD 214. The study met the relevant validity criteria. The following endpoints are considered valid for use in the risk assessment:   | **Species** | **Substance** | **Exposure**  **System** | **Results** | **Reference** | | --- | --- | --- | --- | --- | | *Apis mellifera* | 054-01-05 (Altesse Pro) | Oral | LD50 (72h, 96h) = 529.8 μg 054-01-05/bee = 6.36 μg total a.s./bee | Wilkins, S. (2020a) | | *Apis mellifera* | 054-01-05 (Altesse Pro) | Contact | LD50 (48h, 72h, 96h) = 249.5 μg 054-01-05/bee = 2.99 μg total a.s./bee | Wilkins, S. (2020a) |   **Validity criteria:**  **Contact:**  The toxic reference and control results met the validity criteria from the OECD Guideline – 214 Honeybees, Acute Contact Toxicity Test (toxic reference contact 24-hour LD50 of 0.1 - 0.3 µg/bee & <10% control mortality).      **Oral:**  The toxic reference and control results met the validity criteria from the OECD Guideline – 213 Honeybees, Acute Oral Toxicity Test (toxic reference oral 24-hour LD50 of 0.1 - 0.35 µg/bee & <10% control mortality).      **Deviation from the study:**  1. Starvation period:  According to OECD 213, the bees may be starved for up to 2 hours before the initiation of the test. The study plan stated that bees will be starved 1.5-2 hours before dosing. However, bees were collected at 10:30am and dosing occurred between 12:48 – 12:58. Therefore bees were starved between for a maximum of 2 hours 28 minutes, 28 minutes longer than stated in the study plan. As the bees were visually assessed as healthy after recovering from anaesthesia and there was no impact on control behaviour or survival, this deviation had no impact on the integrity or outcome of the study.  2. Undosed controls:  The use of undosed controls is a deviation from the OECD Guideline 214 that suggest using water dosed controls, however, due to the difficulty involved in pipetting water onto bees, undosed controls were used in conjunction with controls using a wetting agent control; aqueous Triton X 100 solution (1gL-1). This deviation is necessary to successfully provide control bees and so has no negative impact on the integrity or outcome of the study.  3. Timings of contact test toxic reference 4-hour observations:  The study plan states that 4-hour checks would be made ±15 minutes after dosing. Dosing of the toxic reference treated bees occurred between 11:47 and 11:55 while the 4-hour observations occurred between 15:36 and 15:38, thus the top dose observations were 2 minutes before the time tolerance. As this time deviation is so small and the 4 hour observations are not used to produce statistical end points, this deviation had no impact on the integrity or outcome of the study.  4. Significant increase in mortality  The OECD guidelines and study plans state that “If significantly increased mortality is observed between 24 and 48 hours (Classified as 10%) the observation period will be extended to 96 hours…” In the oral test the mortality in the highest Test Item treatment group increased by 2 bees between 24 and 48 hours, 6.7% of the treatment group. This was less than 10% but deemed to be a big enough change to warrant continuing to 96 hours. The extended observation period detected addition mortality in the top two doses with no change in control mortality. This deviation had no detrimental impact on the integrity or outcome of the study. |

|  |  |
| --- | --- |
| Reference: | 10.3.1.1./01 |
| Report | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: Acute contact and oral toxicity to adult worker honeybees (*Apis mellifera* L.), Wilkins, S., 2020a, FR/001918-06 |
| Guideline(s): | OECD 213 (1998), OECD 214 (1998) |
| Deviations: | 1. Starvation period:  According to OECD 213, the bees may be starved for up to 2 hours before the initiation of the test. The study plan stated that bees will be starved 1.5-2 hours before dosing. However, bees were collected at 10:30am and dosing occurred between 12:48 – 12:58. Therefore bees were starved between for a maximum of 2 hours 28 minutes, 28 minutes longer than stated in the study plan. As the bees were visually assessed as healthy after recovering from anaesthesia and there was no impact on control behaviour or survival, this deviation had no impact on the integrity or outcome of the study.  2. Undosed controls:  The use of undosed controls is a deviation from the OECD Guideline 214 that suggest using water dosed controls, however, due to the difficulty involved in pipetting water onto bees, undosed controls were used in conjunction with controls using a wetting agent control; aqueous Triton X 100 solution (1gL-1). This deviation is necessary to successfully provide control bees and so has no negative impact on the integrity or outcome of the study.  3. Timings of contact test toxic reference 4-hour observations:  The study plan states that 4-hour checks would be made ±15 minutes after dosing. Dosing of the toxic reference treated bees occurred between 11:47 and 11:55 while the 4-hour observations occurred between 15:36 and 15:38, thus the top dose observations were 2 minutes before the time tolerance. As this time deviation is so small and the 4 hour observations are not used to produce statistical end points, this deviation had no impact on the integrity or outcome of the study.  4. Significant increase in mortality  The OECD guidelines and study plans state that “If significantly increased mortality is observed between 24 and 48 hours (Classified as 10%) the observation period will be extended to 96 hours…” In the oral test the mortality in the highest Test Item treatment group increased by 2 bees between 24 and 48 hours, 6.7% of the treatment group. This was less than 10% but deemed to be a big enough change to warrant continuing to 96 hours. The extended observation period detected addition mortality in the top two doses with no change in control mortality. This deviation had no detrimental impact on the integrity or outcome of the study. |
| GLP: | Yes |
| Acceptability: | Yes/No/Supplementary |
| Duplication  (if vertebrate study) | N/A |

**Materials and methods**

Objective: The objective of this study was to assess the acute contact and oral toxicity of formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl to adult honeybees (*Apis mellifera* L.) under in-vitro conditions. For the purposes of this study; within the range-finder Niantic: a Wettable Granule (WG) formulation (nominal a.s. content 6 and 30 g/kg respectively), was compared directly to two off the shelf iodosulfuron-methyl-sodium and mesosulfuron-methyl formulations; Altesse Pro: an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively) and Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively). Based on the outcome of the range finder a single formulation was taken through to the definitive test. The choice of formulation for the definitive test, Altesse Pro (054-01-05), was selected, following discussion with the applicant. The basis of this decision was that it was the overall most or equivalently toxic of the three formulations assessed within the range test(s), (information from sister studies FR/001918-10 and FR/001918-11 were also used to make this decision) and it was also the applicant’s commercial priority.

