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| **FINAL REGISTRATION REPORT**  **Part B**  Section 6  Mammalian Toxicology  **Detailed summary of the risk assessment** |
| **Product code: 054-01-05**  **Product name(s): Meso-Iodo OD-Life**  **Chemical active substances:**  **Mesosulfuron-methyl, 10 g/L**  **Iodosulfuron-methyl-sodium, 2 g/L** |
| **Central Zone**  **Zonal Rapporteur Member State: Poland**  **Concerned Member State: Germany** |
| **CORE ASSESSMENT**  **(Authorisation)** |
| **Applicant: Life Scientific Ltd.**  **Submission date: Q1 2023; November 2023;**  **October 2024**  **MS Finalisation date: July 2023; April 2024; September 2024; October 2024;** |

Version history

|  |  |
| --- | --- |
| When | What |
| July 2023 | zRMs evaluated dRR submitted by Applicant |
| November 2023 | dRR and non-dietary risk assessment updated in line with request from evaluator |
| April 2024 | Updated after comments |
| September 2024 | Updated |
| Oct 2024 | Updated by applicant on request of zRMS to include information on metabolite AE F160459 |
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# Mammalian Toxicology (KCP 7)

**Introduction**

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 and Germany.

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 the Central Zone, 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 1107/2009 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 1107/2009, new use data attracts zero data protection when the original 10-year data protection of the product has expired.

Under CLP (Regulation (EC) 1272/2008), it is proposed that product 054-01-05 is classified as H319 from a mammalian toxicology perspective in line with that of the reference product, Atlantis 12 OD.

Section 6.6 of this document, including the non-dietary risk assessment, has been updated to meet the requirements of ‘Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032’. The OPEX calculator version: v 1.0.1 has been used for the non-dietary risk assessment.

**The explanation (as above) is accepted**

## Summary

Table 6.1‑1: Information on 054-01-05 / Meso-Iodo OD-Life\*

|  |  |
| --- | --- |
| Product name and code | 054-01-05 / Meso-Iodo OD-Life |
| Formulation type | Oil dispersion [Code: OD] |
| Active substance(s) (incl. content) | Mesosulfuron-methyl, 10 g/L  \*\*Iodosulfuron-methyl-sodium, 2 g/L  Mefenpyr-diethyl (safener), 30 g/L |
| Function | Herbicide |
| Product already evaluated as the ‘representative formulation’ during the approval of the active substance(s) | No |
| Product previously evaluated in another MS according to Uniform Principles | No |

\*Information on the detailed composition of 054-01-05 / Meso-Iodo OD-Life can be found in the confidential dRR Part C.

\*\* Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No1272/2008 as amended. No classification for toxicology in current harmonised

Justified proposals for classification and labelling

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

Table 6.1‑2: Justified proposals for classification and labelling for 054-01-05 / Meso-Iodo OD-Life according to Regulation (EC) No 1272/2008

|  |  |
| --- | --- |
| Hazard class(es), categories | Eye Irrit 2., Aquatic chronic 1. |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS07 GHS09 |
| Signal word | Warning |
| Hazard statement(s) | H319 – Causes serious eye irritation  H410 - Very toxic to aquatic life with long lasting effects. |
| Precautionary statement(s) | P264, P280, P305 + P351 + P338, P337 + P313, P391 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |
|  | Contains fatty alchol ethoxylate alkyl ether. May produce an allergic  reaction. [EUH208]  **[EUH066] Repeated exposure may cause skin dryness or cracking.** |

**Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for IMS+MSM+MPR OD 42 (2+10+30)**

|  |  |  |
| --- | --- | --- |
|  | **Result** | **PPE / Risk mitigation measures** |
| Operators | Acceptable | Gloves during mixing/loading and when handling contaminated surfaces during application |
| Workers | Acceptable | None |
| Bystanders | Acceptable | None |
| Residents | Acceptable | None |

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

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

**Table 6.1-4 Critical uses and overall conclusion of exposure assessment**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | | | |
| **Use-**  **No.\*** | **Crops and situation (e.g. growth stage of crop)** | **F,**  **Fn,**  **Fpn**  **G,**  **Gn, Gpn**  **or**  **I \*\*** | **Application** | | **Application rate** | | **PHI**  **(d)** | **Remarks:**    **(e.g. safener/synergist**  **(L/ha))**    **critical gap for operator, worker, bystander or resident exposure based on [Exposure mod-**  **el]** | **Acceptability of exposure assessment** | | | |
| **Method / Kind**  **(incl. application technique \*\*\*** | **Max. number**  **(min. interval between applications) a) per use**  **b) per crop/ season** | **Max. application**  **rate**  **g as/ha**     1. **IMS** 2. **MSM**   **c)safener MPR** | **Water**  **L/ha**    **min / max** | **Operator** | **Worker** | **Bystander** | **Residents** |
| 007 | Winter soft wheat  (BBCH 13 - 30) | F | Spraying,  LCTM | 1 ; 1 | 1. 3 2. 15 3. 45 | 200 - 400 | - | *Critical GAP for operator, worker and resident/bystander exposure based on EFSA Journal 2022;20(1):7032* |  |  |  |  |

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

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

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

Explanation for column 10 “Acceptability of exposure assessment”

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

**Data gaps**

No data gaps

There are no noticed data gaps.

## Toxicological Information on Active Substance(s)

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

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

|  | methyl 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-α-(methanesulfonamido)-p-toluate | **sodium ({[5-iodo-2-**  **(methoxycarbonyl)phenyl]sulfonyl}carbamoyl)(4-**  methoxy-6-methyl-1,3,5-triazin-2-yl)azanide | diethyl 1-(2,4-dichlorophenyl)-5-methyl-4,5-dihydro-1H-pyrazole-3,5-dicarboxylate |
| --- | --- | --- | --- |
| Common Name | Mesosulfuron-methyl | Iodosulfuron-methyl-sodium | Mefenpyr-diethyl |
| CAS-No. | 208465-21-8 | 144550-36-7 | 135590-91-9 |
| Classification and proposed labelling | | | |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | None | None | None (based on ECHA harmonised classification) |
| Additional C&L proposal | None | None | None |
| Agreed EU endpoints | | |  |
| AOEL systemic | 0.13 mg/kg bw/d (corrected for 2 % oral absorption) | 0.05 mg/kg bw/d (corrected for 70 % oral absorption) | 0.1 mg/kg bw/d (corrected for 73% oral absorption) |
| AAOEL systemic | No AAOEL derived, not necessary | No AAOEL derived, not necessary | No AAOEL derived, not necessary |
| Vapour pressure | 3.5×10-12 Pa (20°C) | 2.6×10-9 Pa (20 °C) | 6.3×10-6 Pa (20 °C) |
| Reference | EFSA Conclusion  (EFSA Journal 2016;14(10):4584)  SANTE/11827/2016 Rev 2 | EFSA Conclusion  (EFSA Journal 2016;14(4):4453)  SANTE/2016/11167 Rev 3 | FAO specification and evaluations for agricultural pesticides (mefenpyr-diethyl); DAR (2011) |
| Conditions to take into account/critical areas of concern with regard to toxicology | | | |
| According to EFSA Conclusion | Addressed in Point 6.1 above. | Addressed in Point 6.1 above. | Addressed in Point 6.1 above. |

