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| FINAL REGISTRATION REPORT  **Part B**  Section 6  Mammalian Toxicology  Detailed summary of the risk assessment |
| Product code: IMS+MSM+MPR 2+10+30 OD  Product name(s): CERENET  Chemical active substances:  Iodosulfuron-methyl-sodium, 2 g/L  Mesosulfuron-methyl, 10 g/L  Mefenpyr-diethyl (safener), 30 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant: Certiplant BV  Submission date: June 2024 – January 2025  MS Finalisation date: 01.2025; 04.2025 ; 12/2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| June 2024 | dRR submission by applicant |
| January 2025 | dRR updated by applicant in response to evaluator questions |
| January 2025 | Initial evaluation |
| April 2025 | Assessment after an update by the Applicant |
| December 2025 | Updated |

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# Mammalian Toxicology (KCP 7)

This document is a summary of the data submitted to support the registration of the plant protection product IMS+MSM+MPR 2+10+30 OD.

## Summary

Table 6.1‑1: Information on IMS+MSM+MPR 2+10+30 OD \*

|  |  |
| --- | --- |
| Product name and code | 1. IMS+MSM+MPR 2+10+30 OD / CERENET |
| Formulation type | Oil dispersion (OD) |
| Active substance(s) (incl. content) | Iodosulfuron-methyl-sodium; 2 g/L  Mesosulfuron-methyl; 10 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 IMS+MSM+MPR 2+10+30 OD can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

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

Table 6.1‑2: Justified proposals for classification and labelling for IMS+MSM+MPR 2+10+30 OD according to Regulation (EC) No 1272/2008

|  |  |
| --- | --- |
| Hazard class(es), categories | Skin Sens. 1B, Eye Dam 1, Aquatic Chronic 2 |
| Hazard pictograms or Code(s) for hazard pictogram(s) | GHS05, GHS07, GHS09 |
| Signal word | Danger |
| Hazard statement(s) | H317, H318, H411 |
| Precautionary statement(s) | P261, P273, P280, P302+P352, P305+P351+P338, P333+P313, P501 |
| Additional labelling phrases | To avoid risks to man and the environment, comply with the instructions for use. [EUH401] |

Table 6.1‑3: Summary of risk assessment for operators, workers, residents and bystanders for IMS+MSM+MPR 2+10+30 OD

|  | Result | PPE / Risk mitigation measures |
| --- | --- | --- |
| Operators | Acceptable | Gloves during mixing/loading and workwear during mixing/loading and application |
| Workers | Acceptable | None |
| Residents | Acceptable | None |
| Bystanders | Acceptable | None |

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

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

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

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No.\* | Crops and situation (e.g. growth stage of crop) | F, Fn, Fpn G, Gn, Gpn or I \*\* | Application | | Application rate | | PHI (d) | Remarks:   (e.g. safener/synergist (L/ha))  critical gap for operator, worker, resident or bystander exposure based on [Exposure model] | Acceptability of exposure assessment | | | |
| Method / Kind  (incl. application technique \*\*\* | Max. number (min. interval between applications)  a) per use  b) per crop/ season | Max. application rate  kg as/ha   a) IMS b) MSM | Water L/ha  min / max | Operator | Worker | Residents | Bystander |
| 1 | Winter cereals  (BBCH 21-31) | F | Spraying, LCTM | 1 ; 1 | a) 0.003 b) 0.010 | 200 - 400 | - | Safener: mefenpyr-diethyl: 0.045 kg/ha |  |  |  |  |

\* 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

N/A

Noticed data gaps are:

* data gap 1
* data gap 2c
* data gap 3

## 6. 2 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) and safener

|  | Iodosulfuron-methyl-sodium | Mesosulfuron-methyl | Mefenpyr-diethyl (Safener) |
| --- | --- | --- | --- |
| Common Name | Iodosulfuron-methyl-sodium | Mesosulfuron-methyl | Mefenpyr-diethyl |
| CAS-No. | 144550-36-7 | 208465-21-8 | 135590-91-9 |
| Classification and proposed labelling | | |  |
| With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended) | Hazard classes, categories: None  Code(s) for hazard pictogram(s): None  Signal word: None  Hazard statement(s): None | Hazard classes, categories: None  Code(s) for hazard pictogram(s): None  Signal word: None  Hazard statement(s): None | Hazard classes, categories: None  Code(s) for hazard pictogram(s): None  Signal word: None  Hazard statement(s): None |
| Additional C&L proposal | / | / | / |
| Agreed EU endpoints | | |  |
| AOEL systemic | 0.05 mg/kg bw/d  (corrected for 70% oral absorption) | 0.13 mg/kg bw/d  (corrected for 2% oral absorption) | 0.1 mg/kg bw/d  (corrected for 73% oral absorption) |
| Reference | EFSA Journal 2016;14(4):4453 | EFSA Journal 2016;14(10):4584 | FAO specification and evaluations for agricultural pesticides (mefenpyr-diethyl); DAR (2011) |
| Conditions to take into account/critical areas of concern with regard to toxicology | | | |
| Review Report/EFSA Conclusion for active substance | None | None | None |

## 6.3 Toxicological Evaluation of Plant Protection Product

According to Reg. (EC) No. 1107/2009 Art. 62 and the animal welfare Directive Dir. 2010/63/EU, animal testing should be minimised and tests on vertebrates should be undertaken as a last resort. Therefore, no vertebrate studies have been performed to assess the acute toxicity of IMS+MSM+MPR 2+10+30 OD.

IMS+MSM+MPR 2+10+30 OD can be classified by calculation, taking into account the amount and classification of the different components in accordance with Regulation (EC) No 1272/2008. Reference is made to Part C for more detailed information on the components.