The honey bee was chosen as the test organism, being representative of a species of invertebrate likely to be exposed to residues of the active substances of plant protection products occurring in pollen and nectar and for which data are required for the registration of plant protection products in accordance with Regulation (EC) No. 1107/2009.

Test item: Three formulated products containing the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl.

An initial range-finder test was carried out to evaluate the comparative toxicity of three formulations:

Altesse Pro: an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively),

Niantic: a Wettable Granule (WG) formulation (nominal a.s. content 6 and 30 g/kg respectively),

Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively).

Following the range testing, only Altesse Pro was selected to take forward to the definitive test.

Active substances

(a.s.): i. iodosulfuron-methyl-sodium

ii. mesosulfuron-methyl

Toxic reference item: Dimethoate (Danadim Progress)

Test species: Honey bee (*Apis mellifera* L.)

Stage: Adult stage

Source: Home apiary, FERA National Bee Unit

Test system: Worker bees were collected from colonies #219 and #65 (Fera Home Apiary). The bees were kept in perforated stainless-steel holding cages in an incubator (at 25 ± 2oC and 60 ± 10% relative humidity except during observations in the dark). For the oral test bees were starved for 2.5 hours before use.

Immediately prior to treatment each group of bees in its holding cage was anaesthetised by placing the cage into a container (plastic desiccator) which was then filled with carbon dioxide gas. Any bees that were visibly damaged were excluded from the study. Bees for contact dosing were dosed topically with prepared solutions of test item and toxic reference. Bees for the oral test were fed a range of dilutions of test item and toxic reference treatments made up in aqueous sucrose. Any bees that did not recover from anaesthetisation within good time were replaced.

Treatments dose rate

calculation and

expression: All dose rates were originally calculated and expressed in terms of the formulation (Altesse Pro). The dose rates in terms of each a.s. were calculated and used for reporting.

Results are reported here are for the definitive test only (defined as test 2 for the contact test and the main test for the oral test). Results are reported to no more than 4 significant figures, although some calculations (e.g. feed uptake calculations) used figures at higher levels of significance which can be found reported in full in the raw data file.

**Contact Test**

Test item: The contact test was carried out at five dose rates:

|  |  |  |
| --- | --- | --- |
| **Altesse Pro**  **(µg/bee)** | **Iodosulfuron-methyl-sodium  (µg/bee)** | **Mesosulfuron-methyl (µg/bee)** |
| 15. 63 | 0.0312 | 0.1563 |
| 31.25 | 0.0625 | 0.3125 |
| 62.50 | 0.1250 | 0.6250 |
| 125.0 | 0.2500 | 1.250 |
| 250.0 | 0.5000 | 2.500 |

Toxic reference (dimethoate): The toxic reference for the contact test was run at three dose rates: 0.075, 0.15, and 0.30 μg a.s./bee

Controls**:** Untreated control.

Wetting agent control; aqueous Triton X 100 solution (1gL-1)

**Oral test**

Test item: The oral test was carried out at five offered dose rates:

**Offered oral dose rates expressed in terms of formulation and each a.s. – (nominal values based on information in CofA)**

|  |  |  |
| --- | --- | --- |
| **Altesse Pro**  **(µg/bee)** | **Iodosulfuron-methyl-sodium  (µg/bee)** | **Mesosulfuron-methyl (µg/bee)** |
| 31.26 | 0.0625 | 0.3126 |
| 62.52 | 0.1250 | 0.6252 |
| 125.0 | 0.2500 | 1.250 |
| 250 | 0.5000 | 2.500 |
| 502 | 1.004 | 5.020 |

**Actual Oral dose rates expressed in terms of formulation and each a.s based on mean actual uptake values** (**using information in CofA)**

|  |  |  |
| --- | --- | --- |
| **Altesse Pro**  **(µg/bee)** | **Iodosulfuron-methyl-sodium  (µg/bee)** | **Mesosulfuron-methyl (µg/bee)** |
| 27.86 | 0.0557 | 0.2786 |
| 51.70 | 0.1034 | 0.5170 |
| 97.60 | 0.1952 | 0.9760 |
| 222.5 | 0.4450 | 2.235 |
| 428.7 | 0.8574 | 4.281 |

Control: Untreated 50% w/v sucrose

Toxic reference (dimethoate**):** The toxic reference control for the oral test was run at four offered dose rates:0.075, 0.15, 0.30 and 0.60 μg a.s./bee

Control**:** Wetting agent control; 50% w/v sucrose plus aqueous Triton X 100 solution (1gL-1)

All oral dosing solutions were made up in 50% w/v sucrose solution.

Replicates: 3 cages of 10 bees per group

Test duration: 96 hours

Toxicity

endpoints: Mortality at 24, 48, 72 and 96 hours.

Repeat of

contact test: The contact test was repeated due to what was thought to be an unusual mortality pattern of results i.e. two replicates at the highest dose rate showed 100% mortality and one showed no mortality at the end of the test -96 hours). Following this repeat, similar results were obtained in this test too.

