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| FINAL REGISTRATION REPORT  Part A  Risk Management |
| 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: January 2025, April 2025,  May 2025, October 2025 |

Version history

|  |  |
| --- | --- |
| When | What |
| January 2025 | ZRMs evaluated dRR submitted by Applicant. |
| April 2025 | fRR after the commenting period. |
| May 2025 | Reference list updated by Applicant on request of zRMS |
| May 2025 | Lists of data considered for national authorization has been verified by ZRMS |
| October 2025 | zRMS corrected final Registration Report in line to reviewed comments from MRiRW |

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PART A

RISK MANAGEMENT

# Details of the application

With this application, Certiplant BV requests authorisation of a new plant protection product IMS+MSM+MPR 2+10+30 OD, containing 2 g/L iodosulfuron-methyl-sodium (IMS) + 10 g/L mesosulfuron-methyl (MSM) + 30 g/L mefenpyr-diethyl (MPR) (safener) for use as a herbicide for professional uses.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C and where appropriate the addendum for Poland.

The information, data and assessments provided in Registration Report, Parts B include assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to IMS+MSM+MPR 2+10+30 OD where data has not been considered in the EU review. Otherwise assessments for the safe use of IMS+MSM+MPR 2+10+30 OD have been made using endpoints agreed in the EU review of IMS, MSM or MPR.

This documents describes the specific conditions of use and labelling required for Poland for the registration of IMS+MSM+MPR 2+10+30 OD.

## Application background

The application was submitted by Certiplant BV in June 2024.

It concerns an application for the authorisation of IMS+MSM+MPR 2+10+30 OD, an oil dispersion containing 2 g/L iodosulfuron-methyl-sodium (IMS) + 10 g/L mesosulfuron-methyl (MSM) + 30 g/L mefenpyr-diethyl (MPR) (safener) for use as a herbicide in winter wheat, winter rye and triticale, see detailed information in the GAP table, point 2.6

This application is a central zone application for which Poland acts as the zRMS. Belgium and the Netherlands are concerned member states.

In this application reference is made to the unprotected data from the EU review of IMS, MSM and MPR and the Polish reference product Atlantis 12 OD (R555-2020d).

## Letters of Access

Not applicable.

All data which are referred to are not protected anymore.

In this dossier reference is made to the RAR of iodosulfuron-methyl-sodium and mesosulfuron-methyl, to the DAR of mefenpyr-diethyl and to the registration report of the product Atlantis 12 OD (R555-2020d).

The a.s. iodosulfuron-methyl-sodium was renewed on 01/04/2017 and the a.s. mesosulfuron-methyl was renewed on 01/07/2017 in accordance with Regulation (EC) No 1107/2009 and subsequently the product Atlantis 12 OD was renewed according to Art. 43 of Regulation (EC) No 1107/2009 on 24/08/2020 in Poland. This means that data protection of new data used to support the renewal of approval of the active substances IMS and MSM, where the data concerned are also necessary to support the renewal of authorisation of a product containing these a.s. (i.e. Atlantis 12 OD), expired on 24/04/2023 (30 months from data of first renewal of product). These data can therefore be used in support of our application.

IMS+MSM+MPR 2+10+30 OD also contains the safener mefenpyr-diethyl. Safeners are not yet evaluated according to Regulation (EC) No 1107/2009. However, a DAR for MPR was prepared in the framework of an OECD work-sharing project and peer reviewed by Austria and France in 2011. These data are not protected anymore and can be used in support of this application.

## Justification for submission of tests and studies

A justification for submission of tests and studies is provided in the relevant section.

No new vertebrate studies have been performed in view of this application.

## Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for I the list of references in Appendix 4.

# Details of the authorization decision

## Product identity

|  |  |
| --- | --- |
| Product code | IMS+MSM+MPR 2+10+30 OD |
| Product name in MS | CERENET |
| Authorization number | / |
| Function | Herbicide |
| Applicant | Certiplant BV |
| Active substance(s)  (incl. content) | Iodosulfuron-methyl-sodium; 2 g/L  Mesosulfuron-methyl; 10 g/L  Mefenpyr-diethyl; 30 g/L (safener) |
| Formulation type | Oil dispersion (OD) |
| Packaging | 1 L (HDPE/~~EVOH~~PA), 5 L (HDPE/PA), 10 L (HDPE/PA) |
| Coformulants of concern for national authorizations | / |
| Restrictions related to identiy | / |
| Mandatory tank mixtures | / |
| Recommended tank mixtures | / |

## Conclusion

The evaluation of the application for CERENET resulted in the decision to grant the authorization after completion of the cold stability data (see Physical-chemical section).

**Physical-chemical section:**

Data gap~~s are~~:

~~- Dispersion stability and wet sieving should be determined after cold stability testing.~~

- Ambient temperature shelf life study. Expected finalisation – June 2026. Based on the formulation composition and accelerated storage results, a 2-year provisional authorisation is possible after submission of the low temperature stability studies.

**Efficacy section**: Summary of the assessment made for Poland: ***winter wheat*** – ALOMY and APESV accepted as a moderately sensitive weeds against 1.5 1.2 L/ha of CERENET. VIOAR was excluded from label due to not enough number of trials; ***winter rye*** – use excluded from GAP and Polish label due to not enough number of trials and lack of possibility extrapolating results from st. ref. product. use against VIOAR not accepted. ALOMY is accepted as a tolerant weed against CERENET at dose 0.9 L/ha. APESV was correctly not included in the GAP by Applicant due to lack of trials. Section 2 assessed that Atlantis 12 OD and CERENET are not comparable, so its unprotected data cannot by use by ZRMs in this assessment; ***winter triticale*** – ALOMY and APESV accepted as a moderately sensitive weed against 1.5 1.2 L/ha of CERENET. APESV and VIOAR were not included in Polish label by Applicant.

.

**Mammalian toxicology:** Classification for CERENET: Skin Sens.1/H317; Eye Dam.1/H318. According to the model calculations, it can be concluded that the risk for the operator using IMS+MSM+MPR 2+10+30 OD on all the proposed crops is acceptable wearing normal work wear and the risk for the worker using IMS+MSM+MPR 2+10+30 OD on all the proposed crops is acceptable wearing normal work wear. It was also found no unacceptable risk anticipated for residents/ bystanders during treatment with IMS+MSM+MPR 2+10+30 OD.

**Metabolism and residues**: Uses are accepted.

Evaluators verified whether the co-formulants contained in plant protection product CERENET are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product CERENET does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product CERENET meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for in-clusion in Annex III of Regulation (EU) 1107/2009.

Detailed assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574 can be found in the dRR Part C and the Annex to Part C.

## Substances of concern for national monitoring

No national monitoring required.

## Classification and labelling

### Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

|  |  |
| --- | --- |
| Hazard class(es), categories: | Skin Sens. 1B, Eye Dam 1, Aquatic Acute 1, Aquatic Chronic 1 |

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

|  |  |
| --- | --- |
| Hazard pictograms: | A red and black sign  Description automatically generated |
| Signal word: | Danger |
| Hazard statement(s): | **H317, H318, H410** |
| 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] |

|  |  |
| --- | --- |
| Special rule for labelling of plant protection product (PPP): | |
| EUH401 | To avoid risks to man and the environment, comply with the instructions for use. |

**See Part C for justifications of the classification and labelling proposals.**

### Standard phrases under Regulation (EU) No 547/2011

|  |  |
| --- | --- |
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |

### Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

## Risk management

### Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|  |  |
| --- | --- |
| Operator protection: | |
| / |  |
| Worker protection: |  |
| / |  |
| Integrated pest management (IPM)/sustainable use: | |
| / |  |
| Environmental protection | |
| Spe3 | To protect non-target plants, respect 5 meter buffer zone to non-crop land or use 75 % drift reduction nozzels for all uses |
| Other specific restrictions | |
| / | / |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|  |  |
| --- | --- |
| Integrated pest management (IPM)/sustainable use: | |
| / |  |

### Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

|  |  |  |
| --- | --- | --- |
| Integrated pest management (IPM)/sustainable use: | | Relevant for use no. |
| / |  |  |
| Environmental protection: | | Relevant for use no. |
| Spe3 | To protect non-target plants, respect 5 meter buffer zone or use 75% drift reduction nozzels to non-crop land for all uses | All uses |

## Intended uses (only NATIONAL GAP)

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | GAP rev.      , date: year-month-day |
| PPP (product name/code): | IMS+MSM+MPR 2+10+30 OD | Formulation type: | OD |
| Active substance 1: | Iodosulfuron-methyl-sodium | Conc. of as 1: | 2 g/L |
| Active substance 2: | Mesosulfuron-methyl | Conc. of as 2: | 10 g/L |
| Safener: | Mefenpyr-diethyl | Conc. of safener: | 30 g/L |
| Synergist: | / | Conc. of synergist: | / |
| Applicant: | Certiplant BV | Professional use: |  |
| Zone(s): | Central | Non professional use: |  |
| Verified by MS: | yes/no |  |  |
|  |  |  |  |
| Field of use: | herbicide |  |  |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Use-No. (e)** | **Member state(s)** | **Crop and/ or situation  (crop destination / purpose of crop)** | **F, Fn, Fpn G, Gn, Gpn or I** | **Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group) | **Application** | | | | **Application rate** | | | **PHI** (days) | **Remarks:**   e.g. g safener/synergist per ha  (f) |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| **Zonal uses (field or outdoor uses, certain types of protected crops)** | | | | | | | | | | | | | |
| 1 | PL | Winter wheat  (TRZAW) | F | ALOMY  APESV  VIOAR | Spraying | BBCH 21 - 31 | 1 | - | 1.2 | 2.4 (1)  12 (2)  36 (3) | 200 / 400 | - | Spring use  **Eff. section**: VIOAR not accepted |
| 2 | PL | Winter rye  (SECCW) | F | ALOMY | Spraying | BBCH 21 - 31 | 1 | - | 0.9 | 1.8 (1)  9 (2)  27 (3) | 200 / 400 | - | Spring use  **Eff. section**: use not accepted. |
| 3 | PL | Winter triticale  (TTLWI) | F | ALOMY, APESV | Spraying | BBCH 21 - 31 | 1 | - | 1.2 | 2.4 (1)  12 (2)  36 (3) | 200 / 400 | - | Spring use |
| Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms) | | | | | | | | | | | | | |
| 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (zonal uses) | | | | | | | | | | | | | |
| 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (interzonal uses) | | | | | | | | | | | | | |
| 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |

(1) Iodosulfuron-methyl-sodium (2) Mesosulfuron-methyl (3) Mefenpyr-diethyl

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

# Background of authorization decision and risk management

## Physical and chemical properties (Part B, Section 2)

The appearance of the product is that of uniform beige liquid, with a solvent type odour. It is not explosive, has no oxidising properties. The product has a flash point of 94.5 °C. It has a self ignition temperature > 400 °C. In aqueous solution, it has a pH value around 6.54 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Its technical characteristics are acceptable for a OD formulation.

The ambient shelf life study for 2 years is still on-going. Results are expected in June 2026.

The intended concentration of use is 0.225 to 0.75 % (~~0.3~~ 0.225 to 0.6% for PL).

Not intended to be used in tank mixes.

## Efficacy (Part B, Section 3)

In Poland, 25 PPPs with iodosulfuron methyl and 20 PPPs with mesosulfuron methyl are registered (on the basis on the Ministry Register dated 29.11.2024). Eight PPPs with those both active compounds are registered and use in Poland. The product – CERENET (product code: IMS+MSM+MPR 2+10+30 OD) containing iodosulfuron-methyl-sodium (2 g/kg) and mesosulfuron-methyl (10 g/kg) and mefenpyr-diethyl (30 g/kg) as a safener by Certiplant B.V. has not been previously evaluated in any country ac-cording to Uniform Principles. Detailed assessment is presented in B3.

## Efficacy data

This document summarizes the information related to the efficacy of the plant protection product – CERENET (product code: IMS+MSM+MPR 2+10+30 OD). CERENET is an oil dispersion (OD) formulation containing 2 g/L of iodosulfuron-methyl sodium and 10 g/L of mesosulfuron methyl. Also, CERENET is containing a safener – mefenpyr diethyl (30 g/L). For now, those mentioned active compounds are on the list of approved active substances.

*Iodosulfuron-methyl sodium* is a selective active compound of herbicide that mainly targets certain grass and broadleaf weeds. It works by inhibiting photosynthesis and is often used in post-emergence applications. *Mesosulfuron methyl* acts similarly by inhibiting the growth of specific weed species. It is effective against various grass weeds and is commonly used in cereal crops. *Mefenpyr diethyl*: this is typically included as a safener to protect the crop from injury while allowing the herbicides to effectively target weeds. It helps to enhance crop tolerance to the active ingredients.

When combined, these components offer a robust solution for weed control in cereals, effectively managing a range of weed species while minimizing the risk to the crop. The combination of iodosulfuron methyl sodium, mesosulfuron methyl and mefenpyr diethyl targets a broad spectrum of both grass and broadleaf weeds, providing effective control over various competitive species. These active compounds are selective, meaning they primarily affect the targeted weeds while minimizing harm to the cereal crops. This helps in preserving crop yield and quality. The mixture of different modes of action can help in delaying the development of herbicide-resistant wee populations, promoting sustainable weed management practices. Mefenpyr diethyl acts as a safener, enhancing the tolerance of cereal crops to the herbicides, thus reducing the risk of crop injury during applications. The combination is effective when applied post-emergence, allowing farmers to control weeds after the crops have emerged and established. Using such herbicides can be part of a broader IPM strategy, helping to control not only weeds but also potentially reducing pest pressure. Overall, these advantages make the combination of iodosulfuron methyl sodium, mesosulfuron methyl and mefenpyr diethyl a valuable tool for cereal crop management.

While herbicides containing iodosulfuron-methyl sodium, mesosulfuron methyl and mefenpyr diethyl offer several advantages, there are also some disadvantages. Despite the safener, some cereal varieties may still show sensitivity to these herbicides especially under certain environmental conditions, leading to stunted growth of yield loss. There could be concerns regarding the herbicides potential impact on non-target organisms, including beneficial insects, flora and fauna, especially in surrounding ecosystems.

Over reliance on these herbicides may contribute to the development of herbicide-resistant weed populations, compromising long-term weed management strategies. These herbicides can be affected by weather conditions, such as rainfall shortly after application, which may reduce effectiveness or increase runoff. They should be part of an integrated weed management program, which may require additional practices and inputs, making management more complex. There is a risk of herbicide drift during application, which could impact neighboring crops and other vegetation, leading to unintended consequences. Considering these disadvantages, it is essential for farmers to carefully assess their specific situations, follow application guidelines and incorporate this herbicide into comprehensive weed management plans to minimize negative effects.