Table 6.3‑1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for IMS+MSM+MPR 2+10+30 OD

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Type of test, species, model system (Guideline) | Result | Acceptability | Classification  (acc. to the criteria in Reg. 1272/2008) | Reference |
| Acute oral toxicity  (Calculation) | None of the components of the product are classified as acutely oral toxic | Yes | None | - |
| Acute dermal toxicity  (calculation) | None of the components of the product are classified as acutely dermal toxic | Yes | None | - |
| Acute inhalation toxicity  (calculation) | None of the components of the product are classified as acutely inhalation toxic | Yes | None | - |
| Skin irritation  (calculation) | One of the components of the product is classified as skin irritation cateegory 2, however the amount is below the SCL | Yes | None | - |
| Eye irritation,  (calculation) | Two components of the product are classified as eye damage, category 1. Their amount is above the SCL | Yes | Eye Dam.1/H318 | - |
| Skin sensitisation  (calculation) | One of the components of the product is classified as skin sensitisation category 1B in an amount above the SCL | Yes | Skin Sens.1B/H317 | - |
| Supplementary studies for combinations of plant protection products | No data – not required | -- | -- | - |

Table 6.3‑2: Additional toxicological information relevant for classification/labelling of IMS+MSM+MPR 2+10+30 OD

|  | 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) | Iodosulfuron-methyl-sodium (0.22% (w/w)) | 1. Aquatic Acute 1, H400 2. Aquatic Chronic 1, H410 | Reg. 1272/2008 | Aquatic Chronic 2, H411  (M × 10 × Chronic 1) + Chronic 2 ≥ 25 % 🡪 Aquatic Chronic 2 |
| Toxicological properties of active substance(s) (relevant for classification of product) | Mesosulfuron-methyl  (1.04% (w/w)) | Aquatic Acute 1, H400  Aquatic Chronic 1, H410 | Reg. 1272/2008 |
| Toxicological properties of safener (relevant for classification of product) | Mefenpyr-diethyl  (3.10% (w/w)) | Aquatic Chronic 2, H411 | FAO specification and evaluations for agricultural pesticides (mefenpyr-diethyl); DAR (2011) |
| Toxicological properties of non-active substance(s) (relevant for classification of product) | 3 coformulants with a total sum of 62.64 % (w/w)) | Aquatic Chronic 2, H411 | MSDS\*\* |
| Further toxicological information | No data – not required |  |  |  |

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

\*\*Material safety data sheet by the supplier

## 6.4 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.

### The relevance of groundwater metabolite AE F160460 has already been assessed and accepted at EU level (see EFSA conclusion Section 4, and List of Endpoints for mesosulfuron-methyl). Metabolite AE F160460 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11.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.

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 | xxxxxxxxxxxxx  xxxxxx  KCA 5.8.1/04\* |
| Chromosomal aberrations in Chinese hamster V79 cells | Negative | Yes | xxxxxxxxxxxxxx  xxxx  KCA 5.8.1/05\* |
| Gene mutation (HPRT) in Chinese hamster V79 cells | Negative | Yes | xxxxxxxxxxxxxxxx  KCA 5.8.1/06\* |

\* indicates that a study was reviewed at EU level

### 6.4.2 Metabolite 2 – AE F147447, metabolite of mesosulfuron-methyl

The relevance of groundwater metabolite AE F147447 has already been assessed and accepted at EU level (see EFSA conclusion Section 4, and List of Endpoints for mesosulfuron-methyl). Metabolite AE F147447 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. 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.**

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 | xxxxxxxxxxxxxx  xxxxx  KCA 5.8.1/01\* |
| Chromosomal aberrations in Chinese hamster V79 cells | Negative | Yes | xxxxxxxxxxxxxx  xxxx  KCA 5.8.1/02\* |
| Gene mutation (HPRT) in Chinese hamster V79 cells | Negative | Yes | xxxxxxxxxxxxxxxx  KCA 5.8.1/03\* |

### 6.4.3 Metabolite 3 – BCS-CV14885, metabolite of mesosulfuron-methyl

The relevance of groundwater metabolite BCS-CV14885 has already been assessed and accepted at EU level (see EFSA conclusion Section 4, and List of Endpoints for mesosulfuron-methyl). Metabolite BCSCV14885 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.11. 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**

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 | xxxxxxxxxxxxxxxxx  KCA 5.8.1/07\* |
| In vitro chromosome aberration test in Chinese hamster V79 cells (OECD 473) | Negative | Yes | xxxxxxxxxxxx  xxxxx  KCA 5.8.1/08\* |
| Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) | Negative | Yes | xxxxxxxxxxxxxxxxx  KCA 5.8.1/09\* |

\* indicates that a study was reviewed at EU level

## 6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in IMS+MSM+MPR 2+10+30 OD are presented in the following table.

Table 6.5‑1: Dermal absorption rates for active substances and safener in IMS+MSM+MPR 2+10+30 OD

|  | Iodosulfuron-methyl-sodium | | Mesosulfuron-methyl-sodium | | Mefenpyr-diethyl (safener) | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Value | Reference | Value | Reference | Value | Reference |
| Concentrate | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) |
| Dilution | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) | 70% | Default value – EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873) |

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

No data on dermal absorption for iodosulfuron-methyl-sodium in IMS+MSM+MPR 2+10+30 OD 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% | Default value (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 IMS+MSM+MPR 2+10+30 OD 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% | Default value (Concentration < 50 g/L) | Yes |
| Dilution | 70% | Default value | Yes |

* + 1. **Justification for proposed values – mefenpyr-diethyl**

No data on dermal absorption for mefenpyr-diethyl in IMS+MSM+MPR 2+10+30 OD 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 mefenpyr-diethyl**

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| Product name and code | IMS+MSM+MPR 2+10+30 OD / CERENET | | |
| Formulation type | Oil dispersion (OD) | | |
| Category | Herbicide | | |
| Active substance(s) (incl. content) | **Iodosulfuron-methyl-sodium (IMS)**  2 g/L | **Mesosulfuron-methyl (MSM)**  10 g/L | **Mefenpyr-diethyl**  **(MPR)**  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%  Dilution: 70% | Concentrate: 70%  Dilution: 70% | Concentrate: 70%  Dilution: 70% |

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

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

### Operator exposure (KCP 7.2.1)

#### Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of IMS+MSM+MPR 2+10+30 OD according to the critical use(s) is presented in Table 6.6‑2. The outcome of the estimation is presented in Table 6.6‑3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6‑2: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereals (max. 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  OPEX version: 0.3.22 |

