

FINAL REGISTRATION REPORT

Part A

Risk Management

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: PL

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Globachem NV / Ascenza Agro SA

Submission date: December 2019

MS Finalisation date: 09/2021; 01/2022; 10/2022

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.
September 2021	Corrected by IOS PIB in point: 2.4.2 and 2.5.1
January 2022	Final version of the RR after Commenting period
10/2022	Information added by zRMS regarding the uses with adjuvants and correction of classification in area of Ecotoxicology

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Annex I inclusion	5
1.3	Regulatory approach	6
1.4	Data protection claims	6
1.5	Letters of Access	6
1.6	Justification for submission of tests and studies	7
1.7	Data protection claims	7
2	Details of the authorization decision	7
2.1	Product identity	7
2.2	Conclusion	7
2.3	Substances of concern for national monitoring	7
2.4	Classification and labelling	8
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	8
2.4.2	Standard phrases under Regulation (EU) No 547/2011	8
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	8
2.5	Risk management	9
2.5.1	Restrictions linked to the PPP	9
2.5.2	Specific restrictions linked to the intended uses	9
2.6	Intended uses (only NATIONAL GAP)	11
3	Background of authorization decision and risk management	13
3.1	Physical and chemical properties (Part B, Section 2)	13
3.2	Efficacy (Part B, Section 3)	13
3.3	Methods of analysis (Part B, Section 5)	19
3.3.1	Analytical method for the formulation	19
3.3.2	Analytical methods for residues	19
3.4	Mammalian toxicology (Part B, Section 6)	20
3.4.1	Acute toxicity	20
3.4.2	Operator exposure	21
3.4.3	Worker exposure	21
3.4.4	Bystander and resident exposure	21
3.5	Residues and consumer exposure (Part B, Section 7)	21
3.5.1	Residues	21
3.5.2	Consumer exposure	26
3.6	Environmental fate and behaviour (Part B, Section 8)	27
3.6.1	Predicted environmental concentrations in soil (PEC _{soil})	27
3.6.2	Predicted environmental concentrations in groundwater (PEC _{gw})	27
3.6.3	Predicted environmental concentrations in surface water (PEC _{sw})	28
3.6.4	Predicted environmental concentrations in air (PEC _{air})	28
3.7	Ecotoxicology (Part B, Section 9)	29
3.7.1	Effects on terrestrial vertebrates	29
3.7.2	Effects on aquatic species	29

3.7.3	Effects on bees	29
3.7.4	Effects on other arthropod species other than bees.....	30
3.7.5	Effects on soil organisms	30
3.7.6	Effects on non-target terrestrial plants	30
3.7.7	Effects on other terrestrial organisms (Flora and Fauna).....	30
3.8	Relevance of metabolites (Part B, Section 10)	30
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	31
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	31
Appendix 1	Copy of the product authorization	32
Appendix 2	Copy of the product label	33
Appendix 3	Letter of Access	37
Appendix 4	Lists of data considered for national authorization.....	38

PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable used conditions required for the registration of Zeppos, containing iodosulfuron-methyl-sodium, mesosulfuron-methyl as well as the safener mefenpyr-diethyl in Poland. This evaluation is required since the product is a new formulation and has not yet been authorised in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C. The information, data and assessments provided in the Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Zeppos where that data has not been considered in the EU review. Otherwise assessments for the safe use of Zeppos have been made using endpoints agreed in the EU review of Iodosulfuron-methyl-sodium and mesosulfuron-methyl.

This document describes the specific conditions of use and labelling required for Poland for the registration of Zeppos.

Appendix 3 should include letters of access. However, these are classified as confidential and, thus, are not attached to this document.

1.1 Application background

The application is submitted by Globachem N.V. in December 2019.

The application is for the approval of Zeppos, a water dispersible granular formulation, containing 6 g/kg iodosulfuron-methyl-sodium (ISMS), 30 g/kg mesosulfuron-methyl (MSM) and 90 g/kg of the safener mefenpyr-diethyl (MPR) for use as a post-emergence herbicide in cereals.

1.2 Annex I inclusion

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.