## Toxicological Evaluation of Plant Protection Product

The applicant considers product 054-01-05 to be comparable, if not identical, to the 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. Therefore, the applicant requests identical classification to that of Atlantis 12 OD. The classification has previously been evaluated under ‘Toxicological Evaluation of Plant Protection Product’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

A summary of the acute toxicological evaluation for product 054-01-05, taken from the Atlantis 12 OD re-registration report, is given in the Table 6.3-1 below.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for 054-01-05

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study** | **Reference** | **Species (sex)** | **Results** | **Classification According to the Regulation (EC) No 1272/2008** |
| Acute oral | Anon, 2003a | Rat (Female) | LD50 ≥2000 mg/kg bw | No classification. |
| Acute dermal | Anon, 2003b | Rat (Male & Female) | LD50 > 4000 mg/kg bw | No classification |
| Acute inhalation | A.2. 4  Atlantis 12 OD | None | None | No classification |
| Acute skin irritation | Anon, 2004a | Rabbit (Female) | Non irritating | No classification |
| Acute eye irritation | Anon, 2004b | Rabbit (Female) | Irritating | Eye Irrit.2/ H319- Causes serious eye irritation |
| Buehler Skin sensitization | Anon, 2004c | Guinea pig (Female) | Non sensitising | No classification |

The information presented above in Table 6.3-1 concludes product 054-01-05 will be classified H319/Eye Irrit. 2.

**Table 6.3-2: Additional toxicological information relevant for classification/labelling of 054-01-05**

|  | Substance (concentration in product, % w/w) | Classification of the  substance  (acc. to the criteria in Reg. 1272/2008) | Reference | Classification of product (acc. to the criteria in Reg. 1272/2008) |
| --- | --- | --- | --- | --- |
| Toxicological properties of active substance(s) (relevant for classification of product) | Mesosulfuron-methyl (CAS No. 208465-19-4, 1.0% (w/w)) | None | Reg. 1272/2008 | None |
|  | Iodosulfuron-methyl-sodium  (CAS No. 144550-36-7, 0.2% (w/w)) | None | Reg. 1272/2008 | None |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | Safener - Mefenpyr-diethyl  (CAS No. 135590-91-9, 3.0% (w/w)) | None | FAO specification and evaluations for agricultural pesticides (mefenpyr-diethyl); DAR (2011) | None |
|  | Solvent kerosene (oil, Petroleum) heavy aromatic hydrocarbons (CAS No. 64742-94-5, ≥ 25 % (w/w)) | Asp. Tox. 1, H304 | Reg. 1272/2008 | None |
|  | Alcohol, C11-14-iso-, C13, ethoxylated (6 EO), methylated (fatty alcohol ethoxylate – alkyl ether) (CAS No. 1492044-51-5, ≥ 10 – < 20 % (w/w)) | Skin Sens. 1B, H317  Eye Dam. 1, H318 | Reg. 1272/2008 | Eye irritation: Category 2, H319 |
|  | Sodium docusate  (CAS No. 577-11-7, > 5.0 – < 10 % (w/w)) | Skin Irrit. 2, H315  Eye Dam. 1, H318 | Reg. 1272/2008 | Eye irritation: Category 2, H319 |
|  | Solvent kerosene (oil, Petroleum) light aromatic hydrocarbons (CAS No. 64742-95-6, > 2.0 – < 5.0 % (w/w)) | Asp. Tox. 1, H304 | Reg. 1272/2008 | None |
|  | 1,2,4-trimethylbenzene  (CAS No. 95-63-6, > 1.0 - < 5.0 % (w/w)) | Asp. Tox. 1, H304  Skin Irrit. 2, H315  Eye Irrit. 2, H319  Acute Tox. 4, H332  STOT SE 3, H335 | Reg. 1272/2008 | None |
| Further toxicological information | No data – not required |  |  |  |

## Toxicological Evaluation of Groundwater Metabolites

The following data on metabolites with the potential to reach the groundwater in concentrations above 0.1 µg/L and requiring relevance assessment were submitted. Note that the relevance assessment of the metabolites is reported in Part B.10; the submitted toxicological studies are summarized in this document.

### Metabolite 1 - AE F160459, metabolite of mesosulfuron-methyl

According to the EFSA Conclusion on mesosulfuron-methyl, AE F160459 is considered devoid of mutagenic potential based on structural similarities with mesosulfuron-methyl and AE F160460. It is proposed that no further information is required to address this point. For further details, refer to Part B10 of this dossier.

The relevance of groundwater metabolite AE F160459 has already been assessed and accepted at EU level (see EFSA conclusion Section 4, and List of Endpoints for mesosulfuron-methyl). Metabolite AE F160459 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. A summary of the relevance assessment is provided in Table 10.2-1 Part 10.

This agreed assessment is also applicable for the GAP and groundwater scenarios considered in this dRR, as predicted metabolite concentrations were always < 0.75 μg/L.

Table 6.4-4: Summary of the relevance assessment for AE F160459

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Assessment step** | | **Result of assessment** | |
|  | Non-relevance EU-agreed? | | Yes | Reference:  EFSA conclusion and LoEP of mesosulfuron,  EFSA Journal 2016;14(10):4584, Section 4 and Table 2;  EFSA Journal 2016;14(10):4584 |
|  | STEP 1 | | Metabolite of no concern? | No |
| **Quantification of groundwater contamination** | STEP 2 | | Max PECgw | 0.227 µg/L |
| Based on | FOCUS PEARL 5.5.5, Jokioinen  Winter cereals, End of winter to spring application |
| **Hazard assessment** | STEP 3 | Stage 1 | Biological activity comparable to the parent? | no |
| Stage 2 | Genotoxic properties of metabolite | non-genotoxic |
| Stage 3 | Toxic properties of metabolite; |  |
| Classification of parent | No classification and labelling required with respect to toxicological profile |
| Classification of metabolite | None |
| **Consumer health risk assessment** | STEP 4 | | Estimated consumer exposure via drinking water and other sources; threshold of concern approach | acceptable (<0.75 µg/L) |
| STEP 5 | | Refined risk assessment | N/A\* |
| Predicted exposure (% of ADI) | N/A\* |
|  | | ADI based on | N/A\* |

\* N/A: not applicable

### Metabolite 2 - AE F160460, metabolite of mesosulfuron-methyl

An overview of the results of the accepted toxicological studies for groundwater metabolite AE F160460 is given in the following table.

**Table 6.4-1: Summary of the results of toxicity studies for AE F160460**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of test, species (Guideline)** | **Result** | **Acceptability** | **Reference\*** |
| Ames Test on *Salmonella Typhimurium* | Negative | Yes | xxxxxxxxxxxx KCA 5.8.1 /04 |
| Chromosomal aberrations in Chinese Hamster V79 cells | Negative | Yes | Anon. 2012 KCA 5.8.1/05 |
| Gene mutation (HPRT) in Chinese Hamster V79 cells | Negative | Yes | Anon, 2015 KCA 5.8.1 /06 |

\* indicates that a study was reviewed at EU level

### Metabolite 3 - AE F147447, metabolite of mesosulfuron-methyl

An overview of the results of the accepted toxicological studies for groundwater metabolite AE F147447 is given in the following table.

