

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: JME-HER 12 OD

Product name(s): -

Chemical active substance:

iodosulfuron-methyl-sodium, 2 g/L

mesosulfuron-methyl, 10 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(authorization)

Applicant: Pestila Sp. z o.o.

Submission date: December 2023

MS Finalisation date: 25/04/2025

Version history

When	What
January 2024	Dossier sent for evaluation
July 2024	zRMS finalised evaluation
October 2024	Final version prepared by zRMS after Commenting period
January 2025	zRMS update
March 2025	zRMS update

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable used conditions required for the registration of JME-HER 12 OD, containing active substances: iodosulfuron-methyl-sodium – 2 g/L as well as mesosulfuron-methyl – 10 g/L, in Poland.

This document describes the specific conditions of use and labelling required for Poland for the registration in art. 33 based on art 34 Regulation 1107/2009 of JME-HER 12 OD.

1.1 Application background

This application was submitted by Pestila Spółka z ograniczoną odpowiedzialnością (hereinafter referred as Pestila Sp. z o. o.)

This is the application for registration plant protection product under product code JME-HER 12 OD according to Article 33 of Regulation 1107/2009 based on data for which a 10-year protection period has expired (acc. Art. 34 of Reg. 1107/2009). JME-HER 12 OD is an oil dispersion (OD), containing 10 g/L of mesosulfuron-methyl and 2 g/L iodosulfuron-methyl-sodium to be used as herbicide to winter wheat, winter triticale and rye.

This documentation has been prepared by copying the risk assessments and summary of studies included in the Atlantis 12 OD renewal Registration Report (zRMS: Poland, MS finalisation: 12/02019). The information and studies used in this document are not protected in accordance with Art. 59 Reg. 1107/2009 and can be used for purpose of JME-HER 12 OD registration.

1.2 Letters of Access

Letter of Access was separately submitted.

1.3 Justification for submission of tests and studies

Please refer to the justification as provided for in the list of references in Appendix 4.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	JME-HER 12 OD
Product name in MS	Please refer to the cover letter.
Authorization number	Not applicable.
Function	Herbicide.
Applicant	Pestila Sp. z o. o.
Active substance(s) (incl. content)	Iodosulfuron-methyl-sodium 2 g/L Mesosulfuron-methyl 10 g/L Mefenpyr-diethyl (safener), 30 g/L
Formulation type	Oil dispersion [OD]
Packaging	250mL, 0.5L, 1L, 2L, 5L, 10L, 20L bottles, cannisters HDPE/PA (COEX), fHDPE

	and 220L, 1000L drums and containers HDPE/PA (COEX) professional
Coformulants of concern for national authorizations	Not applicable.
Restrictions related to identity	Not applicable.
Mandatory tank mixtures	Not applicable.
Recommended tank mixtures	Not applicable.

2.2 Conclusion

Authorization can be granted.

2.3 Substances of concern for national monitoring



There are no substances of concern for national monitoring.

2.4 Classification and labelling

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

Hazard class(es), categories:	Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
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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:	  GHS07 GHS09
Signal word:	Warning
Hazard statement(s):	H319 - Causes serious eye irritation. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P264 - Wash hands thoroughly after handling P280 - Wear protective gloves, protective clothing, eye protection, face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice and attention. P391 - Collect spillage. P501- Dispose of contents/container to...
Additional labelling phrases:	EUH401 - To avoid risks to human health and the environment, comply with the instructions for use. EUH208 - Contains fatty alcohol ethoxylate - alkyl ether. May produce an allergic reaction. EUH066 - Repeated exposure may cause skin dryness or cracking.

Special rule for labelling of plant protection product (PPP):

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Further labelling statements under Regulation (EC) No 1272/2008:

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

SPe 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).
SPe 3	<p><u>When using a maximum dose of 1.2 l/ha:</u> To protect aquatic organisms, respect a vegetative buffer zone of 10m to surface water bodies.</p> <p><u>When using a dose of 0.45 l product/ha:</u> To protect aquatic organisms, respect buffer zone of 1 m to surface water bodies.</p> <p><u>When using a maximum dose of 1.2 l product/ha:</u> To protect non-target plants and non-target arthropods respect an unsprayed buffer zone to non-agricultural land should be applied: - 5 m or - 1m combined with 75% drift reducing nozzles.</p> <p><u>When using a dose of 0.45 l product/ha:</u> To protect non-target plants and non-target arthropods respect an unsprayed buffer zone to non-agricultural land should be applied: - 1m</p>

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

Not relevant.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Workwear and gloves during mixing/loading step.
Worker protection:	
-	None. Recommended: workwear and gloves during field activities.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe 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).
SPe 3	<p><u>When using a maximum dose of 1.2 l/ha:</u> To protect aquatic organisms, respect a vegetative buffer zone of 10m to surface water bodies. To protect non-target plants and non-target arthropods respect an unsprayed buffer zone to non-agricultural land should be applied: - 5 m or - 1m combined with 75% drift reducing nozzles.</p> <p><u>When using a dose of 0.45 l product/ha:</u> To protect aquatic organisms, respect buffer zone of 1 m to surface water bodies.</p>

	When using a dose of 0.45 l product/ha: To protect non-target plants and non-target arthropods respect an unsprayed buffer zone to non-agricultural land should be applied: - 1 m
Other specific restrictions	
-	-