**Results**:

**Contact Test (Definitive)**

**Contact test- Test Item- cumulative mortality**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dose** | **Number dead (cumulative) (n=30)** | | | | |
| **Treatment Group** | **(µg formulation/bee)** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Undosed control | 0 | 0 | 0 | 0 | 0 | 0 |
| Formulation  (Altesse Pro) | 15.63 | 0 | 0 | 0 | 0 | 0 |
| 31.25 | 0 | 0 | 0 | 0 | 0 |
| 62.5 | 0 | 0 | 0 | 0 | 0 |
| 125 | 0 | 1 | 1 | 1 | 1 |
| 250 | 0 | 12\* | 15\* | 15\* | 15\* |

\*significantly different from control mortality (P<0.05)

**Contact test- Toxic reference cumulative mortality**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dose** | **Number dead (cumulative) (n=30)** | | | | |
| **Treatment Group** | **(µg a.s.**  **dimethoate /bee)** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Wetting agent control | 0 | 0 | 0 | 0 | 0 | 0 |
| Toxic reference | 0.075 | 0 | 0 | 0 | 0 | 0 |
| 0.15 | 0 | 9 | 10 | 10 | 10 |
| 0.30 | 2 | 25 | 26 | 27 | 27 |

**Contact test – Test Item percentage mortality**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dose** | **Percentage mortality (n=30)** | | | | |
| **Treatment Group** | **(µg formulation/bee)** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Undosed control | 0 | 0 | 0 | 0 | 0 | 0 |
| Formulation  (Altesse Pro) | 15.63 | 0 | 0 | 0 | 0 | 0 |
| 31.25 | 0 | 0 | 0 | 0 | 0 |
| 62.5 | 0 | 0 | 0 | 0 | 0 |
| 125 | 0 | 3.3 | 3.3 | 3.3 | 3.3 |
| 250 | 0 | 40.0\* | 50.0\* | 50.0\* | 50.0\* |

\*significantly different from control mortality (P<0.05)

**Contact test – Toxic reference percentage mortality**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Dose** | **Percentage mortality** | | | | |
| **Treatment Group** | **(µg a.s.**  **dimethoate /bee)** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Wetting agent control | 0 | 0 | 0 | 0 | 0 | 0 |
| Toxic reference | 0.075 | 0 | 0 | 0 | 0 | 0 |
| 0.15 | 0 | 30.0 | 33.3 | 33.3 | 33.3 |
| 0.30 | 13.3 | 83.3 | 86.7 | 90.0 | 90.0 |

**Oral Test (Definitive):**

**Oral test-Test Item cumulative mortality**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Offered Dose** | **Actual dose** | |  | **Number dead (cumulative)** | | | | |
| **Treatment Group** | **(µg formulation/ bee)** | | **(µg formulation/ bee)** | **N** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Undosed control | 0 | | 0 | 30 | 0 | 1 | 1 | 1 | 1 |
| Formulation  (Altesse Pro) | 31.25 | | 27.9 | 30 | 0 | 0 | 0 | 0 | 0 |
| 62.5 | | 51.7 | 30 | 0 | 0 | 0 | 0 | 0 |
| 125 | | 97.6 | 30 | 0 | 0 | 0 | 0 | 0 |
| 250 | | 223 | 30 | 0 | 1 | 1 | 2 | 2\* |
| 502 | | 429 | 30 | 3 | 6\* | 8\* | 9\* | 9\* |

\*significantly different from control mortality (P<0.05)

**Oral test-Toxic reference cumulative mortality**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Offered Dose** | **Actual dose** | **Number dead (cumulative) (n=30)** | | | | |
| **Treatment Group** | **(µg a.s. dimethoate /bee)** | **(µg a.s. dimethoate /bee)** | **4**  **hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Wetting agent control | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Toxic reference | 0.075 | 0.071 | 0 | 2 | 2 | 2 | 2 |
| 0.15 | 0.142 | 0 | 15 | 18 | 22 | 23 |
| 0.30 | 0.244 | 0 | 28 | 29 | 29 | 30 |
| 0.60 | 0.481 | 4 | 28 | 29 | 29 | 29 |

**Oral test - Test Item- percentage mortality**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Offered Dose** | **Actual dose** | **Percentage mortality** | | | | |
| Treatment Group | **(µg formulation/ bee)** | **(µg formulation/ bee)** | **4 hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Undosed control | 0 | 0 | 0 | 3.3 | 3.3 | 3.3 | 3.3 |
| Formulation  (Altesse Pro) | 31.25 | 27.9 | 0 | 0 | 0 | 0 | 0 |
| 62.5 | 51.7 | 0 | 0 | 0 | 0 | 0 |
| 125 | 97.6 | 0 | 0 | 0 | 0 | 0 |
| 250 | 223 | 0 | 3.3 | 3.3 | 6.7\* | 6.7\* |
| 502 | 429 | 10.0 | 20.0\* | 26.7\* | 30.0\* | 30.0\* |

\*significantly different from control mortality (P<0.05)

**Oral test – Toxic reference percentage mortality**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Offered Dose** | **Actual dose** | **Percentage mortality** | | | | |
| **Treatment Group** | **(µg a.s. dimethoate /bee)** | **(µg a.s. dimethoate /bee)** | **4**  **hours** | **24 hours** | **48 hours** | **72 hours** | **96 hours** |
| Wetting agent control | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Toxic reference** | 0.075 | 0.071 | 0 | 6.7 | 6.7 | 6.7 | 6.7 |
| 0.15 | 0.142 | 0 | 50.0 | 60.0 | 73.3 | 76.7 |
| 0.30 | 0.244 | 0 | 93.3 | 96.7 | 96.7 | 100 |
| 0.60 | 0.481 | 13.3 | 93.3 | 96.7 | 96.7 | 96.7 |

**Conclusion:**

**Contact:**

The toxic reference and control results met the validity criteria from the OECD Guideline - 214 Honeybees, Acute Contact Toxicity Test (toxic reference contact 24-hour LD50 of 0.1 - 0.3 g/bee & <10% control mortality).