**Table 6.4-2: Summary of the results of toxicity studies for AE F147447**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of test, species (Guideline)** | **Result** | **Acceptability** | **Reference\*** |
| Ames Test on *Salmonella Typhimurium* | Negative | Yes | Sokolowski A., 2012 KCA 5.8.1 /01 |
| Chromosomal aberrations in Chinese Hamster V79 cells | Negative | Yes | Anon, 2015 KCA 5.8.1 /02 |
| Gene mutation (HPRT) in Chinese Hamster V79 cells | Negative | Yes | Anon, 2012 KCA 5.8.1 /03 |

\* indicates that a study was reviewed at EU level

### Metabolite 4 - BCS-CV14885, metabolite of mesosulfuron-methyl

An overview of the results of the accepted toxicological studies for groundwater metabolite BCS CV14885 is given in the following table.

**Table 6.4-3: Summary of the results of toxicity studies for BCS-CV14885**

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of test, species (Guideline)** | **Result** | **Acceptability** | **Reference\*** |
| *Salmonella typhimurium* reverse mutation assay with (OECD 471) | Negative | Yes | Sokolowski A., 2013 KCA 5.8.1 /07 |
| In vitro chromosome aberration test in Chinese hamster V79 cells (OECD 473) | Negative | Yes | Anon |
| Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) | Negative | Yes | Anon, 2015b KCA 5.8.1 /09 |

\* indicates that a study was reviewed at EU level

## Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in product 054-01-05 are presented in Table 6.5-1.

Table 6.5-1: Dermal absorption rates for active substances in product 054-01-05

|  | Mesosulfuron-methyl | | Iodosulfuron-methyl-sodium | | Mefenpyr-diethyl | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Value | Reference | Value | Reference | Value | Reference |
| Concentrate | 70% | EFSA default value | 70% | EFSA default value | 70% | EFSA default value |
| Dilution | 70% | EFSA default value | 70% | EFSA default value | 70% | EFSA default value |

### Justification for proposed values – Iodosulfuron-methyl-sodium

No data on dermal absorption for Iodosulfuron-methyl-sodium in product 054-01-05 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-2: Default dermal absorption rates for Iodosulfuron-methyl-sodium

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Value** | **Justification for value** | **Acceptability of justification** |
| Concentrate | 70% | Concentration < 50 g/L | YES |
| Dilution | 70% | Default value | YES |

### Justification for proposed values – Mesosulfuron-methyl

No data on dermal absorption for Mesosulfuron-methyl in product 054-01-05 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-3: Default dermal absorption rates for Mesosulfuron-methyl

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Value** | **Justification for value** | **Acceptability of justification** |
| Concentrate | 70% | Concentration < 50 g/L | YES |
| Dilution | 70% | Default value | YES |

### Justification for proposed values – Mefenpyr-diethyl

No data on dermal absorption for Mefenpyr-diethyl in product 054-01-05 is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Table 6.5-4: Default dermal absorption rates for Mefenpyr-diethyl

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Value** | **Justification for value** | **Acceptability of justification** |
| Concentrate | 70% | Concentration < 50 g/L | YES |
| Dilution | 70% | Default value | YES |

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

The following non-dietary risk assessment has been updated to meet the requirements of ‘Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032’ and using the OPEX calculator version: v 1.0.1.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Product name and code | **054-01-05** | | | | |
| Formulation type | Oil disperable (OD) | | | | |
| Category | Herbicide | | | | |
| **Active substance(s) (incl. content)** | **Iodosulfuron-methyl-sodium**  2 g/L | **Mesosulfuron-methyl**  10 g/L | **Mefenpyr-diethyl**  30 g/L | |  |
| **AOEL systemic** | 0.05 mg/kg bw/d | 0.13 mg/kg bw/d | 0.1 mg/kg bw/d | | |
| **Inhalation absorption** | 100% | 100% | 100% |  | |
| **Oral absorption** | 70% | 2% | 73% | | |
| **Dermal absorption** | Concentrate: 70% (< 5% in formulation)  Dilution: 70% | Concentrate: 70% (< 5% in formulation)  Dilution: 70% | Concentrate: 70% (< 5% in formulation)  Dilution: 70% | | |

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

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

### Operator exposure (KCP 7.2.1)

No acute non-dietary risk assessment is included in this submission. Lack of scientific guidance or methodology is an acceptable reason for waiving according to Guidance of the European Commission[[1]](#footnote-2). The absence of such guidance on derivation of an appropriate reference dose (“AAOEL”) was recognized by

* the European Food Safety Authority[[2]](#footnote-3), and
* the European Commission Standing Committee[[3]](#footnote-4).

Therefore, this waiver is presented in line with the Guidance of the European Commission. This applies for the same degree with regard to acute operator exposure estimates.

* + - 1. **Estimation of operator exposure**

A summary of the exposure models used for the estimation of operator exposure to the active substance(s) during application of 054-01-05 according to the critical use(s) is presented in the following table. Detailed calculations are presented in Appendix 3.

**Table 6.6‑2: Exposure models for intended uses**

|  |  |
| --- | --- |
| Critical use(s) | Field crops (max. 1 x 1.5 L product/ha) |
| Model(s) | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  calculator version: v 1.0.0 |

The outcome of the estimation is presented in the following table(s).

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Mesosulfuron-methyl | | Iodosulfuron-methyl-sodium | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg/day) | % of systemic AOEL | Total absorbed dose  (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops | | | | | |
| Application rate | | 1 x 0.016125 kg a.s./ha | | 1 x 0.0033 kg a.s./ha | |
| **Spray application** (EFSA Journal 2022;20(1):7032, AOEM**;** 75th percentile)  Body weight: 60 kg | Potential | 0.1 | 93.5 | 0.04 | 83.4 |
| Work wear (arms, body and legs covered) M/L and A | 0.09 | 65.6 | 0.03 | 61.2 |
| Work wear (arms, body and legs covered) M/L and A + gloves M/L | - | 2.5 | - | 1.9 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops | | | |
| Application rate | | 1 x 0.04785 kg a.s./ha | |
| **Spray application**  (EFSA Journal 2022;20(1):7032, AOEM**;** 75th percentile)  Body weight: 60 kg | Potential | 0.3 | 255 |
| Work wear (arms, body and legs covered) M/L and A + gloves M/L | 0.008 | 8.2 |

**Operator exposure estimates performed showed that the permissible operator exposure level (AOEL) will not be exceeded under the intended use conditions when personal protective equipment is used (Work wear (arms, body and legs covered) M/L and A + gloves M/L)**

#### Measurement of operator exposure

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

### Worker exposure (KCP 7.2.3)

shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with 054-01-05 according to the critical use(s). Outcome of the estimation is presented in (longer term exposure). Detailed calculations are in .

Worker exposure is defined by the task being undertaken and the amount of active substance that is available to be dislodged. According to the EFSA guidance, crops that are similar will have similar work tasks undertaken and therefore will result in similar exposures. An exposure assessment has been carried out for the re-entry activity of inspection and irrigation which is the only relevant worker activity for field crops and covers all uses in the GAP.