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

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

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

GAP rev. 1, date: 2023-12-01

Verified by MS: yes

Non professional use: ☐

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Membe r state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or 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	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fnp G, Gn, Gnp 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, other dose rate expression, dose range (min-max)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or 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			
1	Poland	Winter wheat	F	Susceptible weeds (0.45-0.6l/ha): Field chamomile (<i>Anthemis arvensis</i>) ANTAR Wind grass (<i>Apera spica-venti</i>) APESV Oilseed rape (<i>Brassica napus</i>) BRNN Shepherd's purse (<i>Capsella bursa-pastoris</i>) CAPBP Fat-hen (<i>Chenopodium album</i>) CHEAL Wild mustard (<i>Sinapis arvensis</i>) SINAR Common chickweed (<i>Stellaria media</i>) STEME Fanweed (<i>Thlaspi arvense</i>) THLAR Horse daisy (<i>Tripleurospermum inodorum</i>) MATIN Forget-me-not (<i>Myosotis arvensis</i>) MYOAR Susceptible weeds (0.9-1.2 L/ha): Common wild oat (<i>Avena fatua</i>) AVEFA Cheat grass (<i>Bromus secalinus</i>) BROSE Black twitch (<i>Alopecurus myosuroides</i>) ALOMY Moderately susceptible weeds: Field pansy (<i>Viola arvensis</i>) VIOAR Common poppy (<i>Papaver rhoeas</i>) PAPRH Speedwells (<i>Veronica Sp.</i>) 1VERG Resistant weeds: Cleavers (<i>Galium aparine</i>) GALAP Knotgrasses (<i>Polygonum/Fallopia Sp.</i>) 1FOPG	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1		a) 0.45 - 1.2 l/ha	a) 2.4 iodosulfuron 12 mesosulfuron - 0.9 iodosulfuron 4.5 mesosulfuron	200-300	not relevant		
2	Poland	Winter tritcale					b) 1		b) 0.45 - 1.2 l/ha	b) same as a)				

[illegible]

3	PL	Winter wheat	F	<u>Susceptible weeds (0.45-0.6 L/ha):</u> field chamomile (<i>Anthemis arvensis</i>)-ANTAR wind-grass (<i>Apera spica-venti</i>)-APESV oilseed rape (<i>Brassica napus</i>)-BRNN shepherd's purse (<i>Capsella bursa-pastoris</i>)-CAPBP <u>Moderately susceptible weeds:</u> Field pansy (<i>Viola arvensis</i>)-VIOAR Common poppy (<i>Papaver rhoeas</i>)-PAPRH Speedwells (<i>Veronica Sp.-</i>) <u>Resistant weeds:</u> Cleavers (<i>Galium aparine</i>)-GALAP knotgrasses (<i>Polygonum/Fallopia Sp.-</i>) Moderately susceptible (MS) at the dose rate 0,45 l/ha: SINAR	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1	-	a) 0.45 L/ha b) 0.45 L/ha	a) 0.9 - iodosulfuron 4.5 - mesosulfuron b) same as a)	200-300	not relevant	
4	PL	Winter triticale		fat-hen (<i>Chenopodium album</i>)-CHEAL wild mustard (<i>Sinapis arvensis</i>)-SINAR common chickweed (<i>Stellaria media</i>)-STEME fanweed (<i>Thlaspi arvense</i>)-THLAR horse daisy (<i>Tripleurospermum inodorum</i>)-MATIN forget-me-not (<i>Myosotis arvensis</i>)-MYOAR									
5	PL	Rye		<u>Moderately susceptible weeds:</u> Field pansy (<i>Viola arvensis</i>)-VIOAR Common poppy (<i>Papaver rhoeas</i>)-PAPRH Speedwells (<i>Veronica Sp.-</i>) <u>Resistant weeds:</u> Cleavers (<i>Galium aparine</i>)-GALAP knotgrasses (<i>Polygonum/Fallopia Sp.-</i>) Moderately susceptible (MS) at the dose rate 0,45 l/ha: SINAR									

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

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that homogenous, beige liquid of typical, weak smell. It is not explosive, has no oxidizing properties. The product is not flammable. It has a self-ignition temperature of 305 °C. In aqueous solution, it has a pH value around 10.1 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 8 weeks at 40 °C, neither the active ingredients content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA (COEX). Its technical characteristics are acceptable for an OD formulation.

The intended concentration of use is from 0.15 % to 0.6 %.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

This is the application for registration of a plant protection product under working name JME-HER 12 OD according to Article 33 based on Article 34 of Regulation 1107/2009. JME-HER 12 OD is an oil dispersion (OD) formula, containing 2 g/L of iodosulfuron-methyl-sodium and 10 g/L of mesosulfuron-methyl to be used as a herbicide to protect cereals. This is a core dossier in order to allow the approval of product JME-HER 12 OD in Poland (zRMS).

The reference product to the product under the code JME-HER 12 OD is Atlantis 12 OD, that has been first registered in Poland according to authorisation Minister of Agricultural and Rural Development No. 98/2009 of August, 14th 2009 which means, that data protection, for the data presented by Atlantis 12 OD authorisation holder, for purposes of registration, has been expired.