1.3 Regulatory approach

To obtain authorisation, the product Zeppos must meet the conditions of authorisation according to Regulation 1107/2009 and be supported by dossiers satisfying the requirements of regulation 544/2011 and 545/2011, with an assessment to Uniform Principles, using EU reviewed endpoints.

This application was submitted in order to allow the first authorisation of this product in Poland in accordance with the above.

1.4 Data protection claims

Where data protection is being claimed regarding the information supporting registration of Zeppos, it is indicated in the Appendix 1 of each section of the Registration Report.

1.5 Letters of Access

All AIII data are co-owned between Globachem N.V. and Ascenza Agro SA. A letter of co-ownership is submitted with the dossier.

1.6 Justification for submission of tests and studies

1.7 Data protection claims

Data protection is claimed for all documents and data included in this dossier. No part of the document or any information contained therein may be disclosed to any third party without the prior written authorisation of Globachem NV.

2 Details of the authorization decision

2.1 Product identity

Product code	GLOB289H
Product name in MS	Zeppos
Authorization number	/
Function	Herbicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Iodosulfuron-methyl-sodium: 6 g/kg Mesosulfuron-methyl: 30 g/kg Safener: Mefenyr-diethyl: 90 g/kg
Formulation type	Water dispersible granule [Code: WG]
Packaging	0,1 – 25 kg HDPE 25kg laminated Paper or PET (outer layer) / PE or Al (mid layer) / PE (inner layer)
Coformulants of concern for national authorizations	/
Restrictions related to identity	/
Mandatory tank mixtures	For a better efficacy, a non-esterified rapeseed oil (e.g. Actirob) or a non-ionic surfactant (e.g. Pottok) can be added in tankmix
Recommended tank mixtures	-

2.2 Conclusion

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

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

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

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

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

Hazard pictograms:	GHS05, GHS09
Signal word:	Danger
Hazard statement(s):	H318, H400, H410
Precautionary statement(s):	P280, P305 + P351 + P338, P310 P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies. To protect non-target plants respect: Winter cereals – 0.5 kg/ha <ul style="list-style-type: none"> - 1m buffer zone combined with 90% drift reducing nozzles - 5m buffer zone combined with 50% drift reducing nozzles - 10m buffer zone Winter and spring cereals – 0.3 kg/ha <ul style="list-style-type: none"> - 1m buffer zone combined with 90% drift reducing nozzles - 5 m buffer zone.

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

--	--

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:	
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.
P310	Immediately call a POISON Center or doctor/physician.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
P391	Collect spillage.
P501	Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.
SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies. To protect non-target plants respect: Winter cereals – 0.5 kg/ha <ul style="list-style-type: none"> - 1m buffer zone combined with 90% drift reducing nozzles - 5m buffer zone combined with 50% drift reducing nozzles - 10m buffer zone Winter and spring cereals – 0.3 kg/ha <ul style="list-style-type: none"> - 1m buffer zone combined with 90% drift reducing nozzles - 5 m buffer zone.
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

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

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
	-	
Environmental protection:		Relevant for use no.

	-	
--	---	--

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Zeppos / GLOB289H	Formulation type:	WG ^(a,b)
Active substance 1:	Iodosulfuron-methyl-sodium	Conc. of as 1:	6 g/kg ^(c)
Active substance 2:	Mesosulfuron-methyl	Conc. of as 2:	30 g/kg ^(c)
Safener:	Mefenpyr-diethyl	Conc. of safener:	90 g/kg ^(c)
Synergist:	/	Conc. of synergist:	/ ^(c)
Applicant:	Globachem NV / Ascenza Agro SA	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		

Field of use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	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: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number/year	Min. interval between appli- cations (days)	L product/ha max. rate per appl.	kg as/ha a) max. rate per appl.	Water L/ha min/max		
1	PL	Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)	F	Annual grassy weeds and Annual dicotyle- donous 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)	F	Annual grassy weeds and Annual dicotyle- donous weeds: VERPE, APESV, POAAN, STEME, PAPRH, MATIN,	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

		and winter rye)		ALOMY, CAPBP, VIOAR, GALAP MATCH									oil/wetting agent
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) 0.3 b) 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

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

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.

(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.

