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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 |
| NATIONAL ASSESSMENT - Poland  (authorization) |
| Applicant: Certiplant BV  Submission date: June 2024  MS Finalisation date: 01/2025; 04/2025; 12/2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| January 2025 | Initial evaluation |
| April 2025 | The Final Registration Report |
| December 2025 | Corrected |
|  |  |

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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.

The product contains 2 active substances (iodosulfuron-methyl-sodium and mesosulfuron-methyl) and 1 safener (mefenpyr-diethyl). Since no EU agreed regulation for the evaluation of safeners exists, review may differ amongst countries. As peer recommendation of the central zone Steering Committee (czSC), the full risk assessment for the safener is not addressed in the core dossier but left to the review by Member States as part of their national evaluation.

The data for both active substances are presented in the core assessment. The data for the safener are presented in this national addendum.

## Summary

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

|  |  |
| --- | --- |
| Product name and code | 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

Reference is made to the core dossier.

Table 6.1‑2: 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 6.1‑2 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 6.1‑3: 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 2
* data gap 3

## Toxicological Information on Active Substance(s)

For iodosulfuron-methyl-sodium and mesosulfuron-methyl, reference is made to the core dossier.

Information regarding classification of the safener mefenpyr-diethyl 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 mefenpyr-diethyl (safener)

|  | Safener: mefenpyr-diethyl |
| --- | --- |
| Common Name | Mefenpyr-diethyl |
| CAS-No. | 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 |
| Additional C&L proposal | / |
| Agreed EU endpoints | |
| AOEL systemic | 0.1 mg/kg bw/d  (corrected for 73% oral absorption) |
| Reference | 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 |

## 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.

## Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1 µg/L – no groundwater assessment is required.

## Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the safener mefenpyr-diethyl in IMS+MSM+MPR 2+10+30 OD is presented in the following table.

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

|  | Mefenpyr-diethyl | |
| --- | --- | --- |
|  | Value | Reference |
| Concentrate | 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) |

### 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) | **Mefenpyr-diethyl (MPR)**  30 g/L |
| AOEL systemic | 0.1 mg/kg bw/d |
| Inhalation absorption | 100% |
| Oral absorption | 73% |
| Dermal absorption | 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 safener 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 6.6‑3: Estimated operator exposure (long-term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data | Level of PPE | Total absorbed dose  (mg/kg bw/day) | % of systemic AOEL |
| Outdoor, downward spraying, vehicle-mounted, field crops | | | |
| Application rate | | 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 | 0.166 | 166 |
| Work wear (arms, body and legs covered) + gloves during M/L  Work wear (arms, body and legs covered) during A | 0.008 | 7.8 |

#### 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),

#### Measurement of operator exposure

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

### Worker exposure (KCP 7.2.3)

#### Estimation of worker exposure

Table 6.6‑5 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 6.6‑4: 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 6.6‑5: Estimated worker exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data | Level of PPE | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL  ~~Total absorbed dose (mg/kg bw/day)~~ |
| Inspection, outdoor  Work rate: 2 hours/day,c  DT50: 30 days  DFR: 3 µg/cm2/kg a.s./ha  Interval between treatments: NA | | | |
| Number of applications and application rate | | 1 x 0.045 kg a.s./ha | |
| Body weight:  60 kg | ~~0.04~~  Potential  TC: 12500 cm2/person/h | 0.04 | 39.4  ~~5.3~~ |

#### The worker exposure estimations carried out indicated that the acceptable ~~operator~~ worker exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE

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

Not necessary.

#### Measurement of worker exposure

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

### Resident and bystander exposure (KCP 7.2.2)

#### Estimation of resident and bystander exposure

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

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. There is no acute AOEL assessed for the safener mefenpyr-diethyl, 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 mefenpyr-diethyl. The outcome of the estimation is presented in Table 6.6‑7. Detailed calculations are in Appendix 3.