***Preliminary studies***:

Herbicides containing iodosulfuron-methyl sodium, mesosulfuron methyl and mefenpyr diethyl have been known and used in agriculture since their development and approval for use. *Mesosulfuron methyl* developed in the late 1990s, it was first registered for use in various countries in the early 2000s. It is widely used in winter cereals, particularly for controlling grass weeds. *Iodosulfuron-methyl sodium* developed slightly later than mesosulfuron, it was introduced into the market in the mid-2000s. It is used mainly for its effectiveness against broadleaf and grass weeds in cereals. *Mefenpyr diethyl* – this safener was developed in the late 1990s and has been use in use since the early 2000s. It is primarily used to protect cereal crops from potential herbicide induced injury. All three active compounds are part of integrated weed management programs in agriculture, particularly in Europe and other regions where winter cereals are grown. Their usage has been refined based on efficacy studies, environmental assessments and regulatory approvals, and they continue to be integral tools for managing weed populations in cereal crops.

The Applicant did not provide preliminary range finding tests. The active substances in CERENET, iodosulfuron-methyl sodium and mesosulfuron methyl are widely registered and have been commonly utilized in agricultural practices for many years. Consequently, numerous efficacy trials are available to assess the effectiveness of products containing these active compounds, making preliminary tests unnecessary in this instance, according to ZRMs. Furthermore, the Applicant did not submit a justification for combining these two active substances in CERENET. However, ZRMs consider such a justification unnecessary in this case.

***Minimum effective dose***

The minimal effective dose of herbicides containing iodosulfuron-methyl sodium, mesosulfuron methyl and mefenpyr diethyl can vary depending on the specific formulation, target weeds and environmental conditions. However, general guidelines for effective usage in winter cereals are as follows: *Mesosulfuron methyl*: typical application rates range from 15 to 30 grams per hectare (g/ha). *Iodosulfuron-methyl sodium*: typical application rates range from 25 to 50 grams per hectare (g/ha). *Mefenpyr diethyl*: when used a safener, application rates range from 50 to 100 grams per hectare (g/ha). These rates can vary by country and specific product formulation. It is crucial to check the product label for the most accurate application guidance and ensure compliance with local regulations. Additionally, efficacy can be influenced by factors such as weed type, growth stage and environmental conditions, so consulting an agronomist or agricultural extension service is advisable for localized recommendations.

To determine the minimum effective dose, some efficacy trials should include at least two doses lower than the recommended one. However, the relevant efficacy studies evaluated various doses and the lowest effective dose was selected for registration, in compliance with EPPO 1/225 (2).

Applicant studied MED dose during efficacy studies (lack of MED trials). In total 15 trials was submitted by Applicant. Nine trials were carried out on winter wheat in Maritime EPPO zone (5 trials: BE-1, CZ-1, DE-3) and N-E EPPO zone (4 trials: PL) in 2022 and 2023. Three trials were performed on winter rye in Maritime EPPO zone (DE) in 2022 and 2023 and three trials on winter triticale in DE (Maritime EPPO zone) in 2022 and 2023.

Three different doses were studied during trials. For winter wheat and winter triticale following doses were studied: 0.9 L/ha (0.6N), 1.2 L/ha (0.8N – recommended for PL) and 1.5 L/ha (N recommended for BE and NL) and for winter rye: 0.45 L/ha (0.5N), 0.72 L/ha (0.8N) and 0.9 L/ha (N recommended for BE, NL and PL).

Following weed species were studied in trials:

* winter wheat: ALOMY (5) and APESV (1) in Maritime EPPO zone and ALOMY (4), APESV (3), CHEAL (1), GALAP (1), MATIN (1), PAPRH (1), POLCO (1), STEME (1), VERHE (1), VERPE (1) and VIOAR (2) in N-E EPPO zone;
* winter triticale: ALOMY (3), GALAP (1) and VERPE (1) in Maritime EPPO zone;
* winter rye: ALOMY (3), BROST (1), GALAP (1) and GERDI (1) in Maritime EPPO zone.

On the basis on submitted documentation it can be stated that CERENET was the most effectively in control weeds in winter wheat and winter triticale at dose 1.5 L/ha and in winter rye at dose 0.9 L/ha. For Poland dose 1.2 L/ha for winter triticale and winter wheat and dose 0.9 L/ha for winter rye can be recommended (detailed assessment is presented in next chapter).

Submitted documentation is sufficient for Poland. Section 2 (Physical and chemical properties) stated that those two PPPs: CERENET and Atlantis 12 OD (st. ref. product) are not comparable. So, ZRMs from efficacy section evaluated CERENET only on the basis on submitted data reports (in line to Art. 33). cMS from Maritime EPPO zone should decide if limited number of trials for CERENET can be acceptable..

***Efficacy***

The efficacy of herbicides containing iodosulfuron methyl sodium, mesosulfuron methyl and mefenpyr diethyl against weeds in winter cereals is significant, particularly for controlling various grass and broadleaf weed species. This herbicide is considered effective components of integrated weed management in winter cereals. Efficacy can also be influenced by application timing, environmental conditions and weed growth stages. Properly timed applications can lead to excellent weed control, minimizing crop competition and maximizing yield potential.

All details about efficacy methodology used during efficacy trials is presented above by Applicant. Number of trials is not in line to EPPO standards. However, Applicant would like to register CERENET in line to Article 33 and Art. 34 with using unprotected data from st. ref. product (Atlantis 12 OD). For bridging approach number of trials would be acceptable, however Section 2 stated that CERENET and Atlantis 12 OD are not comparable, so we could not register CERENET on the basis on Art. 34. cMS from Maritime EPPO zone should decide if limited number of trials for CERENET can be acceptable, especially when it is not assessed in line to Art. 34 or should consider using other unprotected data from similar products, if such approach is acceptable due to national rules. In Poland, always bridging trials are needed and comparison that both PPPs are comparable. So, we can assessed CERENET only in line to Art. 33 on the basis on submitted documentation.

Applicant properly presented results separately for each EPPO zone. In the tables presented by Applicant are presented results from Maritime EPPO zone and N-E EPPO zone carried out on winter wheat, Maritime EPPO zone on winter triticale and Maritime EPPO zone on winter rye. However, in the opinion of ZRMs it is possible to present CERENET efficacy results for different winter cereals (winter triticale and winter wheat). Results from winter rye should be treated separately as different doses were studied and differ doses is recommended. Winter wheat and winter triticale exhibit similar sensitivity to CERENET and comparable environmental and agronomic conditions, so results may be presented together.

Winter wheat was studied in 9 trials (Maritime – 5 trials: BE-1, CZ-1, DE-3 and N-E – 4 trials: PL). Winter triticale was studied in 3 trials (Maritime EPPO zone: DE) and winter rye in 3 trials (Maritime EPPO zone: DE).

Only trials with greater than 5 weeds/m2 or over 2% ground cover should be taken for assessment. According to EPPO PP 1/226 at least 6 fully supportive results for major weeds and 2 trials for minor weeds should be required. Therefore, based on knowledge of major/minor status of weeds in each country, weeds with insufficient results should be excluded. Considering comparable results in all zones (Maritime and N-E in the case of winter wheat), it is recommended to take into account results from all zones to get more reliable set of data. The results should be adjusted to known efficacy from long term use of iodosulfuron methyl sodium and mesosulfuron methyl standard products by cMS. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in line to Uniform Principles.

For Poland, considering that the active substances have been widely used for many years across numerous countries, the list of weed controlled should include only those species observed (at significant intensity) in at least two locations. For species presenting the highest risk to crops, data from a minimum of four locations should be included.

Each cMS should assess the sensitivity of the accepted weed species based on their respective internal regulations. In Poland, the classification of weed sensitivity differs from SANCO standards. Accepted weed species for Poland (N-E EPPO zone) should follow this sensitivity scale: S (susceptible weeds) >85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70% and T (tolerant weeds) <60%.

The active substances have been in use for many years in various countries. The Applicant submitted data from 2022 and 2023. These trials were conducted by a certified testing unit authorized by the Chief Inspector of Plant Health and Seed Inspection, with GEP. The studies examined application timings, number of applications and water volume.

The reference data provided by the original registrant on iodosulfuron methyl sodium and mesosulfuron methyl, which are now off patent, do not fully support some of the recommendations on the draft label. Such extrapolations should be evaluated at the national level by individual member states, considering current registration status, data protection and experience with similar products. Additionally, the spectrum of weeds should align with the label claims of these reference products.

**Assessment for cMS (Maritime EPPO zone):**

Applicant submitted 5 trials carried out on winter wheat, 3 trials on winter triticale and 3 trials on winter rye in 2022 and 2023. Submitted trials show the efficacy comparability between CERENET and st. ref. product. Atlantis 12 OD was studied as the ref. product in most of efficacy studies. Sigma max as a st. ref. product was studied in 4 efficacy trials – one carried out on winter triticale in DE and 3 trials on winter wheat (DE-2 and BE-1).

Weeds characterized by only one valid trial should be not taken into the assessment (in the opinion of ZRMs). Following weed species were characterized by only one valid trial: GALAP and VERPE in winter triticale, BROST, GALAP and GERDI in winter rye and APESV in winter wheat.

Only ALOMY (5 trials in winter wheat and 3 trials in winter triticale) have enough number of trials. In winter rye – ALOMY was studied only in 3 trials. cMS should decide about list of accepted weed species and their sensitivity on the basis on national rules and possibility of uses data from similar products.

**Assessment for Poland (N-E EPPO zone**):

Poland can use data from N-E EPPO zone and neighboring countries from other zones. Winter wheat was studied in 8 trials (PL-4, CZ-1, DE-3), winter triticale and rye in 3 trials (DE). In the opinion of ZRMs, in the Polish label use on winter wheat and winter triticale can be accepted (on the basis of extrapolating results from winter wheat). Winter rye was represented only by 3 trials, in the case that it is not bridging approach (Atlantis 12 OD was not assessed as a comparable PPP) and recommended different doses than in for winter rye (0.9 L/ha) was also studied in the efficacy studies carried out in winter wheat and winter triticale, results from winter wheat and winter triticale cannot be extrapolated to winter rye. This use (on winter rye) should can be excluded from accepted in GAP table and Polish label project due to insufficient submitted documentation. However Also, use on winter triticale and winter wheat can be included in GAP and Polish label.

Weeds represented by only one valid trial should not be taken for the assessment. Applicant would like to register CERENET against ALOMY, APESV and VIOAR. ALOMY and APESV are a major weed in winter wheat and winter triticale. VIOAR is a major weed winter wheat and a minor weed in winter triticale.

Below, ZRMs presented the efficacy of CERENET for winter wheat and winter triticale. Results for and winter rye are not present, due to fact that this use was not accepted.

**ALOMY** – 11 trials (PL-4, DE-3, CZ-1 on winter wheat and 3 DE on winter triticale) – major weed in winter wheat and winter triticale – number of trials is sufficient, CERENET at recommended dose (1.5 1.2 L/ha) moderately effectively control ALOMY in Maritime trials (79.3 74.9% eff.) and N-E trials (81.8 %) on winter wheat and moderately tolerant in winter triticale (80.0 65.8% eff. from Maritime). Results were comparable to st. ref. product. Given that the application windows for both cereal species are identical, it is possible to average the test results concerning the effectiveness of controlling the field vole after applying CERENET at a dose of 1.2 l/ha for winter wheat (average eff.: 78,4%) and winter triticale (65.8% eff.) cultivation. **It can be stated that CERENET moderately effectively control ALOMY at recommended dose (1.5 1.2 L/ha) in winter wheat and winter triticale.**

Additionally, the Applicant proposes to register the use of CERENET at a dose of 0.9 L/ha for the control of ALOMY in **winter rye** in Poland. A total of three efficacy trials conducted in Germany on winter rye have been submitted. The dose of 0.9 L/ha was evaluated, and the observed efficacy against ALOMY was 57.9%. Although **ALOMY** is considered a minor weed in winter rye in PL and three trials may be sufficient, **it is known to be tolerant to CERENET**. Also, ALOMY at dose 0.9 L/ha was studied in winter wheat (5 trials from DE) – eff. 62.38%, and NE (PL-4 trials -69.65%) and winter triticale in DE (3 trials) – eff. 52.9%).

**APESV –** 4 trials (PL-3, CZ-1) on winter wheat. APESV was not studied in trials carried out on winter triticale. CERENET at recommended dose (1.5 1.2 L/ha) effectively control APESV in CZ trial (Maritime-100% eff.) and moderately effectively (82.4% eff.) in N-E trials. **On the basis on submitted results, it can be concluded that CERENET moderately effectively control APESV in winter wheat.** Lack of trials against APESV for winter triticale. Using the extrapolation table, the study conducted at a dose of 1.2 l/ha for winter wheat can be extrapolated for winter triticale. Without any efficacy studies for this weed species in winter triticale, extrapolating results from winter wheat would be challenging. Therefore, the Applicant correctly not included APESV for winter triticale in the Polish label (moderately sensitive against 1.2 L/ha of CERENET).

In the absence of results demonstrating the effectiveness of controlling APESV when a dose of 0.9 l/ha is applied to winter rye crops, it is impossible to determine this weed species' sensitivity to the product at this dosage.

**VIOAR** – 2 trials (PL) on winter wheat. VIOAR is a major weed in winter wheat and minor weed in winter triticale. VIOAR was not studied in trials carried out on winter triticale and winter rye. Extrapolating results from winter wheat to winter triticale and rye cannot be done, due to fact that for winter wheat not enough number of trials were presented.Also, Applicant would like to register VIOAR only in winter wheat. **Weed not accepted in Polish label.**

**Summary of the assessment made for Poland:**

* *winter wheat* – ALOMY and APESV as a moderately sensitive weeds against 1.5 1.2 L/ha of CERENET. VIOAR was excluded from label due to not enough number of trials;
* *winter rye* – use excluded from GAP and Polish label due to not enough number of trials and lack of possibility extrapolating results from st. ref. product against APESV and VIOAR – not accepted. ALOMY accepted as a tolerant weed against CERENET at dose 0.9 L/ha. Section 2 assessed that Atlantis 12 OD and CERENET are not comparable, so its unprotected data cannot by use by ZRMs in this assessment.
* *winter triticale* – ALOMY and APESV as a moderately sensitive weed against 1.5 1.2 L/ha of CERENET.