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)

Overall Summary: 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 of light brown coloured granules, which were approximately 1mm to 10mm in size, with a characteristic odour. It is not explosive, has no oxidizing properties. The product is not considered highly flammable. In aqueous solution, it has a pH value around 6.7 at 20 °C.

A 2 years and 3 years storage stability study are still ongoing.

Based on the accelerated storage study a shelf life of at least 1 year at ambient temperature is expected when stored in HDPE bottles.

Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use lowest 0.25 g of product/L to highest 5 g of product/L.

According to the GAP provided, the minimal intended concentration is 0.25 g/L and the maximal is 5 g/L. The differences to the values used in the study (0.75 g lowest and 4 g highest) are slight and it is very low probability that they could influence the final results, so the concentration proposed is accepted.

The product should/can be mixed in the tank together with non-ionic surfactant or vegetal oil adjuvant. Studies regarding the combination with non-ionic surfactant and vegetal oil adjuvant were submitted and the application as tank mixture is acceptable.

The studies are accepted

Implications for labelling: none

Compliance with FAO specifications: The product GLOB289H complies with FAO specifications.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Formulation used for tests

The product used in the tests performed has the same composition as the one cited in Part C.

3.2 Efficacy (Part B, Section 3)

GLOB289H is a water dispersible granulate formulation (WDG) containing the active ingredients iodosulfuron-methyl sodium (6 g/kg) and mesosulfuron-methyl (30 g/kg) for post-emergence weed control in cereals, in combination with the safener Mefenpyr-diethyl (90 g/kg).

Both iodosulfuron-methyl-sodium and mesosulfuron-methyl are inhibitors of the branched chain amino acid synthesis (ALS/AHAS). They act by inhibiting the biosynthesis of the essential amino acids valine and isoleucine, hence stopping cell division and plant growth. The selectivity to cereals is due to differential degradation, compared with that in grass weeds, which is enhanced by the addition of the safener mefenpyr-diethyl. GLOB289H is used for post-emergence control of grass and broadleaved weeds in

cereals.

GLOB289H can be used in combination with an oil (esterified rapeseed oil) to ensure the optimal uptake of the active ingredients by the weeds. For the lower dose of 0.3 kg/ha, the addition of oil is optional. For the higher dose it is obligatory since dose is especially used against difficult weeds that are also capable of developing resistance. Therefore the trials are also performed like this with different esterified rapeseed oils tested.

A total of 35 trials were carried out to evaluate the efficacy of GLOB289H for the control of dicotyledonous and grass weeds in cereals. 25 trials were performed in the Maritime EPPO Zone while 10 other trials were performed in the North-East EPPO Zone (Poland). Trials were conducted on winter wheat, barley and triticale in 2017, 2018 and 2019 in Germany, France, Belgium, the Netherlands, the United Kingdom, the Czech Republic and Poland. The trials are conducted by officially recognized company in the respective countries to carry out field efficacy testing in accordance with European Commission Directive 93/71/EEC.

EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.

The applicant was notified that according to PP 1/226 at least 6 trials from each climatic zone are required (in case of reduced number of trials in major pest on major crop). Number of trials for efficacy from North-east EPPO zone (10 trials carried out on winter cereals) and Maritime EPPO zone (25 trials carried out on winter cereals) is sufficient, according to EPPO rules.

For winter wheat Applicant submitted in total – 23 trials from Maritime and 6 trials from N-E EPPO zone. For winter triticale Applicant submitted 1 trial from Maritime EPPO zone (DE) and 4 trials carried out in N-E EPPO zone (PL). For winter barley Applicant submitted only one trial performed in Maritime EPPO zone (DE).

According to EPPO extrapolation tables, results from any winter cereal can be extrapolated to other winter cereal (wheat TRZSS, barley HORSS, rye SECCE, triticale TTLWI, TTLSO, spelt TRZSP, durum TRZDU, oat AVESA, AVESW, grassland, amenity grassland). In the opinion of Evaluator, such cereals as winter durum wheat or spelt can be registered in cMS according to possibility of extrapolation results. Also, uses in winter cereals can be further supported by the nationally registered reference products (on Member State level) based on the same active ingredients: iodosulfuron-methyl-sodium, mesosulfuron-methyl and safener mefenpyr-diethyl. So, **extrapolation decisions for winter cereals, supported by the EPPO extrapolation tables, should be made on national level by the cMS.** In Poland at least 3-4 selectivity trials carried out on cereals on which we extrapolate the results are required. So, registered the winter durum wheat and spelt is not possible. However, Poland can accept winter rye according to extrapolating results from winter wheat, triticale and barley and submitted selectivity trials.