Table 6.6‑4: Exposure models for intended uses

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Use No.** | **Crop type** | **Crop** | **Max. No. Applications** | **Min Application Interval (days)** | **Application rate (kg a.s./ha)**   1. **mesosulfuron** 2. **iodosulfuron** 3. **safener** | **Worker tasks** |
| 7 | Field crops | Winter soft wheat | 1 | N/A | 1. 0.016125 kg a.s./ha mesosulfuron-methyl\*, 2. 0.0033 kg a.s./ha iodosulfuron-methyl\*\*, 3. 0.04785 kg a.s./ha mefenpyr-diethyl\*\*\* | Inspection, irrigation |

\* minimum purity of ≥ 930 g/kg (Commission Implementing Regulation (EU) 2017/755)

\*\* minimum purity of ≥ 910 g/kg (Commission Implementing Regulation (EU) 2017/407)

\*\*\* minimum purity of ≥ 940 g/kg (FAO specification mefenpyr-diethyl)

Table 6.6‑5: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Field crops (max. 1 x 1.5 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  calculator version: v 1.0.0 |

The outcome of the estimation is presented in the following tables.

Table 6.6‑6: Estimated worker exposure (longer term exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Mesosulfuron-methyl | | Iodosulfuron-methyl-sodium | |
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Inspection, irrigation  Outdoor  Work rate: 2 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | | | |
| Number of applications and application rate | | 1 x 0.016125 kg a.s./ha | | 1 x 0.0033 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 12500 cm2/person/h | 0.01 | 10.9 | 0.003 | 5.8 |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0.002 | 1.2 | 0.0003 | 0.6 |
| Work wear (arms, body and legs covered) and gloves  TC: 1250 cm2/person/h | 0.001 | 1.1 | 0.0003 | 0.6 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Inspection, irrigation  Outdoor  Work rate: 2 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 0.04785 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 12500 cm2/person/h | 0.04 | 41.9 |
| Work wear (arms, body and legs covered)  TC: 1400 cm2/person/h | 0.005 | 4.7 |
| Work wear (arms, body and legs covered) and gloves  TC: 1250 cm2/person/h | 0.004 | 4.2 |

**The assessment of worker exposure carried out indicated that the permissible operator exposure level (AOEL) would not be exceeded under the conditions of intended use when personal protective equipment is used.**

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

In accordance with the EFSA guidance document, where experimentally determined DFR data are not available, the initial DFR in a first-tier assessment should assume 3µg a.s./cm2 per kg of foliage. As the risk assessment passes at the first tier, the DFR has not been refined.

#### Measurement of worker exposure

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

### Resident and bystander exposure (KCP 7.2.2)

#### Estimation of resident and bystander exposure

No acute non-dietary risk assessment is included in this submission. Lack of scientific guidance or methodology is an acceptable reason for waiving according to Guidance of the European Commission[[4]](#footnote-5). The absence of such guidance on derivation of an appropriate reference dose (“AAOEL”) was recognized by

* the European Food Safety Authority[[5]](#footnote-6), and
* the European Commission Standing Committee[[6]](#footnote-7).

Therefore, this waiver is presented in line with the Guidance of the European Commission.

Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

shows the exposure model(s) used for estimation of resident and bystander exposure to mesosulfuron-methyl, iodosulfuron-methyl-sodium and mefenpyr-diethyl. The outcome of the estimation is presented in (longer term resident exposure). Detailed calculations are in .

Table 6.6‑7: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Field crops (max. 1 x 1.5 L product/ha) |
| Model | Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032  calculator version: v 1.0. |

Table 6.6‑8: Estimated resident exposure (longer term exposure)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Mesosulfuron-methyl | | Iodosulfuron-methyl-sodium | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops  **Buffer zone: 2-3 (m)**  Drift reduction technology: No  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | | | |
| Number of applications and application rate | | 1 x 0.016125 kg a.s./ha | | 1 x 0.0033 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.002 | 1.2 | 0.0003 | 0.6 |
| Vapour (75th perc.) | 6e-10 | 4e-07 | 5e-07 | 0.0009 |
| Deposits (75th perc.) | 0.0002 | 0.1 | 4e-05 | 0.07 |
| Re-entry (75th perc.) | 0.002 | 1.5 | 0.0004 | 0.8 |
| **Sum (mean)** | 0.002 | 1.9 | 0.0005 | 1 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.0004 | 0.3 | 7e-05 | 0.1 |
| Vapour (75th perc.) | 2e-10 | 1e-07 | 2e-07 | 0.0003 |
| Deposits (75th perc.) | 8e-05 | 0.06 | 2e-05 | 0.03 |
| Re-entry (75th perc.) | 0.001 | 0.8 | 0.0002 | 0.4 |
| **Sum (mean)** | 0.001 | 0.8 | 0.0002 | 0.4 |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Tractor mounted boom spray application outdoors to low crops  **Buffer zone: 2-3 (m)**  Drift reduction technology: No  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: 365 days | | | |
| Number of applications and application rate | | 1 x 0.04785 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.005 | 4.5 |
| Vapour (75th perc.) | 0.0008 | 0.8 |
| Deposits (75th perc.) | 0.0005 | 0.5 |
| Re-entry (75th perc.) | 0.006 | 5.7 |
| **Sum (mean)** | 0.008 | 8.2 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.001 | 1.1 |
| Vapour (75th perc.) | 0.0003 | 0.3 |
| Deposits (75th perc.) | 0.0002 | 0.2 |
| Re-entry (75th perc.) | 0.003 | 3.1 |
| **Sum (mean**) | 0.003 | 3.4 |

**The assessment of the exposure of residents and/or bystanders indicated that the permissible operator exposure level (AOEL) for mesosulfuron-methyl, iodosulfuron-methyl-sodium and mefenpyr-diethyl will not be exceeded under the conditions of the intended use and maintaining a buffer zone of 2-3 m.**

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

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

### Combined exposure

The product is a mixture of two active substances and the safener mefenpyr-diethyl.

#### Exposure assessment of mesosulfuron-methyl, iodosulfuron-methyl-sodium and mefenpyr-diethyl in 054-01-05

Note: The combined toxicological effect of these active substances has not been investigated with regard to repeated dose toxicity.

At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity. Initially, the individual Hazard Quotients (HQ) are calculated for all active substances in the PPP by assessing the exposure according to appropriate models and dividing the individual exposure levels by the respective systemic AOEL. This is equivalent to the predicted exposure as % of systemic AOEL from converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6‑9: Risk assessment from combined exposure (longer term exposure)