**Proposed entry for label:**

* **winter rye**

**Dose 0.9 L/ha**

|  |  |
| --- | --- |
| Tolerant weeds | ALOMY |

* **winter wheat, winter triticale**

**Dose 1.2 L/ha**

|  |  |
| --- | --- |
| Moderately sensitive weeds | ALOMY, APESV |

### Information on the occurrence or possible occurrence of the development of resistance

Iodosulfuron-methyl-sodium and mesosulfuron-methyl are classified as HRAC group 2 (legacy HRAC group B) herbicides which inhibit the enzyme acetolactate synthase (ALS). According to “The International Herbicide-Resistant Weed Database”, several studies on the mechanisms of resistance to these two active substances have been conducted in several resistant weed species growing in (winter) wheat and/or triticale fields, including ALOMY and APESV. These studies indicate that the observed resistance results from an altered target site, enhanced metabolism and/or altered translocation.

Considering the variation in the level of target site-related resistance across resistant weeds, different functional changes to the target site in ALS are expected. This is evidenced by several genetic studies suggest that inheritance of resistance is determined by one dominant nuclear gene trait (as observed in resistant *Alopecurus myosuroides*, *Lolium rigidum*, *Papaver rhoeas*, and *Stellaria media*), one semi-dominant nuclear gene trait (as observed in resistant *Apera spica-venti* and *Raphanus raphanistrum*), or two dominant nuclear gene traits (as observed in resistant *Apera spica-venti*).

Evidence of resistance

Weed species resistant to ALS-inhibiting herbicides are by far the most recorded in the International Herbicide-Resistant Weed Database. As of May 2023, 172 species had been reported as resistant to HRAC group 2 herbicides, including 105 dicots and 67 monocots.

Four weed species have observed to be resistant to iodosulfuron-methyl-sodium and/or mesosulfuron-methyl in the central zone:

* *Alopecurus myosuroides*: major grass weed in winter cereals in north-western Europe;
* *Apera spica-venti:* major grass weed in cereals widely present and problematic in Denmark, Germany, Poland, Czech Republic, Slovakia, Lithuania, Latvia, and Austria, and locally present in Belgium, Netherlands. Luxembourg, France, and Sweden;
* *Lolium perenne (ssp. multiflorum)*: grass weed in winter wheat;
* *Stellaria media*: annual broad-leaved weed in winter cereals.

The development of resistance to herbicides is a significant concern in agricultural practices, especially when using specific active compounds like iodosulfuron methyl sodium and mesosulfuron methyl. Resistance can occur due to various factors that influence the effectiveness of this herbicide against target weed species.

*Mechanism of resistance*: often develops through genetic mutations in weed populations, enabling them to survive applications of specific herbicides. Common resistance mechanisms include altered target site sensitivity, enhanced herbicide metabolism and changes in weed physiology.

*Occurrence of resistance*: instances of resistance have been documented for herbicides that share similar mechanisms of action, particularly by species such as black-grass (*Alopecurus myosuroides*). Resistance to ALS-inhibiting herbicides (which includes mesosulfuron and iodosulfuron) is becoming more common in certain regions, especially where these herbicides have been used extensively.

*Factors contributing* to resistance: repeated use of the same herbicide or herbicides with similar modes of action without tank mixing or rotating with herbicides from different groups can lead to resistance. Continuous cropping practices and neglecting cultural practices that include crop rotation, cover crops or other weed management strategies also contribute.

*Risk assessment and management strategies*: regular monitoring of weed populations for resistance is crucial. Implementing integrated weed management strategies that combine chemical, cultural and mechanical methods can help mitigate resistance. Rotating herbicides with different modes of action, using mixtures, and adopting non-chemical methods (like tillage or cover cropping) are effective strategies to delay or manage resistance.

Resistance patterns can vary by region due to differences in agronomic practices, weed species prevalence and historical herbicide use.

In regard to the use of CERENET for controlling target weeds, the following conclusion can be drawn:

* The product poses a significant risk of developing weed resistance both inherently and from an agronomic perspective
* To mitigate the likehood of resistance, it is recommended to apply an additional herbicide with a different mode of action, which is highly effective against the targeted weed species.
* It is advisable to alternate or combine the product with other herbicides that have a distinct mode of action
* To minimize the risk of resistance, one application of CERENET at the recommended dosage per seasons is recommended.

To reduce the likehood of herbicide resistance in weed, adherence to Good Agricultural practices is essential:

* Strictly follow the instructions on the plant protection product label
* Use the product at the prescribed dosage and timing to ensure optimal weed control
* Employ integrated weed management strategies that include crop rotation, herbicide usage and diverse tillage methods
* Rotate herbicides with varying mechanisms of action
* Use mixtures of herbicides that target different mechanisms of action
* Rotate or mix herbicides that act on multiple weed life processes with different mechanisms of action.

The resistant management plan proposed by the applicant is acceptable:

*“To minimize the risk of weed resistance to herbicide and its development, the following Good Agricultural Practice guidelines should be followed:*

* *Strictly adhere to the instructions provided on the plant protection product label – use the product at the recommended dose and application timing to ensure optimal weed control.*
* *Select herbicides and determine application timing based on the current (or potential) weed infestation, considering dominant species and economic thresholds.*
* *Rotate herbicides (active substances) with different modes of action.*
* *Use herbicide mixtures (active substances) with different modes of action.*
* *Apply, in rotation and/or mixtures, herbicides that target multiple weed life processes (with different modes of action)*
* *Use herbicides with a specific mode of action only per growing season for a particular crop.*
* *Adapt cultivation practices to field conditions, particularly to the type and intensity of weed infestation.*
* *Employ diverse weed control methods, including crop rotation, among others.*
* *Use certified seed material.*
* *Clean agricultural machinery to prevent the transfer of weed propagules to other fields.*
* *Inform the authorization holder of any unsatisfactory weed control.*
* *For detailed information, consult an advisor, the authorization holder, or the holder’s representative”.*

Final assessment of the resistance risk has to be carried out on member state level since the agronomic factors influencing the risk of resistance development tend to vary between the Member States.

### Adverse effects on treated crops

***Phytotoxicity assessment***:

Adverse effects of herbicides like iodosulfuron methyl sodium, mesosulfuron methyl and mefenpyr diethyl on treated crops can occur due to various factors. Phytotoxicity refers to the harmful effects that herbicides can have on non-target crops. Symptoms may include leaf burn, discoloration, stunting and ultimately reduced growth or yield. Different crops may exhibit varying sensitivities to this herbicide. Factors like temperature, humidity and soil moisture can influence herbicide efficacy and crop safety. High temperatures can increase volatility, leading to drift and potential non-target crop damage. To minimize these adverse effects, it is crucial to follow label instructions, use appropriate application methods and consider the specific sensitivities of the crops being treated. It is also advisable to implement integrated management practices that balance herbicide use with other agronomic strategies.

During the evaluation process, the fact that the active ingredients – iodosulfuron methyl sodium and mesosulfuron methyl are widely used in various plant protection products and have been extensively applied in crop protection was taken into account by the ZRMs.

The Applicant submitted a total of 16 selectivity studies on the herbicide CERENET, which contains these two active substances. The selectivity assessment of the herbicide was conducted following the EPPO guidelines outlined below. The trials were carried out 4 to 5 times per season. The results were expressed as the percentage of plant destruction due to the herbicide treatment compared untreated plants, where 0% represents no phytotoxicity and 100% indicate complete destruction.

Phytotoxicity was assed using various cultivars (commercially grown varieties). The recommended dosage (N) and a doubled recommended dosage (2N) were tested during the selectivity trials. The experimental design and evaluation methods adhered to EPPO standards. The Applicant provided detailed information on the trials. These trials were conducted solely on winter wheat (6 trials: 4 Maritime – CZ-1, FR-1, DE-1, NL-1 and 2 trials N-E: PL), winter rye (5 trials: 3 Maritime – CZ-1, DE-1, NL-1 and 2 N-E: PL) and winter triticale (5 trials: 3 Maritime – FR-2, CZ-1 and 2 N-E: PL). All selectivity trials were carried out in one growing season (2022). Also, phytotoxic effect was studied in 13 efficacy trials carried out on winter wheat (9 trials: 5 Maritime- DE-3, CZ-1, BE-1 and 4 NE: PL), winter rye (3 trials; Maritime- DE) and winter triticale (3 trials: Maritime – DE).

Transient phytotoxicity symptoms exceeding the 5% damage threshold were observed in 12 out of 31 efficacy and selectivity trials with IMS+MSM+MPR 2+10+30 OD at the proposed dose rate (N). These symptoms included changes in crop color, chlorosis, stunting, deformation, delays in development, reduced crop vigor, and impacts on non-target organisms (such as pollinators, adjacent crops or wildlife). The symptoms were primarily noted shortly after application and typically resolved by the final assessment in 23 of the 31 trials. Application at double the proposed dose rate (2N) generally led to significantly more severe phytotoxicity effects compared to the recommended rate (N). Similar symptoms were observed after treatment by st. ref. product (Atlantis 12 OD or Sigma max).

For Poland with using trials from neighboring countries – documentation submitted by Applicant for phytotoxicity assessment can be stated as a sufficient. cMS should decide if submitted documentation can be acceptable.

In the opinion of ZRMs follow entry should be put in the label: *under very unfavorable weather conditions there is a possibility of crop damage, which typically disappears within 3 weeks and does not negatively affect yield or its parameters*.

***Impact on the yield***:

The application of herbicide with iodosulfuron methyl sodium and mesosulfuron methyl can have potential impacts on crop yield, both positive and negative. As mentioned earlier, herbicide injury can lead to symptoms such as leaf burn, stunting and reduced overall plant vigor. Severe toxicity may directly result in yield loss as plants struggle to recover. Following best practices for herbicide application, such as timing, dosage and technique can help minimize negative impacts on yield. In summary, while herbicides can enhance yield through effective weed control, misuse or adverse interactions can also lead to significant yield reductions. Careful management is crucial to strike a balance and achieve optimum yield potential.

Applicant submitted 16 selectivity trials in which impact of CERENET of yield was assessed. Those trials were carried out on winter wheat (6 trials: 4 Maritime – CZ-1, FR-1, DE-1, NL-1 and 2 NE-PL), winter rye (5 trials: 3 Maritime – CZ-1, DE-1, NL-1 and 2 NE: PL) and winter triticale (5 trials: 3 Maritime – FR-2, CZ-1 and 2 NE: PL). Although phytotoxicity symptoms were observed in 10 out of 16 selectivity trials, grain yield was significantly impacted in only one of these trials. The correlation between phytotoxicity and yield is summarized in Table 3.4-5.

For Poland with using trials from neighboring countries – documentation submitted by Applicant for yield assessment can be stated as a sufficient. cMS should decide if submitted documentation can be acceptable. On the basis on documentation, it can be stated that CERENET used at recommended dose is safe for yield of treated winter cereals (wheat, rye and triticale).

***Impact on the quality of yield***:

The application of herbicide can significantly influence the quality of crop yields, encompassing various factors that contribute to the overall marketability and nutritional value of the produce. While herbicide can improve the quality of yields through effective weed control and enhanced crop vigor, improper application can lead to decreased quality and market value. Balancing weed management practices with consideration of crop health is essential for achieving high-quality yields.

Applicant submitted 16 selectivity trials in which impact of CERENET of yield was assessed. Those trials were carried out on winter wheat (6 trials: 4 maritime – CZ-1, FR-1, DE-1, NL-1 and 2 NE-PL), winter rye (5 trials: 3 maritime – CZ-1, DE-1, NL-1 and 2 NE: PL) and winter triticale (5 trials: 3 maritime – FR-2, CZ-1 and 2NE: PL). Although phytotoxicity symptoms were observed in 10 of `16 selectivity trials, grain quality was significantly impacted in only one of these trials. The correlation between phytotoxicity and yield is summarized in table 3.4-5.

For Poland with using trials from neighboring countries – documentation submitted by Applicant for quality of yield assessment can be stated as a sufficient. cMS should decide if submitted documentation can be acceptable. On the basis on documentation, it can be stated that CERENET used at recommended dose is safe for quality of yield of treated winter cereals (wheat, rye and triticale).

### Observations on other undesirable or unintended side-effects

No detrimental effects on succeeding crops are expected. IMS+MSM+MPR 2+10+30 OD poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed GAP. No negative effects on beneficial and other non-target organisms are expected.

**Impact on succeeding crops**:

Iodosulfuron methyl sodium and mesosulfuron methyl are sulfonylurea herbicide commonly used in agriculture for controlling broadleaf and grassy weeds. Their impact on succeeding crops can vary based on several factors, including their residual effects in the soil and the sensitivity of subsequent crops to these herbicides. With reduced weed pressure, succeeding crops may establish more effectively, leading to healthier and more robust plants. Iodosulfuron methyl sodium and mesosulfuron methyl can persist in the soil, leading to potential carryover effects that can negatively impact sensitive succeeding crops. Certain succeeding crops may be sensitive to residual herbicides, causing phytotoxicity, which can lead to stunted growth, chlorosis or even plant death. Proper timing and dosage are crucial to minimize negative effects on succeeding crops. Following label recommendations is essential.

Iodosulfuron methyl sodium and mesosulfuron methyl can significantly impact succeeding crops, primarily benefiting through weed control but also posing risks through residual activity and potential phytotoxicity. Understanding their effects and implementing best management practices are crucial for maximizing benefits while minimizing negative impacts on subsequent crops.

EU regulations regarding plant protection products stipulate that adequate data must be provided to assess any potential negative effects of a treatment with a plant protection product on subsequent crops. This is especially the case if studies and evaluations within other parts of the dossier indicate that significant residues of the active substance, its metabolites or degradation products (substances that may have biological activity on succeeding crops) persist in the soil or plant materials until the sowing or planting of subsequent crops. Consequently, the Applicant is required to present an assessment of the potential effects of CERENET on crops grown as rotational or replacement crops following the use of the product. This assessment should be prepared according to the EPPO Standard on Efficacy Evaluation of Plant Protection Products and the guideline on Effects on Succeeding Crops (PP 1/207 (2)), which provides a general framework for determining whether the active substance of a plant protection product may negatively affect crops grown after the treated crops. These subsequent crops can include normal rotational crops or replacement crops in the event of crop failure.