Table 6.6.2-1: Estimated operator exposure (long-term exposure)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | Iodosulfuron-methyl-sodium | | Mesosulfuron-methyl | | Mefenpyr-diethyl | |
| 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 | Total absorbed dose  (mg/kg bw/day) | % of systemic AOEL |
| Outdoor, downward spraying, vehicle-mounted, field crops | | | | | | | | |
| Application rate | | 0.003 kg a.s./ha | | | 0.015 kg a.s./ha | | 0.045 kg a.s./ha | |
| **Spray application outdoor** (75th percentile)  Body weight: 60 kg | Work wear (arms, body and legs covered) M/L and A | 0.03 | | 57.5 | 0.08 | 62.6 | 0.166 | 166 |
| Work wear (arms, body and legs covered) + gloves during M/L  Work wear (arms, body and legs covered) during A | 0.001 | | 1.8 | 0.003 | 2.4 | 0.008 | 7.8 |

#### The operator exposure estimates performed showed that the permissible operator exposure level (AOEL) will not be exceeded under the intendent of use and using work wear (arms, body and legs covered) + gloves during M/L oraz work wear (arms, body and legs covered) during A.

#### ~~6.6.2.1 Measurement of operator exposure~~

#### ACCEPTED

#### 6.6.2.2 Measurement of operator exposure

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

### 6.6.3 Worker exposure (KCP 7.2.3)6.6.3 Estimation of worker exposure

Table 6.6‑5 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with IMS+MSM+MPR 2+10+30 OD according to the critical use(s). Outcome of the estimation is presented in Table 6.6‑5 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6.3-1: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereals (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  OPEX version: 0.3.22 |

Table 6.6.3-1: Estimated worker exposure (longer term exposure)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Iodosulfuron-methyl-sodium | | Mesosulfuron-methyl | | | Mefepyr-diethyl | |
| 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 | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL |
| Inspection, outdoor  Work rate: 2 hours/day,  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: NA | | | | | | | | |
| Number of applications and application rate | | 1 x 0.003 kg a.s./ha | | 1 x 0.015 kg a.s./ha | | | 1 x 0.045 kg a.s./ha | |
| Body weight: 60 kg | Potential  TC: 12500 cm2/person/h | 0.003 | 5.3 | 0.01 | 10.1 | | 0.04 | 39.4 |

#### The estimations of worker exposure after entering a previously treated area or handling a crop treated indicated that the permissible ~~operator~~ worker exposure level (AOEL) will not be exceeded

ACCEPTED

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

Not necessary.

#### 6.6.3.3 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.

### 6.6.4 Resident and bystander exposure (KCP 7.2.2)

#### 6.6.4 -1.Estimation of resident and bystander exposure

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

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

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

Table 6.6.4-1‑: Exposure models for intended uses

|  |  |
| --- | --- |
| Critical use(s) | Cereals (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  OPEX version: 0.3.22 |

Table 6.6.4-1: Estimated resident exposure (longer term exposure)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Iodosulfuron-methyl-sodium | | Mesosulfuron-methyl | | Mefenpyr-diethyl | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL | 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: NA | | | | | | | |
| Number of applications and application rate | | 1 x 0.003 kg a.s./ha | | 1 x 0.015 kg a.s./ha | | 1 x 0.045 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.0003 | 0.6 | 0.001 | 1.1 | 0.004 | 4.3 |
| Vapour (75th perc.) | 0.0008 | 1.6 | 0.0008 | 0.6 | 0.0008 | 0.8 |
| Deposits (75th perc.) | 3 x 10-5 | 0.06 | 0.0002 | 0.1 | 0.0005 | 0.5 |
| Re-entry (75th perc.) | 0.0004 | 0.7 | 0.002 | 1.4 | 0.005 | 5.3 |
| **Sum (mean)** | 0.001 | 2.5 | 0.003 | 2.4 | 0.008 | 7.7 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 7 x 10-5 | 0.1 | 0.0003 | 0.3 | 0.001 | 1 |
| Vapour (75th perc.) | 0.0003 | 0.5 | 0.0003 | 0.2 | 0.0003 | 0.3 |
| Deposits (75th perc.) | 0.00005 | 0.03 | 7 x 10-5 | 0.06 | 0.0002 | 0.2 |
| Re-entry (75th perc.) | 0.0002 | 0.4 | 0.001 | 0.8 | 0.003 | 3 |
| **Sum (mean)** | 0.0005 | 0.9 | 0.001 | 1 | 0.003 | 3.3 |

#### The resident and/or bystander exposure estimations carried out indicated that the acceptable ~~operator~~ resident exposure level (AOEL) for iodosulfuron-methyl-sodium and mesosulfuron-methyl will not be exceeded under conditions of intended uses

ACCEPTED

#### 6.6.4.2 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 iodosulfuron-methyl-sodium and mesosulfuron-methyl 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.

### 6.6.4-3 Combined exposure

The product is a mixture of two active substances and 1 safener.

#### Exposure assessment of iodosulfuron-methyl-sodium and mesosulfuron-methyl in IMS+MSM+MPR 2+10+30 OD

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 Table 6.6‑3 converted to decimal. The Hazard Index (HI) is the sum of the individual HQs.

Table 6.6.5: Risk assessment from combined exposure

| Application scenario | Active ingredient | Estimated exposure / AOEL (HQ) |
| --- | --- | --- |
| Operators, with PPE  For details please refer to 6.6.2. | Iodosulfuron-methyl-sodium | 0.018 |
| Mesosulfuron-methyl | 0.024 |
| Mefenpyr-diethyl | 0.078 |
| Cumulative risk operators (HI) | 0.1 |
| Workers, no PPE  For details please refer to 6.6.3 | Iodosulfuron-methyl-sodium | 0.053 |
| Mesosulfuron-methyl | 0.101 |
| Mefenpyr-diethyl | 0.394 |
| Cumulative risk workers (HI) | 0.5 |
| Resident – child  For details please refer to 6.6.4 | Iodosulfuron-methyl-sodium | 0.025 |
| Mesosulfuron-methyl | 0.024 |
| Mefenpyr-diethyl | 0.077 |
| Cumulative risk bystander – child (HI) | 0.1 |
| Resident – adult  For details please refer to 6.6.4 | Iodosulfuron-methyl-sodium | 0.009 |
| Mesosulfuron-methyl | 0.001 |
| Mefenpyr-diethyl | 0.033 |
| Cumulative risk bystander – adult (HI) | 0.05 |