| Application scenario | Active ingredient | Estimated exposure / AOEL (HQ) |
| --- | --- | --- |
| Operators – Tractor mounted boom spray application outdoors to low crops (work wear and gloves) | mesosulfuron-methyl | 0.025 |
| iodosulfuron-methyl-sodium | 0.019 |
| mefenpyr-diethyl | 0.082 |
| **Cumulative risk operators (HI)** | **0.126** |
| Workers – Inspection, irrigation (work wear - arms, body and legs covered) | mesosulfuron-methyl | 0.012 |
| iodosulfuron-methyl-sodium | 0.006 |
| mefenpyr-diethyl | 0.047 |
| **Cumulative risk workers (HI)** | **0.065** |
| Resident - child | **mesosulfuron-methyl** |  |
| Drift | 0.012 |
| Vapour | 0.000 |
| Deposits | 0.001 |
| Re-entry | 0.015 |
| Sum (mean) | 0.019 |
| **iodosulfuron-methyl-sodium** |  |
| Drift | 0.006 |
| Vapour | 0.000 |
| Deposits | 0.001 |
| Re-entry | 0.008 |
| Sum (mean) | 0.010 |
| **mefenpyr-diethyl** |  |
| Drift | 0.045 |
| Vapour | 0.008 |
| Deposits | 0.005 |
| Re-entry | 0.057 |
| Sum (mean) | 0.082 |
| **Cumulative risk bystander – child (HI)** |  |
| Drift | **0.063** |
| Vapour | **0.008** |
| Deposits | **0.007** |
| Re-entry | **0.08** |
| Sum (mean) | **0.111** |
| Resident - adult | **mesosulfuron-methyl** |  |
| Drift | 0.003 |
| Vapour | 0.000 |
| Deposits | 0.001 |
| Re-entry | 0.008 |
| Sum (mean) | 0.008 |
| **iodosulfuron-methyl-sodium** |  |
| Drift | 0.001 |
| Vapour | 0.000 |
| Deposits | 0.000 |
| Re-entry | 0.004 |
| Sum (mean) | 0.004 |
| **mefenpyr-diethyl** |  |
| Drift | 0.011 |
| Vapour | 0.003 |
| Deposits | 0.002 |
| Re-entry | 0.031 |
| Sum (mean) | 0.034 |
| **Cumulative risk bystander – adult (HI)** |  |
| Drift | **0.015** |
| Vapour | **0.003** |
| Deposits | **0.003** |
| Re-entry | **0.043** |
| Sum (mean) | **0.046** |

**The Hazard Index is < 1. Thus, combined exposure to all active substances in 054-01-05 is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.**

1. Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

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

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

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP 7.1.1 / 01 | Anon | 2003 | Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10 + 2 + 30 (AE  F115008 06 OD04 A1 - Atlantis liquid) Acute toxicity in the rat after oral administration  Report No.: C038675, Edition Number: M-225480-01-1 xxxxxxxxx  GLP/GEP: Yes  Unpublished | Yes | Bayer |
| KCP 7.1.2 / 01 | Anon | 2003 | Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10 + 2 + 30 (AE  F115008 06 OD04 A1 - Atlantis liquid) Acute toxicity in the rat after dermal administration  Report No.: C038677, Edition Number: M-225482-01-1 xxxxxxxxxxxxx  GLP/GEP: Yes  Unpublished | Yes | Bayer |
| KCP 7.1.4 / 01 | Anon | 2004 | Acute skin irritation / corrosion on rabbits Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10 + 2 +30 (AE F115008 06 OD04 A1 - Atlantis Liquid) 1st revised version of report AT00973  Report No.: C042947, Edition Number: M-227101-02-1 xxxxxxxxxxxxx... amended: 2004-07-21  GLP/GEP: Yes  Unpublished | Yes | Bayer |
| KCP 7.1.5 / 01 | Anon | 2004 | Acute eye irritation/corrosion on rabbits - Atlantis liquid Mesosulfuron-methyl & iodosulfuronmethyl-sodium & mefenpyr-diethyl, OD 10 + 2 + 30 Code: AE F115008 06 OD04 A1  Report No.: C039670, Edition Number: M-227104-01-1 xxxxxxxxxxxxxx  GLP/GEP: Yes  Unpublished | Yes | Bayer |
| KCP 7.1.6 / 01 | Anon | 2004 | Study for the skin sensitization effect in guinea pigs (Buehler patch test) Code: AE F115008 06 OD04 A104  Report No.: C039780, Edition Number: M-227212-02-1 xxxxxxxxxxxxxxxxx... amended: 2004-03-18  GLP/GEP: Yes  Unpublished | Yes | Bayer |