~~Spring cereals should be excluded from GAP table and label project due to~~ Lack of trials carried out on ~~them~~ spring cereals. At least 6 trials carried out on spring wheat in the Maritime EPPO zone ~~is required~~ should be presented and 6 trials performed in Poland (or neighbouring countries, ex. DE, CZ) in the opinion of ZRMS. Also, for registration in Poland is required at least 3-4 selectivity trials for spring durum wheat, spring spelt and spring triticale. However, we should remember that most spring cereal uses included in GAP table by Applicant e.g. spring durum wheat, spring spelt, spring triticale and spring rye (and possibly spring wheat) are considered as minor crops in different concerned member states. Furthermore, member states such as the Netherlands have their own extrapolation tables for cereal uses. Therefore, **the applicant believes and ZRMs agree that spring cereal uses should be evaluated on cMS level, especially since only the lower dose rate is applied for.** This is in accordance with nationally registered reference products based on the same active ingredients: iodosulfuron-methyl-sodium, mesosulfuron-methyl and safener mefenpyr-diethyl.

Concerned Member States will need to consider the relevance of the submitted formulation compa-

rability data in relation to the current authorized uses for the reference product in their own Member State. The evaluation was conducted in accordance with Uniform Principles.

For Poland we can consider results from neighboring countries (ex. DE, CZ). So, Applicant properly presented efficacy results separately for Maritime and N-E EPPO zone. In the tables presented by Applicant are presented results from UK, FR, BE, DE and CZ for Maritime EPPO zone and results from PL, CZ and DE for Poland as N-E EPPO zone. Considering GAP and registration from N-E only in PL, the Applicant correctly presented results.

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

For Poland, as we are dealing with the active substances used commonly for many years in many countries, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations.

Applicant presented sensitivity of studied weeds according to SANCO scale. cMS should decide if SANCO is acceptable. If not, **cMS should determine the sensitivity of the accepted weed species in accordance with their applicable internal regulations.** For Poland the classification of weed sensitivity differ to SANCO. Accepted weed species for Poland (N-E EPPO zone) should be presented to following scale of sensitivity: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.

The cite of the original registrant's data on iodosulfuron-methyl-sodium and mesosulfuron-methyl now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar iodosulfuron-methyl-sodium and mesosulfuron-methyl products. The spectrum of weeds should be checked with label claims on these reference products.

In the opinion of Evaluator, results of weed sensitivity from winter wheat, winter triticale and winter barley can be assessed together as winter cereals group.

Below we present a list of weed species for each zone separately for which at least two studies have been submitted:

• ALOMY

For Maritime and Poland – number of trials is sufficient for registration. In 2 trials carried out in North France – the efficacy was very low at all studied doses. Further investigations have shown that the blackgrass in these trials is resistant (KCP 6.2-5b and 6b). Those results were excluded from the assessment. ALOMY can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	13	-	-	MS (11)	MS (9)	S (11)
Poland	9	MT (1)	MT (6)	MS (9)	MS (4)	-

In brackets it is given the number of trials for each studied dose.

• APESV (all trials were valid)

APESV can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	6	-	-	S (6)	S (6)	HS (1)

Poland	11	MS (5)	MS (8)	S (11)	S (11)	-
--------	----	--------	--------	--------	--------	---

In brackets it is given the number of trials for each studied dose.

- **AVEFA** (all trials were valid)

AVEFA is a serious threat to winter cereals, so at least 4 valid trials are required. Due to not enough trials this weed should be excluded from GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	-	-	-	-	-	-
Poland	3	-	T (3)	MS (3)	S (3)	-

In brackets it is given the number of trials for each studied dose.