According to the current Polish registration requirements, performing 1-2 trials for use is sufficient for the applications for registration of a plant protection products according to Article 33 based on Article 34 of Regulation 1107/2009.

In respect to the above and taking into account Polish requirements applicant provides five efficacy bridging trials to confirm that herbicidal properties of JME-HER 12 OD are comparable to properties of Atlantis 12 OD in protection of cereals against weeds.

~~It should be emphasised that in the bridging trials, the highest of the proposed doses of 1.2 l/ha provided high efficacy against the most weeds tested, such as that indicated for doses of 0.45-0.6 l/ha on the label of the reference product Atlantis 12 OD. In such a case, it would be concluded that a shift in weed sensitivity to the test products (JME-HER 12 OD and Atlantis 12 OD) towards higher doses was observed. Nevertheless, such conclusion should be supported by more efficacy trials.~~

In all bridging trials, the efficacy of the product tested was comparable to the reference product Atlantis 12 OD when applied at dose rates 0.45; 0.6; 1.2 l/ha. Nevertheless, both products (JME-HER 12 OD and the reference product) showed lower efficacy against most tested weed species in bridging trials compared to weeds susceptibility classification presented on the label currently authorised reference product Atlantis 12 OD. The noticed decrease in efficacy may indicate potential resistance to the active substances.

For both products the lower efficacy than at the national label classification of the reference product ATLANTIS 12OD was observed:

- at the dose rate 0,45 l/ha, against the following weed species: APESV, STEME, SINAR
- at the dose rate 0,6 l/ha, against the following weed species: ANTAR, APESV, BRSNW, CAPBP, CHEAL, STEME, THLAR.

What is more following weed species, recognised susceptible on the reference product label were not tested in bringing trials:

- at the dose 0,45 l/ha: ANTAR, BRSNW, CAPBP, MATIN, THLAR, MYOAR.
- at the dose 0,9 l/ha: AVEFA, BROSE, ALOMY

Taking into consideration the fact that for majority of weed species one efficacy result each was presented it may not be sufficient to conclude about efficacy of both products in above clarified situation.

Therefore it is proposed to conditionally accept weeds susceptibility classification presented on the label of reference product Atlantis 12 OD for the JME-HER 12 OD.

To determine the confirmation of the efficacy of the JME-HER 12 OD in the scope of weed classification indicated on the Atlantis 12 OD label, it is suggested to submit additionally 2-3 trials each on the indicated weed species:

- APESV, BRSNW, CAPBP, CHEAL, MATIN, ANTAR, STEME, THLAR, SINAR, MYOAR at the dose 0,45 l/ha;
- AVEFA, BROSE, ALOMY at the dose 0,9 l/ha.

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

According to the HRAC code list active substances of JME-HER 12 OD - iodosulfuron-methyl-sodium and mesosulfuron-methyl, both are an ALS-inhibiting herbicide (Chemical Family: Sulfonylurea) classified in Group 2. ALS is a key enzyme re-sponsible for biosynthesis of amino acids such as valine, leucine and isoleucine. Susceptible weeds ex-posed to iodosulfuron-methyl-sodium and mesosulfuron-methyl show various injuries as: inhibition of plant growth, shortening of internodes, purplish foliage, and shortening of lateral roots, resulting in plant death, caused by deficiency in branched-chain amino acids.

ALS-inhibiting herbicides are used in all major agronomic crops and have been widely adopted due to their low dose rates and high efficacy against a broad spectrum of weeds, relatively low mammalian toxicity, mild toxicological profile, and excellent crop selectivity. However, the widespread use of ALS-inhibiting herbicides led to rapid selection of many resistant weed populations. ALS-resistant weeds represent the fastest-growing group of herbicide-resistant weeds worldwide.

3.3.1 Adverse effects on treated crops

Selectivity trials were not carried out. Not relevant for new registration according to art. 34 of Reg. 1107/2009 based on data which protection period has expired. For the purpose of evaluation of JME-HER 12 OD please refer to Renewal RR for Atlantis 12 OD.

Phytotoxicity of JME-HER 12 OD was tested in all 5 efficacy trials. The maximum tested dose rate was 1,2 l/ha. No phytotoxicity symptoms were observed in the efficacy trials.

The point (selectivity data, effect on yield and quality of yield) was also completed based on the unprotected data of the reference product Atlantis 12 OD. The evaluator has no comments.

3.3.2 Observations on other undesirable or unintended side-effects

JME-HER 12 OD (containing iodosulfuron-methyl-sodium and mesosulfuron-methyl) is not harmful for succeeding plants since its active substance decomposes relatively quick (According to PPDB by University of Hertfordshire¹, DT₉₀ values from field tests are in range between 28 and 257 days). Consequently, the product decomposes within the growing season without making any damage to succeeding plants. It is concluded that after the appropriate application of JME-HER 12 OD in cereals, all the possible following crops can be grown when usual crop rotation and seedbed preparation is used.

Considering raised arguments and the fact that the literature does not say anything about the adverse impact on succeeding crops after application of herbicides containing this active substances, no specific plant-back restrictions related to JME-HER 12 OD are required. However, in case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), only cereals can be grown on the same field. After deep seedbed preparation (by ploughing) also sorghum can be grown on the same field.

