

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: GLOB289H / SAP63H

Product name(s): Zeppos

Chemical active substances:

Iodosulfuron-methyl sodium, 6 g/kg

Mesosulfuron-methyl, 30 g/kg

Safener: Mefenpyr-diethyl, 90 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV / Ascenza Agro SA

Submission date: December 2019

MS Finalisation date: 09/2021 ; 01/2022

Version history

When	What
December 2019	V0 - Original version from applicant for submission to zRMS POLAND in the frame of new PPP registration
September 2021	ZRMs evaluated version of dRR submitted by Applicant.
January 2022	ZRMs corrected RR according to commenting period.

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0 Product background, regulatory context and GAP information

0.1 Introduction

This document summarises the information related to the analytical methods for the plant protection product Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (0.6+3+9)% WG (also referred to as SAP63H, GLOB289H, Iodosulfuron + Mesosulfuron (0.6% + 3%) WG and Zeppos in the dossier). The product contains two active substances iodosulfuron-methyl-sodium and mesosulfuron-methyl-sodium, and safener mefenpyr-diethyl.

Where appropriate, this document refers to the conclusions of the EU reviews of the active substances. This will be where:

- The active substance data is relied upon in the risk assessment of the formulation; or
- The EU review concluded that additional data/information should be considered at national registration.

Note: This Part B document only reviews data (Annex II and/or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New Annex II or Annex III data were included if they are considered essential for the evaluation and in this case a full study summary is provided. In the case where studies have been previously evaluated at European level, detailed summaries have not been provided.

The product Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (0.6% + 3% + 9%) WG was not the representative formulation during the Annex I inclusion of Iodosulfuron-methyl-sodium or Mesosulfuron-methyl and has thus not yet been evaluated.

Iodosulfuron-methyl-sodium

Iodosulfuron-methyl-sodium was included into Annex I of Directive 91/414/EEC in 2003 (Directive 2003/84/EC) and re-evaluated in accordance with Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) No 844/2012, leading to the renewal of the approval of the active substance iodosulfuron-methyl-sodium (Commission Implementing Regulation (EU) 2017/407 of 8 March 2017, entry into force 1st of April 2017).

For the implementation of the Uniform Principles of Annex VI, the conclusions of the Renewal Report on iodosulfuron-methyl-sodium, as finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 7 December 2016 shall be taken into account.

In this overall assessment Member States should pay attention to:

- The protection of consumers,
- The protection of non-target terrestrial plants,
- The protection of aquatic plants

The Renewal Report (SANTE/2016/11167 Rev 3, 7/12/2016) for iodosulfuron-methyl-sodium provides a summary of the relevant scientific information from the EU review.

Mesosulfuron-methyl

Mesosulfuron-methyl was included in Annex I of Directive 91/414/EEC in 2003 (Directive 2003/119/EEC) and re-evaluated in accordance with Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) No 844/2012, leading to the renewal of the approval of the active substance mesosulfuron-methyl (Commission Implementing Regulation (EU) 2017/755 of 28 April 2017, entry into force 1st of July 2017).

For the implementation of the Uniform Principles of Annex VI, the conclusions of the Renewal Report on mesosulfuron-methyl, as finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 23 March 2017 shall be taken into account.

In this overall assessment Member States should pay attention to:

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

The Renewal Report (SANTE/11827/2016 Rev 2, 23/03/2017) for mesosulfuron-methyl provides a summary of the relevant scientific information from the EU review.

Safener mefenpyr-diethyl

Mefenpyr-diethyl is a safener used in combination with herbicides and was not reviewed under Directive 91/414/EEC or Regulation (EC) No 1107/2009. In order to facilitate the assessment of products containing mefenpyr-diethyl, France and Austria in a work-sharing project prepared an assessment report for this substance in the format of a DAR. France was responsible for the sections “Phys-Chem Properties” (B.1-B.5), Environmental Fate and Ecotoxicology (B.8-B.9) and Austria for sections Toxicology and Residue Data (B.6-B.7). A bilateral peer-review in the form of comments took place between the two rapporteurs; the respective reporting tables were made available to all MS. In September 2011 the assessment report was “peer-reviewed” (in an unscheduled procedure on voluntary basis) by all MS. The revised assessment report can be found on CIRCA (Archive individual substances – Mefenpyr-diethyl (safener)). All exposure and risk assessments presented will be based on agreed endpoints, if not otherwise stated.

0.1.1 Reason for application

This application is made for a new product containing 6 g/kg iodosulfuron-methyl sodium, 30 g/kg mesosulfuron-methyl and 90 g/kg of the safener mefenpyr-diethyl formulated as a water dispersible granule (WG).

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The Annex II data for mesosulfuron-methyl are matched, for the Annex II data of iodosulfuron-methyl sodium a letter of access is available. Our intended source of iodosulfuron-methyl sodium and mesosulfuron-methyl have been positively evaluated in the EU.

With regard to the Annex III data, all necessary data is co-owned by Globachem N.V. and Ascenza Agro SA.

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 (PL), <i>Zeppos</i>	Belgium (BE), <i>Zeppos</i> The Netherlands (NL), <i>Zeppos</i> Germany (DE), <i>Zeppos</i> Czech Republic (CZ), <i>Zeppos</i>
Southern zone	France, <i>Zeppos</i>	Italy (IT), <i>Zeppos</i> Spain (ES), <i>Zeppos</i> Portugal (PT), <i>Zeppos</i>

0.1.3 Regulatory history of the actives

0.1.3.1 Iodosulfuron-methyl sodium

Table 0.1-2: Summary of regulatory history of CAS No: 185119-76-0

Status	
Approved in EU	Y
Original Inclusion Directive	Commission Directive 2003/84/EC
RMS	Sweden
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/04/2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/04/2018
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?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- The risk to consumers,
- The risk to non-target terrestrial plants,
- The risk to aquatic plants

The SANTE report for iodosulfuron (SANTE/2016/11167 – 7/12/2016) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 19 April 2016.