Table 6.6‑6: 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 2014;12(10):3874~~  ~~calculator version: 30/03/2015~~  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 6.6‑7: Estimated resident exposure (longer term exposure)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Mefenpyr-diethyl | |
| Model data |  | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL  ~~Total absorbed dose (mg/kg bw/day)~~ |
| 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 0.045 kg a.s./ha | |
| Resident child  Body weight: 10 kg | Drift (75th perc.) | 0.004 | ~~0.6~~  4.3 |
| Vapour (75th perc.) | 0.0008 | ~~1.6~~  0.8 |
| Deposits (75th perc.) | 0.0005 | ~~0.06~~  0,5 |
| Re-entry (75th perc.) | 0.005 | ~~0.7~~ 5.3 |
| **Sum (mean)** | 0.008 | ~~2.5~~ 7.7 |
| Resident adult  Body weight: 60 kg | Drift (75th perc.) | 0.001 | ~~0.1~~ 1 |
| Vapour (75th perc.) | 0.0003 | ~~0.5~~ 0.~~3~~ |
| Deposits (75th perc.) | 0.0002 | ~~0.03~~ 0.2 |
| Re-entry (75th perc.) | 0.003 | ~~0.4~~  3 |
| **Sum (mean)** | 0.003 | ~~0.9~~  3.3 |

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

#### 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 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 1 safener.

#### Exposure assessment of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl 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.

The HQ values for iodosulfuron-methyl-sodium and mesosulfuron-methyl were taken from the core dossier.