**The Hazard Index is < 1. Thus, combined exposure to all active substances in IMS+MSM+MPR 2+10+30 OD is not expected to present a risk for operators, workers, residents/bystanders~~.~~** ACCEPTED

### 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 |
| --- | --- | --- | --- | --- | --- |
| KCP 7.2 | Anonymous | 2023 | OPEX calculation IMS+MSM+MPR 2+10+30 OD  Certiplant BV  Not GLP or GEP  Not published | N | Certiplant BV |
|  |  |  |  |  |  |

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 |
| --- | --- | --- | --- | --- | --- |
| **Mesosulfuron-methyl** | | | | | |
| KCA 5.1.1 /01 | Anonymous | 1997 | Rat preliminary toxicokinetics: Absorption, distribution and elimination - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code: (2- pyrimidyl-14C) AE F130060  Bayer CropScience,  Report No.: C006347,  Edition Number: M-193715-01-1  EPA MRID No.: 45386407  Date: 1997-07-01  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /02 | Anonymous | 2000 | Rat preliminary toxicokinetics: Metabolism - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code:(2- 14C-pyrimidyl)- AE F130060  Bayer CropScience,  Report No.: C008354,  Edition Number: M-197417-01-1  EPA MRID No.: 45386408  Date: 2000-07-19  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /03 | Anonymous | 1997 | Rat - Absorption, distribution and elimination - single oral low dose (10 mg/kg body weight) Code: (phenyl-U-14C) AE F130060  Bayer CropScience,  Report No.: C006348,  Edition Number: M-193718-01-1  Date: 1997-07-21  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /04 | Anonymous | 1999 | Rat - Excretion via the bile - single oral low dose (10 mg/kg body weight) Code: (phenyl-U-14C) AE F130060  Bayer CropScience,  Report No.: C006349,  Edition Number: M-193724-01-1  Date: 1999-07-23  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /05 | Anonymous | 2000 | Rat metabolism - single oral low dose (10 mg/kg body weight) (U-14C-phenyl)-AE F130060  Bayer CropScience,  Report No.: C008356,  Edition Number: M-197419-01-1  EPA MRID No.: 45386411  Date: 2000-05-15  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /06 | Anonymous | 1998 | (Phenyl-U-14C) AE F130060 - Rat absorption, distribution and elimination - oral high dose (1000 mg/kg body weight)  Bayer CropScience,  Report No.: A67074,  Edition Number: M-147473-01-1  Date: 1998-01-29  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /07 | Anonymous | 2000 | Rat metabolism - single oral high dose (1000 mg/kg body weight) Code: (U-14C-phenyl)- AE F130060  Bayer CropScience,  Report No.: C008355,  Edition Number: M-197418-01-1  EPA MRID No.: 45386413  Date: 2000-08-03  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /08 | Anonymous | 1999 | Rat - Absorption, distribution and elimination - repeated oral dose ( 7 x 250 mg/kg body weight) Code: (phenyl-U-14C) AE F130060  Bayer CropScience,  Report No.: C006350,  Edition Number: M-193730-01-1  Date: 1999-08-26  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /09 | Anonymous | 2000 | Rat metabolism - repeated oral dose (7 x 250 mg/kg body weight) (U-14Cphenyl)-AE F130060  Bayer CropScience,  Report No.: C008357,  Edition Number: M-197420-01-1  EPA MRID No.: 45386415  Date: 2000-05-15  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.1.1 /10 | Anonymous | 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 CropScience |
| KCA 5.1.2 /01 | Anonymous | 2000 | In vivo dermal absorption in the rat using an oil suspension formulation (14C)-AE F130060 Code: AE F130060 01 1K12 A7  Bayer CropScience,  Report No.: C009130,  Report includes Trial Nos.: 194/2 23 TOX0 0028  Edition Number: M-198123-01-1  Date: 2000-08-02  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.1 /01 | Anonymous | 1996 | Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for acute oral toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A56612,  Report includes Trial Nos.: 96.00 09  Edition Number: M-140405-01-1  Date: 1996-04-09  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.2 /01 | Anonymous | 1996 | Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for acute dermal toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A56613,  Report includes Trial Nos.: 96.00 10  Edition Number: M-140406-01-1  Date: 1996-04-09  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.3 /01 | Anonymous | 1999 | Testing for acute dust inhalation toxicity in male and female Sprague Dawley rats 4-hour LC50 AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C003755,  Report includes Trial Nos.: 1998. 0681 98.06 81  Edition Number: M-186735-02-1  Date: 1999-04-21 ...Amended: 2001-03-22  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.4 /01 | Anonymous | 1996 | Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for primary dermal irritation in the rabbit  Bayer CropScience,  Report No.: A56736,  Report includes Trial Nos.: 96.00 11  Edition Number: M-140524-01-1  EPA MRID No.: 45386325  Date: 1996-04-19  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.5 /01 | Anonymous | 1996 | Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for primary eye irritation in the rabbit  CropScience,  Report No.: A56729,  Report includes Trial Nos.: 96.00 12  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.6 /01 | Anonymous | 1998 | Sensitizing properties in the Pirbright-White guinea pig in a maximization test AE F130060 substance, technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: A67665,  Report includes Trial Nos.: 98.00 16  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.2.6 /02 | Anonymous | 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 CropScience |
| KCA 5.2.7 /01 | Heppenhei mer, A. | 2014 | Mesosulfuronmeth yl (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 CropScience |
| KCA 5.3 /01 | Anonymous | 2000 | Dog 12 month dietary toxicity study Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C009410,  Report includes Trial Nos.: TOX9 8014  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.3.1 /01 | Anonymous | 1997 | AE F130060 - substance technical; Code: AE F130060 00 1C94 0001 - 28 day repeated dose toxicity study in dogs (range finding study with dietary administration)  Bayer CropScience,  Report No.: A59274,  Report includes Trial Nos.: 96.06 64  Edition  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.3.2 /01 | Anonymous | 1999 | Subchronic (90 days feeding) oral toxicity study in rats Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002  Bayer CropScience,  Report No.: C004205,  Report includes Trial Nos.: 96.0458  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.3.2 /02 | Anonymous | 1999 | Subchronic (90 days feeding) oral toxicity study in mice Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002  Bayer CropScience,  Report No.: C006716,  Report includes Trial Nos.: 96.04 59  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.3.2 /03 | Anonymous | 2000 | Dog oral 90 day repeated dose toxicity study (dietary administration) AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C009014,  Report includes Trial Nos.: 1997.0445 97.04 45  Edition  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.4.1 /01 | xxxxxxxxxxx | xxxx | Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Bacterial reverse mutation test  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A56743,  Report includes Trial Nos.: 96.0013 1996-04-24  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.4.1 /02 | xxxxxxxxxxx. | 1998 | In vitro mammalian chromosome aberration test in V79 Chinese hamster lung cells AE F130060 substance, technical Code: AE F130060 00 1C95 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A67555,  Report includes Trial Nos.: 97.0444  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.4.1 /03 | xxxxxxxxxxxx | xxxx | AE F130060; substance, technical; Code: AE F130060 00 1C95 0001 - In vitro chinese hamster lung V79 cell HPRT mutation test  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A67081,  Report includes Trial Nos.: 97.0442  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.4.1 /04 | xxxxxxxxxx | xxxx | Detection of DNA strand breaks in primary hepatocytes of male rats in vitro. UDS-test in primary rat hepatocytes AE F130060 substance, technical Code: AE F130060 00 1C95 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A67689,  Report includes Trial Nos.: 97.0443  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.4.1 | xxxxxxxxxx | xxxx | 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 CropScience |