In the opinion of ZRMS, in case of treated winter wheat, triticale, rye failure (e.g. by hail, disease, pests or frost), only these crops may be sown on the field. After harvesting winter wheat, triticale, rye grown

¹ <http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/401.htm>
<http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/441.htm>

under normal growing conditions, all crops can be cultivated (the product decomposes within the growing season).

None of the efficacy/crop safety trials reported any effects on adjacent crops or plants. Application of JME-HER 12 OD, according to the requirements of “Good Agricultural Practice” excludes lapses, e.g. overspray of boundary stripes, overdose or applications in other than the registered crops or at other application times. Furthermore, GAP rules say that to avoid spray drift to adjacent crops the wind speed, the droplet size and positioning of the spray boom have to be taken into account. As JME-HER 12 OD is intended for control of mono and dicotyledonous weeds, the product may cause damages on mono (f.e. cereals) and dicotyledonous adjacent crops if it is misused.

Therefore, it is not expected that appropriate applications of JME-HER 12 OD will lead to adverse effects on adjacent crops.

At a maximum application rate of 1.2 l/ha:

according to the label of the reference product, in order to protect non-target plants, it is necessary to demarcate a buffer zone of:

- 5 m or

- 1 m and use a drift reduction nozzle of 75%

Tank cleaning

There are no special requirements for cleaning application equipment and protective clothing. Normal procedures should be followed for the cleaning and use of protective clothing and equipment.

During the evaluation the unprotected efficacy data performed for Atlantis 12 OD was also used for JME-HER 12 OD.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The analytical methods were successfully validated for the determination of iodosulfuron-methyl-sodium and mesosulfuron-methyl in the test item JME-HER 12 OD according to the requirements laid down by SANCO3030/99 rev. 4. Therefore, all relevant data are provided and are considered adequate.

The method for determination of mesosulfuron-methyl and iodosulfuron-methyl-sodium in JME-HER 12 OD formulation is based on LC liquid chromatograph equipped with DAD detector and external standard. In order to confirm method specificity, chromatograms of acetonitrile, placebo, standard and analysed sample were superimposed and compared.

Mesosulfuron-methyl

There were no peaks interfering with the mesosulfuron-methyl peak. The correlation coefficient was $R^2 = 0.99981$ (the criterion of acceptability is $R^2 \geq 0.98$). The relative standard deviation of instrument precision for the determined active substance was $RSD = 0.51 \%$ (criterion of acceptability is $H_r \leq 1$). Acceptable relative standard deviation of repeatability for the determined active substance is $\leq 2.66 \%$. The obtained results of 0.19% is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The recovery value for the main component should be $90\% \div 110\%$. The obtained result 101.54% is acceptable.

The method for determination of mesosulfuron-methyl in JME-HER 12 OD fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

Iodosulfuron-methyl-sodium

There were no peaks interfering with the iodosulfuron-methyl-sodium peak. The correlation coefficient was $R^2 = 0.99984$ (the criterion of acceptability is $R^2 \geq 0.98$). The relative standard deviation of instrument precision for the determined active substance was $RSD = 0.65\%$ (criterion of acceptability is $H_r \leq 1$). Acceptable relative standard deviation of repeatability for the determined active substance is \leq

3.39 %. The obtained results of 0.19 % is acceptable. The accuracy of active ingredient determination was estimated by the recovery measurement. The recovery value for the main component should be 80% ÷ 120%. The obtained result 102.02 % is acceptable.

The method for determination of iodosulfuron-methyl-sodium in JME-HER 12 OD fulfils acceptability criteria contained in SANCO/3030/99 rev.5, 22 March 2019 guidance and assure appropriate active substance determination in the formulation.

3.4.2 Analytical methods for residues

Analytical methods for the determination of residues for pre- and post-authorisation control are presented in section B5 of the draft Registration Report.

A number of validated methods are available for the analysis of iodosulfuron-methyl-sodium (and its salts), mesosulfuron-methyl and mefenpyr-diethyl (and metabolites AE F094270, AE F109453 and AE F11322) for the generation of pre-authorisation data in crop matrices that satisfy the requirements according to SANCO/3029/99 rev.4.

For post-authorisation control and monitoring purposes, validated LC-MS/MS methods (01360 and 01208/M001) are available to analyse residues of iodosulfuron-methyl-sodium and mesosulfuron-methyl in foodstuffs of plant and animal origin to an LOQ of 0.01 mg/kg that satisfy the requirements according to SANCO/825/00 rev. 8.1.

The Applicant did not provide any new data. dRR is based on data evaluated in the Atlantis 12 OD renewal Registration Report (zRMS PL, 2020). The dRR Part B7 assessment for Atlantis 12 OD has been made available by the Ministry of Agriculture and Rural Development for review by zRMS.

The cGAPs assessed and accepted for Atlantis 12 OD covers the cGAPs proposed for JME-HER 12 OD. Since the assessment for Atlantis 12 OD, there have been no changes to the residue definitions of both active substances. The MRL values have also not changed, the MRL values in accordance with Reg. (EU) 289/2014 for both active substances still apply. It should therefore be considered that the conclusion of the Atlantis 12 OD evaluation also applies to JME-HER 12 OD.