- **CAPBP** (all trials were valid)

This weed overwinters, troublesome during mass occurrence. It occurs on various types of soil. It prefers plump and airy soils. In the opinion of Evaluator, 2 trials should be sufficient for registration in Poland. In the Maritime EPPO zone registration is not possible due to lack of trials.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	-	-	-	-	-	-
Poland	2	S (2)	S (2)	S (2)	S (2)	-

In brackets it is given the number of trials for each studied dose.

- **GALAP** (all trials were valid)

This weed can be registered in PL and in the Maritime EPPO zone.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	6	-	-	MS (6)	MS (4)	S (5)
Poland	7	S (1)	MT (3)	MS (7)	MS (5)-	-

In brackets it is given the number of trials for each studied dose.

- **MATCH** (In one trial from DE – not enough level of infestation).

A fast-growing, competitive species - it takes up water and nutrients, and shades heavily in the early stages of growth. It is an indicator of clay soils. In the opinion of Evaluator at least 4 valid trials are required. On the basis on submitted documentation, MATCH can be registered in Maritime EPPO zone. In PL – it should be excluded from GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	5	-	-	MS (5)	S (4)	S (5)
Poland	3	-	S (2)	S (2)	S (2)	-

In brackets it is given the number of trials for each studied dose.

- **CHEAL** (all trials were valid)

It is a fast-growing, highly competitive plant that draws water and nutrients and also shades heavily. In winter crops it is dangerous during long warm autumns, although it eventually dies out. Spring emergence are also very competitive for both spring and winter cereals. In the opinion of Evaluator, at least 4 valid trials are required for CHEAL. On the basis on submitted documentation it can be registered in Maritime EPPO zone. In Poland, CHEAL should be excluded from GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	4	-	-	S (4)	S (4)	HS (2)
Poland	3	MT (2)	MT (2)	MS (3)	S (3)	-

In brackets it is given the number of trials for each studied dose.

- **POAAN** (all trials were valid)

POAAN can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO	Number	Eff.	Eff.	Eff	Eff.	Eff.
------	--------	------	------	-----	------	------

zone/ Country	of trials	0,1-0,14 kg/ha	0,2 kg/ha	0,3 kg/ha	0,4 kg/ha	0,5 kg/ha
Maritime	8	-	-	S (8)	S (7)	HS (1)
Poland	7	MT (3)	MS (4)	S (7)	S (6)	-

In brackets it is given the number of trials for each studied dose.

• **STEME** (all trials were valid)

STEME can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	6	-	-	S (6)	S (6)	HS (3)
Poland	9	MS (4)	MS (8)	S (9)	S (9)	-

In brackets it is given the number of trials for each studied dose.

• **LAMPU** (all trials were valid)

cMS should decide if LAMPU can be accepted on the basis on 2 trials. In Poland this weed should be excluded from GAP table and label project due to lack of trials.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	2	-	-	MS (2)	MT (2)	MS (2)
Poland	-	-	-	-	-	-

In brackets it is given the number of trials for each studied dose.

• **VERPE** (all trials were valid)

VERPE can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	6	-	-	S (6)	S (6)	S (5)
Poland	4	S (2)	MS (4)	MS (4)	MS (4)	-

In brackets it is given the number of trials for each studied dose.

• **VIOAR** (all trials were valid)

VIOAR can be accepted for PL and Maritime EPPO zone in GAP table and label project. All doses in PL can be accepted in the label.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	5	-	-	MS (5)	MS (5)	S (3)
Poland	4	MT (2)	MT (3)	MT (3)	MS (4)	-

In brackets it is given the number of trials for each studied dose.

• **POLAV** (all trials were valid)

Typically, light-loving, in winter cereals less common and not very competitive weed. In the opinion of Evaluator 2 trials can be accepted. POLAV can be registered in Maritime EPPO zone and Poland. In Poland only at dose 0,3 kg/ha POLAV can be included in label. Dose 0,4 kg/ha was supported only by 1 trials, whilst dose 0,2 kg/ha – lack of trials.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	2	-	-	T (2)	MT (1)	MS (2)
Poland	2	-	-	T (2)	MT (1)	-

In brackets it is given the number of trials for each studied dose.

