FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

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

CORE 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

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zRMS comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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, whinter triticale and rye.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland	Not relevant

0.1.3 Regulatory history of the active(s)

0.1.3.1 Iodosulfuron-methyl-sodium

Table 0.1-2: Summary of regulatory history of CAS No: 185119-76-0 (variant: 144550-36-7)

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Implementing Regulation (EU) 2017/407 of 8 March 2017 renewing the approval of the active substance iodosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No

	540/2011.
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/04/2017 (renewal)
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/03/2032
Date of final Commission (re-registration) deadline (Step 2)	01/04/2018
Current expiration of approval	31/03/2032
Low risk substance or Candidate for Substitution?	Not applicable.

Issues that need to be considered as part of the EU approval are listed below:
In this overall assessment Member States shall pay particular attention to:

- the risk to consumers (request linked to the confirmatory Data);
- the risk to non-target terrestrial plants;
- the risk to aquatic plants.

Conditions of use shall include risk mitigation measures, where appropriate.
The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:

(1) the genotoxic potential of the metabolite triazine-amine (IN-A4098), in order to confirm that this metabolite is not genotoxic and not relevant for the risk assessment (Data submitted in September 2016 by the Notifiers of Metsulfuron-methyl. LoA will be available for BCS);

(2) the effect of water treatment processes on the nature of residues present in drinking water.

The applicant shall submit the information requested under point (1) by *[OJ please insert the date 6 months from the date of approval]* and the information requested under point (2) by two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

Table 0.1-3: Information on minimum purity of iodosulfuron-methyl-sodium

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ** **
minimum purity of active substance 910 g/kg	minimum purity of active substance - confidential information reffered in Part C of dRR Equivalence report available: Y RMS: confidential information reffered in Part C of dRR

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Active Substance**	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
Not relevant.	Not relevant.	Not relevant.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data).

0.1.3.2 Mesosulfuron methyl

Table 0.1-4: Summary of regulatory history of CAS No: 208465-21-8

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. Commission Implementing Regulation (EU) 2017/755 of 28 April 2017 renewing the approval of the active substance mesosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
RMS	France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/07/2017 (renewal)
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	3~~1~~0/06/2032
Date of final Commission (re-registration) deadline (Step 2)	01/07/2018
Current expiration of approval	3~~1~~0/06/2032
Low risk substance or Candidate for Substitution?	Not applicable.

Issues that need to be considered as part of the EU approval are listed below:
In this overall assessment Member States shall pay particular attention to:

- the protection of aquatic organisms and non-target terrestrial plants;
- the protection of groundwater.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for mesosulfuron-methyl (SANTE/11827/2016 Rev 2) is considered to provide the relevant information on the evalu4ation or a reference to where such information can be found. An EFSA Scientific Report was made available on 20 September 2016.

Table 0.1-5: Information on minimum purity of mesosulfuron methyl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, ****
minimum purity of active substance ≥ 930 g/kg (expressed as mesosulfuron-methyl)	minimum purity of active substance - confidential information reffered in Part C of dRR Equivalence report available: Y

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
	RMS: confidential information reffered in Part C of dRR

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Not relevant.	Not relevant.	Not relevant.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data).

0.1.3.3 Safener Mefenpyr-diethyl

Table 0.1-6: Summary of regulatory history of 135591-00-3 (variant: 165590-91-9)

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	DAR July 2011 Not in the scope Regulation 1107/2009 (not a plant protection product).
RMS	Austria and France conducted a bilateral peer review.
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	Not applicable.
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Not applicable.
Date of final Commission (re-registration) deadline (Step 2)	Not applicable.
Current expiration of approval	Not applicable.
Low risk substance or Candidate for Substitution?	Not applicable.

Table 0.1-7: Information on minimum purity of mefenpyr-diethyl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
940 g/kg (this purity is in full compliance to the FAO specification 651.229/TC; May 2011)	Not applicable.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please

refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
From physicochemical perspective JME-HER 12 OD is considered equivalent/comparable to already registered Atlantis 12 OD in Poland. So, unprotected physicochemical data taken from Atlantis 12 OD can be used to support JME-HER 12 OD registration in Poland. Therefore, please refer to the Atlantis 12 OD dossier for shelf life details. In summary, based on Atlantis 12 OD dossier, the two-year shelf life is acceptable for this PPP in Poland.

Section 3. Efficacy
The evaluation of the application of JME-HER 12 OD resulted in the decision to grant authorization for use according to the GAP table presented in section B3.

Section 5. Analytical methods
Please refer to Part B5.

Section 6. Mammalian Toxicology
Classification: Eye Irrit. 2, H319 - *Causes serious eye irritation*, EUH208 - *Contains fatty alcohol ethoxylate - alkyl ether. May produce an allergic reaction*, EUH066 - *Repeated exposure may cause skin dryness or cracking*.
Operator: workwear, gloves during mixing/loading step.
Worker: workwear, gloves recommended during field activities.

Section 7. Metabolism and Residues
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 / Growth stage of crop	Max. number a) per use b) per crop/ season	g a.s./ha 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.

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.

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.

Section 8. Environmental Fate
In accordance with proposed pattern use, an exposure assessment for the formulation of JME-HER 12 OD was submitted and sufficient.

Section 9. Ecotoxicology
In accordance with proposed use pattern, Risk Assessment to non-target organisms for the formulation JME-HER 12 OD was sufficient.
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of JME-HER 12 OD as herbicide in cereals (winter wheat, winter triticale and rye) poses an acceptable risk to non-target organisms (uses 1-2).

Section 10. Assessment of the relevance of metabolites in groundwater
JME-HER 12 OD was considered equivalent/comparable to already registered Atlantis 12 OD, therefore the unprotected toxicological studies and relevance of metabolites assessment performed for Atlantis 12 OD is acceptable.

Toxicological data on the metabolites of mesosulfuron-methyl with the potential to reach the groundwater in concentrations above 0.1 µg/L have been already reviewed during the EU peer review process. Data has been accepted based on EU peer review.

Uses to be considered safe on the basis of EU methodology:

1, 2

Uses to be considered non-safe on the basis of EU methodology:

None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

None

All uses/ GAPs are covered by established MRLs.

Appendix 1 ALL intended uses

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

PPP (product name/code):	JME-HER 12 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:	Pestila sp. z o. o.	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes		

Field of use: herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	Conclusion Residues
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)	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	PL	Winter wheat Winter triticale	F	weeds (for details please refer to Section B3 and Part A)	Spray/ broadcast	BBCH 21 - BBCH 31	a) 1 b) 1		a) 1.2 l/ha b) 1.2 l/ha	a) 2.4 - iodosulfuron 12 - mesosulfuron b) same as a)	200-300	not relevant		A
2	PL	Winter wheat Winter triticale Rye	F	weeds (for details please refer to Section B3 and Part A)	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		A

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