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

3.5 Mammalian toxicology (Part B, Section 6)

3.5.1 Acute toxicity

No acute toxicity studies were performed for product JME-HER 12 OD. The classification of product is based on the composition of the product as well as studies for the reference product Atlantis 12 OD of Bayer AG, for which a 10-year data protection period has expired and unprotected data can be used for classification. Classification was performed according to the Regulation (EC) of the European Parliament and of the Council No. 1272/2008 of December 16th, 2008, *on classification, labelling and packaging of substances and mixtures*. Details are provided in dRR Part C.

Hazard categories with regard to toxicological data	Classification of product
Acute oral toxicity	Not classified.
Acute dermal toxicity	Not classified.
Acute inhalation toxicity	Not classified.
Skin Irritation	Not classified.
Eye Irritation	Eye Irrit. 2, H319
Skin sensitisation	Not classified.

3.5.2 Operator exposure

The operator exposure was assessed against the AOEL for iodosulfuron-methyl-sodium (EFSA Journal

2016;14(4):4453) and mesosulfuron-methyl (EFSA Journal 2016;14(10):4584). The default dermal absorption values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1 of 24 October 2018) were used for the calculations.

Operator exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

According to the model calculations, it can be concluded that the risk for the operator using product JME-HER 12 OD according to the GAP table is acceptable if operator is equipped with work wear (arms, body and legs covered) and gloves during mixing/loading (including combined exposure assessment).

3.5.3 Worker exposure

The worker exposure was assessed against the AOEL for iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453) and mesosulfuron-methyl (EFSA Journal 2016;14(10):4584). The default dermal absorption values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1 of 24 October 2018) were used for the calculations.

Worker exposure was modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

The results of the exposure calculations performed by AOEM EFSA models show that the use of JME-HER 12 OD according to the GAP Table, causes no health risk for the worker in case of potential exposure. However, it's recommended for worker to be equipped with work wear (arms, body and legs covered) and gloves during field activities.

As a standard rule, it should be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.5.4 Bystander and resident exposure

The bystander/resident exposure was assessed against the AOEL for iodosulfuron-methyl-sodium (EFSA Journal 2016;14(4):4453) and mesosulfuron-methyl (EFSA Journal 2016;14(10):4584). The default dermal absorption values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873 and SANTE/2018/10591 rev.1 of 24 October 2018) were used for the calculations.

Bystander/resident exposure were modelled using the AOEM EFSA model (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2022;20(1):7032) OPEX version: 1.0.1.).

The reference value acutely toxic active substance (RVAAS) for iodosulfuron-methyl-sodium and mesosulfuron-methyl is not allocated. Consequently, it is assumed that the estimation of bystander exposure is covered by the calculation of resident exposure towards this active substance.

All estimated values are below the AOEL values for active substances. It can be concluded that the exposure of bystander and resident (children and adult) to iodosulfuron-methyl-sodium and mesosulfuron-methyl contained in the formulation JME-HER 12 OD causes no risk to human health if the product is used in accordance with the intended uses listed in the GAP table.

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

The Applicant did not provide any new data. dRR is based on data evaluated in the Atlantis 12 OD renewal Registration Report (zRMS PL, 2020). The dRR Part B7 assessment for Atlantis 12 OD has been made available by the Ministry of Agriculture and Rural Development for review by zRMS.

cGAP evaluated and accepted in dRR for Atlantis 12 OD and cGAP proposed for JME-HER 12 OD:

Crop	Application			PHI (days)	Remarks
	Timing	/	Max. number g a.s./ha		

	Growth stage of crop	a) per use b) per crop/ season	a) max. rate per appl. b) max. total rate per crop/season		
Atlantis 12 OD					
Cereals	BBCH 12-39	1	2.4 iodosulfuron-methyl-sodium 12 mesosulfuron-methyl	-	plus 36 g mefenpyr-diethyl as a safener
JME-FER 12 OD					
Winter wheat	BBCH 21-31	1	2.4 iodosulfuron-methyl-sodium 12 mesosulfuron-methyl	-	plus 36 g mefenpyr-diethyl as a safener
Winter triticale					
Rye			0.9 iodosulfuron-methyl-sodium 4.5 mesosulfuron-methyl		

The cGAPs assessed and accepted for Atlantis 12 OD covers the cGAPs proposed for JME-HER 12 OD.

The residues arising from the proposed uses of iodosulfuron-methyl-sodium in JME-HER 12 OD (max: 1×2.4 g a.s./ha, BBCH 12-31, PHI not relevant) will not exceed the MRLs established for cereals (0.01 mg/kg according to the current Reg. (EU) No 289/2014 and not yet applicable Reg. (EU) 2024/1077 (will apply on 06/11/2024)).

The residues arising from the proposed uses of mesosulfuron-methyl in JME-HER 12 OD (max: 1×12 g a.s./ha, BBCH 12-31, PHI not relevant) will not exceed the MRLs established for cereals (0.01 mg/kg according to the current Reg. (EU) No 289/2014)

No livestock feeding studies to investigate the residue levels of iodosulfuron-methyl-sodium and mesosulfuron-methyl in food of animal origin are required as the calculated dietary burdens for all groups of live-stock 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 are not required as significant residues are not expected to be found in cereals.