**24-hour Dimethoate toxic reference contact LD50 values**

|  |  |  |
| --- | --- | --- |
|  | **Contact LD50 value (µg a.s. dimethoate/bee)** | **Upper and lower 95 % Confidence Limits** |
| 24-hour | 0.21 | 0.19 - 0.25 |

A step-down test, equivalent to a Cochrane Armitage test, for a linear trend in proportions was used to detect significant trends in contact mortality observations at 24, 48, 72 and 96 hours to identify the NOED as 125 µg formulation/bee and LOED as µg 250 formulation/bee.

The mortality data at each time point was expressed as a dose-response relationship using a suitable statistical model to estimate an LD10, LD20, and LD50 (the dose causing 10, 20 or 50% mortality) for the contact data.

**Test Item 24 hour, and 48-, 72- and 96-hour test item contact** **LD10, LD20 and LD50 values for formulation and constituent a.s. (mortality results were the same at 48, 72 and 96 hours)**

|  |  |  |  |
| --- | --- | --- | --- |
| **24 hour** | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LD10** | 173.9 (106.0-206.9) | 0.3478 (0.212-0.4138) | 1.739 (1.060-2.069) |
| **LD20** | 206.1 (162.0-240.7) | 0.4122 (0.3240-0.4814) | 2.061 (1.620-2.407) |
| **LD50** | 267.7 (234.2-340.3) | 0.5354 (0.4684-0.6806) | 2.677 (2.342-3.403) |
| **48, 72 & 96 hour** | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LD10** | 166.3 (74.5-202.0) | 0.3326 (0.1490-0.4040) | 1.663 (0.7450-2.020) |
| **LD20** | 194.8 (134.1-229.4) | 0.3896 (0.2682-0.4588) | 1.948 (1.341-2.294) |
| **LD50** | 249.5 (215.3-314.7) | 0.4990 (0.4306-0.6294) | 2.495 (2.153-3.147) |

**Oral:**

The toxic reference and control results met the validity criteria from the OECD Guideline - 213 Honeybees, Acute Oral Toxicity Test (toxic reference oral 24-hour LD50 of 0.1 - 0.35 g/bee & <10% control mortality).

**24-hour and 48-hour Dimethoate toxic reference oral LD50 values**

|  |  |  |
| --- | --- | --- |
|  | **Oral LD50 value (µg a.s. dimethoate/bee)** | **Upper and lower 95 % Confidence Limits** |
| 24-hour | 0.17 | 0.14 - 0.20 |

A step-down test, equivalent to a Cochrane Armitage test, for a linear trend in proportions was used to detect significant trends in oral mortality observations at 24, 48 and 72 hours to identify the NOED as 222.4 µg formulation/bee and LOED as 427µg formulation/bee based on actual uptake, and at 96 hours to identify the NOED as 97.6 µg formulation/bee and LOED as 222.4 µg formulation/bee based on actual uptake.

The mortality data at each time point was expressed as a dose-response relationship using a suitable statistical model to estimate an LD10, LD20, and LD50 (the dose causing 10, 20 or 50% mortality) for the oral data.

**Test Item 24 hour, and 48-, 72- and 96-hour test item oral** **LD10, LD20 and LD50 values for formulation and constituent a.s. (mortality results were the same at 72 and 96 hours)**

|  |  |  |  |
| --- | --- | --- | --- |
| **24 hour** | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LD10** | 355.5 (256.3-469.5) | 0.7110 (0.5126-0.9390) | 3.555 (2.563-4.695) |
| **LD20** | 448.5(359.0-630.9) | 0.8790 (0.7180-1.2618) | 4.485 (3.590-6.309) |
| **LD50** | 626.4(500.9-994.3) | 1.2528 (1.0018-1.9886) | 6.264 (5.009-9.943) |
| **48 hour** | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LD10** | 328.1 (235.0-405.5) | 0.6562 (0.4700-0.8110) | 3.281 (2.350-4.055) |
| **LD20** | 406.8 (332.8-512.5) | 0.8136(0.6656-1.025) | 4.068 (3.328-5.125) |
| **LD50** | 557.4(466.4-770.7) | 1.1148 (0.9328-1.5414) | 5.574 (4.664-7.707) |
| **72 & 96 hour** | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LD10** | 300.6 (214.8-370.5) | 0.6012 (0.4296-0.7410) | 3.006 (2.148-3.705) |
| **LD20** | 379.3 (310.1-468.3) | 0.7586 (0.6202-0.9366) | 3.793 (3.101-4.683) |
| **LD50** | 529.8 (446.4-701.5) | 1.0596 (0.8928-1.403) | 5.298 (4.464-7.015) |

* + - * 1. KCP 10.3.1.1.1 Acute oral toxicity to bees

Please refer to KCP 10.3.1.1

* + - * 1. KCP 10.3.1.1.2 Acute contact toxicity to bees

Please refer to KCP 10.3.1.1

* + - 1. KCP 10.3.1.2. Chronic toxicity to bees

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered as valid. This study was evaluated according to OECD 213 and OECD 245 (2017). The study met the relevant validity criteria.  **Validity criteria:**  There was 3.3% mortality recorded in the control group meeting the validity criterion of <15% mortality. In the toxic reference group 100% mortality was observed, meeting the validity criterion of > 50% mortality at day 10.  Deviation:    **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| Reference: | 10.3.1.2/01 |
| Report | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: 10 Day chronic oral toxicity test (repeated dose) for adult honey bees (*Apis mellifera* L.), Wilkins., S., 2020b, FR/001918-10 |
| Guideline(s): | OECD 245 (2017) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes/No/Supplementary |
| Duplication  (if vertebrate study) | N/A |

**Materials and methods**

Objective: The objective of this study was to assess the toxicity of formulated iodosulfuronmethyl-sodium and mesosulfuron-methyl to adult honey bees (*Apis mellifera* L.) in a 10-day continuous feeding test. For the purposes of this study; within the range-finder: Niantic a Wettable Granule (WG) formulation (nominal a.s. content 6 and 30 g/kg respectively), was compared directly to two off the shelf iodosulfuron-methyl-sodium and mesosulfuron-methyl formulations; Altesse Pro: an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively) and Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively). Based on the outcome of the range finder a single formulation was taken through to the definitive test. The choice of formulation for the definitive test, Altesse Pro (054-01-05), was selected, following discussion with the applicant.