| KCA 5.4.2 /01 | Anonymous | 1998 | AE F130060; substance, technical; Code: AE F130060 00 1C95 0001 - Mouse micronucleus test  Bayer CropScience,  Report No.: A67143,  Report includes Trial Nos.: 97.0441  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.5 /01 | Anonymous | 2000 | Rat combined dietary chronic (12 and 24 months) and oncogenicity study AE F130060 technical substance Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C009379,  Report includes  Trial Nos.: 97.0175  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.5 /02 | Anonymous | 2000 | Mouse dietary oncogenicity (18 months) study AE F130060 technical substance Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C009460,  Report includes  Trial Nos.: 97.0176  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.1 /01 | Anonymous | 2000 | Range finding feeding-reproduction study for a rat two-generation reproduction toxicity study AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C010056,  Report includes Trial Nos.: 98.0354  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.1 /02 | Anonymous | 2000 | Rat two-generation feeding-reproduction toxicity study with AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C010081,  Report includes Trial Nos.: 98.0808  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /01 | Anonymous | 1997 | Range finding embryotoxicity study after oral administration in sprague dawley rats substance, technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: A67310,  Report includes  Trial Nos.: 97.04 46  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /02 | Anonymous | 1999 | Rat oral developmental toxicity (teratogenicity) study AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C003932,  Report includes Trial Nos.: 98.04 00  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /03 | Anonymous | 1998 | Range finding embryotoxicity study after oral administration in rabbits substance, technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: A67309,  Report includes Trial Nos.: 97.0447  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /04 | Anonymous | 1998 | Rabbit oral developmental toxicity (teratogenicity) study AE F130060 substance technical Code: AE F130060 00 1C95 0001  Bayer CropScience,  Report No.: C000843,  Report includes Trial Nos.: 97.0789  GLP/GEP: yes, unpublished | Y | Bayer CropScience |
| KCA 5.8.1 /01 | xxxxxxxxxxxxx | xxxx | Salmonella typhimurium reverse mutation assay with AE F147447  Harlan CCR, Rossdorf, Germany  Bayer CropScience,  Report No.: 1462101,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /02 | xxxxxxxxxxxxxx | xxxx | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F147447  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1462102,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /03 | xxxxxxxxxx | xxxx | Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F147447  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1462103,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /04 | xxxxxxxxxxx | xxxx | Salmonella typhimurium reverse mutation assay with AE F160460  Harlan CCR, Rossdorf, Germany  Bayer CropScience,  Report No.: 1462301,  Edition  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /05 | xxxxxxxxxxxxx | xxxx | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with AE F160460  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1462302,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /06 | xxxxxxxxxx. | xxxx | Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79 / HPRT) - AE F160460  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1462303,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /07 | xxxxxxxxxxxxx. | xxxx | Salmonella typhimurium reverse mutation assay with BCSCV14885  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1490201,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /08 | xxxxxxxxxxxxxx. | xxxx | Report amendment - In vitro chromosome aberration test in Chinese hamster V79 cells with BCS-CV14885  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1490202,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.1 /09 | xxxxxxxxxx. | xxxx | Report amendment no. 1 - Gene mutation assay in Chinese hamster V79 cells in vitro (V79/HPRT) - BCS-CV14885  Harlan Cytotest Cell Research GmbH (Harlan CCR), Rossdorf, Germany  Bayer CropScience,  Report No.: 1490203,  GLP/GEP: yes, unpublished | N | Bayer CropScience |
| KCA 5.8.3 /01 | xxxxxxxxxxx xxxxxx  xxxxxxxxx  xxxxxxxxxxxxxx | xxxx | Currently used pesticides and their mixtures affect the function of sex hormone receptors and aromatase enzyme activity.  Toxicology and Applied Pharmacology (2013), 272(2), 453-464.  GLP/GEP: none.  Published | N | N/A |
| KCA 5.9.1 /01 | xxxxxxx. | xxxx | Medical surveillance of manufacturing plant personnel Medical data mesosulfuron-methyl Code: AE F130060  InfraServ GmbH & Co Hoechst KG, Frankfurt, Germany  Bayer CropScience,  Report No.: C009926,  GLP/GEP: no, unpublished | N | Bayer CropScience |
| **Iodosulfuron-methyl-sodium** | | | | | |
| KCA 5.1.1/01 | Anonymous | 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  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 | Anonymous | 1996 | Absorption, distribution and elimination - rat, oral high dose (500 mg/kg body weight) 14C-Hoe 115008  Bayer CropScience,  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 | Anonymous | 1996 | Blood levels following single oral administration of 500 mg/kg body weight to male and female rats 14C-Hoe 115008  Bayer CropScience,  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 | Anonymous | 1998 | Metabolism - rat, oral high dose (500 mg/kg body weight) 2-14C-triazinyl Code: Hoe 115008  Bayer CropScience,  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 | Anonymous | 1997 | Metabolism - rat, oral high dose (500 mg/kg body weight) U-14C-phenyl Code: Hoe 115008  Bayer CropScience,  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 | Anonymous | 1996 | Absorption, distribution and elimination - rat, oral low dose (10 mg/kg body weight) Triazinyl-2-14C Code: Hoe 115008  Bayer CropScience,  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 | Anonymous | 1996 | Blood levels following single oral and intravenous administration of 10 mg/kg body weight to male and female rats 14C-Hoe 115008  Bayer CropScience,  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 | Anonymous | 1997 | Metabolism - rat, oral low dose (10 mg/kg body weight) 2-14C-triazinyl Code: Hoe 115008 Germany  Bayer CropScience,  Report No.: A57611,  Edition Number: M-141312- 01-1  EPA MRID No.: 45108801  Date: 1997-05-06  GLP/GEP: yes | Y | Bayer CropScience |