Table 6.6‑8: 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 and the safener in IMS+MSM+MPR 2+10+30 OD is not expected to present a risk for operators, workers, residents/ 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 |
| --- | --- | --- | --- | --- | --- |
| 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 |
| --- | --- | --- | --- | --- | --- |
| IIA, 5.1.1 /01 | Anonymous | 1992 | Hoe 107892-14C Pharmacokinetics in the rat after oral administration of 1 and 100 mg/kg body weight  Bayer CropScience,  Report No.: A49005,  Edition Number: M-138087-02-1  Date: 1992-10-26 ...  Amended: 1993-12-09  GLP, unpublished | Y | BCS |
| IIA, 5.1.2 /01 | Anonymous | 1992 | Hoe 107892-14C, Metabolnsm in the Rat Following a Single Dose of 1 and 100 mg/kg Body Weight p.o.  Bayer CropScience,  Report No.: A49252,  Edition Number: M-138320-01-1  Date: 1992-11-03  GLP, unpublished | Y | BCS |
| IIA, 5.2.1 / 01 | Anonymous | 1990b | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for acute oral toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A43614,  Edition Number: M-126562-01-1  Date: 1990-06-18  GLP, unpublished | Y | BCS |
| IIA, 5.2.1 / 01 | Anonymous | 1990b | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for acute oral toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A43614,  Edition Number: M-126562-01-1  Date: 1990-06-18  GLP, unpublished | Y | BCS |
| IIA, 5.2.1 / 02 | Anonymous | 1990a | HOE 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for acute oral toxicity in the male and female NMRI mouse  Bayer CropScience,  Report No.: A43378,  Edition Number: M-126339-01-1  Date: 1990-05-07  GLP, unpublished | Y | BCS |
| IIA, 5.2.2 / 01 | Anonymous | 1990c | Hoe 107892; substance, technical (Code: Hoe 107892 00 ZC99 0001) Testing for acute dermal toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A43325,  Edition Number: M-126286-01-1  Date: 1990-05-14  GLP, unpublished | Y | BCS |
| IIA, 5.2.3 / 01 | Anonymous | 1991a | Hoe 107892; substance, technical Code: Hoe 107892 00 ZC97 0001 Testing for acute aerosol inhalation toxicity in the male and female SPF Wistar rat 4-hour LC50  Bayer CropScience,  Report No.: A44883,  Edition Number: M-127729-01-1  Date: 1991-01-07  GLP, unpublished | Y | BCS |
| IIA, 5.2.4 / 01 | Anonymous | 1990a | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Testing for primary dermal irritation in the rabbit  Bayer CropScience,  Report No.: A43416,  Edition Number: M-126376-01-1  Date: 1990-05-22  GLP, unpublished | Y | BCS |
| IIA, 5.2.5 / 01 | Anonymous | 1990b | Hoe 107892; substance, technical (Code: Hoe 107892 00 ZC99 0001) Testing for primary eye irritation in the rabbit  Bayer CropScience,  Report No.: A43537,  Edition Number: M-126489-01-1  Date: 1990-05-29  GLP, unpublished | Y | BCS |
| IIA, 5.2.6 / 01 | Anonymous | 1991a | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC97 0001) Testing for sensitising properties in the Pirbright-White guinea pig in a maximisation test  Bayer CropScience,  Report No.: A45698,  Edition Number: M-129800-01-1  Date: 1991-03-26  GLP, unpublished | Y | BCS |
| IIA, 5.2.7 / 01 | Anonymous | 1992a | HOE 107892; SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Testing for phototoxicity after cutaneous application in the Pirbright-White guinea pig  Bayer CropScience,  Report No.: A48037,  Edition Number: M-136891-01-1  Date: 1992-05-20  GLP, unpublished | Y | BCS |
| IIA, 5.2.7 / 02 | Anonymous | 1992b | HOE 107892; SUBSTANCE, TECHNICAL; (Code: Hoe 107892 00 ZC94 0001) Testing for photosensitising properties in the Pirbright-White guinea pig  Bayer CropScience,  Report No.: A48235,  Edition Number: M-137187-01-1  Date: 1992-06-12  GLP, unpublished | Y | BCS |
| IIA, 5.2.8 / 01 | Anonymous | 1991c | HOE 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC97 0001) Testing for acute intraperitoneal toxicity in the male and female Wistar rat  Bayer CropScience,  Report No.: A45328,  Edition Number: M-129470-01-1  Date: 1991-03-07  GLP, unpublished | Y | BCS |
| IIA, 5.3.1.1 / 01 | Anonymous | 1992a,b | Hoe 107892 - SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the Wistar rat  Bayer CropScience,  Report No.: A47872,  Edition Number: M-136540-01-1  Date: 1992-05-07  GLP, unpublished | Y | BCS |
| IIA, 5.3.1.1 / 02 | Anonymous | 1992 | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hae 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the Wistar rat Glutathione contents and enzyme acitivities in liver and kidneys  Bayer CropScience,  Report No.: A49720,  Edition Number: M-138747-01-1  Date: 1992-12-02  GLP, unpublished | Y | BCS |