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 *, **
≥ 910 g/kg (expressed as iodosulfuron-methyl-sodium)	970 g/kg Equivalence report available: Y RMS: PL (2018)

* 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.

0.1.3.2 Mesosulfuron-methyl

Table 0.1-4: Summary of regulatory history of CAS No: 185119-76-0

Status	
Approved in EU	Y

Status	
Original Inclusion Directive	Commission Directive 2003/119/EC
RMS	France
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/07/2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/07/2018
Date of final Commission (re-registration) deadline (Step 2)	01/07/2018
Current expiration of approval	30/06/2032
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- The protection of aquatic organisms and non-target terrestrial plants,
- The protection of groundwater

The SANTE report for mesosulfuron-methyl (SANTE/11827/2016 – 23/03/2017) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 17 October 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 equivalence report *, **
≥ 930 g/kg (expressed as mesosulfuron-methyl)	Confidential information unknown by the applicant. Reference is made to the Technical Equivalence Dossier Evaluator Comment: Letter of Access has been provided

* 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

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

Efficacy section: 2 -7
Residues section: 1-7
Environmental fate and behavior section: 1-7
Ecotoxicology section: 1-7

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

Efficacy section: 1
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: 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:

Ecotoxicology section:
The risk mitigation measures should be decided at MSs level for aquatic organism and non-target plants.

The following text is to be shortened or to be amended as necessary.

Residues section: All uses/ GAPs are covered by established MRLs

Conclusions:

Phys-chem section:

The evaluation of the application for Zeppos resulted in the decision to grant the authorization.

Shelf life – 1 year.

Recommended packaging: HDPE (Point 4, Part B1-2,4) have been accepted.

Efficacy section:

spring cereals cannot be registered due to lack of trials in Poland. **Extrapolation decisions for spring and winter cereals, supported by the EPPO extrapolation tables, should be made on national level by the cMS.** In Poland recommended dose is 0.2-0.4 kg/ha, in the Maritime EPPO zone – 0.3-0.5 kg/ha. Each cMS should decide about classification of weeds sensitivity. Detailed assessment is presented in B3.

Toxicology section:

Classification of GLOB289H is acceptable (Eye Dam.1/H318). No unacceptable risk for operators, workers bystanders/residents and was identified when the product is used as intended.

Metabolism and Residues section:

All uses are accepted.

Fate section:

No risk of groundwater contamination are expected when the product is applied according to proposed use in GAP.

Appendix 1 ALL intended uses

GAP rev. 4, date: 2019/08/13

PPP (product name/code): 0.6% Iodo + 3% meso + 9% mefenpyr WG
Active substance 1: Iodosulfuron
Active substance 2: Mesosulfuron
Safener: Mefenpyr
Applicant: Globachem N.V. / Ascenza Agro S.A.
Zone(s): Central
Verified by MS: --
Field of use: Herbicide

Formulation type: WG
Conc. Of as 1: 6 g/kg
Conc. Of as 2: 30 g/kg
Conc. Of safener: 90 g/kg
Professional use: ☒
Non professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ¹	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: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (¹)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber a) per use b) per crop/ season	Min. interval between applications (days)	kg or L prod- uct / 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	Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: CAPBP	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.1 b) 0.1	a) 0.6 + 3 b) 0.6 + 3	100- 400	NA	Mefenpyr (safener): 9 g/ha Applied with 0.2 L/ha oil/wetting agent
2	PL	Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: VERPE, APESV, POAAN, STEME, PAPRH, MATIN, ALOMY, CAPBP, VIOAR, GALAP	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.2 b) 0.2	a) 1.2 + 6 b) 1.2 + 6	100- 400	NA	Mefenpyr (safener): 18 g/ha Applied with 0.4 L/ha oil/wetting agent

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3	PL	Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: APESV GALAP MATIN STEME, VERPE CABP, ALOMY POAAN, PAPRH VIOAR	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.3b) 0.3	a) 1.8 + 9 b) 1.8 + 9	100-400	NA	Mefenpyr (safener): 27 g/ha Applied with 0.6 L/ha oil/wetting agent
4	PL	Cereals (winter soft wheat, winter durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: ALOMY, POAAN AVEFA STEME CHEAL MATIN PAPRH, CAPBP VIOAR, GALAP VERPE, VIOAR	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.4 b) 0.4	a) 2.4 + 12 b) 2.4 + 12	100-400	NA	Mefenpyr (safener): 36 g/ha Applied with 0.8 L/ha oil/wetting agent
5	BE, NL, DE, CZ	Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: POAAN PAPRH LAMP APESV CHEAL MATIN STEME	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.3 b) 0.3	a) 1.8 + 9 b) 1.8 + 9	100-400	NA	Mefenpyr (safener): 27 g/ha Optionally with 0.6 L/ha oil/wetting agent
6	BE, NL, DE, CZ	Cereals (winter soft wheat, winter durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: MATCH MATIN STEME	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.4 b) 0.4	a) 2.4 + 12 b) 2.4 + 12	100-400	NA	Mefenpyr (safener): 36 g/ha Applied with 0.8 L/ha oil/wetting agent
7	BE, NL, DE, CZ	Cereals (winter soft wheat, winter durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyledonous weeds: ALOMY STEME MATIN GALAP	Downwards spraying	BBCH 21-32	a) 1 b) 1	/	a) 0.5 b) 0.5	a) 3 + 15 b) 3 + 15	100-400	NA	Mefenpyr (safener): 45 g/ha Applied with 1 L/ha oil/wetting agent

				VIOAR									
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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