The honey bee was chosen as the test organism, being representative of the pollinating insects likely to be at risk of exposure if flowering crops or weeds are sprayed with plant protection products. Honey bees may be exposed to plant protection products from foraging on sprayed plants leading to the oral uptake of contaminated food (pollen, nectar etc.).

Test item(s): Three formulated products containing the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl.

An initial range-finder test was carried out to evaluate the comparative toxicity of three formulations:

Altesse Pro (054-01-05): an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively),

Niantic: a Wettable Granule (WG) formulation (nominal a.s. content 6 and 30 g/kg respectively),

Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively). Following the range testing, Altesse Pro was selected to take forward to the definitive test. The decision for the selection of Altesse Pro, was based on the fact that it was one of the most or equivalently toxic of the three formulations assessed, based on combined a.s. content (information from sister studies FR/001918-06 and FR/001918-11 were also used to make this decision) and this formulation was also the applicant’s commercial priority

Toxic reference

item: Danadim progress

Active substance

(a.s.): Dimethoate

Test species: Honey bee (*Apis mellifera* L.)

Stage: Newly emerged adult workers (< 48 hours old)

Source: Home apiary, FERA National Bee Unit

Test system: Newly emerged honey bees (*Apis mellifera* L.), no more than 48 hours old were used in the chronic test. They were allowed continual access to a 50% (w/v) aqueous sucrose solution either with or without the test/reference item, through the form of a feeder inserted into the side of the plastic housing cage. This feeder was changed and weighed in and out every day, allowing the amount of sucrose and dose consumed to be calculated.

Temperature:

(Except during

observations) 33 ± 2 °C

Humidity:

(Except during

observations) 60 + 10% RH

Photoperiod &

lighting: Test units were held in darkness except during handling and observations.

Treatments: All dose rates were originally calculated and expressed in terms of the formulation (Altesse Pro). The dose rates in terms of each a.s. were calculated and used for reporting. A fresh batch of test item stock dosing solutions and dosed feeding solutions were prepared daily. Subsamples of the initial stock solution, control feed and all 5 dosed feed solutions were collected on day 0, day 5 and the final set on day 9. All samples were analysed by liquid chromatography with diode array detection (LC-DAD) to assess the concentration, homogeneity, and stability of iodosulfuron-methyl-sodium. The method used was validated to SANCO 3029/99 rev4.0 and found to be suitable. The stock solutions were analysed using method FR/001918-M1 which was validated under Fera Study Number FR/001918-06. The mean results of this analysis showed less than 20% deviation from expected concentrations iodosulfuron-methyl-sodium in the stocks and in each feed batch at the start and end of use. Triplicate dosed feed samples taken on day 0 all showed less than 5% relative standard deviation (RSD) confirming the homogeneity of the solutions. A sample of control (undosed) feed was negative for either active substance. This confirmed that the test item was at the required doses, homogeneous and stable in solution for the duration of the test. All results for the active substance and formulation are quoted based on nominal values.

The test item dose rates for the main test were chosen based on the results of the range finding test. The main test was run as a dose response test at five nominal concentrations of 1562.5, 3125.0, 6250.0, 12500, and 25000 mg formulation/kg 50% (w/v) aqueous sucrose solution.

Each cage of bees was offered approximately 1.5mL treated/control diet each day.

The mean measured doses consumed by the bees in the test item treated groups were calculated to be 47.7, 82.7, 106, 205, and 175 μg formulation/bee/day.

The toxic reference item was offered at a rate of 1 mg a.s./kg 50% (w/v) aqueous sucrose solution. The mean measured dose consumed by the bees in the reference item treated group was calculated to be 0.03 μg a.s./bee/day.

The control group was fed untreated 50% (w/v) aqueous sucrose solution.

Replicates: 3 cages of 10 bees were used for each treatment group

Test duration: 10 days

Toxicity

endpoints: The toxicity endpoint are the mortality rates after 10 days

**Results**

The results of the definitive bioassay are summarised in the table below.

**Mean percentage mortality in the control, reference and test item treated groups over 10 days**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Treatment group** | **Nominal Concentration (mg formulation/kg)** | **Mean nominal dose ug formulation/ bee/day** | **Mean Percentage Mortality** | | | | | | | | | |
| **Day 1** | **Day 2** | **Day 3** | **Day 4** | **Day 5** | **Day 6** | **Day 7** | **Day 8** | **Day 9** | **Day 10** |
| **Control** | 0 | - | 0.0 | 0.0 | 0.0 | 0.0 | 3.33 | 3.33 | 3.33 | 3.33 | 3.33 | 3.33 |
| **Altesse Pro** | 1562.5 | 47.7 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 6.67 |
| 3125.0 | 82.7 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 3.33 | 6.67 | 6.67 |
| 6250.0 | 106 | 3.33 | 6.67 | 6.67 | 13.3 | 13.3 | 16.7 | 20.0 | 33.3 | 43.3 | 56.7 |
| 12500 | 205 | 3.33 | 13.3 | 40.0 | 66.7 | 83.3 | 100 | 100 | 100 | 100 | 100 |
| 25000 | 175 | 20.0 | 96.7 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |
| **Toxic reference** | 1.0 mg a.s./kg | 0.03 μg a.s./bee/day | 0.0 | 0.0 | 0.0 | 6.67 | 26.7 | 56.7 | 73.3 | 93.3 | 100 | 100 |

**Conclusions**

There was 3.3% mortality recorded in the control group meeting the validity criterion of <15% mortality. In the toxic reference group 100% mortality was observed, meeting the validity criterion of > 50% mortality at day 10.