| IIA, 5.3.1.2 / 01 | Anonymous | 1992d | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the NMRI mouse  Bayer CropScience,  Report No.: A47423,  Edition Number: M-135826-01-1  Date: 1992-02-11  GLP, unpublished | Y | BCS |
| IIA, 5.3.1.2 / 02 | Anonymous | 1992 | Hoe 107892; SUBSTANCE, TECHNICAL (Code: Hoe 107892 00 ZC99 0001) Repeated-dose oral toxicity (4-week feeding study) in the NMRI mouse Renal glutathione contents and enzyme activities  Bayer CropScience,  Report No.: A48480,  Edition Number: M-137592-01-1  Date: 1992-07-29  GLP, unpublished | Y | BCS |
| IIA, 5.3.1.3 / 01 | Anonymous | 1991a | 30-day oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC99 0001) in the dog  Bayer CropScience,  Report No.: A45830,  Edition Number: M-129927-01-1  Date: 1991-05-06  GLP, unpublished | Y | BCS |
| IIA, 5.3.2.1 / 01 | Anonymous | 1992a | HOE 107892 substance technical (Code: HOE 107892 00 ZC97 0001) Sub-chronic oral toxicity 13-week feeding study in rats  Bayer CropScience,  Report No.: A47873,  Edition Number: M-136542-01-1  Date: 1992-04-27  GLP, unpublished | Y | BCS |
| IIA, 5.3.2.2 / 01 | Anonymous | 1991b | Hoe 107892 SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC97 0001) Sub-chronic oral toxicity 13-week feeding study in mice  Bayer CropScience,  Report No.: A48481,  Edition Number: M-137593-01-1  Date: 1991-01-18  GLP, unpublished | Y | BCS |
| IIA, 5.3.3/01 | Anonymous | 1992a | 13-week oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC97 0001) in the dog  Bayer CropScience,  Report No.: A47753,  Edition Number: M-136357-01-1  Date: 1992-04-08  GLP, unpublished | Y | BCS |
| IIA, 5.3.4 /01 | Anonymous | 1992b | 52-week oral toxicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the dog  Bayer CropScience,  Report No.: A49032,  Edition Number: M-138113-01-1  Date: 1992-10-23  GLP, unpublished | Y | BCS |
| IIA, 5.3.7 /01 | Anonymous | 1992h | Hoe 107892 - SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Repeated-dose dermal toxicity (21 treatments in 29 days) in the Wistar rat  Bayer CropScience,  Report No.: A48666,  Edition Number: M-137769-01-1  Date: 1992-08-03  GLP, unpublished | Y | BCS |
| IIA, 5.4.1 / 01 | xxxxxxxxxx | 1990a | Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test) and Escherichia coli  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A44259,  Report includes Trial Nos.: 90.0421  Edition Number: M-127158-02-1  Date: 1990-08-31 .  ..Amended: 1995-12-14  GLP, unpublished | Y | BCS |
| IIA, 5.4.2 / 01 | xxxxxxxxxx. | 1990b | Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Chromosome aberrations in vitro in V79 Chinese hamster cells  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A44267,  Edition Number: M-127164-01-1  Date: 1990-08-20  GLP, unpublished | Y | BCS |
| IIA, 5.4.3 / 01 | xxxxxxxxx | 1990c | Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Detection of gene mutations in somatic cells in culture HGPRT-test with Y79 cells  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A44823,  Edition Number: M-127679-01-1  Date: 1990-12-10  GLP, unpublished | Y | BCS |
| IIA, 5.4.4 / 01 | Anonymous | 1990e | Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) Micronucleus test in male and female NMRI mice after oral administration  Bayer CropScience,  Report No.: A44264,  Edition Number: M-127162-01-1  Date: 1990-09-07  GLP, unpublished | Y | BCS |
| IIA, 5.4.7 / 01 | xxxxxxxxx. | 1990d | Evaluation of Hoe 107892 - substance, technical (Code: Hoe 107892 00 ZC99 0001) in the unscheduled DNA synthesis test in mammalian cells in vitro  Hoechst AG, Frankfurt am Main, Germany  Bayer CropScience, Report No.: A44405,  Edition Number: M-127283-01-1  Date: 1990-09-14  GLP, unpublished | Y | BCS |
| IIA, 5.5.1 / 01 | Anonymous | 1994 | Combined chronic toxicity/oncogenicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the rat  Bayer CropScience,  Report No.: A53310,  Edition Number: M-134048-02-1  Date: 1994-11-18  ...Amended: 1995-12-22  GLP, unpublished  ...also filed: KIIA 5.5.2 /01 | Y | BCS |
| IIA, 5.5.3 / 01 | Anonymous | 1994a | Oncogenicity (feeding) study with Hoe 107892 substance technical (Code: Hoe 107892 00 ZC94 0001) in the mouse  Bayer CropScience,  Report No.: A53241,  Edition Number: M-133984-02-1  Date: 1994-11-10  ...Amended: 1995-12-22  GLP, unpublished | Y | BCS |