Iodosulfuron -methyl-sodium and mesosulfuron-methyl residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that they are applied in compliance with the GAPs of JME-HER 12 OD.

Mefenpyr used as a safener was not yet assessed at EU level nevertheless, it was assessed and accepted in national addendum for Atlantis 12 OD.

3.6.1 Residues

Storage stability

Iodosulfuron-methyl-sodium

The report from a new stability study was presented in the framework of this application because data gap was identified in this area during the renewal of approval process (EFSA Journal 2016;14(4):4453). The storage stability report shows that iodosulfuron-methyl and its metabolites AE F059411 and AE 0031838 are stable in wheat grain, green material and straw for at least 24 months (721 days) under deep-freezer storage conditions ($\leq -18^{\circ}\text{C}$) except for AE 0031838 in wheat, shoot (68% recovery after 24 months) for which it is recommended to analyse the residues within 587 days.

The study is accepted. The test meets the requirements OECD Guidelines for the Testing of Chemicals. Stability of Pesticide Residues in Stored Commodities. 506. 2007-10-16.

The residue trials on the intended use presented in this dossier are valid in regard to storage stability data.

Mesosulfuron-methyl

No new studies submitted in the framework of this application. Stability of residues has been evaluated during the Peer review (EFSA Journal 2016;14(10):4584). Mesosulfuron-methyl is stable for 40 months

in wheat shoot, grain and straw. The residue trials on the intended use presented in this dossier are valid in regard to storage stability data.

Metabolism in plants and animals

Iodosulfuron-methyl-sodium

No new data submitted in the framework of this application.

<i>EU Endpoints</i>	
<i>Plant</i>	
<i>Plant groups covered</i>	<i>Cereals (Wheat)</i>
<i>Rotational crops covered</i>	<i>Yes</i>
<i>Metabolism in rotational crops similar to metabolism in primary crops?</i>	<i>Yes</i>
<i>Processed commodities</i>	<i>Not relevant</i>
<i>Residue pattern in processed commodities similar to pattern in raw commodities?</i>	<i>Not applicable</i>
<i>Plant residue definition for monitoring</i>	<i>Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016; Reg. (EU) No 289/2014)</i>
<i>Plant residue definition for risk assessment</i>	<i>Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016)</i>
<i>Conversion factor from enforcement to RA</i>	<i>1 (EFSA, 2012, 2016)</i>

<i>Animal</i>	
<i>Animals covered</i>	-
	-
<i>Time needed to reach a plateau concentration</i>	-
	-
<i>Animal residue definition for monitoring</i>	<i>Not necessary (EFSA, 2012, 2016)</i>
	<i>Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (Reg. (EU) No 289/2014)</i>
<i>Animal residue definition for risk assessment</i>	<i>Not necessary (EFSA, 2012, 2016)</i>
<i>Conversion factor</i>	-
<i>Metabolism in rat and ruminant similar</i>	-
<i>Fat soluble residue</i>	<i>No</i>

No further data are required to support the proposed uses.

Mesosulfuron-methyl

No new data submitted in the framework of this application.

<i>Endpoints</i>

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

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

No further data are required to support the proposed uses.

Magnitude of residues in plants

Iodosulfuron-methyl-sodium

Cereals

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

EU GAP (EFSA Journal 2016;14(4):4453):

Wheat

1×0.010 kg as/ha, BBCH 13-32, PHI not relevant, outdoor.

Barley

1×0.0075 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.

Proposed GAP: 1×0.0009 - 0.0024 kg as/ha, BBCH 21-31, PHI not relevant, outdoor.

Sufficient trials on cereals (wheat and barley) are available to support the proposed uses. Extrapolation from wheat to rye and triticale is possible (SANTE/2019/12752 - revision1 - 10 May 2023).

The data submitted show that no exceedance of the MRL will occur.

Mesosulfuron-methyl

Cereals

Trials GAP on which EU a.s. assessment is based (wheat and rye): 1×0.015 -0.020 kg as/ha, BBCH 13-32; 39, PHI not relevant, outdoor.

EU GAP - representative uses (SANTE/11827/2016 Rev 2, 23 March 2017):

Wheat

$1 \times 0.015 \text{ kg as/ha}$, BBCH 20-32, PHI not relevant, outdoor.

Rye

$1 \times 0.006 \text{ kg as/ha}$, BBCH 20-32, PHI not relevant, outdoor.

Proposed GAP: $1 \times 0.0045 - 0.012 \text{ kg as/ha}$, BBCH 21-31, PHI not relevant, outdoor.

Sufficient trials on cereals (wheat and barley) are available to support the proposed uses. Extrapolation from wheat to rye and triticale is possible (SANTE/2019/12752 - revision1 - 10 May 2023).

The data submitted show that no exceedance of the MRL will occur.

Magnitude of residues in processed commodities

Not required as significant residues are not expected to be found in cereals.

Magnitude of residues in representative succeeding crops

Iodosulfuron -methyl-sodium and mesosulfuron-methyl residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that they are applied in compliance with the GAPs of IMS+MSM+MPR OD 42.

3.6.2 Dietary burden calculation and livestock feeding studies

The active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl are authorised in EU for use on crops that might be fed to livestock, so dietary burden calculation was performed in EFSA reasoned opinion on the review of the existing maximum residue levels/import tolerances for iodosulfuron-methyl-sodium according to Article 12 of Regulation (EC) No 396/2005.