The components of CERENET are established active ingredients that have been authorized for cereal production for an extended period. The restrictions on rotational crops are well documented. Based on scientific data, the half-life (DT50) of iodosulfuron in field tests is 9-15 days, while laboratory conditions, it ranges from 1 to 22 days. For mesosulfuron methyl sodium, the DT50 in laboratory tests is between 6 and 91 days, and in field tests, it ranges from 77 to 114 days in autumn and 29 to 73 days in spring. Therefore, it can be concluded that the herbicide CERENET degrades in the soil during the growing season to levels that do not pose a risk to succeeding crops. The information provided on the label regarding effects on succeeding crops is deemed sufficient.

ZRMs have accepted the following statement in the label for CERENET: *The product decomposes in the soil and does not pose a risk to subsequent crops. In the event that the treated crop needs to be terminated, spring wheat can be cultivated after plowing.*

**Impact on the adjacent crops**:

The impact of iodosulfuron methyl sodium and mesosulfuron methyl herbicide on adjacent crops can also encompass a range of positive and negative effects. These impacts can be due to drift, leaching and residual effects in the soil. Effective weed control can benefit adjacent crops by reducing competition for resources, allowing them to grow more vigorously. However, application of this herbicide can lead to drift, where small particles are carried by wind to nearby fields, potentially causing damage to non-target crops sensitive to those active compounds.

Residues can leach into nearby fields, affecting the growth of adjacent crops, particularly if they are sensitive to sulfonylurea herbicides. Adjacent crops may be subjected to limitations in rotation practices due to the residual presence of this herbicide in the soil.

Establishing buffer zones between fields treated with this herbicide and adjacent crops can help reduce the risk of drift and contamination. Applying herbicides during less windy conditions and at appropriate growth stages can help minimize drift and its impact on nearby crops.

Iodosulfuron methyl sodium and mesosulfuron methyl can have both positive and negative impacts on adjacent crops, depending on factors such as application methods, sensitive crop varieties and environmental conditions. Careful management practices are essential to reduce adverse effects while maximizing the benefits of effective weed control.

CERENET is effective against certain monocot and dicot weeds. However, its use may result in discoloration and damage to non-target foliage, including neighbouring crops. The information provided in this registration report and label adequately addresses the potential risks of spray overlap and drift.

As such, the label should include warnings to prevent spray drift onto adjacent crops. ZRMs agree with the Applicants findings that non-target plant studies indicate a potential risk to neighbouring crops from application and caution should be exercised to prevent drift. Based on the available data, the risk to non-target plants is considered minimal when a drift reduced nozzle (75% reduction) or a 5-meter buffer zone is used. A detailed assessment of this is provided in the Ecotoxicology section.

**Impact on transformation processes**:

The tested herbicide can have significant effects on the transformation processes involved in alcohol production, particularly in the context of crops used for fermentation. While herbicides can contribute positively to the efficiency and yield of crops used in alcohol production, careful management is crucial to avoid adverse effects that could compromise the transformation processes and the final product quality. The ZRMs has accepted the Applicant’s statement regarding the absence of trials on transformation processes for winter cereals. However, each member state (cMS) is responsible for determining whether this statement is acceptable.

CERENET is a formulated product that is similar to several other products authorised in the EU for an extended period, with no known adverse effects on transformation processes in the target crops. Additionally, no residues of any active ingredients are present at harvest. A per EPPO guideline PP 1/243, further data is not considered necessary. Therefore, the use of CERENET can be considered safe for crops involved in transformation processes. Moreover, the tested plant protection product is comparable to st. ref. product (Atlantis 12 OD), for which no effect on transformation processes has been observed.

**Impact on propagation purposes**:

Herbicides can significantly impact the process of propagation, either positively by controlling weeds and increasing yields or negatively by harming non-target species and compromising soil health. The key is to use them judiciously and consider integrated weed management strategies to balance these effects and promote sustainable propagation practices.

The ZRMs has accepted the Applicant’s statement regarding the absence of trials on propagation. However, each cMS is responsible for deciding whether this statement can be accepted. CERENET has been shown to be identical to older formulations that have been authorized in the EU for many years. No negative impact from these similar formulations has ever been observed on products intended for propagation. CERENET, like the reference product (Atlantis 12 OD) it was compared to, has proven to be selective to the treated crops, causing minimal phytotoxicity symptoms and no effect on yield at the recommended dose. Additionally, no residues are detected at harvest. Consequently, no additional data is considered necessary. The use of CERENET can be regarded as safe for plant products intended for propagation.

**Impact on beneficial and non-target organisms**:

Comprehensive studies on the potential adverse effects to beneficial organisms have been provided and summarized in the Ecotoxicology section. However, based on the documentation submitted by the Applicant (including efficacy and selectivity trials), no negative effects were observed on non-target organisms throughout all trials.

## Methods of analysis (Part B, Section 5)

### Analytical method for the formulation

Analytical methods for the determination of the active substances and safener in the formulation are available and validated according to SANCO/3030/99 rev. 5. As the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl do not contain relevant impurities, no analytical method is required.

### Analytical methods for residues

All analytical methods are active substance data and were provided in the EU review of iodosulfuron-methyl-sodium and mesosulfuron-methyl and were considered adequate.

In addition, reference is made to the renewal dossier of Atlantis 12 OD.

Noticed data gaps are:

* none

| Commodity/crop | Supported/ Not supported |
| --- | --- |
| Cereals | Supported |

## Mammalian toxicology (Part B, Section 6)

### Acute toxicity

Acute toxicity studies with IMS+MSM+MPR 2+10+30 OD were not evaluated as part of the EU review of IMS or MSM. 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 done to assess the acute toxicity of IMS+MSM+MPR 2+10+30 OD. The classification of IMS+MSM+MPR 2+10+30 OD has been calculated based on the amount and classification of the active substances and co-formulants.

Classification is: Skin Sens.1/H317; Eye Dam.1/H318.

### Operator exposure

Operator exposure was modelled following the 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).

According to the model calculations, it can be concluded that the risk for the operator using IMS+MSM+MPR 2+10+30 OD on all the proposed crops is acceptable wearing normal work wear.

### Worker exposure

Worker exposure was modelled following the 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).

According to the model calculations, it can be concluded that the risk for the worker using IMS+MSM+MPR 2+10+30 OD on all the proposed crops is acceptable wearing normal work wear.

### Bystander and resident exposure

*Resident exposure*

Resident exposure was modelled following the 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).

According to the model calculations, it can be concluded that there is no unacceptable risk anticipated for residents during treatment with IMS+MSM+MPR 2+10+30 OD.

*Bystander exposure*

No bystander risk assessment is required for PPPS that do not have significant acute toxicity or the potential to exert toxicity effects after a single exposure. There is not acute AOEL assessed for the active substances IMS or MSM or for the safener MPR, 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.

It is concluded that there is no unacceptable risk anticipated for bystanders during treatment with IMS+MSM+MPR 2+10+30 OD.

## Residues and consumer exposure (Part B, Section 7)

### Residues

**Iodosulfuron-methyl-sodium**

**Stability of Residues**

The storage stability report shows that iodosulfuron-methyl and its metabolite triazine amine (AE F059411) are stable in wheat grain, green material and straw for at least 24 months under deep-freezer storage conditions (≤-18°C).

The Applicant refers to data included in the Registration Report of Atlantis 12 OD.

NOTE: The data protection of Atlantis 12 OD should be confirmed by the competent authority at national level before registration.

**Metabolism in plants and animals**

No new data submitted in the framework of this application.

|  |  |
| --- | --- |
| EU Endpoints  Plant | |
| Plant groups covered | Cereals (Wheat) |
| Rotational crops covered | Yes |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not relevant |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Not applicable |
| Plant residue definition for monitoring | Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016 Reg. (EU) 2024/1077) |
| Plant residue definition for risk assessment | Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016)  Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a final decision is pending further clarification regarding the toxicological properties and the related consumer risk. Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment. |
| Conversion factor from enforcement to RA | 1 (EFSA, 2012, 2016) |

|  |  |
| --- | --- |
| Animal |  |
| Animals covered | - |
| - |
| Time needed to reach a plateau concentration | - |
| - |
| Animal residue definition for monitoring | Not necessary (EFSA, 2012, 2016)  Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (Reg. (EU) 2024/1077) |
| Animal residue definition for risk assessment | Not necessary (EFSA, 2012, 2016) |
| Conversion factor | - |
| Metabolism in rat and ruminant similar | - |
| Fat soluble residue | No |

EFSA Journal 2020;18(3):6053 (Scientific Opinion of the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on the genotoxic potential of triazine amine (metabolite common to several sulfonylurea active substances): *Based on the overall weight of evidence, the Panel, in agreement with the cross-cutting Working Group Genotoxicity, concluded that there is no concern for the potential of triazine amine to induce gene mutations and clastogenicity; however, the potential to induce aneugenicity was not adequately investigated. For a conclusion, an in vitro micronucleus assay performed with triazine amine would be needed.*

No further data are required to support the proposed uses.

**Magnitude of residues in plants**

Proposed GAPs:

Cereals (wheat, triticale, rye)

BBCH 21-31; 1 application 3 g as./ha; PHI: N/A

No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data and new studies submitted in the framework of the renewal of Atlantis 12 OD. These studies have to be considered only as additional information regarding the magnitude of triazine, AE F059411 and AE 0031838.

GAP on which EU a.s. assessment is based: 1 × 0.010-0.015 kg as/ha, BBCH 32-39, PHI not relevant, outdoor.

Residues (12 trials on wheat, 1 trial on barley and 1 trial on rye): 14 × <0.01 mg/kg

The results from studies evaluated on the EU level are all below LOQ (0.01 mg/kg). Differences due to formulations have not been observed. The residue data are valid with regard to storage stability. In these studies the applications were made at higher than proposed doses. Overdosed trials may be used to support a less critical GAP, when they indicate that no residues above the LOQ are to be expected.

New studies on the magnitude of residue have been submitted in the framework of the renewal of Atlantis 12 OD to support the proposed cGAP. These studies have to be considered only as additional information regarding the magnitude of triazine, AE F059411 and AE 0031838.

The residues arising from the proposed use will not exceed the MRLs established for cereals (Reg. (EU) 2024/1077: 0.01 mg/kg).

According to SANTE/2019/12752 rev.1 extrapolation the residue trials on barley may be extrapolate to oat, rye, wheat and triticale and residue trials on wheat may be extrapolate to oat, rye and barley, before forming of the edible part.

Note:

Mefenpyr-diethyl was a component of the formulations used in the field studies.

Sufficient trials on cereals are available to support the proposed uses.

**Magnitude of residues in livestock**

The calculated dietary burdens were found to not exceed the trigger value of 0.004 mg/kg bw (0.1 mg/kg dry matter (DM) for all groups of livestock. Further investigation of residues is therefore not required.

**Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation**

As residues in wheat grain are below the LOQ (<0.01 mg/kg) at the intended maximum application rate of 3 g a.s./ha, studies on the effects of processing on the nature of the residues are not required.

**Magnitude of residues in representative succeeding crops**

Iodosulfuron-methyl residue levels in rotational commodities were not expected to exceed 0.01 mg/kg, provided that iodosulfuron-methyl-sodium is applied in compliance with the representative GAPs.

**Other / special studies**

Cereals have not melliferous capacity. Studies are not required.

**Mesosulfuron-methyl**

**Stability of Residues**

No new data submitted in the framework of this application. Stability of residues has been evaluated dur-ing the Peer review (EFSA, 2016) showing that mesosulfuron-methyl is stable for 40 months in in wheat grain, shoot and straw.

The residue trials on the intended uses presented in this dossier are covered by the storage stability study.

**Metabolism in plants**

No new data submitted in the framework of this application.

|  |  |
| --- | --- |
| Endpoints | |
| Plant groups covered | Cereals (Wheat) |
| Rotational crops covered | Yes |
| Metabolism in rotational crops similar to metabolism in primary crops? | Yes |
| Processed commodities | Not relevant |
| Residue pattern in processed commodities similar to pattern in raw commodities? | Not applicable |
| Plant residue definition for monitoring | mesosulfuron-methyl (EFSA, 2016; Reg. (EU) No 289/2014) |
| Plant residue definition for risk assessment | mesosulfuron-methyl (EFSA, 2016) |
| Conversion factor from enforcement to RA | 1 (EFSA, 2016) |

|  |  |
| --- | --- |
|  |  |
| Animals covered | Ruminant |
| Poultry |
| Time needed to reach a plateau concentration | Egg yolks: day 10; egg whites: day 8; |
| Milk : day 5 |
| Animal residue definition for monitoring | Mesosulfuron-methyl (EFSA, 2016; Reg. (EU) No 289/2014) |
| Animal residue definition for risk assessment | Mesosulfuron-methyl (EFSA, 2016) |
| Conversion factor | 1 |
| Metabolism in rat and ruminant similar | Yes |
| Fat soluble residue | No |

No further data are required to support the proposed uses.

**Magnitude of residues in plants**

Proposed GAP (wheat, triticale, rye):

BBCH 21-31; 1 application 15 g as./ha; PHI: N/A

No new data are submitted in the framework of this application. Applicant refers to the unprotected EU data and new studies submitted in the framework of the renewal of Atlantis 12 OD.

Two types of formulations have been used: an OD (representative formulation) and a WG. No differences in terms of residues are expected applying the WG or the OD formulations.

Trials GAP(EU data): 15 g a.s./ha, up to BBCH 32, outdoor, formulation types WG and OD

E and RA: Wheat: 15 x < 0.01 mg/kg

Rye: 1 x < 0.01 mg/kg

Trials GAP (Atlantis 12 OD): 15 g a.s./ga, BBCH 39, outdoor

E and RA: 4 x < 0.01 mg/kg

Extrapolation from wheat to rye, and triticale is possible (SANTE/2019/12752 Rev01). Sufficient number of trials are available to support the proposed uses. The residues arising from the proposed uses will not exceed the MRLs established for cereals (Commission Regulation (EU) No 289/2014).

Mefenpyr-diethyl was a component of the formulations used in the field studies.

**Magnitude of residues in livestock**

No livestock feeding studies to investigate the residue levels of mesosulfuron-methyl in food of animal origin are required as the calculated dietary burdens for all groups of livestock were found to be below the threshold intake for the submission of an animal study, 0.004 mg/kg bw/d.

**Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation**

As residues in wheat grain are below the LOQ (< 0.01 mg/kg) at the intended maximum application rate of 15 g a.s./ha, studies on the effects of processing on the nature of the residues are not required.