**LOEC/NOEC and LOEDD/NOEDD Values for Day 10**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Altesse Pro**  **(mg formulation/kg)** | **Iodosulfuron-methyl-sodium (mg a.s./kg)** | **Mesosulfuron-methyl**  **(mg a.s./kg)** |
| **LOEC** | 6250.0 | 12.500 | 62.50 |
| **NOEC** | 3125.0 | 6.250 | 31.25 |
|  | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium (µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LOEDD** | 102.0 | 0.2040 | 1.0200 |
| **NOEDD** | 79.8 | 0.1596 | 0.7980 |

**LCx and LDD Values**

There was a clear dose response observed and it was possible to fit a model to estimate a lethal concentration for 10, 20, and 50% (LC10, 20, & 50) and 10, 20, and 50% (LDD10, 20, & 50).

**10 day LC10, LC20 and LC50 values plus 95% CI levels**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Altesse Pro**  **(mg formulation/kg)** | **Iodosulfuron-methyl-sodium (mg a.s./kg)** | **Mesosulfuron-methyl**  **(mg a.s./kg)** |
| **LC10** | 5165 (2047-13030) | 10.33 (4.094-26.06) | 51.65 (20.47-130.3) |
| **LC20** | 5487 (2175-13843) | 10.97 (4.350-27.69) | 54.87 (21.75-138.4) |
| **LC50** | 6162 (2442-15545) | 12.32 (4.884-31.09) | 61.62 (24.42-155.5) |
|  | **Altesse Pro**  **(µg formulation/bee)** | **Iodosulfuron-methyl-sodium (µg a.s./bee)** | **Mesosulfuron-methyl**  **(µg a.s./bee)** |
| **LDD10** | 88.03 (78.19-93.76) | 0.1761 (0.1564-0.1875) | 0.8803 (0.7819-0.9376) |
| **LDD20** | 92.23 (83.95-97.58) | 0.1845 (0.1679-0.1952) | 0.9223 (0.8395-0.9758) |
| **LDD50** | 100.8 (94.88-106.8) | 0.2016 (0.1898-0.2136) | 1.008 (0.9488-1.068) |

* + - 1. KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

|  |  |
| --- | --- |
| Comments of zRMS: | The study is considered as valid. This study was evaluated according to OECD 213 and OECD 239 (2016). The study met the relevant validity criteria.  **Validity criteria:**  There was 4.17 % mortality observed in the water controls up to D8 meeting the validity criterion of <15% control mortality. The adult emergence rate in the water control group was 83.33 % exceeding the required minimum of 70%. The toxic reference treated group mortality was 89.58 % on D8 exceeded the 50% mortality required to meet the validity criterion.  **Deviation:**  **1) Dose solution and diet preparation**  In the study plan it states that *“the initial stock solutions will be prepared on day 0”*. It should have stated day 3. The stock solutions were prepared on day 3, the first day of dosing, and then stored in a refrigerator (6 ±2ºC) for the remainder of the test. Therefore, this has had no effect on the outcome or integrity of the study.  **2) Provision of feed for emerging bees**  The study plan states that candy and sucrose would be provided from D20-22 however, the feed was actually provided on D16. This deviation had no impact on the integrity or outcome of the study as this candy and sucrose is provided to allow *ad libitum* feed for any emerging bees so as long as the feed is provided before the bees begin to emerge the actual day that it is provided does not matter.  **3) LOEC/LOEDD and NOEC/NOEDD Values**  In accordance with the requirements of OECD Test Guideline 245 the LOEC/LOEDD (lowest observable effect concentration/ lowest observable effect dietary dose) and NOEC/NOEDD (no observable effect concentration/ no observable effect dietary dose) for day 10 were estimated, using a step-down test, equivalent to a Cochrane Armitage test. This was not included in the original Study Plan, which was an oversight. This has no impact on the integrity or outcome of the study.  **Agreed toxicity endpoints:** |

|  |  |
| --- | --- |
| Reference: | 10.3.1.3/01 |
| Report | Formulated iodosulfuron-methyl-sodium and mesosulfuron-methyl: In vitro 22 day toxicity test - repeated exposure to larval stage honeybees (*Apis*  *mellifera* L.), Wilkins., S., 2020c, FR/001918-11 |
| Guideline(s): | OECD Guidance Document 239 (2016) |
| Deviations: | No |
| GLP: | Yes |
| Acceptability: | Yes/No/Supplementary |
| Duplication  (if vertebrate study) | N/A |

**Materials and methods**

Objective: The objective this study was to assess the toxicity of formulated iodosulfuronmethyl-sodium and mesosulfuron-methyl to the larval stage of honeybees (*Apis mellifera* L.) under in-vitro conditions. For the purposes of this study; within the range-finder Niantic: a Wettable Granule (WG) formulation (nominal active substance (a.s.) content 6 and 30 g/kg respectively), was compared directly to two off the shelf iodosulfuron-methyl-sodium and mesosulfuron-methyl formulations; Altesse Pro: an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively) and Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively). Based on the outcome of the range finder a single formulation was taken through to the definitive test. The choice of formulation for the definitive test, Altesse Pro, was selected, following discussion with the applicant.

The honey bee larva was chosen as the test organism, being representative of a species of invertebrate likely to be exposed to residues of the active substances of plant protection products occurring in pollen and nectar and for which data are required for the registration of plant protection products in accordance with Regulation (EC) No. 1107/2009.

Test item(s): Three formulated products containing the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl.