**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  5.1.1/01 | Maas, J.; Braun, R. | 1996 | Biostability after a single oral administration of 500 mg/kg body weight to a male and female rat (Phenyl-U-14C) Code: Hoe 115008  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A58314, Edition Number: M-142006-01-1  Date: 1996-08-15  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/02 | Anon | 1996 | Absorption, distribution and elimination - rat, oral high dose (500 mg/kg body weight) 14C-Hoe 115008 xxxxxxxxxxxxx  Report No.: A56257, Edition Number: M-140088-01-1, EPA MRID No.: 45108727  Date: 1996-01-29  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/03 | Anon | 1996 | Blood levels following single oral administration of 500 mg/kg body weight to male and female rats 14C-Hoe  115008 xxxxxxxxxxx, Report No.: A56258, Edition Number: M-140089-01-1, EPA MRID No.: 45108728  Date: 1996-01-29  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/04 | Anon | 1998 | Metabolism - rat, oral high dose (500 mg/kg body weight) 2-14C-triazinyl Code: Hoe 115008 xxxxxxxxxxxx  Report No.: A57609, Edition Number: M-141310-01-1, EPA MRID No.: 45108729  Date: 1998-01-23  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/05 | Anon | 1997 | Metabolism - rat, oral high dose (500 mg/kg body weight) U-14C-phenyl Code: Hoe 115008 xxxxxxxxxxxxxxx  Report No.: A57610, Edition Number: M-141311-01-1, EPA MRID No.: 45108731  Date: 1997-03-19  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/06 | Anon | 1996 | Absorption, distribution and elimination - rat, oral low dose (10 mg/kg body weight) Triazinyl-2-14C Code: Hoe 115008 xxxxxxxxxxxxx,  Report No.: A57608, Edition Number: M-141309-01-1, EPA MRID No.: 45108732  Date: 1996-12-05  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/07 | Anon | 1996 | Blood levels following single oral and intravenous administration of 10 mg/kg body weight to male and female rats 14C-Hoe 115008 xxxxxxxxxxxxx  Report No.: A58313, Edition Number: M-142005-01-1, EPA MRID No.: 45108733  Date: 1996-08-20  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/08 | Anon | 1997 | Metabolism - rat, oral low dose (10 mg/kg body weight) 2-14C-triazinyl Code: Hoe 115008 xxxxxxxxxxxxx  Report No.: A57611, Edition Number: M-141312-01-1, EPA MRID No.: 45108801  Date: 1997-05-06  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/09 | Anon | 1998 | Dog absorption, distribution, elimination - oral low (6 mg/kg b.w.) and high (200 mg/kg b.w.) dose (Phenyl-U-14C)AE F115008 xxxxxxxxxxxxxxx,  Report No.: C000382, Edition Number: M-180570-01-1  Date: 1998-01-21  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/10 | Anon | 1998 | Dog metabolism - oral high (200 mg/kg body weight) and low dose (6 mg/kg body weight) U-14C-phenyl-AE F115008 xxxxxxxxxxxxxxx  Report No.: A67649, Edition Number: M-148018-01-1, EPA MRID No.: 45108804  Date: 1998-06-15  GLP/GEP: yes Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/11 | Anon | 1998 | Rat absorption, distribution, elimination - repeated oral dose (7 x 100 mg/kg bw) (Phenyl-U-14C) Code: AE F115008 xxxxxxxxxxxxxxxxxx  Report No.: C000383, Edition Number: M-180572-01-1, EPA MRID No.: 45108802  Date: 1998-03-27  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/12 | Anon | 1998 | Rat metabolism - Repeated oral dose (7 x 100 mg/kg body weight) U-14C-phenyl-AE F115008 xxxxxxxxxxxxx,  Report No.: C000362, Edition Number: M-180530-01-1, EPA MRID No.: 45108803  Date: 1998-07-31  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/13 | Anon | 2013 | [Triazinyl-2-14C]iodosulfuron-methyl-sodium: Metabolic stability and profiling in liver microsomes from rats and humans for inter-species comparison xxxxxxxxxxxxxxxxxx  Report No.: EnSa-13-0828, Edition Number: M-470475-01-1  Date: 2013-11-15  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.1.1/14 | Koester, J. | 2013 | [Triazinyl-2-14C]Iodosulfuron-methyl-sodium :Isolation and identification of metabolite(s) from an in-vitro study with human liver microsomes Bayer CropScience,  Report No.: EnSa-13-0692, Edition Number: M-465993-01-1  Date: 2013-10-01  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.1.2/01 | Anon | 1998 | Dermal absorption in the rat (14C)-AE F115008 xxxxxxxxxxxxxx  Report No.: C001303, Report includes Trial Nos.: TOX98090, Edition Number: M-182308-01-1, EPA MRID No.: 45108915  Date: 1998-10-28  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.1/01 | Anon | 1993 | Acute oral toxicity in the male and female Wistar rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001 xxxxxxxxxxxxxx  Report No.: A51192, Edition Number: M-132162-01-1, EPA MRID No.: 45133404  Date: 1993-08-10  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.2/01 | Anon | 1993 | Acute dermal toxicity in the male and female Wistar rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001 xxxxxxxxxxxxxxxxxx  Report No.: A51142, Edition Number: M-132113-01-1, EPA MRID No.: 45133405  Date: 1993-07-21  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.3/01 | Anon | 1996 | Acute aerosol inhalation toxicity in the male and female SPF Wistar rat 4-hour LC50 Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxxxxxxxxxx  Report No.: A57043, Report includes Trial Nos.: 95.0516, Edition Number: M-140802-01-1, EPA MRID No.: 45108805,  Date: 1996-05-29  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.4/01 | Anon | 1993 | Primary dermal irritation in the rabbit Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001 xxxxxxxxxxxxxxxxxx,  Report No.: A51143, Edition Number: M-132114-01-1, EPA MRID No.: 45133406  Date: 1993-07-26  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.5/01 | Anon | 1993 | Primary eye irritation in the rabbit Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001 xxxxxxxxxxxxxxxx  Report No.: A51144, Edition Number: M-132115-01-1, EPA MRID No.: 45133407  Date: 1993-07-22  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.6/01 | Anon | 1996 | Sensitizing properties in the Pirbright-White guinea pig in a maximization test Hoe 115008 substance, technical  Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxx  Report No.: A57254, Report includes Trial Nos.: 96.0122, Edition Number: M-140993-01-1, EPA MRID No.: 45108806  Date: 1996-07-22  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.2.7/01 | Heppenheimer, A. | 2013 | Iodosulfuron-methyl sodium TC: Cytotoxicity assay in vitro with BALB/c 3T3 cells: Neutral Red (NR) test during simultaneous irradiation with artificial sunlight  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience,  Report No.: 1579600, Edition Number: M-479598-01-1  Date: 2013-12-03  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.3/01 | Anon | 1998 | Dog 12 month oral (dietary) toxicity study AE F115008 (Hoe 115008) code:AE F115008 00 1C89 0001 xxxxxxxxxxxxxxxxx  Report No.: C000689, Report includes Trial Nos.: TOX94466, Edition Number: M-181091-01-1, EPA MRID No.: 45108810  Date: 1998-08-20  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.3.1/01 | Anon | 1998 | Dog 28-day dietary range-finding study Hoe 115008 (AE F115008) technical substances Code: Hoe 115008 00 ZC93 0001 xxxxxxxxxxxxxxxx  Report No.: C000688, Report includes Trial Nos.: TOX94463, Edition Number: M-181089-01-1, EPA MRID No.: 45108807  Date: 1998-08-20  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.3.2/01 | Anon | 1997 | 90-day dietary repeat dose study on rat with 4 week regression Hoe 115008 93.8 % w/w Code: Hoe 115008 00 ZC93  0001 xxxxxxxxxxxxxxxxxxxxx  Report No.: A58942, Report includes Trial Nos.: TOX94238, Edition Number: M-142651-01-1, EPA MRID No.: 45133408  Date: 1997-06-19  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.3.2/02 | Anon | 1998 | Dog 90-day oral (dietary ) toxicity study Hoe 115008 (AE F115008) technical substance Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxx  Report No.: C000173, Report includes Trial Nos.: Tox94465, Edition Number: M-180321-01-1, EPA MRID No.: 45108809  Date: 1998-07-14  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.3.2 /03 | Anon | 1997 | Mouse 90-day dietary repeat dose study (report and addendum) Hoe 115008 93.8 % w/w Code: Hoe 115008 00 ZC93 0001 xxxxxxxxxxxxxxxxxxxxxx  Report No.: A59401, Report includes Trial Nos.: TOX/94236, Edition Number: M-143075-01-1, EPA MRID No.: 45108808  Date: 1997-10-07  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.4.1 /01 | Stammberger, I. | 1993 | Mutagenic potential in strains of Salmonella typhimurium (Ames test) and Escherichia coli Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience, Report No.: A51035, Edition