**Other / special studies**

Cereals have not melliferous capacity. Studies are not required.

### Consumer exposure

The consumer risk assessment was calculated with the EFSA PRIMo v 3.1 model for each a.s. separately. Existing MRLs were taken from Regulation (EU) No. 289/2014 for iodosulfuron-methyl-sodium and mesosulfuron-methyl.

No MRLs for mefenpyr-diethyl are set on European level. Nevertheless, in most European countries MRLs for mefenpyr-diethyl in cereal grain were established on national level at values between 0.01 and 0.2 mg/kg.

|  |  |  |  |
| --- | --- | --- | --- |
|  | IMS | MSM | MPR |
| TMDI (% ADI) according to EFSA PRIMO v 3.1 | 6% (based on NL toddler) | 0.2% (based on NL toddler) | 2% (based on NL toddler) |
| IEDI (% ADI) according to EFSA PRIMO v 3.1 | Not required, as TMDI is below 100% | Not required, as TMDI is below 100% | Not required, as TMDI is below 100% |
| IESTI (% ARfD) according to EFSA PRIMO v 3.1 | 0.00% (wheat) for children and adults | No ARfD derived, not necessary | Cereal grain (wheat):  0.1% (based on adult diet)  0.2% (based on children diet)  Commodities of animal origin:  ≤ 0.06% (based on adult diet)  ≤ 0.08% (based on children diet)  Milk:  0.1% (based on adult diet)  0.3% (based on children diet)  Processed commodities  Wheat/milling (flour):  0.2% (based on children diet)  Barley/beer:  0.1% (based on adult diet) |

**Combined exposure**

From a scientific point of view it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.”

Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

## Environmental fate and behaviour (Part B, Section 8)

No new studies are presented. All data were reviewed in the EU review of IMS, MSM and MPR. Appropriate endpoints from the EU review were used to calculated PEC values for the active substances and its metabolites in soil, surface water, ground water and air for the intended use pattern.

### Predicted environmental concentrations in soil (PECsoil)

The PEC of IMS, MSM, MPR and its metabolites in soil has been assessed with the FOCUS model and the DT50 values established in the EU review. PECs were calculated by assuming that residues were evenly distributed through the upper 5 cm of soil and the soil had a bulk density of 1.5 g/cm³.

The results of the PECsoil for the active substances and metabolites were used for the ecotoxicological risk assessment.

In the core dossier, a dose rate of 1.5 L/ha is proposed whereas in Poland, a maximum application rate of 1.2 L/ha will apply. No separate PEC calculations have been performed in the national addendum for Poland for IMS and MSM. The dose rate of 1.5 L/ha presented in the core dossier covers the dose rate for Poland.

Taking into account a maximum application of 1.5 L product/ha (3 g IMS/ha + 15 g MSM/ha + 45 g MPR/ha) at an early post-emergence development stage application and 0% crop interception, the maximum initial predicted environmental concentration in soil of IMS, MSM and MPR and its metabolites is:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Compound** | **PECsoil (mg/kg)** | **Compound** | **PECsoil (mg/kg)** | **Compound** | **PECsoil (mg/kg)** |
| Iodosulfuron-methyl-sodium | 0.004 | Mesosulfuron-methyl | 0.020 | Mefenpyr-diethyl | 0.060 |
| AE F075736 | 0.003 | AE F154851 | 0.003 | AE F113225 | 0.024 |
| AE F145741 | < 0.001 | AE F160459 | 0.002 | AE F094270 | 0.031 |
| AE F145740 | < 0.001 | AE F099095 | 0.002 | AE 2211046 | 0.004 |
| AE 0002166 | 0.001 | AE F092944 | 0.001 |  |  |
| AE F161778 | < 0.001 | AE F160460 | 0.002 |  |  |
| BCS-CW81253 | 0.001 | AE F140584 | 0.001 |  |  |
| AE 0000119 | < 0.001 | AE F147447 | 0.001 |  |  |
| AE F059411 | < 0.001 |  |  |  |  |

### Predicted environmental concentrations in groundwater (PECgw)

Predicted Environmental Concentrations of IMS, MSM and MPR and its metabolites in groundwater were calculated using the latest version of FOCUS PEARL (v5.5.5) and FOCUS PELMO (v6.6.4). The PEC values have been calculated for all scenarios relevant for the central zone and Poland (i.e. Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto).

In the core dossier, a dose rate of 1.5 L/ha is proposed whereas in Poland, a maximum application rate of 1.2 L/ha will apply. No separate PEC calculations have been performed in the national addendum for Poland for IMS and MSM. The dose rate of 1.5 L/ha presented in the core dossier covers the dose rate for Poland.

**Iodosulfuron-methyl-sodium**

The active substance iodosulfuron-methyl-sodium and its metabolites do not breach the EU threshold value of 0.1 µg/L for the intended uses of the present formulation after a Tier 1 simulation. The risk for groundwater is acceptable and no relevance assessment for any of the assessed metabolites is required.

Based on this assessment, unacceptable leaching of iodosulfuron-methyl-sodium and its metabolites after application of IMS+MSM+MPR 2+10+30 OD within the risk envelope GAP is therefore unlike to occur.

**Mesosulfuron-methyl**

The EU limit value of 0.1 µg/L is exceeded for mesosulfuron-methyl parent active substance in some of the simulation scenarios for end of winter-spring application of 15 g a.s./ha. A Tier 2 simulation was therefore performed to further address this use situation, based on an implementation of the observed biphasic degradation in the exposure modelling.

For the end of winter to spring use at 15 g a.s./ha (1.5 L product/ha), PECgw of mesosulfuron-methyl and its metabolites AE F154851, AE F099095, AE F092944 and AE F140584 in the refined Tier 2 simulation does not exceed the parametric threshold of 0.1 µg/L for any FOCUS scenario. Therefore, the risk to groundwater with regard to mesosulfuron-methyl is acceptable for that intended use of the present formulation.

For metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885 an assessment of metabolite relevance in groundwater is triggered by the simulated PECgw values, and accordingly presented in dRR Section 10. For these compounds the toxicological relevance for groundwater was assessed in the EU peer review, and non-relevance was agreed.

Based on this assessment, unacceptable leaching of mesosulfuron-methyl and its metabolites after application of IMS+MSM+MPR 2+10+30 OD within the risk envelope GAP is therefore unlike to occur.

**Mefenpyr-diethyl**

Neither the parent safener substance nor any of its metabolites breach the EU threshold value of 0.1 µg/L for all uses. The risk to groundwater with regard to mefenpyr-diethyl and its metabolites is therefore acceptable for the intended uses of the present formulation.

### Predicted environmental concentrations in surface water (PECsw)

The calculations of PEC in surface water following in principle the four steps, tiered approach as recommended by the corresponding FOCUS working group with various evaluation tools to include spray drift, run-off/erosion and drainage as pathways for the entry of residues into surface water systems.

Predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) of IMS, MSM, MPR and its metabolites were assessed for the use of IMS+MSM+MPR 2+10+30 OD in winter cereals using the EU-agreed stepwise approach. Step 1&2 simulations were carried out for IMS, MSM, MPR and all metabolites. Step 3 to 4 simulations were conducted for the active substance IMS and its metabolite AE F075736 and for the a.s. MSM using the modelling tools FOCUS SWASH 5.3, and SWAN 5.0.1. For MPR, no Step 3 or 4 calculations were considered necessary.

### Predicted environmental concentrations in air (PECair)

The vapour pressure at 20 °C of the active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl is < 10-5 Pa. Hence both active substances are regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems due to volatilization with subsequent deposition is not expected.

The vapour pressure of the safener mefenpyr-diethyl at 20°C is 6.3 x 10-6 Pa. Hence the safener mefenpyr-diethyl is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems from volatilization followed by subsequent deposition is not expected to occur.

## Ecotoxicology (Part B, Section 9)

### Effects on terrestrial vertebrates

The risk assessments for birds and mammals meet the trigger criteria at screening level, for all intended uses of product IMS+MSM+MPR 2+10+30 OD. No unacceptable risk resulted also from the assessment of exposure via drinking water, and for secondary poisoning via prey like fish and earthworms. The above assessments do not raise specific concern for other terrestrial vertebrate wildlife such as reptiles and amphibians.

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

### Effects on aquatic species

Acceptable risk for all aquatic organisms other than macrophytes could be demonstrated in a screening-level risk assessment (FOCUS Steps 1-2) for the active substances and safener contained in IMS+MSM+MPR 2+10+30 OD, and their metabolites.

Acceptable risk for macrophytes would be demonstrated with PECsw FOCUS Step 3 calculations for Poland, the risk for aquatic organisms is considered acceptable without any risk mitigation measures.

### Effects on bees

The risk to bees was demonstrated to be acceptable for all intended uses of product IMS+MSM+MPR 2+10+30 OD, based on assessments for the active substances, and the formulated product.

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

### Effects on other arthropod species other than bees

The risk to arthropods other than bees based on LR50 values for indicator species is acceptable for all intended uses of product IMS+MSM+MPR 2+10+30 OD, based on the presented assessments for the in-field and the off-field exposure situations.

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

### Effects on soil organisms

No unacceptable risk to the soil meso- and macrofauna and to the soil microbial activity is concluded from the risk assessments presented, for all intended uses of the product IMS+MSM+MPR 2+10+30 OD.

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

### Effects on non-target terrestrial plants

Based on the risk assessment it is concluded that the use of IMS+MSM+MPR 2+10+30 OD will not produce unacceptable effects on terrestrial non-target plants growing near treated fields, when considering the following mitigation measures:

* 5 m buffer or alternatively 75% drift reducing spray nozzles for all application rates.

### Effects on other terrestrial organisms (Flora and Fauna)

No further information is available or considered to be necessary.

## Relevance of metabolites (Part B, Section 10)

**Relevance assessment of iodosulfuron-methyl-sodium metabolites**

None of the soil metabolites of iodosulfuron-methyl-sodium is predicted to occur in groundwater recharge at concentrations above 0.1 µg/L for the intended uses of the product (see dRR part B.8, Point 8.8). An assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required for this active substance.

**Relevance assessment of AE F154851, AE F099095, AE F092944, AE F140584 and BCS-CO60720, metabolites of mesosulfuron-methyl**

None of the soil metabolites AE F154851, AE F099095, AE F092944, AE F140584 and BCS-CO60720 of mesosulfuron-methyl are predicted to occur in groundwater recharge at concentrations above 0.1 µg/L for the intended uses of the product (see dRR part B.8, Point 8.8). An assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

**Relevance assessment of AE F160459, metabolite of mesosulfuron-methyl**

The relevance of groundwater metabolite AE F160459 has already been assessed and accepted at EU level (see EFSA conclusion Section 4, and List of Endpoints for mesosulfuron-methyl). Metabolite AE F160459 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is provided in dRR Section 10. This agreed assessment is also applicable for the GAP and groundwater scenarios considered in dRR Section 10, as predicted metabolite concentrations were always < 0.75 μg/L.

**Relevance assessment of AE F160460, metabolite of mesosulfuron-methyl**

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.10. A summary of the relevance assessment is provided in dRR Section 10. This agreed assessment is also applicable for the GAP and groundwater scenarios considered in dRR Section 10, as predicted metabolite concentrations were always < 0.75 μg/L.

**Relevance assessment of 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.10. A summary of the relevance assessment is provided in dRR Section 10. This agreed assessment is also applicable for the GAP and groundwater scenarios considered in dRR Section 10, as predicted metabolite concentrations were always < 0.75 μg/L.

**Relevance assessment of 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 BCS-CV14885 is not considered relevant according to the criteria laid down in the EC guidance document SANCO/221/2000 –rev.10. A summary of the relevance assessment is provided in dRR Section 10. This agreed assessment is also applicable for the GAP and groundwater scenarios considered in dRR Section 10 as predicted metabolite concentrations were always < 0.75 μg/L.

**Relevance assessment of mefenpyr-diethyl (safener) metabolites**

None of the soil metabolites of mefenpyr-diethyl is predicted to occur in groundwater recharge at concentrations above 0.1 µg/L for the intended uses of the product (see dRR part B.8, Point 8.8). An assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required for this safener component.

# Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not applicable.

# Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

1. Copy of the product authorization

MS assessor to insert details of the product authorization for MS country.

1. Copy of the product label

|  |
| --- |
| **Sekcja skuteczność**: zgodnie z zaakceptowaną tabelą GAP –rekomendowana dawka dla pszenicy ozimej i pszenżyta ozimego to 1,5 1,2 L/ha a dla żyta ozimego – 0.9 L/ha. Z uwagi na niewystarczającą ilość badań oraz brak możliwości rejestracji w trybie Art. 34 – żyto ozime zostało wykreślone z etykiety. Zmieniono listę zaakceptowanych gatunków chwastów oraz skalę ich wrażliwości. Pozostałych zapisów etykiety – nie zmieniono.  **Sekcja pozostałości:** brak uwag.  **Sekcja los zachowanie w środowisku:** bez uwag  **Sekcja ekotoksykologia:**  Zmieniono klasyfikację środka ochrony roślin Cerenet z H411 na H410 oraz zmieniono zarządzanie  ryzykiem dla roślin lądowych niebędących celem zwalczania. |

Posiadacz zezwolenia:

Certiplant BV, Lichtenberglaan 2045, B-3800 Sint-Truiden, Królestwo Belgii, tel.: +32 11 88 03 92, fax: +32 11 70 74 84, e-mail: info@certiplant.be

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

**CERENET**

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

jodosulfuron metylosodowy (związek z grupy pochodnych sulfonylomocznika) - 2 g/l (0,2 %), mezosulfuron metylowy (związek z grupy pochodnych sulfonylomocznika) - 10 g/l (1 %).

**Zezwolenie MRiRW nr R- z dnia r.**

|  |  |
| --- | --- |
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| **Niebezpieczeństwo** | |
| H317  H318 | Może powodować reakcję alergiczną skóry.  Powoduje poważne uszkodzenie oczu. |
| H410 ~~H411~~ | Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki. |
| H317  H318 | Może powodować reakcję alergiczną skóry.  Powoduje poważne uszkodzenie oczu. |
| P261  P273 | Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.  Unikać uwolnienia do środowiska. |
| P280  P302+P352 | Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.  W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody. |
| P305+P351+P338  P333+P313  P501 | W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć.  W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.  Zawartość/pojemnik usuwać do… |

**OPIS DZIAŁANIA**

Herbicyd selektywny o działaniu układowym, stosowany nalistnie, koncentrat w formie zawiesiny olejowej do rozcieńczania wodą (OD).