| IIA, 5.6.1 / 01 | Anonymous | 1993 | HOE 107892 SUBSTANCE TECHNICAL (CODE: HOE 107892 00 ZC94 0001) Preliminary study to the two-generation reproduction study in the rat  Bayer CropScience,  Report No.: A51532,  Edition Number: M-132466-01-1  Date: 1993-10-15  GLP, unpublished | Y | BCS |
| IIA, 5.6.1 / 02 | Anonymous | 1994 | HOE 107892 SUBSTANCE TECHNICAL (CODE: Hoe 107892 00 ZC94 0001) Two-generation reproduction study in the rat  Bayer CropScience,  Report No.: A52643,  Edition Number: M-133451-02-1  Date: 1994-05-24  ...Amended: 1995-12-22  GLP, unpublished | Y | BCS |
| IIA, 5.6.10 / 01 | Anonymous | 1992a | Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC97 0001) Testing for embryotoxicity in the Wistar rat after oral administration (limit test)  Bayer CropScience,  Report No.: A48150,  Report includes Trial Nos.: 90.0988 RR0620  Edition Number: M-137035-02-1  Date: 1992-05-19  ...Amended: 1995-12-19  GLP, unpublished | Y | BCS |
| IIA, 5.6.10 / 02 | Anonymous | 1992b | Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC94 0001) Testing for embryotoxicity and effects on post-natal development in Wistar rats after oral administration (limit test)  Bayer CropScience,  Report No.: A48786,  Edition Number: M-137883-01-1  Date: 1992-09-04  GLP, unpublished | Y | BCS |
| IIA, 5.6.10 / 03 | Anonymous | 1999 | Rat oral developmental toxicity (teratogenicity) study Mefenpyr-diethyl substance technical Code: AE F107892 00 1C97 0001  Bayer CropScience,  Report No.: C003858,  Report includes Trial Nos.: 98.0055  Edition Number: M-186899-01-1  Date: 1999-04-29  GLP, unpublished | Y | BCS |
| IIA, 5.6.11 / 01 | Anonymous | 1992 | Hoe 107892 - substance technical (Code: Hoe 107892 00 ZC97 0001) Testing for embryotoxicity in the Himalayan rabbit after oral administration  Bayer CropScience,  Report No.: A49620,  Report includes Trial Nos.: 90.0989 RK0621  Edition Number: M-138652-03-1  Date: 1992-12-03  ...Amended: 2000-09-11  GLP, unpublished | Y | BCS |
| IIA, 5.9 / 01 | xxxxxxxxxxxx  xxxxxx | xxxx | Occupational medical experiences with mefenpyr-diethyl  Generated by: Bayer CropScience AG, Monheim, DEU;  Document No: C046326  GLP / GEP No  unpublished | Y | BCS |
| IIA, 5.10.1 / 01 | xxxxxxxxx | xxxx | Hoe 091271 - substance, technical (Code: Hoe 091271 0Z ZC98 0001) Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test) and Escherichia coli  Hoechst AG, Frankfurt am Main, Germany  Report No.: A39907,  Edition Number: M-121481-01-1  Date: 1988-01-29  GLP, unpublished | Y | BCS |
| IIA, 5.10.1 / 02 | Anonymous | 1988 | Hoe 091271 - Substance, technical (code: Hoe 091271 0Z ZC98 0001) - Acute oral toxicity study in male and female wistar rats  Bayer AG,  Report No.: A39904,  Report includes Trial Nos.: 87.1441  Edition Number: M-121478-01-2  Date: 1988-03-03  GLP, unpublished | Y | BCS |
| IIA, 5.10.1 / 03 | Anonymous | 1988 | Hoe 091271 - active ingredient technical (Code: Hoe 091271 0Z ZC98 0001) Testing for acute dermal toxicity in the male and female Wistar rat  Report No.: A39903,  Edition Number: M-121477-01-1  Date: 1988-03-03  GLP, unpublished | Y | BCS |
| IIA, 5.10.2 / 01 | xxxxxxxxx | xxxx | Hoe 083211 - substance, technical (Code: Hoe 083211 0U ZC99 0001) Study of the mutagenic potential in two strains of Salmonella typhimurium (Ames Test)  Hoechst AG, Frankfurt am Main, Germany  Report No.: A42601,  Date: 1989-08-04  GLP, unpublished | Y | BCS |
| IIA, 5.10.2 / 02 | xxxxxxxxxx | xxxxx | Hoe 083211 - substance, technical (Code: Hoe 083211 00 ZC95 0001) Study of the mutagenic potential in strains of Salmonella typhimurium (Ames Test) and Escherichia coli in the absence and in the presence of rat liver,...  Hoechst AG, Frankfurt am Main, Germany  Report No.: A43692,  Edition Number: M-126634-02-1  Date: 1990-06-21  ...Amended: 1990-09-25  GLP, unpublished | Y | BCS |
| IIA, 5.10.2 / 03 | Anonymous | 1991a | Hoe 083211 - substance; technical (Code: Hoe 083211 00 ZC 95 0001) Screening of renal mode of action genotoxicity in kidneys and urine with enzyme-biochemical and microscopic examinations following repeated oral treatment (14-day gavage) to  Report No.: A45572,  Edition Number: M-129690-01-1  Date: 1991-04-23  GLP, unpublished | Y | BCS |
| IIA, 5.10.2 / 04 | Anonymous | 1991b | Hoe 083211 - substance, technical (Code: Hoe 083211 00 ZC95 0001) Screening of the renal and hepatic modes of action Genotoxicity in kidneys and urine with enzyme-biochemical and microscopic examinations followint repeated oral ...  Report No.: A45868,  Edition Number: M-129961-01-1  Date: 1991-04-23  Non GLP, unpublished | Y | BCS |

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 |