| KCA 5.1.1/09 | Anonymous | 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  Bayer CropScience,  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 | Anonymous | 1998 | Dog metabolism - oral high (200 mg/kg body weight) and low dose (6 mg/kg body weight) U-14C-phenyl-AE F115008  Bayer CropScience,  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 | Anonymous | 1998 | Rat absorption, distribution, elimination - repeated oral dose (7 x 100 mg/kg bw) (Phenyl-U-14C) Code: AE F115008  Bayer CropScience,  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 | Anonymous | 1998 | Rat metabolism - Repeated oral dose (7 x 100 mg/kg body weight) U-14C-phenyl-AE F115008  Bayer CropScience,  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 | Anonymous | 2013 | [Triazinyl-2- 14C]iodosulfuron-methyl-sodium: Metabolic stability and profiling in liver microsomes from rats and humans for inter-species comparison  Bayer CropScience,  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 | Y | Bayer CropScience |
| KCA 5.1.2/01 | Anonymous | 1998 | Dermal absorption in the rat (14C)-AE F115008  Bayer CropScience,  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 | Anonymous | 1993 | Acute oral toxicity in the male and female Wistar rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001  Bayer CropScience,  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 | Anonymous | 1993 | Acute dermal toxicity in the male and female Wistar rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001  Bayer CropScience,  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 | Anonymous | 1996 | Acute aerosol inhalation toxicity in the male and female SPF Wistar rat 4-hour LC50 Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1993 | Primary dermal irritation in the rabbit Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001  Bayer CropScience,  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 | Anonymous | 1993 | Primary eye irritation in the rabbit Hoe 115008 substance, technical Code: Hoe 115008 00 ZC97 0001  Bayer CropScience,  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 | Anonymous | 1996 | Sensitizing properties in the Pirbright-White guinea pig in a maximization test Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | xxxxxxxxxxxxxxx | xxxx | 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 | Anonymous | 1998 | Dog 12 month oral (dietary) toxicity study AE F115008 (Hoe 115008) code:AE F115008 00 1C89 0001  Bayer CropScience,  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 | Anonymous | 1998 | Dog 28-day dietary range-finding study Hoe 115008 (AE F115008) technical substances Code: Hoe 115008 00 ZC93 0001  Bayer CropScience,  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 | Anonymous | 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  Bayer CropScience,  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 | Anonymous | 1998 | Dog 90-day oral (dietary ) toxicity study Hoe 115008 (AE F115008) technical substance Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 /02 | Anonymous | 1998 | Dog 90-day oral (dietary ) toxicity study Hoe 115008 (AE F115008) technical substance Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1997 | Mouse 90-day dietary repeat dose study (report and addendum) Hoe 115008 93.8 % w/w Code: Hoe 115008 00 ZC93 0001  Bayer CropScience,  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 | xxxxxxxxxxxxxxx | xxxx | 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 | Y | Bayer CropScience |
| KCA 5.4.1 /02 | xxxxxxxxxx | xxxx | In vitro mammalian chromosome aberration test in V79 Chinese hamster cells Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  Report 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 | xxxxxxxxxx | xxxx | 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  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  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 | xxxxxxxxxx | xxxx | In vitro mammalian cell gene mutation test HPRT-test with V79 Chinese Hamster cells Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Bayer CropScience,  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 | Anonymous | 1996 | Mammalian erythrocyte micronucleus test in male and female NMRI mice Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1998 | Rat dietary combined chronic toxicity and oncogenicity study AE F115008 (Hoe 115008) Code: AE F115008 00 1C89 0001  Bayer CropScience,  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 | Anonymous | 1998 | Mouse dietary 18 month oncogenicity study AE F115008 (Hoe 115008) Code: AE F115008 00 1C89 0001  Bayer CropScience,  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 | xxxxxxxxxx xxxxxxxxxxx xxxxxxxxxx | xxxx | Frequency of Hydronephrosis in Wistar Rats  Laboratory Animal Science  Oct; 29(5):642-4  Published | Y | N/A |
| KCA 5.6 | xxxxxxxxxxxxx  xxxxxx | xxxx | Laboratory Animals  11, 193-194  Published | Y | N/A |
| KCA 5.6.6 | Anonymous | 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 | Anonymous | 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 | Anonymous | 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  Bayer CropScience,  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 | Anonymous | 1998 | Two-generation feeding-reproduction toxicity study in rats Hoe 115008 substance technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1996 | Range finding embryotoxicity study after oral administration in Wistar rats Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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: no  Unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /02 | Anonymous | 1996 | Oral developmental toxicity (teratogenicity) study - rat Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1996 | Range finding embryotoxicity study after oral administration in Himalayan rabbits Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  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: no  Unpublished | Y | Bayer CropScience |
| KCA 5.6.2 /04 | Anonymous | 1996 | Rabbit oral developmental toxicity (teratogenicity) study Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  Bayer CropScience,  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 | Anonymous | 1989 | Acute oral toxicity study in rats with 2-amino-4-methoxy-6-methyl-S-triazine  SKW Trostberg, Germany,  Report No.: C001299,  Edition Number: M-182294- 01-1  Date: 1989-10-05  GLP/GEP: yes  Unpublished | Y | Bayer CropScience |
| KCA 5.8.1 /03 | xxxxxxxxxxxx xxxxxxxx. | xxxx | 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 | Anonymous | 1998 | Acute oral toxicity in the male and female Sprague Dawley rat AE F114368 substance, technical Code: AE F114368 00 1C99 0001  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 | N | Bayer CropScience |
| KCA 5.8.1 /05 | xxxxxxxxxxxx xxxxxxx | xxxx | 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 | Anonymous | 1998 | Acute oral toxicity in the male and female Sprague Dawley rat AE F143133 substance, technical Code: AE F143133 00 1C98 0001  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 | xxxxxxxxxxxx xxxxxxxxx. | xxxx | 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 | Anonymous | 1998 | Acute dermal toxicity in the male and female Sprague Dawley rat AE F114844 substance, technical Code: AE F114844 00 1C97 0001  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 | xxxxxxxxxxxx xxxxxxxx. | xxxx | 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 | Anonymous | 2001 | 4-week toxicity study by oral route (dietary admixture) in beagle dogs followed by a 12- week treatment-free period  Bayer CropScience,  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 | xxxxxxxxxx | xxxx | Medical data. Medical surveillance of manufacturing plant personnel. Proposed first aid measures Jodosulfuron Code: AE F115008  InfraServ GmbH & Co Hoechst KG, Frankfurt, Germany  Bayer CropScience,  Report No.: C001333,  Edition Number: M-182378- 01-1  EPA MRID No.: 45108914  Date: 1998-10-29  GLP/GEP: no  Unpublished | Y | Bayer CropScience |
| KCA 5.9.1 /02 | xxxxxxxxxxxx | xxxx | 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: no  Unpublished | N | Bayer CropScience |