Zgodnie z klasyfikacją HRAC substancje czynne jodosulfuron metylosodowy i mezosulfuron metylowy zaliczane są do grupy 2 (dawnej grupy B).

**DZIAŁANIE NA CHWASTY**

Środek zawiera dwie substancje czynne zaliczane do inhibitorów syntazy acetylomleczanowej (ALS), co prowadzi do blokowania biosyntezy aminokwasów rozgałęzionych, a tym samym do zaburzeń w biosyntezie białek, a w efekcie zahamowania wzrostu i rozwoju chwastów.

Środek pobierany jest poprzez liście, w mniejszym stopniu poprzez korzenie chwastów i jest transportowany po całej roślinie.

Widocznymi objawami działania środka są: wstrzymanie wzrostu chwastów w ciągu pierwszych kilku dni po zabiegu, pojawienie się nekrotycznych plam i postępujące powolne zamieranie roślin. Całkowite zamieranie chwastów następuje w 4-6 tygodni po zabiegu.

Najskuteczniej niszczy chwasty roczne intensywnie rosnące, znajdujące się w fazie 2-3 liści.

Pszenica ozima, pszenżyto ozime

dawka1.2 L/ha

|  |  |
| --- | --- |
| Chwasty wrażliwe | miotła zbożowa |
| Chwasty średniowrażliwe | wyczyniec polny, fiołek polny, miotła zbożowa |

Pszenżyto ozime

|  |  |
| --- | --- |
| Chwasty średnioodporne średniowrażliwe | wyczyniec polny, |

**Żyto ozime**

dawka 0.9 L/ha

|  |  |
| --- | --- |
| Chwasty odporne | wyczyniec polny |

**STOSOWANIE ŚRODKA**

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

**Pszenica ozima, pszenżyto ozime**

*Zwalczanie wyczyńca polnego, miotły zbożowej, fiołka polnego*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,2 1,5 l/ha.

Termin stosowania: środek stosować wiosną po ruszeniu wegetacji roślin od początku fazy krzewienia, gdy widoczne jest pierwsze rozkrzewienie do fazy gdy pierwsze kolanko co najmniej 1 cm nad węzłem krzewienia (BBCH 21-31).

Zalecana ilość wody: 200-400 l/ha**.** Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym w uprawie zbóż: 1.

Żyto ozime

Zwalczanie wyczyńca polnego

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,9 l/ha.

Termin stosowania: środek stosować wiosną po ruszeniu wegetacji roślin od początku fazy krzewienia, gdy widoczne jest pierwsze rozkrzewienie do fazy gdy pierwsze kolanko co najmniej 1 cm nad węzłem krzewienia (BBCH 21-31).

Zalecana ilość wody: 200-400 l/ha**.** Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym w uprawie zbóż: 1.

**Pszenżyto ozime**

*Zwalczanie wyczyńca polnego*

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,2 1,5 l/ha.

Termin stosowania: środek stosować wiosną po ruszeniu wegetacji roślin od początku fazy krzewienia, gdy widoczne jest pierwsze rozkrzewienie do fazy gdy pierwsze kolanko co najmniej 1 cm nad węzłem krzewienia (BBCH 21-31).

Zalecana ilość wody: 200-400 l/ha**.** Zalecane opryskiwanie: średniokropliste.

Maksymalna liczba zabiegów w sezonie wegetacyjnym w uprawie zbóż: 1.

**NASTĘPSTWO ROŚLIN**

Środek rozkłada się w glebie i nie stwarza zagrożenia dla roślin uprawianych następczo. W przypadku konieczności likwidacji opryskiwanej plantacji, po wykonaniu orki można uprawiać pszenicę jarą.

**OKRESY KARENCJI**

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji): Nie wymagany

**ŚRODKI OSTROŻNOŚCI I SZCZEGÓLNE WARUNKI STOSOWANIA**

1. W przypadku bardzo niekorzystnych warunków atmosferycznych istnieje możliwość wystąpienia uszkodzeń roślin uprawnych, które przemijają najdalej po 3 tygodniach i które nie wpływają ujemnie na plon i jego parametry.
2. Strategia zarządzania odpornością

W celu zminimalizowania ryzyka wystąpienia i rozwoju odporności chwastów na herbicydy należy zgodnie z Dobrą Praktyką Rolniczą:

* + postępować ściśle zgodnie ze wskazówkami zawartymi w etykiecie środka ochrony roślin – stosować środek w zalecanej dawce, w zalecanym terminie zapewniającym optymalne zwalczanie chwastów,
  + dostosować dobór środka chwastobójczego oraz decyzji o wykonaniu zabiegu do panującego (ewentualnie potencjalnego) zachwaszczenia, z uwzględnieniem gatunków dominujących i progów szkodliwości,
  + stosować rotację herbicydów (substancji czynnych) o różnym mechanizmie działania,
  + stosować mieszankę herbicydów (substancji czynnych) o różnym mechanizmie działania,
  + stosować w rotacji i/lub mieszaninie herbicydy działające na kilka procesów życiowych chwastów (o różnym mechanizmie działania),
  + stosować herbicyd o danym mechanizmie działania tylko 1 raz w ciągu sezonu wegetacyjnego rośliny uprawnej,
  + dostosować zabiegi uprawowe do warunków panujących na polu, zwłaszcza do rodzaju i nasilenia chwastów,
  + używać różnych metod kontroli zachwaszczenia, w tym zmianowania upraw itp.,
  + używać kwalifikowanego materiału siewnego,
  + czyścić maszyny rolnicze, aby zapobiec przenoszeniu materiału rozmnożeniowego chwastów na inne stanowiska,
  + informować posiadacza zezwolenia o nie satysfakcjonującym zwalczaniu chwastów,
  + w celu uzyskania szczegółowych informacji należy się skontaktować z doradcą, posiadaczem zezwolenia lub przedstawicielem posiadacza zezwolenia.

1. Środka nie stosować:
   * na rośliny osłabione lub uszkodzone przez choroby, szkodniki czy przymrozki,
   * przed spodziewanym silnym przymrozkiem,
   * w zbożach z wsiewką roślin bobowatych.
2. Podczas stosowania środka nie dopuścić do:

* znoszenia cieczy użytkowej na sąsiadujące plantacje roślin uprawnych,
* nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.

**SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. Uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać. Środek łatwo tworzy zawiesinę i nie wymaga dodatkowego mieszania w osobnym naczyniu. Opryskiwać z włączonym mieszadłem. W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

**POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

* jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
* unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
* unieszkodliwić w inny sposób, zgodny z przepisami o odpadach. Po pracy aparaturę dokładnie wymyć.

Ze względu na bardzo dużą wrażliwość niektórych roślin uprawnych nawet na znikome ilości środka, bardzo ważne jest dokładne wymycie opryskiwacza po zabiegu, zwłaszcza przed użyciem w innych roślinach niż zalecane.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

**ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH**

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy roboczej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

**ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO**

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg. Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 5 ~~1~~ m od terenów nieużytkowanych rolniczo lub zastosowanie końcówek redukujących znoszenie o 75%.

**WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

* w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
* w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
* z dala od źródeł ciepła, w temperaturze 0ºC - 30ºC.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

**PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania.

W PRZYPADKU KONTAKTU ZE SKÓRĄ: Natychmiast zdjąć całą zanieczyszczoną odzież. Spłukać skórę pod strumieniem wody/prysznicem.

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć.

W PRZYPADKU POŁKNIĘCIA: Wypłukać usta. NIE wywoływać wymiotów. Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.

Okres ważności - 2 lata Data produkcji - .........

Zawartość netto - .........

Nr partii - .........

1. Letter of Access

Applicant to provide copies of the letters of access to the protected data / third party data that was needed for evaluation of the formulation.