An initial range-finder (details of the results from the range testing can be seen in test was carried out to evaluate the comparative toxicity of three formulations:

Altesse Pro: an Oil Dispersion (OD) formulation (nominal a.s. content 2 and 10 g/L respectively),

Niantic: a Wettable Granule a (WG) formulation (nominal a.s. content 6 and 30 g/kg respectively),

Archipel Duo: an OD formulation (nominal a.s. content 7.5 and 7.5 g/L respectively).

Following the range testing, Altesse Pro was selected to take forward to the definitive test. The decision for the selection of Altesse Pro, was based on the fact that it was one of the most or equivalently toxic formulations assessed in the range tests based on combined a.s. content (information from sister studies FR/001918-06 and FR/001918-10 were also used to make this decision) and this formulation was also the applicant’s commercial priority.

Reference item: Dimethoate Pestanal

Test species: Honey bee (*Apis mellifera* L.)

Stage: Larval stage

Source: Home apiary, FERA National Bee Unit Test system: Larval honey bees (*Apis mellifera* L.) (<24 hours old) were collected from colonies and grafted (D1) into artificial queen cell cups and fed an artificial diet. On Days 3-6 (dosing days) diet dosed with appropriate levels of test item as required was fed to each larva. Equivalent water dose controls and toxic reference controls were also set up.

Treatments

(definitive test): • Untreated Control

• 5 test item treatment groups

**Treatment concentrations – (nominal values based on information in CofA)**

|  |  |  |
| --- | --- | --- |
| **Altesse Pro**  **(mg /kg)** | **Iodosulfuron-methyl-sodium  (mg /kg)** | **Mesosulfuron-methyl (mg /kg)** |
| 128 | 0.256 | 1.28 |
| 320 | 0.640 | 3.20 |
| 800 | 1.60 | 8.00 |
| 2000 | 4.00 | 20.0 |
| 5113 | 10.2 | 51.1 |

**Treatment dose rates (nominal values based on information in CofA)) – assuming complete consumption of dosed diet**

|  |  |  |
| --- | --- | --- |
| **Altesse Pro  (µg /larva)** | **Iodosulfuron-methyl-sodium (µg /larva)** | **Mesosulfuron-methyl (µg /larva)** |
| 19.71 | 0.0394 | 0.197 |
| 49.28 | 0.0986 | 0.493 |
| 123.2 | 0.246 | 1.23 |
| 308.0 | 0.616 | 3.08 |
| 787.4 | 1.57 | 7.87 |

* Toxic reference item at 1 concentration of 48 mg a.s./kg diet = 7.39 µg a.s /larva assuming complete consumption of offered diet.

Treatments dose

calculation and

expression: All nominal dose rates for the definitive test were based in terms of formulation. They /were also reported in terms of nominal a.s., based on the nominal values as declared by the manufacturer for the product. The formulation used for the definitive test is an ‘off the shelf’ product and no C of A was provided. Results are shown to no more than 4 significant figures (s.f.) in the report although data to higher levels of accuracy may be provided in the appendices or the raw data file.

Dosing solution

analysis: The analysed content of iodosulfuron-methyl-sodium in the highest dosing stock and in dosed feed samples collected on each dosing day (D3-6) were within 20% of expected values and as this is within the expected range all doses will be reported in terms of nominal dose based on information provided with the test item. Analysis also showed that the test item was homogeneous in the dosed larvae feed and stable for the storage period prior to analysis.

Replicates: 48 larvae per dose rate, control or toxic reference plate, 16 provided from each of 3 individual colonies (i.e. replicates).

Exposure period: 4 days feeding with test item dosed larval diet.

Toxicity endpoints: The toxicity endpoints were larval mortality rates from D3 to D8, pupal mortalities from D8 to D15, and emergence rate on D 22. Estimates of toxicity endpoints for the formulation are nominal and were based on calculations from test item dispensing. For conversion to constituent a.s values the calculations were based on analysed content of the dosed larval diet.

**Results**

**Number of surviving larvae, pupae or adult bees at each treatment dose over the test period**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Nominal concentration**  **(mg Altesse Pro /kg diet)** | **Nominal Dose**  **(µg Altesse Pro /larva/test period)** | **Day 3** | **Day 4** | **Day 5** | **Day 6** | **Day 7** | **Day 8** | **Day 15** | **Day 22** |
| Control | **0** | 48 | 48 | 48 | 47 | 47 | 46 | 43 | 40 |
| 128 | **19.71** | 48 | 48 | 48 | 48 | 46 | 46 | 45 | 41 |
| 320 | **49.28** | 48 | 48 | 48 | 48 | 47 | 47 | 44 | 38 |
| 800 | **123.2** | 48 | 48 | 48 | 47 | 45 | 44 | 38 | 24 |
| 2000 | **308.0** | 48 | 48 | 46 | 27 | 21 | 19 | 8 | 8 |
| 5113 | **787.4** | 48 | 28 | 6 | 0 | 0 | 0 | 0 | 0 |
| Toxic Reference | **7.39 µg a.s./larva** | 48 | 33 | 19 | 13 | 5 | 5 | 2 | 2 |

**Percent cumulative mortality of larvae, pupae or adults at each test item treatment dose, at each observation time point (corrected using Abbott 1925 with control group mortality data)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Nominal concentration (Altesse Pro** **/kg diet)** | **Nominal Dose**  **(µg Altesse Pro /larva/test period)** | **Day**  **4** | **Day**  **5** | **Day**  **6** | **Day**  **7** | **Day**  **8** | **Day 15** | **Day 22** |
| **128** | **19.71** | 0.0 | 0.0 | -2.1 | 2.1 | 0.0 | -4.7 | -2.5 |
| **320** | **49.28** | 0.0 | 0.0 | -2.1 | 0.0 | -2.2 | -2.3 | 5.0 |
| **800** | **123.2** | 0.0 | 0.0 | 0.0 | 4.3 | 4.3 | 11.6 | 40.0 |
| **2000** | **308.0** | 0.0 | 4.2 | 42.6 | 55.3 | 58.7 | 81.4 | 80.0 |
| **5113** | **787.4** | 41.7 | 87.5 | 100 | 100 | 100 | 100 | 100 |