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

1. Detailed evaluation of the studies relied upon

No new studies submitted with this application.

1. Exposure calculations
   1. Operator exposure calculations (KCP 7.2.1.1)
      1. Calculations for iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl

Table A 12: Input parameters considered for the estimation of operator exposure

|  |  |
| --- | --- |
| **Product name** | IMS+MSM+MPR 2+10+30 OD |
| **Formulation type** | Soluble concentrates, emulsifiable concentrate, etc. |
| **Product category** | Herbicide |
| **Name of active substance** | Mesosulfuron-methyl |
| **Concentration of active substance [g a.s./l or kg]** | 10 |
| **AOEL [mg/kg bw/day]** | 0.13 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 2 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Mefenpyr-diethyl |
| **Concentration of active substance [g a.s./l or kg]** | 30 |
| **AOEL [mg/kg bw/day]** | 0.1 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 73 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Iodosulfuron-methyl-sodium |
| **Concentration of active substance [g a.s./l or kg]** | 2 |
| **AOEL [mg/kg bw/day]** | 0.05 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 70 |
| **Dermal absorption [%] (concentrate)** | 70 |

Table A 13: Estimation of short term operator exposure towards active substance according to EFSA guidance

#### Summary data - Short term exposure

| **Model data** | **Level of PPE** | **Total absorbed dose [mg/kg bw per day]** | **% of systemic AOEL** |
| --- | --- | --- | --- |
| Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0 %/75th percentile Crop density: Normal | | | |
| Mesosulfuron-methyl | Number of applications and application rate: 1 x 0.015 kg a.s./ha  Dermal absorption (concentrate): 70 %  Dermal absorption (in-use dilution): 70 % | | |
| M/L: Workwear  App: Workwear | 0.08 | 62.6 |
| Mefenpyr-diethyl | Number of applications and application rate: 1 x 0.045 kg a.s./ha  Dermal absorption (concentrate): 70 %  Dermal absorption (in-use dilution): 70 % | | |
| M/L: Workwear + Protected hands  App: Workwear | 0.008 | 7.8 |
| Iodosulfuron-methyl-sodium | Number of applications and application rate: 1 x 0.003 kg a.s./ha  Dermal absorption (concentrate): 70 %  Dermal absorption (in-use dilution): 70 % | | |
| M/L: Workwear  App: Workwear | 0.03 | 57.5 |
| **Combined exposure** |  |  | Hazard index |
|  | M/L: Workwear + Protected hands  App: Workwear |  | 0.119 |

* 1. Worker exposure calculations (KCP 7.2.3.1)
     1. Calculations for iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl

Table A 15: Input parameters considered for the estimation of worker exposure

|  |  |
| --- | --- |
| **Product name** | IMS+MSM+MPR 2+10+30 OD |
| **Formulation type** | Soluble concentrates, emulsifiable concentrate, etc. |
| **Product category** | Herbicide |
| **Name of active substance** | Mesosulfuron-methyl |
| **Concentration of active substance [g a.s./l or kg]** | 10 |
| **AOEL [mg/kg bw/day]** | 0.13 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 2 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Mefenpyr-diethyl |
| **Concentration of active substance [g a.s./l or kg]** | 30 |
| **AOEL [mg/kg bw/day]** | 0.1 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 73 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Iodosulfuron-methyl-sodium |
| **Concentration of active substance [g a.s./l or kg]** | 2 |
| **AOEL [mg/kg bw/day]** | 0.05 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 70 |
| **Dermal absorption [%] (concentrate)** | 70 |