1. Lists of data considered for national authorization

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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP ~~2/01~~  2.7.1  2.8.3.3 | Mattioli B. | 2024 | IMS+MSM+MPR 2+10+30 OD: Determination of the accelerated storage stability and corrosion characteristics  Report No. CH-0228-2024  LabAnalysis Life Science Srl  GLP  Not published | N | ~~N~~Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP ~~2/02~~  2.1  2.3.1  2.3.3  2.4.2  2.5.1  2.5.2  2.6.1  2.7.1  2.7.4  2.8.2  2.8.5.2.1  2.8.7.2 | Sowle J. | 2024 | Determination of Storage Stability and Shelf Life Specification Data for an OD Formulation containing Iodosulfuron-Methyl-Sodium, Mesosulfuron-Methyl and Mefenpyr-Diethyl, stored at 54°C±2°C for Two Weeks, in Compliance with Good Laboratory Practice  Report No. DNA7599  David Norris Analytical Laboratories Ltd.  GLP  Not published | N | ~~N~~Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP ~~2/03~~  2.2.1  2.2.2 | Anonymous | 2024 | Explosive and oxidising properties of IMS+MSM+MPR 2+10+30 OD  CONFIDENTIAL  --  Not GLP/GEP  Not published | N | N | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 2.7.4/01 | Mattioli B. | 2025 | IMS+MSM+MPR 2+10+30 OD: Determination of the low temperature stability.  Report No. CH-0101-2025  LabAnalysis Life Science Srl  GLP  Not published | N | ~~N~~Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 2.7.4/02 | Sowle J. | 2025 | Determination of Storage Stability and Shelf Life Specification Data for an OD Formulation containing Iodosulfuron-Methyl-Sodium, Mesosulfuron-Methyl and Mefenpyr-Diethyl, stored at 0°C±2°C for One Weeks, in Compliance with Good Laboratory Practice  Report No. DNA8012  David Norris Analytical Laboratories Ltd.  GLP  Not published | N | ~~N~~Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 5.1.1/01 | Mattioli B. | 2024 | IMS+MSM+MPR 2+10+30 OD: Validation of the analytical method for the determination of the active ingredient content  CH-0227-2024  LabAnalysis Life Science Srl  GLP  Not published | N | ~~N~~Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /01 | Anonymous | 2023 | Biological Assessment Dossier – IMS + MSM + MPR 2+10+30  Certiplant BV  −  non GLP/GEP  Unpublished | N | N | / | Certiplant BV |
| KCP 6  /02 | Biaunier, M. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: FR22-CER-106-03  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /03 | Dommes, A. B. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-106-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /04 | Endres, U. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-03  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /05 | Gezova, V. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: CZ22-CER-106-03  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /06 | Gilet, G. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: FR22-CER-106-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /07 | Heitsch, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /08 | Hrabovsky, J. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: CZ22-CER-106-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /09 | Hrabovsky, J. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: CZ22-CER-106-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /10 | Jergl, Z. | 2022 | Evaluation of the effecacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: CZ22-CER-105-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /11 | Kohrman, E. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: NL22-CER-106-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /12 | Kohrman, E. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: NL22-CER-106-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /13 | Kolditz, M.. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /14 | Kolditz, M. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-04  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /15 | Kolditz, M. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-06  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /16 | Krüger, D. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-05  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /17 | Krüger, D. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-06  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /18 | Lamers, K. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-106-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /19 | Laug, S. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-04  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /20 | Laug, S. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: DE22-CER-105-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /21 | Legros, S. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: FR22-CER-106-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /22 | Reynens, P. | 2022 | Evaluation of the effecacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Redebel S.A., Report/Document No.: BE22-CER-105-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /23 | Rusef, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-105-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /24 | Rusef, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-105-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /25 | Rusef, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-105-03  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /26 | Rusef, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-105-04  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /27 | Rusef, K. | 2022 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /28 | Rusef, K. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-03  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /29 | Rusef, K. | 2022 | Evaluation of the selectivity of IMS+MSM+MPR applied in post-emergence in winter cereals in 2022  Rhizome Solutions Provider, Report/Document No.: PL22-CER-106-05  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /30 | Maβmann, K-W. | 2023 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2023  Rhizome Solutions Provider, Report/Document No. : DE23-CER-102-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /31 | Heitsch, K. | 2023 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter cereals in 2023  Rhizome Solutions Provider, Report/Document No. : DE23-CER-102-02  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 6  /32 | Hetterich, F. | 2023 | Evaluation of the efficacy and selectivity of IMS+MSM+MPR applied post-emergence against weeds (ALOMY) in winter rye in 2023  Rhizome Solutions Provider, Report/Document No.: DE23-CER-103-01  −  GEP  Unpublished | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 5.1.2/01 (also submitted as KCP 10.2.1/01) | Schuler, L. | 2022 | IMS+MSM+MPR 2+10+30 OD: Toxicity to the Duckweed Lemna gibba under laboratory conditions (semi-static test design).  S22-01264  Eurofins Agroscience services  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 5.1.2/02 (also submitted as KCP 10.3.1.2/01) | Vergé, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Honey bee Apis mellifera L. Chronic oral toxicity test 10 day feeding in the laboratory  S22-01252  Eurofins Agroscience services  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 5.1.2/03 (also submitted as KCP 10.3.1.3/01) | Vergé, E. | 2023 | IMS+MSM+MPR 2+10+30 OD: Honey bee Apis mellifera 22 day larval toxicity test (repeated exposure)  S22-01253  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 5.1.2/04 (also submitted as KCP 10.6.2/01) | Ripperger, D. | 2022 | IMS+MSM+MPR 2+10+30 OD: Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions.  S22-01280  Eurofins Agroscience services  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 7.2 | Anonymous | 2023 | OPEX calculation IMS+MSM+MPR 2+10+30 OD  Certiplant BV  Not GLP or GEP  Not published | N | N | / | Certiplant BV |
| KCP 7.2 | Anonymous | 2023 | OPEX calculation IMS+MSM+MPR 2+10+30 OD  Certiplant BV  Not GLP or GEP  Not published | N | N | / | Certiplant BV |
| KCP 7/01 | Anonymous | 2023 | Expert statement – Residue Levels of Mesosulfuron-methyl and Iodosulfuron-methyl-sodium in Honey for MRL Setting and Risk Assessment  --  Not GLP or GEP  Not published | N | N | / | Certiplant BV |
| KCP 7/02 | Anonymous | 2023 | Expert statement – Residue Levels of Mesosulfuron-methyl and Iodosulfuron-methyl-sodium in Honey for MRL Setting and Risk Assessment\_Background data  --  Not GLP or GEP  Not published | N | N | / | Certiplant BV |
| ~~KCP 7.2.4.1/01~~ | ~~Anonymous~~ | ~~2023~~ | ~~Dietary burden calculation IMS~~  ~~--~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | / | Certiplant BV |
| ~~KCP 7.3.4.1/01~~ | ~~Anonymous~~ | ~~2023~~ | ~~Dietary burden calculation MSM~~  ~~--~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | / | Certiplant BV |
| ~~KCP 7.2.8/01~~ | ~~Anonymous~~ | ~~2023~~ | ~~EFSA PRIMo v3.1 – Consumer risk assessment IMS~~  ~~Certiplant BV~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | ~~/~~ | Certiplant BV |
| ~~KCP 7.3.8/01~~ | ~~Anonymous~~ | ~~2023~~ | ~~EFSA PRIMo v3.1 – Consumer risk assessment MSM~~  ~~Certiplant BV~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | ~~/~~ | Certiplant BV |
| ~~KCP 7.2.4.1/02~~ | ~~Anonymous~~ | ~~2023~~ | ~~Dietary burden calculation MPR~~  ~~--~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | ~~/~~ | Certiplant BV |
| ~~KCP 7.2.8/02~~ | ~~Anonymous~~ | ~~2023~~ | ~~EFSA PRIMo v3.1 – Consumer risk assessment MPR~~  ~~Certiplant BV~~  ~~Not GLP or GEP~~  ~~Not published~~ | ~~N~~ | ~~N~~ | ~~/~~ | Certiplant BV |
| KCP 9.1.3/01 | Anonymous | 2023 | PECsoil IMS, MSM and metabolites calculations  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.1.3/02 | Anonymous | 2023 | PECsoil MPR and metabolites calculations  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/01 | Anonymous | 2023 | PECgw IMS and metabolites  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/02 | Anonymous | 2023 | PECgw MSM and metabolites  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/03 | Anonymous | 2023 | PECgw IMS, MSM and metabolites – FOCUS PEARL input and output files  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/04 | Anonymous | 2023 | PECgw IMS, MSM and metabolites – FOCUS PELMO input and output files  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/05 | Anonymous | 2023 | PECgw IMS, MSM and metabolites – FOCUS MACRO input and output files  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.4.1/06 | Anonymous | 2023 | PECgw MPR and metabolites  -  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.5/01 | Anonymous | 2023 | PECsw and PECsed IMS, MSM and metabolites – FOCUS input and output files  Certiplant BV  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 9.2.5/02 | Anonymous | 2023 | PECsw and PECsed MPR and metabolites – FOCUS input and output files  Certiplant BV  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.1.1/01 | Anonymous | 2024 | Birds & mammals risk assessment\_IMS  ---  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.1.1/02 | Anonymous | 2024 | Birds & mammals risk assessment\_MSM  ---  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.1.1/03 | Anonymous | 2024 | Birds & mammals risk assessment\_MPR  ---  Not GLP  Not published | N | N | / | Certiplant BV |
| KCP 10.2.1/01 | Schuler, L. | 2022 | IMS+MSM+MPR 2+10+30 OD: Toxicity to the Duckweed *Lemna gibba* under laboratory conditions (semi-static test design).  S22-01264  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.3.1/01 | Anonymous | 2023 | Bee tool\_IMS  ---  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.3.1/02 | Anonymous | 2023 | Bee tool\_MSM  ---  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.3.1/03 | Anonymous | 2023 | Bee tool\_IMS+MSM+MPR 2+10+30 OD  ---  Not GLP/GEP  Not published | N | N | / | Certiplant BV |
| KCP 10.3.1.1/01 | Vergé, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Acute oral and contact toxicity to the honey bee *Apis mellifera* L. (Hymenoptera, Apidae) under laboratory conditions.  S22-01251  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.3.1.2/01 | Vergé, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Honey bee Apis mellifera L. Chronic oral toxicity test 10 day feeding in the laboratory.  S22-01252  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.3.1.3/01 | Vergé, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Honey bee *Apis mellifera* 22 day larval toxicity test (repeated exposure).  S22-01253  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.3.2/01 | Wagenhoff, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Toxicity to the predatory mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) under laboratory conditions.  S22-01276  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.3.2/02 | Wagenhoff, E. | 2022 | IMS+MSM+MPR 2+10+30 OD: Toxicity to the aphid parasitoid *Aphidius rhopalosiphi* De Stefani Perez (Hymenoptera, Braconidae) under laboratory conditions.  S22-01275  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.4.1.1/01 | Stäbler, D. | 2022 | IMS+MSM+MPR 2+10+30 OD: Effects on the reproduction of the earthworm *Eisenia fetida* in artificial soil with 10% peat.  S22-01277  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.4.2.1/01 | Stäbler, D. | 2022 | IMS+MSM+MPR 2+10+30 OD: Effects on the reproduction of the springtail *Folsomia candida* Willem in artificial soil.  S22-01278  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.4.2.1/02 | Stäbler, D. | 2022 | IMS+MSM+MPR 2+10+30 OD: Effects on the reproduction of the predatory mite *Hypoaspis aculeifer* Canestrini in artificial soil.  S22-01279  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | Certiplant BV |
| KCP 10.6.2/01 | Ripperger, D. | 2022 | IMS+MSM+MPR 2+10+30 OD: Effects on the vegetative vigour of non-target terrestrial plant species under greenhouse conditions.  S22-01280  Eurofins Agroscience Services Ecotox GmbH  GLP  Not published | N | Y | Data/study report never submitted before in Poland. | 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Mesosulfuron-methyl** | | | | | | | |
| KCA 4.1.2 /01 | Wrede, A. | 1999 | Data generation method and validation for cereal by LC-MS/MS Code: AE F130060  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C005129, Report includes Trial Nos.: CR99 /003  Edition Number: M-191437-01-1  Date: 1999-10- 20  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
| KCA 4.1.2 /02 | Wrede, A. | 2000 | Data generation method for soil by LC-MS/MS Amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, AE F130060, AE F130360  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C008681,  Edition Number: M-197688-01-1  Date: 2000-06- 28  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
| KCA 4.1.2 /03 | Wrede, A. | 2000 | Validation of the method DGM F04/99-0 in soil by LC-MS/MS - Amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, AE F130060, AE F130360  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C008682,  Edition Number: M-197689-01-1  Date: 2000-06-28  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.1.2 /04 | Reichert, N. | 2000 | Development and validation of an analytical method for the determination of AE F130060 in air  Institut Fresenius Chem.und Biolog. Lab. AG, Taunusstein, Germany  Bayer CropScience,  Report No.: C009587,  Edition Number: M-198860-01-1  Date: 2000-10- 02  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
| KCA 4.1.2 /05 | Lecointre, B. | 2016 | Mesosulfuron-methyl - Request for additional information - Response document to answer 12 (analytical methods)  Bayer CropScience Bayer CropScience,  Report No.: M-549830-01-1,  Edition Number: M-549830-01-1  Date: 2016-03- 15  GLP/GEP: n.a., unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /02 | Wrede, A. | 2000 | Validation of the Enforcement Method EM F08/99-0 of cereal grain, straw and shoot by LC-MS/MS - Amidosulfuron (AE F075032) – Metsulfuron-methyl (AE F075736) Iodosulfuron-methyl-sodium (AE F115008) - AE F130060 - AE F 130360  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C006735,  Edition Number: M-194531-01-1  Date: 2000-03- 02  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /06 | Wrede, A. | 2000 | Multi-residue method for the determination of AE F130060 in cereal grain (statement) Mesosulfuron Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C009649,  Edition Number: M-198985-01-1  Date: 2000-09- 14  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /07 | Wrede, A. | 2000 | Enforcement method and validation of soil by HPLC-UV Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C009151,  Edition Number: M-198143-01-1  Date: 2000-09- 08  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /09 | Wrede, A. | 2000 | Validation of the enforcement method EM F13/99-0 of soil by LC-MS/MS - Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C009563,  Edition Number: M-198810-01-1  Date: 2000-10- 06  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /10 | Wrede, A. | 2000 | Enforcement method for surface and drinking water by HPLC-UV Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience, Report No.: C008689, Edition Number: M-197696-01-1  Date: 2000-06- 16  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /11 | Wrede, A. | 2000 | Validation of the enforcement method EM F15/99-0 for surface and drinking water by HPLC-UV - Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C008686, Edition Number: M-197693-01-1  Date: 2000-06- 16  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /12 | Wrede, A. | 2000 | Validation of the enforcement method EM F13/99-0 in soil by LC-MS/MS – Metsulfuron-methyl – Iodosulfuron-methyl-sodium -Code: AE F075736, AE F115008  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C006396,  Edition Number: M-193814-01-1 EPA MRID No.: 45108720  Date: 2000-02- 04  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /13 | Wrede, A. | 2001 | Enforcement method for surface and drinking water by LC-MS/MS Amidosulfuron (AE F075032) Metsulfuron-methyl (AE F075736) lodosulfuron-methyl-sodium (AE F115008) Mesosulfuron-methyl (AE F130060) Foramsulfuron (AE F130360)  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C011206,  Edition Number: M-200404-01-1  Date: 2001-02- 14  GLP/GEP: no, unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /16 | Heinemann, O. | 2004 | Modification M001 to method 00815 for the determination of residues of amidosulfuron, iodosulfuron-methyl-sodium including metabolite metsulfuron-methyl, foramsulfuron and mesosulfuron-methyl in/on flax and wheat matrices by HPLC-MS/MS  Bayer CropScience,  Report No.: 00815/M001,  Edition Number: M-226888-01-1  Date: 2004-01- 30  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /17 | Reichert, N. | 2001 | Independent laboratory validation of the method of analysis EM F08/99-0 for the determination of AE F130060 in cereal (plant and straw)  Institut Fresenius Chem.und Biolog. Lab. AG, Taunusstein, Germany  Bayer CropScience,  Report No.: C011938,  Edition Number: M-201813-01-1  Date: 2001-03- 13  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /21 | Freitag, T. | 2008 | Amendment no. 0001 to report no.: MR-08/138 - Analytical Method 01115 for the determination of residues of amidosulfuron, iodosulfuron-methyl-sodium, metsulfuron-methyl, mesosulfuron-methyl and foramsulfuron in soil by HPLC-MS/MS  Bayer CropScience,  Report No.: M-310074-03-1,  Edition Number: M-310074-03-1  Date: 2008-10- 27 ...Amended: 2013-08-08  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /22 | Krebber, R.; Braune, M. | 2013 | Analytical method 01387 for the determination of various pesticides in drinking and surface water by HPLC-MS/MS  Bayer CropScience,  Report No.: MR-13/085,  Edition Number: M-466732-01-1  Date: 2013-10- 09  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /23 | Stanislowski, T. | 2013 | Independent laboratory validation of BCS analytical methods 01333 and 01387 for determination of various pesticides in surface water by Di-HPLC-MS/MS  PTRL Europe, Ulm, Germany  Bayer CropScience,  Report No.: P3117 G,  Edition Number: M-470714-02-1  Date: 2013-12- 13  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| KCA 4.2 /26 | Stuke, S. | 2015 | Modification 001 of analytical method 01360 for the determination of amidosulfuron, metsulfuron-methyl, iodosulfuron-methyl-sodium, mesosulfuron-methyl, and foramsulfuron in samples from plant origin by HPLC-MS/MS  Bayer CropScience,  Report No.: MR-15/090,  Edition Number: M-537921-01-1  Date: 2015-10- 30  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 4.2 /27 | Netzband, D. | 2010 | Independent laboratory validation of an analytical method 01208/M001 for the determination of amidosulfuron (AE F075032), metsulfuron-methyl (AE F075736), iodosulfuron-methyl-sodium (AE F115008), mesosulfuron-methyl (AE F130060), foramsulfuron (AE F130360) in animal tissues (meat, fat, liver, kidney), egg, and milk by HPLC-MS/MS  Bayer CropScience LP, Stilwell, KS, USA  Bayer CropScience,  Report No.: RAMML014-01,  Edition Number: M-398300-02-1  Date: 2010-12- 22 ...Amended: 2015-11-03  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | Bayer CropScience |