Nonetheless in this document, the additional calculation of the dietary burden was conducted based on requested uses of JME-HER 12 OD. The modelling was performed by Excel spreadsheet Animal model 2017. For the evaluation data included in EFSA Journal 2012;10(11):2974 and EFSA Journal 2012;10(11):2976 were applied. The calculated dietary burdens for ruminants, swine and poultry are below the trigger of 0.004 mg/kg bw.

3.6.3 Consumer exposure

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

Iodosulfuron-methyl-sodium

ADI	0.03 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	6% (based on diet: NL toddler) with the highest contributors: 4% Milk: Cattle 0.4% Apples 0.2% Maize/corn
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	not relevant
ARfD	3.15 mg/kg bw

IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	<p><u>Unprocessed commodities (children):</u> 0.08% Milk: Cattle (based on diet: UK infant) 0.05% Potatoes (based on diet: UK infant) 0.05% Melons (based on diet: BE toddlers)</p> <p><u>Unprocessed commodities (adults):</u> 0.02% Milk: Cattle (based on diet: NL general population) 0.01% Head cabbages (based on diet: CZ females 1-17 years) 0.01% Watermelons (based on diet: IT adult)</p> <p><u>Processed commodities (children):</u> 0.03% Sugar beets (root) / sugar (based on diet: NL child) 0.03% Potatoes / fried (based on diet: NL child) 0.03% Pumpkins / boiled (based on diet: NL child)</p> <p><u>Processed commodities (adults):</u> 0.02% Pumpkins / boiled (based on diet: NL general population) 0.01% Sugar beets (root) / sugar (based on diet: FR adult) 0.01% Cauliflower / boiled (based on diet: NL general population)</p>
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

* include raw and processed commodities if both values are required for PRIMo

** if national model is available

The proposed uses of iodosulfuron-methyl-sodium in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

Mesosulfuron-methyl

ADI	1 mg/kg bw per day
TMDI (% ADI) according to EFSA PRIMo rev. 3.1	0.19% (based on diet: NL toddler) with the highest contributors: 0.12% Milk: Cattle 0.01% Apples 0.01% Maize/corn
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	not relevant
ARfD	not available
IESTI (% ARfD) according to EFSA PRIMo rev. 3.1*	not relevant
NTMDI (% ADI) **	not relevant
NEDI (% ADI)**	not relevant
NESTI (% ARfD) **	not relevant

The proposed uses of mesosulfuron-methyl in the formulation JME-HER 12 OD does not represent unacceptable acute and chronic risks for the consumer.

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

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC_{SOIL} assessment for active substances and their metabolites was accepted.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The calculations for Predicted Environmental Concentrations in groundwater (PEC_{gw}) with the latest versions of the FOCUS-PELMO v6.6.4 FOCUS - PEARL v5.5.5 and MACRO v.5.5.4 Modeling using the EU agreed input parameters, application dates as suggested by App Date 3.06 and relevant crop interception according FOCUS groundwater guidance (2014) was conducted.

The 80th percentiles of the predicted annual average leachate concentrations of iodosulfuron-methyl sodium and its metabolites were below 0.1 µg/L in all calculated scenarios.

The relevant trigger of 0.1 µg/L mesosulfuron-methyl is not exceeded. Respect to the metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885, PEC_{gw} are greater than the regulatory threshold of 0.1 µg/L in some scenarios with a maximum of 0.391 µg/L (Jokionen). Nevertheless, these metabolites are considered non-relevant according to Sanco/221/2000 –rev.10- final. Besides, the relevance of these, has been evaluated in the RAR of mesosulfuron-methyl. The risk to groundwater is therefore low.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw}/sed assessment for active substances and their metabolites was accepted.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

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.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 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 OD 42 (2+10+30). 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.

3.8.2 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 contained in product IMS+MSM+MPR OD 42 (2+10+30), and their metabolites.

Acceptable risk for macrophytes could be demonstrated with PEC_{sw} FOCUS Steps 3 calculation for Poland for use group B (end of winter to spring use on winter cereals at rate 0.45 L prod/ha, **the risk for aquatic organisms is considered acceptable without requiring risk mitigation measures, with 1 meter buffer zone.**

For use group B (end of winter to spring use on winter cereals, rate 1.2 L prod/ha, **the risk for aquatic organisms is considered acceptable with 10 meter vegetative buffer zone.**

3.8.3 Effects on bees

The risk to bees was demonstrated to be acceptable for all intended uses of product IMS+MSM+MPR OD 42 (2+10+30), 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.

No chronic adult or larval study with the formulation was provided, despite being required under (EU)

No. 284/2013 points 10.3.1.2 and 10.3.1.3. Whilst this is noted as a data gap, this is not a barrier to authorization and is noted for procedural correctness in the context of the applicable regulation and data requirements. For Poland, the deficiencies need to be filled till new guidance would come in to force.

3.8.4 Effects on other arthropod species other than bees

The risk to arthropods other than bees is acceptable for all intended uses of product IMS+MSM+MPR OD 42 (2+10+30), 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.

3.8.5 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 OD 42 (2+10+30).