Number: M-132017-01-1, EPA MRID No.: 45133409  Date: 1993-07-07  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.4.1 /02 | Anon | 1996 | In vitro mammalian chromosome aberration test in V79 Chinese hamster cells Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxReport No.: A57511, Edition Number: M-141224-01-1, EPA MRID No.: 45108812  Date: 1996-09-23  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.4.1 /03 | Anon | 1996 | Detection of DNA strand breaks in primary hepatocytes of male rats in vitro UDS - test in primary rat hepatocytes  Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxx  Report No.: A57977, Edition Number: M-141703-01-1, EPA MRID No.: 45108813  Date: 1996-10-28  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.4.1 /04 | Anon | 1996 | In vitro mammalian cell gene mutation test HPRT-test with V79 Chinese Hamster cells Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 Xxxxxxxxxx  Report No.: A57293, Edition Number: M-141032-01-1, EPA MRID No.: 45108811  Date: 1996-08-13  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.4.2 /01 | Anon | 1996 | Mammalian erythrocyte micronucleus test in male and female NMRI mice Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxxxxxxxx  Report No.: A57253, Edition Number: M-140992-01-1, EPA MRID No.: 45108814  Date: 1996-08-21  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA 5.5  /01 | Anon | 1998 | Rat dietary combined chronic toxicity and oncogenicity study AE F115008 (Hoe 115008) Code: AE F115008 00 1C89 0001 xxxxxxxxxxxxxxxxxx  Report No.: C001157, Report includes Trial Nos.: TOX94468, Edition Number: M-181889-01-1, EPA MRID No.: 45108815  Date: 1998-10-23  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA 5.5  /02 | Anon | 1998 | Mouse dietary 18 month oncogenicity study AE F115008 (Hoe 115008) Code: AE F115008 00 1C89 0001 xxxxxxxxxxxxxxxx  Report No.: C001158, Report includes Trial Nos.: TOX94467, Edition Number: M-181896-01-1, EPA MRID No.: 45108816  Date: 1998-10-23  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.6 | Anon | 2014 | Position Paper: Iodosulfuron-methyl-sodium. Response to initial questions from kemI during 2014 re-registration process.  Edition Number: M-502267-01-1  Date: 2014-11-18 | Y | Bayer CropScience |
| KCA  5.6.6 | Anon | 2015 | Position Paper: Iodosulfuron-methyl-sodium. Response to further questions from kemI during re-registration process. Edition Number: - Date: 2015-01-27 | Y | Bayer CropScience |
| KCA  5.6.1 /01 | Anon | 1998 | Range finding feeding-reproduction study for a two-generation reproduction toxicity study in rats Hoe 115008 substance technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxx  Report No.: C001447, Report includes Trial Nos.: 96.0406, Edition Number: M-182647-01-1, EPA MRID No.: 45108817  Date: 1998-10-16  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.1 /02 | Anon | 1998 | Two-generation feeding-reproduction toxicity study in rats Hoe 115008 substance technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxxxxxx  Report No.: C001514, Report includes Trial Nos.: 96.0699, Edition Number: M-182825-01-1, EPA MRID No.: 45108818  Date: 1998-11-09  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.2 /01 | Anon | 1996 | Range finding embryotoxicity study after oral administration in Wistar rats Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxxxxx,  Report No.: A56889, Report includes Trial Nos.: 95.0316  Edition Number: M-140665-01-1, EPA MRID No.: 45108819  Date: 1996-05-16  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.2 /02 | Anon | 1996 | Oral developmental toxicity (teratogenicity) study - rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxx  Report No.: A57677, Report includes Trial Nos.: 95.0354, Edition Number: M-141359-01-1, EPA MRID No.: 45108820  Date: 1996-10-23  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.2 /03 | Anon | 1996 | Range finding embryotoxicity study after oral administration in Himalayan rabbits Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 Hoechst AG, Frankfurt am Main, Germany Bayer CropScience,  Report No.: A56721, Report includes Trial Nos.: 95.0315, Edition Number: M-140510-01-1, EPA MRID No.: 45108821  Date: 1996-04-16  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.6.2 /04 | Anon | 1996 | Rabbit oral developmental toxicity (teratogenicity) study Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001 xxxxxxxxxxxxxxxx  Report No.: A57676, Report includes Trial Nos.: 96.0353, Edition Number: M-141358-01-1, EPA MRID No.: 45108901  Date: 1996-10-10  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.8.1 /01 | Anon | 1989 | Acute oral toxicity study in rats with 2-amino-4-methoxy-6-methyl-S-triazine xxxxxxxxxxxxxxxxxxxxx x  Edition Number: M-182294-01-1  Date: 1989-10-05  GLP/GEP: Yes  Unpublished | Y | SKW  Trostberg,  Germany |
| KCA  5.8.1 /02 | Mertschenk B. | 1998 | Letter of access to use HLA Study No. 2319-132 for registration purposes 2-Amino-4-methoxy-6-methyl-s-triazin SKW Trostberg AG, Germany;Product Safety/Toxicology  Report No.: C001736, Edition Number: M-182299-01-2  Date: 1998-10-16  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.8.1 /03 | Stammberger, I.; Braun, K | 1998 | Bacterial reverse mutation test AE F059411 substance, technical Code: AE F059411 00 1C99 0001 Hoechst Marion Roussel, Frankfurt am Main, Germany  Report No.: C000993, Report includes Trial Nos.: 98.0460, Edition Number: M-181601-01-1, EPA MRID No.: 45108903  Date: 1998-09-15  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.8.1 /04 | Anon | 1998 | Acute oral toxicity in the male and female Sprague Dawley rat AE F114368 substance, technical Code: AE F114368 00 1C99 0001 xxxxxxxxxxxxxxxxxxxx  Report No.: C001347, Report includes Trial Nos.: 98.0457, Edition Number: M-182408-01-1, EPA MRID No.: 45108907  Date: 1998-10-01  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.8.1 /05 | Stammberger, I.; Braun, K. | 1998 | Bacterial reverse mutation test AE F114368 substance, technical Code: AE F114368 00 1C99 0001 Hoechst Marion Roussel, Frankfurt am Main, Germany  Report No.: C001107, Report includes Trial Nos.: 98.0458, Edition Number: M-181800-01-1, EPA MRID No.: 45108908  Date: 1998-09-07  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.8.1 /06 | Anon | 1998 | Acute oral toxicity in the male and female Sprague Dawley rat AE F143133 substance, technical Code: AE F143133  00 1C98 0001 xxxxxxxxxxxxxxxxxxxx  Report No.: C001252, Report includes Trial Nos.: 98.0539, Edition Number: M-182169-01-1, EPA MRID No.: 45108909  Date: 1998-11-11  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.8.1 /07 | Stammberger, I.; Braun, K. | 1998 | Bacterial reverse mutation test AE F143133 substance, technical Code: AE F143133 00 1C98 0001 Hoechst Marion Roussel, Frankfurt am Main, Germany  Report No.: C001348, Report includes Trial Nos.: 98.0540, Edition Number: M-182410-01-1, EPA MRID No.: 45108910  Date: 1998-10-29  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.8.2 /01 | Anon | 1998 | Acute dermal toxicity in the male and female Sprague Dawley rat AE F114844 substance, technical Code: AE F114844 00 1C97 0001 xxxxxxxxxxxxxxxxxxx  Report No.: C001253, Report includes Trial Nos.: 98.0541, Edition Number: M-182172-01-1, EPA MRID No.: 45108905  Date: 1998-10-22  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.8.2 /02 | Stammberger, I.; Braun, K. | 1998 | Bacterial reverse mutation test AE F114844 substance, technical Code: AE F114844 00 1C97 0001 Hoechst Marion Roussel, Frankfurt am Main, Germany  Report No.: C001344, Report includes Trial Nos.: 98.0543, Edition Number: M-182403-01-1, EPA MRID No.: 45108906  Date: 1998-10-15  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |
| KCA  5.8.2 | Anon | 2001 | 4-week toxicity study by oral route (dietary admixture) in beagle dogs followed by a 12-week treatment-free period xxxxxxxxxxxxxxxxxxxxxxx,  Report No.: 21602 TSC, Edition Number: M-454791-01-1  Date: 2001-10-29  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.9.1 /01 | Anon | 1998 | Medical data. Medical surveillance of manufacturing plant personnel. Proposed first aid measures Jodosulfuron  Code: AE F115008 xxxxxxxxxxxxxxxx  Report No.: C001333, Edition Number: M-182378-01-1, EPA MRID No.: 45108914  Date: 1998-10-29  GLP/GEP: Yes  Unpublished | Y | Bayer CropScience |
| KCA  5.9.1 /02 | Steffens, W. | 2014 | Occupational medical experiences with iodosulfuron-methyl-sodium  Bayer CropScience,  Report No.: M-476230-01-1, Edition Number: M-476230-01-1  Date: 2014-01-20  GLP/GEP: Yes  Unpublished | N | Bayer CropScience |