• **PAPRH** (all trials were valid)

PAPRH can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	5	-	-	S (5)	S (3)	S (5)

Poland	6	MS (1)	MS (4)	S (6)	S (4)	-
--------	---	--------	--------	-------	-------	---

In brackets it is given the number of trials for each studied dose.

• MATIN

MATIN can be accepted for PL and Maritime EPPO zone in GAP table and label project.

EPPO zone/ Country	Number of trials	Eff. 0,1-0,14 kg/ha	Eff. 0,2 kg/ha	Eff. 0,3 kg/ha	Eff. 0,4 kg/ha	Eff. 0,5 kg/ha
Maritime	10	-	-	S (10)	S (9)	HS (6)
Poland	13	MS (5)	MS (9)	S (13)	S (12)	-

In brackets it is given the number of trials for each studied dose.

GLOB289H can be used in combination with an oil (esterified rapeseed oil) to ensure the optimal uptake of the active ingredients by the weeds. For the lower dose of 0.3 kg/ha, the addition of oil is optional. For the higher dose it is obligatory since dose is especially used against difficult weeds that are also capable of developing resistance. Therefore, the trials are also performed like this with different esterified rapeseed oils tested. Furthermore, the reference product Atlantis WG is also sprayed in combination with this oil.

Recommended dose for Maritime EPPO zone is 0,3 -0,5 kg/ha and for Poland is 0,2-0,4 kg/ha. Use the higher of the recommended rates for heavy weed infestation and for weeds more advanced in development. Only for CAPBP Applicant in the GAP table proposed 0,1 kg/ha as max dose, however in Polish label recommended dose are 0,2-0,4 kg/ha. Also, in MED trials in conclusion is mentioned that dose 0,12-0,19 kg/ha in the case of some weed species can be characterized by sufficient efficacy. So, in the opinion of Evaluator in Poland dose 0,2 kg/ha, should be recommended as the lowest effective for CAPBP. Especially since the minimum effective dose for the remaining weed species is dose 0,2 kg/ha.

Accepted volume: 200-300 L/ha.

Studied BBCH: winter wheat -23-32, winter triticale 25-30, winter barley 30. In the opinion of Evaluator, designated application window on BBCH 21-32 is correct and should be accepted.

Final decision about list of accepted weed and their sensitivity classification is left to each cMS. Below, Evaluator presented the list of weed sensitivity for Polish label:

- dose 0,2 kg/ha:
 - *susceptible weed* – CAPBP
 - *moderately susceptible weeds* – APESV, POAAN, STEME, VERPE, PAPRH, MATIN
 - *moderately tolerant weeds*- ALOMY, GALAP, VIOAR
- dose 0,3 kg/ha:
 - *susceptible weeds* – CAPBP, APESV, POAAN, STEME, PAPRH, MATIN
 - *moderately susceptible weeds* – ALOMY, GALAP, VERPE
 - *moderately tolerant weeds*- VIOAR
 - *tolerant weeds* - POLAV
- dose 0,4 kg/ha
 - *susceptible weeds*– CAPBP, APESV, POANN, STEME, PAPRH, MATIN
 - moderately susceptible weeds* – ALOMY, GALAP, VRERPE, VIOAR

It can be concluded that GLOB289H + oil and Atlantis WG + oil applied at the same dose rate have approximately the same efficacy against the different weeds with very comparable results. Furthermore, depending on the weed species and pressure, an increasing dose rate shows an increased efficacy. Finally, for most weed species, the addition of oil to 0.3 kg/ha of GLOB289H increases the efficacy by approximately 5-10 %, however sometimes 0.3 kg/ha of GLOB289H without oil is sufficient. These results support to the use of GLOB289H against grassy weeds and annual dicotyledonous weeds in cereals.

Following EPPO Standard PP 1/213 'Resistance risk analysis', it is reported the relevant information to the risk of resistance assessment. A resistance management strategy is proposed.