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| 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | Bayer CropScience |
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| KCA 5.4.1 /03 | Mueller, W. | 1998 | 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 | N | / | Bayer CropScience |
| KCA 5.4.1 /04 | Mueller, W. | 1998 | 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 | N | / | Bayer CropScience |
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| 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | Bayer CropScience |
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| 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 | N | / | 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 | N | / | Bayer CropScience |
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| KCA 5.8.1 /03 | Wollny, H. E. | 2012 | 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 | N | / | Bayer CropScience |
| KCA 5.8.1 /04 | Sokolowski, A. | 2012 | Salmonella typhimurium reverse mutation assay with AE F160460  Harlan CCR, Rossdorf, Germany  Bayer CropScience,  Report No.: 1462301,  Edition  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
| KCA 5.8.1 /05 | Bohnenber ger, S. | 2015 | 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 | N | / | Bayer CropScience |
| KCA 5.8.1 /06 | Wollny, H. E. | 2015 | 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 | N | / | Bayer CropScience |
| KCA 5.8.1 /07 | Sokolowski, A. | 2012 | 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 | N | / | Bayer CropScience |
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| KCA 5.8.1 /09 | Wollny, H. E. | 2015 | 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 | N | / | Bayer CropScience |
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| KCA 6.1 /03 | Wrede, A. | 2000 | Stability of AE F130060 in wheat shoot during deep freeze storage Mesosulfuron-methyl Code: AE F130060  Aventis CropScience GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: C028928,  Edition Number: M-198617-03-1  EPA MRID No.: 46229002  Date: 2000-08-29  ...Amended: 2003-01-27  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| KCA 8.2.6.1 /12 | Herno, V. | 2016 | Calculation of EC10 and EC20 for algae study (M-198314-01- 1) in context of mesosulfuron approval renewal (EFSA request, Point 42)  Bayer CropScience  Bayer CropScience,  Report No.: M-549793-01-1,  Edition Number: M-549793-01-1  Date: 2016-03- 08  GLP/GEP: no, unpublished | N | N | / | BCS |
| KCA 8.2.6.1 /13 | Herno, V. | 2016 | Calculation of EC10 and EC20 for algae study (M-254084-01- 1) in context of mesosulfuron approval renewal (EFSA request, Point 42)  Bayer CropScience  Bayer CropScience,  Report No.: M-549798-01-1,  Edition Number: M-549798-01-1  Date: 2016-03- 08  GLP/GEP: no, unpublished | N | N | / | BCS |
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| KCA 8.2.7 /04 | Sowig, P.; Weller, O. | 2000 | Duckweed (Lemna gibba G3) growth inhibition test AE F160460 (metabolite of AE F130060) substance, pure Code: AE F160460 00 1B96 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Report No.: C009792,  Edition Number: M-199266-01-1  EPA MRID No.: 45386312  Date: 2000-10- 13  GLP/GEP: yes, unpublished | N | N | / | BCS |
| KCA 8.2.7 /05 | Sowig, P.; Weller, O. | 2000 | Duckweed (Lemna gibba G3) growth inhibition test AE F147447, substance, technical (Metabolite of AE F130060) Code: AE F147447 00 1C93 0001  Aventis CropScience GmbH, Frankfurt am Main, Germany  Report No.: C009245,  Edition Number: M-198273-01-1  Date: 2000-09- 29  GLP/GEP: yes, unpublished | N | N | / | BCS |
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| 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | Bayer CropScience |
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| KCA 5.4.1 /02 | Mueller, W. | 1996 | 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 | N | / | Bayer CropScience |
| KCA 5.4.1 /03 | Mueller, W. | 1996 | Detection of DNA strand breaks in primary hepatocytes of male rats in vitro UDS - test in primary rat hepatocytes Hoe 115008 substance, technical Code: Hoe 115008 00 ZC89 0001  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 | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
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| 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | 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 | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
| KCA 5.8.1 /07 | Stammberger, I.; Braun, K. | 1998 | Bacterial reverse mutation test AE F143133 substance, technical Code: AE F143133 00 1C98 0001  Hoechst Marion Roussel, Frankfurt am Main, Germany  Report No.: C001348,  Report includes Trial Nos.: 98.0540  Edition Number: M-182410- 01-1  EPA MRID No.: 45108910  Date: 1998-10-29  GLP/GEP: yes  Unpublished | N | 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 | N | / | Bayer CropScience |
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| KCA 6.2.2 /01 | XXX | 1999 | Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: (14C)-AE F115008  Bayer CropScience,  Report No.: C005548,  Report includes Trial Nos.: TOX95291  Edition Number: M-192269-01- 1  EPA MRID No.: 45108923  Date: 1999-10-11  GLP/GEP: yes, unpublished | Y | N | / | Bayer CropScience |
| KCA 6.2.3 /01 | XXX | 1999 | Ruminant - Metabolism, distribution and nature of residues in milk and edible tissues (14C) AE F115008 Code: AE F115008  Bayer CropScience,  Report No.: C005678,  Report includes Trial Nos.: TOX95290  Edition Number: M-192483-01- 1  EPA MRID No.: 45108924  Date: 1999-12-15  GLP/GEP: yes, unpublished | Y | N | / | Bayer CropScience |
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| KCA 6.3.1 /04 | Helgers, A. | 1998d | AE F115008 and AE F107892 EG (emulsifiable granule) and WG (water dispersible granule) 50 and 150 g/kg Code: AE F115008 02 EG20 A401 and Code: AE F115008 02 WG20 A903 Residue trials on cereals with two different coformulations to determine a residue decline of AE F115008 and AE F107892 following 1 application; European Union (Northern zone), 1996  Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany  Bayer CropScience,  Report No.: A59541,  Edition Number: M-143212-01- 1  Date: 1998-05-18  GLP/GEP: yes, unpublished | N | N | / | Bayer CropScience |
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| 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 | N | / | Bayer CropScience |
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| KIIA, 7.1.1/02 | Buerkle W.L. | 1994d | Code: Hoe 107892 00 ZE99 0001 Hoe 107892 14C, Aerobic Degradation in Two Soils at Different Conditions in the Laboratory  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Chemistry Frankfurt  Document No: A52824  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.1.3/01 | Tarara G. | 1995a | Code: Hoe 107892 00 ZE99 0001 Hoe 107892-14C, Photolytic Degradation on Soil Surfaces  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Chemistry Frankfurt  Document No: A53645  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.2.2/01 | Buerkle W.L. | 1994d | Code: Hoe 107892 00 ZE99 0001 Hoe 107892 14C, Aerobic Degradation in Two Soils at Different Conditions in the Laboratory  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Chemistry Frankfurt  Document No: A52824  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.3.1/02 | Baedelt H., Idstein H., Junker H. | 1994b | Fenoxaprop-P-ethyl + Hoe 107892 oil in water emulsion (69+75 g/l) (Code: Hoe 046360 24 EW1l4 A201) Investigation of the degradation behaviour of Hoe 107892 in soil under field conditions (Stufe 2 in accordance with Richtlinie BBA, Teil IV, 4-1)  Generated by: Hoechst AG; GB C / Produktentwicklung Oekologie 2  Document No: A53311  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.4.3/01 | Schwab W., Buerkle W.L., Mueller A. | 1993b | Hoe 107892-14C Leaching behaviour of the formulated non-aged active ingredient in the LUFA standard soils 2.1, 2.2 and 2.3 in the presence of Hoe 046360 (Hoe 046360 24 EW14 A2)  Generated by: Hoechst AG; GB C / Produktentwicklung Oekologie 1  Document No: A51617  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.7/01 | Voelskow H. | 1994h | Testing for ready biodegradability of Hoe 107892  Generated by: Hoechst AG; Abteilung Umweltschutz  Document No: A58716  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.8.3/03 | Sur, R. | 2007a | Kinetic evaluation of the aerobic aquatic metabolism of mefenpyr-diethyl and its monocarboxylic acid metabolites AE F113225 and AE F114952 in water-sediment systems  Bayer CropScience,  Report No.: MEF-06/506,  Edition Number: M-289041-01-1  Date: 2007-06-05  Non GLP, unpublished | N | N | / | Bayer CropScience |
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| KIIA, 7.10/02 | Deas A.H.B. | 1994a | The Volatility Of [14C]-Hoe 107892 (formulated as Hoe 046360 24 EW14 A7) from plant and soil surfaces  Generated by: AgrEvo UK Ltd.;  Document No: A53472  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA 8.1.1/01 | Anonymous | 1991j | Hoe 107892; substance, technical (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Japanese quail (Coturnix coturnix japonica)  Document No: A45647  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
|  | Anonymous | 1994 | 1st Amendment - Hoe 107892; substance, technical (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Japanese quail (Coturnix coturnix japonica)  Document No: A45647  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA 8.1.1/02 | Anonymous | 1991k | Hoe 107892; SUBSTANCE, TECHNICAL (CODE: Hoe 107892 00 ZC97 0001) Testing for acute oral toxicity in the male and female Mallard duck (Anas platyrhynchos)  Document No: A45650  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.1.2/01 | Anonymous | 1991i | Hoe 107892; substance, technical; (Code: Hoe 107892 00 ZC94 0001) 8-day dietary LC50 test in the Japanese quail (Coturnix coturnix japonica)  Document No: A46491  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.1.3/01 | Anonymous | 1992e | Hoe 107892; SUBSTANCE, TECHNICAL (CODE: Hoe 107892 00 ZC94 0001) 8-day dietary LC50 test in the mallard duck (Anas platyrhynchos)  Document No: A49551  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.1.4/01 | Anonymous | 1994i | HOE 107892; SUBSTANCE TECHNICAL (Code: Hoe 107892 00 ZC94 0001) Avian subchronic toxicity test - oral toxicity (including effects on reproduction) in the Japanese quail (Coturnix coturnix japonica, Temminck und Schlegel, 1849) following a 6-week administration period  Document No: A52539  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.1/01 | Anonymous | 1991de | Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to Oncorhynchus mykiss (Rainbow trout) in a Static-Acute Toxicity Test (method OECD)  Document No: A47038  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.2/01 | Anonymous | 1992bj | Hoe 107892 - substance, technical (Hoe 107892 00 ZC94 0001) Effect to Cyprinus carpio (Mirror carp) in a Static-Acute Toxicity Test (method OECD)  Document No: A47925  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.3/01 | Anonymous | 2002s | Acute toxicity to Lepomis macrochirus (bluegill sunfish) AE F113225; substance, technical (Metabolite of AE F107892)  Code: AE F113225 00 1C92 0001  Document No: C015647  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.3/02 | Anonymous | 1999al | Acute toxicity to Oncorhynchus mykiss (Rainbow trout) AE F109453 (metabolite of mefenpyr-diethyl AE F107892) substance, technical  Code: AE F109453 00 1C96 0001  Document No: C003087  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.3/03 | Anonymous | 1997j | AEF094270 Substance, technical Metabolite of AE F107892  Code: AE F094270 00 1C99 0003 Acute toxicity to rainbow trout (Oncorhynchus mykiss)  Document No: A59135  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.1.3/04 | Anonymous | 2005c | Zebra fish (Danio rerio) acute toxicity test - dynamic conditions AE F094270, substance technical  Code: AE F094270 00 1C99 0004  Document No: C046109  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.3/01 | Anonymous | 1994a | Hoe 107892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to Oncorhynchus mykiss (Rainbow trout) in a 28-days Juvenile Growth Test under Flow-Through Conditions  Document No: A53107  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.3/02 | Anonymous | 2004c | Rainbow trout (Oncorhynchus mykiss), Juvenile growth test (OECD 215), flowthrough conditions AE F113225, substance pure  Code: AE F113225 00 1C97 0001  Document No: C046106  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.4/01 | Anonymous | 2005b | Zebra fish (Danio rerio) toxicity test on embryo and sac-fry stages - dynamic conditions AE F094270, substance technical  Code: AE F094270 00 1C99 0004  Document No: C046110  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.5/01 | Anonymous | 2005a | Zebra fish (Danio rerio) two-generation test - dynamic conditions AE F094270, substance technical  Code: AE F094270 00 1C99 0004  Document No: C046111  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.2.6.1/01 | Anonymous | 1995a | Code: Hoe 107892 00 ZE99 0003 Hoe 107892 (dichlorophenyl-14C) Flow-through Bioaccumulation and Metabolism Study with Bluegill Sunfish (Lepomis macrochirus)  Document No: A53225  GLP / GEP Yes  unpublished | Y | N | / | Bayer CropScience |
| IIA, 8.3.1.1/01 | Heusel R. | 1997l | AE F107892 substance technical Code: AE F107892 00 1C97 0001 Acute toxicity to Daphnia magna (Waterflea)  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Biology Frankfurt  Document No: A58156  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.1.1/02 | Sowig P., Gosch H. | 2002r | Acute toxicity to Daphnia magna (waterflea) AE F113225; substance, technical (Metabolite of AE F107892) Code: AE F113225 00 1C92 0001  Generated by: Aventis CropScience GmbH, DEU; Oekotoxikologie, Frankfurt  Document No: C014740  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.1.1/03 | Sowig P., Weller O., Gosch H. | 1999ak | Acute toxicity to Daphnia magna (Waterflea) AE F109453 substance, technical Code: AE F109453 00 1C96 0001  Generated by: Hoechst Schering AgrEvo GmbH; Entwicklung Umweltforschung, Frankfurt  Document No: C003086  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.1.1/04 | Heusel R. | 1997k | AE F094270 Substance, technical Metabolite of AE F107892 Code: AE F094270 00 1C99 0003 Acute toxicity to Daphnia magna (Waterflea)  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Biology Frankfurt  Document No: A59055  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.2.1/01 | Heusel R. | 1994j | Hoe 907892 - substance, technical Code: Hoe 107892 00 ZC97 0001 Effect to Daphnia magna (Waterflea) in a 21-day Reproduction Test (method OECD)  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Biology Frankfurt  Document No: A53108  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.2.1/02 | Schaefers C. | 2004d | Daphnia magna, Reproduction test (OECD 211) Semi-static conditions AE F113225, substance pure Code: AE F113225 00 1C97 0001  Generated by: Fraunhofer Institut, IME, DEU;  Document No: C046107  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.3.2.1/03 | Schaefers C. | 2005a | Daphnia magna, Reproduction test (OECD 211), Semi-static conditions AE F094270, substance technical Code: AE F094270 00 1C99 0004  Generated by: Fraunhofer Institut, IME, DEU;  Document No: C046108  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.4.1/01 | Scheerbaum D. | 1998a | Mefenpyr-diethyl (Draft lSO), substance, technical Code: AE F107892 00 1 C97 0001 Alga, Growth Inhibition Test (Pseudokirchneriella subcapitata, 96 [h])  Generated by: Dr.U.Noack-Laboratorium fuer Angewandte Biologie;  Document No: C000738  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.4.1/02 | Sowig P., Weller O. | 1999i | Algal growth inhibition - Navicula pelliculosa Mefenpyr-diethyl (draft ISO) substance, technical Code: AE F107892 00 1C97 0001  Generated by: Hoechst Schering AgrEvo GmbH; Entwicklung Umweltforschung, Frankfurt  Document No: C001644  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.4.2/01 | Sowig P., Gosch H. | 2002t | Algal growth inhibition - Pseudokirchneriella subcapitata AE F113225; substance, technical Code: AE F113225 00 1C92 0001  Generated by: Aventis CropScience GmbH, DEU; Oekotoxikologie, Frankfurt  Document No: C015166  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.4.2/02 | Sowig P., Gosch H., Weller O. | 1999a | Algal growth inhibition - Pseudokirchneriella subcapitata AE F109453 (Metabolite of the safener AE F107892) substance, technical Code: AE F109453 00 1C96 0001  Generated by: Hoechst Schering AgrEvo GmbH; Entwicklung Umweltforschung, Frankfurt  Document No: C002636  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.4.2/03 | Heusel R. | 1997i | AE F094270 Substance, technical Metabolite of AE F107892 Code: AE F094270 00 1C99 0003 Algal growth inhibition - Pseudokirchneriella subcapitata  Generated by: Hoechst Schering AgrEvo GmbH; Environmental Biology Frankfurt  Document No: A59218  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
| IIA, 8.5.2/01 | Dorgerloh M. | 2004o | Chironomus riparius 28-day Chronic Toxicity Test with Mefenpyr-diethyl-metabolite (AE F094270) in a Water-Sediment System using Spiked Water  Generated by: Bayer CropScience AG, Monheim, DEU  Document No: C045893  GLP / GEP Yes  unpublished | N | N | / | Bayer CropScience |
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**\*BCS → 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** | **Verte-brate study**  **Y/N** | **Data protection claimed**  **Y/N** | **Justification if data protection is claimed** | **Owner** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | Owner |
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List of data relied on and not submitted by the applicant but necessary for evaluation

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| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Y/N | Data/study report never submitted before to <insert MS>  If previously submitted in **this** MS:  Data protection started with: <insert authorization number of first authorization> | Owner |
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