**Toxicity end points: larval mortality rate, pupal mortality rate and adult emergence rate.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Nominal concentration  (mg Altesse Pro /kg larval diet)** | **Nominal Dose (µg Altesse Pro /larva/test period)** | **Larval mortality rate (%)** | **Pupal mortality rate (%)** | **Adult emergence rate (%)** |
| Water control | **0** | 4.17 | 13.04 | 83.33 |
| 128 | **19.71** | 4.17 | 10.87 | 85.42 |
| 320 | **49.28** | 2.08 | 19.15 | 79.17 |
| 800 | **123.2** | 8.33 | 45.45 | 50.00 |
| 2000 | **308.0** | 60.42 | 57.89 | 16.67 |
| 5113 | **787.4** | 100.00 | 0.00 | 0.00 |
| Toxic Reference | **7.39 µg a.s./larva** | 89.58 | 60.00 | 4.17 |

**Conclusion:**

There was 4.17 % mortality observed in the water controls up to D8 meeting the validity criterion of<15% control mortality. The adult emergence rate in the water control group was 83.33 % exceeding the required minimum of 70%. The toxic reference treated group mortality was 89.58 % on D8 exceeded the 50% mortality required to meet the validity criterion.

**LOEC/NOEC and LOEDD/NOEDD Values for Day 22**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Altesse Pro**  **(mg formulation/kg)** | **Iodosulfuron-methyl-sodium**  **(mg a.s./kg)** | **Mesosulfuron-methyl**  **(mg a.s./kg)** |
| **LOEC** | 800 | 1.60 | 8.00 |
| **NOEC** | 320 | 0.640 | 3.20 |
|  | **Altesse Pro**  **(µg formulation/larva)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./larva)** | **Mesosulfuron-methyl**  **(µg a.s./larva)** |
| **LOEDD** | 123.2 | 0.246 | 1.23 |
| **NOEDD** | 49.28 | 0.0986 | 0.493 |

There was a clear dose response allowing LC10, LC20 and LC50 values to be estimated:

**22 day LC10, LC20 and LC50 values plus 95% CI levels**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Altesse Pro**  **(mg formulation/kg)** | **Iodosulfuron-methyl-sodium**  **(mg a.s./kg)** | **Mesosulfuron-methyl**  **(mg a.s./kg)** |
| **LC10** | 395.4 (131.8 - 620.8) | 0.791 (0.264 – 1.242) | 3.954 (1.318 -6.208) |
| **LC20** | 541.6 (230.9 – 786.5) | 1.083 (0.462 – 1.573) | 5.416 (2.309 - 7.865) |
| **LC50** | 989.2 (635.1 – 1313.2) | 1.978 (1.270 – 2.626) | 9.892 (6.351 – 13.13) |
|  | **Altesse Pro[[6]](#footnote-6)**  **(µg formulation/larva)** | **Iodosulfuron-methyl-sodium**  **(µg a.s./larva)** | **Mesosulfuron-methyl**  **(µg a.s./larva)** |
| **LD10** | 60.89 (20.30 – 95.60) | 0.122 (0.041 – 0.191) | 0.609 (0.203 – 0.956) |
| **LD20** | 83.41 (35.56 – 121.1) | 0.167 (0.071 – 0.242) | 0.834 (0.356 – 1.211) |
| **LD50** | 152.3 (97.81- 202.2) | 0.305 (0.196 – 0.404) | 1.523 (0.978 – 2.022) |

* + - 1. KCP 10.3.1.4 Sub-lethal effects
      2. KCP 10.3.1.5 Cage and tunnel tests
      3. KCP 10.3.1.6 Field tests with honeybees
  1. KCP 10.4 Effects on non-target soil meso- and macrofauna
     1. KCP 10.4.1 Earthworms
        1. KCP 10.4.1.1 Earthworms - sub-lethal effects
        2. KCP 10.4.1.2 Earthworms - field studies
     2. KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)
        1. KCP 10.4.2.1 Species level testing
        2. KCP 10.4.2.2 Higher tier testing
  2. KCP 10.5 Effects on soil nitrogen transformation
  3. KCP 10.6 Effects on terrestrial non-target higher plants
     1. KCP 10.6.1 Summary of screening data
     2. KCP 10.6.2 Testing on non-target plants
     3. KCP 10.6.3 Extended laboratory studies on non-target plants
  4. KCP 10.7 Effects on other terrestrial organisms (flora and fauna)
  5. KCP 10.8 Monitoring data

1. CJ Sinclair PhD Thesis University of York Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products https://www.researchgate.net/publication/235934684\_Predicting\_the\_environmental\_fate\_and\_ecotoxicological\_and\_toxic ological\_effects\_of\_pesticide\_transformation\_products - BCS documentation no. M-551653-01-1 - see Appendix 2, A.2.2. [↑](#footnote-ref-1)
2. CJ Sinclair PhD Thesis University of York, Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products https://www.researchgate.net/publication/235934684\_Predicting\_the\_environmental\_fate\_and\_ecotoxicological\_and\_toxic ological\_effects\_of\_pesticide\_transformation\_products - BCS documentation no. M-551653-01-1 - see Appendix A 2.2. [↑](#footnote-ref-2)
3. EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance metsulfuron-methyl. EFSA Journal 2015;13(1):3936, 106 pp.

   [↑](#footnote-ref-3)
4. For formal completeness, RQ calculations to FOCUS Step 4 PECsw values can be found in Appendix A 3.6 of the present document. [↑](#footnote-ref-4)
5. Agnès RORTAIS, Gérard ARNOLD, Marie-Pierre HALM, Frédérique TOUFFET-BRIENS (2005) Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36 (2005) 71–83 [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)