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

3.8.6 Effects on non-target terrestrial plants

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

- a 5 m buffer zone, or alternatively 75% drift reducing spray nozzles for application rates 1.2 L prod/ha to non-agricultural land should be applied.

For application rate 1 x 0.45 L product/ha

- a 1 m buffer zone to non-agricultural land should be applied.

~~no mitigation measures are required~~

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

No further information is available or considered to be necessary.

3.9 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.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Uwagi do etykiety:

Fizykochemia – po uwzględnieniu niechronionych badań trwałości dla środka Atlantis 12 OD możliwe jest zaakceptowanie dwuletniego okresu ważności dla środka JME-HER 12 OD zgodnie z art. 34 rozporządzenia 1107/2009.

Toksykologia – dodano: zwrot EUH066, zapis o sejfnerze, zapis „Rekomendowane jest stosowanie rękawic podczas prac polowych.”

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – dodano zwrot P501. Wprowadzono strefy ochronne.

Skuteczność działania – zaktualizowano projekt etykiety.

Posiadacz zezwolenia:

Pestila Sp. z o. o., Studzianki 24a, 97-320 Wolbórz, tel./fax: xxxxxxxxxxxxxxxxxxxx,
e-mail: xxxxxxxxxxxxxxxxxxxx.

JME-HER 12 OD

Środek przeznaczony do stosowania przez użytkowników profesjonalnych



Zawartość substancji czynnych:

jodosulfuron metylosodowy (związek z grupy pochodnych sulfonilomocznika) - 2 g/l (0,2 %),

mezosulfuron metylowy (związek z grupy pochodnych sulfonilomocznika) - 10 g/l (1 %).

Zawiera sejfner: mefenpyr dietylowy – 30 g/L (3.0%)

Zezwolenie MRiRW nr R - z dnia

 	
Uwaga	
H319 H410	Działa drażniąco na oczy. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH066	Zawiera węglowodory aromatyczne C10-C13, <1% naftalenu. Powtarzające się narażenie może powodować wysuszenie lub pękanie skóry.
EUH208	Zawiera etoksylat alkoholu tłuszczowego - eter alkilowy. Może powodować wystąpienie reakcji alergicznej.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P264 P280	Dokładnie umyć ręce po użyciu. Stosować rękawice ochronne, odzież ochronną, ochronę oczu, ochronę twarzy.

P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P337+P313	W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady i zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać zgodnie z ustawą.

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.

DZIAŁANIE NA CHWASTY

Środek zawiera dwie substancje czynne zaliczane do inhibitorów syntazy acetylmleczanowej (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.

Chwasty wrażliwe w dawce 0,45-0,6l/ha	gorczyca polna, gwiazdnica pospolita, komosa biała, maruna bezwonna miotła zbożowa, niezapominajka polna, rumian polny, samosiewy rzepaku, tasznik pospolity, tobołki polne.
Chwasty wrażliwe w dawce 0,9-1,2l/ha	owies głuchy, stokłosa żytnia, wyczyniec polny.
Chwasty średniowrażliwe:	fiólek polny, mak polny, przetaczniki.
Chwasty odporne:	przytulia czepna, rdesty

STOSOWANIE ŚRODKA

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

Pszenica ozima, pszenżyto ozime, **żyto**

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

Zalecana dawka dla jednorazowego zastosowania: 0,45 l/ha, 1,2 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).

Zalecenia szczegółowe:

Do zwalczania miotły zbożowej i wrażliwych chwastów dwuliściennych środek stosować w dawce 0,45-0,6 l/ha (wyższą z zalecanych dawek stosować w przypadku intensywnego zachwaszczenia i na chwasty bardziej zaawansowane w rozwoju).

Do zwalczania owsa głuchego, stokłosy żytniej, wyczyńca polnego środek stosować w dawce 0,9-1,2 l/ha (wyższą z zalecanych dawek stosować w przypadku intensywnego zachwaszczenia i na chwasty bardziej zaawansowane w rozwoju).

Żyto

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,45 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: 200-300 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 następnie. W przypadku konieczności likwidacji opryskiwanej plantacji, po wykonaniu orki można uprawiać pszenicę jara.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

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

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 zalecany 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.
- 3. Środka nie stosować:
 - na rośliny osłabione lub uszkodzone przez choroby, szkodniki czy przymrozki, – przed spodziewanym silnym przymrozkiem,
 - w zbożach z wsiewką roślin bobowatych.
- 4. 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 wlewaniu 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.

Rekomendowane jest stosowanie rękawic podczas prac polowych.

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.

Przy zastosowaniu maksymalnej dawki 1,2 l/ha:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

Przy zastosowaniu dawki 0,45 l/ha:

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie następujących stref:

Przy zastosowaniu maksymalnej dawki 1,2 l/ha:

- 5 m lub,
- 1 m z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%. od terenów nieużytkowanych rolniczo

Przy zastosowaniu dawki 0,45 l/ha:

- 1 m strefy ochronnej od terenów nieużytkowanych rolniczo.

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 0°C - 30°C.

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 oczu: Ostrożnie płukać wodą przez kilka minut.

Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto

Nr partii

Appendix 3 Letter of Access

Letter of Access is provided in a separate appendix.

Appendix 4 Lists of data considered for national authorization

Please refer to the reference list.