Table A 17: Estimation of longer term worker exposure towards iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl according to EFSA guidance

| **Level of PPE** | **Total absorbed dose [mg/kg bw per day]** | **% of systemic AOEL** | **Re-entry restriction [days]** |
| --- | --- | --- | --- |
| Inspection, irrigation / Outdoor  Work rate: 2 hours/day  Interval: NA  Body weight: 60 kg  TC (potential): 12500 cm²/h  TC (workwear (arms, body and legs covered)): 1400 cm²/h  TC (workwear (arms, body and legs covered) and gloves): 1250 cm²/h  TC (gloves): NA cm²/h | | | |
| **Mesosulfuron-methyl** | Number of applications & application rate: 1 x 0.015 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Potential | 0.01 | 10.1 | 0 |
| Workwear | 0.001 | 1.1 | 0 |
| Workwear and gloves | 0.001 | 1 | 0 |
| Hands covered, no workwear |  |  |  |
| **Mefenpyr-diethyl** | Number of applications & application rate: 1 x 0.045 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Potential | 0.04 | 39.4 | 0 |
| Workwear | 0.004 | 4.4 | 0 |
| Workwear and gloves | 0.004 | 3.9 | 0 |
| Hands covered, no workwear |  |  |  |
| **Iodosulfuron-methyl-sodium** | Number of applications & application rate: 1 x 0.003 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Potential | 0.003 | 5.3 | 0 |
| Workwear | 0.0003 | 0.6 | 0 |
| Workwear and gloves | 0.0003 | 0.5 | 0 |
| Hands covered, no workwear |  |  |  |
| **Combined** |  | Hazard index |  |
| potential |  | 0.9 | 0 |
| Workwear |  | 0.1 | 0 |
| Workwear and gloves |  | 0.09 | 0 |
| Hands covered, no workwear |  |  | 0 |

* 1. Resident and bystander exposure calculations (KCP 7.2.2.1)
     1. Calculations for iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl

Table A 18: Input parameters considered for the estimation of longer term resident exposure

|  |  |
| --- | --- |
| **Product name** | IMS+MSM+MPR 2+10+30 OD |
| **Formulation type** | Soluble concentrates, emulsifiable concentrate, etc. |
| **Product category** | Herbicide |
| **Name of active substance** | Mesosulfuron-methyl |
| **Concentration of active substance [g a.s./l or kg]** | 10 |
| **AOEL [mg/kg bw/day]** | 0.13 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 2 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Mefenpyr-diethyl |
| **Concentration of active substance [g a.s./l or kg]** | 30 |
| **AOEL [mg/kg bw/day]** | 0.1 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 73 |
| **Dermal absorption [%] (concentrate)** | 70 |
| **Name of active substance** | Iodosulfuron-methyl-sodium |
| **Concentration of active substance [g a.s./l or kg]** | 2 |
| **AOEL [mg/kg bw/day]** | 0.05 |
| **AAOEL [mg/kg bw]** |  |
| **Inhalation absorption [%]** | 100 |
| **Oral absorption [%]** | 70 |
| **Dermal absorption [%] (concentrate)** | 70 |

Table A 19: Estimation of longer term resident exposure towards iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl according to EFSA guidance

| **Model data** | **Level of PPE** | **Total absorbed dose [mg/kg bw per day]** | **% of systemic AOEL** |
| --- | --- | --- | --- |
| Season: Not relevant  Buffer zone: 2-3 m  Drift reduction technology: 0 %  Interval between treatments: NA  Minimum volume of water: 200 l | | | |
| **Mesosulfuron-methyl** | Number of applications and application rate: 1 x 0.015 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.001 | 1.1 |
| Vapour (75th perc.) | 0.0008 | 0.6 |
| Deposits (75th perc.) | 0.0002 | 0.1 |
| Re-entry (75th perc.) | 0.002 | 1.4 |
| Sum (mean) | 0.003 | 2.4 |
| Resident adult   Body weight: 60 kg | Drift (75th perc.) | 0.0003 | 0.3 |
| Vapour (75th perc.) | 0.0003 | 0.2 |
| Deposits (75th perc.) | 7e-05 | 0.06 |
| Re-entry (75th perc.) | 0.001 | 0.8 |
| Sum (mean) | 0.001 | 1 |
| **Mefenpyr-diethyl** | Number of applications and application rate: 1 x 0.045 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.004 | 4.3 |
| Vapour (75th perc.) | 0.0008 | 0.8 |
| Deposits (75th perc.) | 0.0005 | 0.5 |
| Re-entry (75th perc.) | 0.005 | 5.3 |
| Sum (mean) | 0.008 | 7.7 |
| Resident adult   Body weight: 60 kg | Drift (75th perc.) | 0.001 | 1 |
| Vapour (75th perc.) | 0.0003 | 0.3 |
| Deposits (75th perc.) | 0.0002 | 0.2 |
| Re-entry (75th perc.) | 0.003 | 3 |
| Sum (mean) | 0.003 | 3.3 |
| **Iodosulfuron-methyl-sodium** | Number of applications and application rate: 1 x 0.003 kg a.s./ha  Dermal absorption: 70 %  DFR: 3 µg/cm² foliage per kg a.s./ha  DT50: 30 days | | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.0003 | 0.6 |
| Vapour (75th perc.) | 0.0008 | 1.6 |
| Deposits (75th perc.) | 3e-05 | 0.06 |
| Re-entry (75th perc.) | 0.0004 | 0.7 |
| Sum (mean) | 0.001 | 2.5 |
| Resident adult   Body weight: 60 kg | Drift (75th perc.) | 7e-05 | 0.1 |
| Vapour (75th perc.) | 0.0003 | 0.5 |
| Deposits (75th perc.) | 1e-05 | 0.03 |
| Re-entry (75th perc.) | 0.0002 | 0.4 |
| Sum (mean) | 0.0005 | 0.9 |
| **Combined exposure** |  |  | Hazard index |
| Resident child  Body weight: 10 kg | Drift (75th perc.) |  | 0.06 |
| Vapour (75th perc.) |  | 0.03 |
| Deposits (75th perc.) |  | 0.007 |
| Re-entry (75th perc.) |  | 0.07 |
| Sum (mean) |  | 0.1 |
| Resident adult   Body weight: 60 kg | Drift (75th perc.) |  | 0.01 |
| Vapour (75th perc.) |  | 0.01 |
| Deposits (75th perc.) |  | 0.003 |
| Re-entry (75th perc.) |  | 0.04 |
| Sum (mean) |  | 0.05 |