**Mesosulfuron-methyl**

| 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 5.1.1 /10 | Anon | 2013 | [Pyrimidyl-2-14C]mesosulfuron-methyl: Metabolic stability and profiling in liver microsomes from rats and humans for Inter-Species Comparison  Bayer CropScience,  Report No.: EnSa-13-0829, Edition Number: M-470477-01-1  Date: 2013-11-15  GLP/GEP: Yes  Unpublished | Y | Bayer |
| KCA 5.2.6 /02 | Anon | 2003 | 1st amentment to report no.: AT00537 of July 10.2003 - Study for the skin sensitization effect in guinea pigs (Guinea pig maximization test according to Magnusson and Kligman)  Bayer CropScience,  Report No.: T3072716, Edition Number: M-235831-02-1  Date: 2003-07-10...Amended: 2016-02-29  GLP/GEP: Yes  Unpublished | Y | Bayer |
| KCA 5.2.7 /01 | Heppenheimer, A. | 2014 | Mesosulfuron-methyl (AE F130060) technical: Cytotoxicity assay in vitro with BALB/c3T3 c31 cells:  Neutral Red (NR) test during simultaneous irradiation with artificial sunlight  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience,  Report No.: 1592100,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.4.1 /05 | Sokolowski, A | 2016 | Mesosulfuron-methyl (AE F130060): Salmonella typhimurium reverse mutation assay Envigo CRS GmbH, Rossdorf, Germany  Bayer CropScience,  Report No.: 1744700,  Edition Number: M-547488-01-1  Date: 2016-02-12  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /01 | Sokolowski, A. | 2012 | Salmonella typhimurium reverse mutation assay with AE F147447  Harlan CCR, Rossdorf, Germany  Bayer CropScience,  Report No.: 1462101,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /02 | Anon | 2015 | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F147447 xxxxxxxxxxxxxxxx  Report No.: 1462102,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /03 | Anon | 2012 | Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F147447 xxxxxxxxxxxxxxxxx  Report No.: 1462103,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /04 | Sokolowski, A. | 2012 | Salmonella typhimurium reverse mutation assay with AE F160460  Harlan CCR, Rossdorf, Germany  Bayer CropScience,  Report No.: 1462301,  Edition GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /05 | Anon | 2015 | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F160460 xxxxxxxxxxxxxxxxx  Report No.: 1462302,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /06 | Anon | 2015 | Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE  F160460 xxxxxxxxxxxxxxxxxxxxx  Report No.: 1462303,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1/07 | Sokolowski, A. | 2012 | Salmonella typhimurium reverse mutation assay with BCS-CV14885  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany Bayer CropScience,  Report No.: 1490201,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /08 | Anon | 2015 | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with BCSCV14885 xxxxxxxxxxxxxxxxx  Report No.: 1490202,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KCA 5.8.1 /09 | Anon | 2015 | Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) - BCS-CV14885 xxxxxxxxxxxxxxxxx  Report No.: 1490203,  GLP/GEP: Yes  Unpublished | N | Bayer |
| KIIIA  7.1.1 /01  (KCP  7.1.1/01) | Anon | 2003a | Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10+2+30 (AE F115008 06 OD04 A1 - Atlantis liquid) Acute toxicity in the rat after oral administration  Report No: AT00872. Bayer CropScience, No.: C038675,  Date: 2003-12-12  GLP/GEP: Yes  Unpublished | Y | Bayer |
| KIIIA  7.1.2 /01  (KCP  7.1.2/01) | Anon | 2003b | Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10+2+30 (AE F115008 06 OD04 A1 - Atlantis liquid) Acute toxicity in the rat after dermal administration  Report No.: AT00871. Bayer CropScience, Report No.: C038677,  Date: 2003-12-12  GLP/GEP: Yes  Unpublished | Y | Bayer |
| KIIIA  7.1.4 /01  (KCP 7.1.4/01) | Anon | 2004a | Acute skin irritation / corrosion on rabbits Mesosulfuron-methyl & iodosulfuron-methyl-sodium & mefenpyr-diethyl OD 10 + 2 +30 (AE F115008 06 OD04 A1 - Atlantis Liquid) 1st revised version of report AT00973  Report No.: AT01349. Bayer CropScience, Report No.: C042947  Date: 2004-02-05, Amended: 2004-07-21  GLP/GEP: Yes  Unpublished | Y | Bayer |
| KIIIA  7.1.6 /01  (KCP  7.1.6/01) | Anon | 2004 | Study for the skin sensitization effect in guinea pigs (Buehler patch test) Code: AE F115008 06 OD04 A104  Report No.: AT00991A. Bayer CropScience, Report no.: C039780/C040677  Date: Mar. 22, 2004.  GLP/GEP: Yes  Unpublished | Y | 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 |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |

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

Please refer to Part B6 Section A 2.1 ‘Statement on bridging possibilities’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | N/A |

* 1. Acute oral toxicity (KCP 7.1.1)

Please refer to Part B6 Section A 2.2 ‘Acute oral toxicity (KCP 7.1.1)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | **The study for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is not classified LD50 ≥2000 mg/kg bw** |

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

Please refer to Part B6 Section A 2.3 ‘Acute percutaneous (dermal) toxicity (KCP 7.1.2)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | **The study for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is not classified LD50 >4000 mg/kg bw** |

* 1. Acute inhalation toxicity (KCP 7.1.3)

Please refer to Part B6 Section A 2.4 ‘Acute inhalation toxicity (KCP 7.1.3)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | **Calculation for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is not classified** |

* 1. Skin irritation (KCP 7.1.4)

Please refer to Part B6 Section A 2.5 ‘Skin irritation (KCP 7.1.4)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

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| --- | --- |
| Comments of zRMS: | **The study for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is not classified** |

* 1. Eye irritation (KCP 7.1.5)

Please refer to Part B6 Section A 2.6 ‘Eye irritation (KCP 7.1.5)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | **The study for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is classified H319/Eye Irrit.2** |

* 1. Skin sensitisation (KCP 7.1.6)

Please refer to Part B6 Section A 2.7 ‘Skin sensitisation (KCP 7.1.6)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

|  |  |
| --- | --- |
| Comments of zRMS: | **The study for ATLANTIS is acceptable**  **According to the Regulation (EC) No 1272/2008 as amended, the formulation ATLANTIS 12 OD is not isensitisating to skin and then is not classified** |

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

Please refer to Part B6 Section A 2.8 ‘Supplementary studies for combinations of plant protection products (KCP 7.1.7)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

* 1. Data on co-formulants (KCP 7.4)

Please refer to Part B6 Section A 2.9 ‘Data on co-formulants (KCP 7.4)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

* 1. Studies on dermal absorption (KCP 7.3)

Please refer to Part B6 Section A 2.10 ‘Studies on dermal absorption (KCP 7.3)’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

* 1. Other/Special Studies

Please refer to Part B6 Section A 2.11 ‘Other/Special Studies’ of the Atlantis 12 OD re-registration report submitted by Bayer AG.

1. Exposure calculations

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| --- | --- | --- | --- |
| **Crop** | **Active substance assessment carried out** | **EFSA modelling file** | **Model Output** |
| Field crop | Mesosulfuron-methyl, Iodosulfuron-methyl-sodium, Mefenpyr-diethyl |  |  |

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

1. Guidance Document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013, May 2013 [↑](#footnote-ref-2)
2. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2022;20(1):7032 [↑](#footnote-ref-3)
3. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. SANTE-10832-2015 [↑](#footnote-ref-4)
4. Guidance Document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013. SANCO/10181/2013, May 2013 [↑](#footnote-ref-5)
5. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2022;20(1):7032 [↑](#footnote-ref-6)
6. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. SANTE-10832-2015 [↑](#footnote-ref-7)