For the use of ZEPPOS (product code:GLOB289H) against target weeds it can be concluded, that:

- The product has a high inherent and agronomical risk for resistance weed development.
- To decrease the risk of selecting resistant weeds, the application of an additional herbicide belonging to a different mode of action and having high efficacy on the species to be controlled is recommendable.
- It is recommended to use the product in alternation or in combinations with compounds having a different mode of action.
- To avoid the selection of resistance it is recommended to perform one application of GLOB289H at the recommended dose(s) per season

In order to minimize the risk of occurrence and development of herbicide weed resistance we should follow Good Agricultural Practice:

- follow strictly the directions provided in the plant protection product label,
- plant protection product should be used at the recommended dose in the recommended time to ensure optimum weed control
- use integrated weed control practices covering fields such as history crop rotation, herbicides used and various tillage (mechanical, cultural, biological and chemical)
- use rotation of herbicides (active substances) with different mechanisms of action,
- use a mixture of herbicides (active substances) with different mechanisms of action,
- use herbicides acting on several life processes in rotation and / or a mixture weeds (with different mechanisms of action).

Label for the plant protection product ZEPPoS (product code:GLOB289H):

- observe the field after applying the herbicide to ensure that weeds are being controlled,
- use different methods of weed control, including crop rotations, etc.,
- inform the authorization holder of unsatisfactory weed control,
- for more information please contact your advisor, holder permit or a representative of the permit holder.

Resistance management strategy proposed by the applicant is acceptable and the applicant has to continue with intensive monitoring after reregistration of GLOB289H as well.

GLOB289H is a formulated product equivalent to several other products authorised in EU for long ago. Enough data to study the adverse effects on treated crops of GLOB289H has been submitted. 30 efficacy trials and 29 specific selectivity trials demonstrates the safe use of GLOB289H at target rates on cereals, with the absence of negative effects on treated crops. Only in winter rye the double dose had a small phytotoxic effect. These trials demonstrates the equivalent behaviour in terms of effects on treated crops compared to the reference products.

Restrictions on rotational crops are well-known. Two trials to ensure the crop safety on 6 usual cereals succeeding crops has been performed. Data shows no negative effect on winter oilseed rape, winter barley, maize, potato, field pea and sunflower, even with a superficial soil cultivation.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

An analytical method has been developed for the determination of the active substances iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl in GLOB289H.

A HPLC-DAD method was submitted to analyse both active ingredients and the safener in the formulation.

The validation parameters for the Iodosulfuron-methyl-sodium Mesosulfuron-methyl and safener Mefenpyr-diethyl methodology have been met for this study under the SANCO/3030/99 rev.4 guidelines

but because the test started at December 2019. it should be under rev. 5.
After analysis, it was found that all results are within acceptable limits.

3.3.2 Analytical methods for residues

Analytical methods for the determination of residues in crops are active substance data. However, since some of the residue studies provided during the EU review of Iodosulfuron-methyl-sodium and Mesosulfuron-methyl are still protected, new residue studies were performed with Zeppos, in which a new analytical method was developed and validated, apart from the method provided during the EU review. In addition, for both iodosulfuron-methyl-sodium and mesosulfuron-methyl, a method for body fluids and tissues was developed and validated as this was a data-gap in the EU review.

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

Commodity/crop	Supported/ Not supported
Cereals	Supported

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

Acute toxicity studies for GLOB289H were not evaluated as part of the EU review of iodosulfuron-methyl-sodium or mesosulfuron-methyl. Therefore, all relevant data were provided here and considered adequate.

No tests were performed on GLOB289H. For the acute oral, dermal and inhalation toxicity, skin and eye irritation and skin sensitisation, the assessment has been conducted according Regulation EC 1272/2008. Full details on composition, the classification of formulants and calculations are provided in part C of this registration report.

In other hand, a summary of the toxicological evaluation for POTTOK is provided in the core.

Table 3.4-1 shows the classification of the product based on theoretical calculation and toxicity data for ingredients of GLOB289H.

Table 3.4-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for GLOB289H

Type of test, species, model system (Guideline)	Classification (acc. to the criteria in Reg. 1272/2008)
LD ₅₀ oral, rat	None
LD ₅₀ dermal, rat	None
LC ₅₀ inhalation, rat	None
Skin irritation	None
Eye irritation	Eye Dam. 1; H318
Skin sensitisation	None
Supplementary studies for combinations of plant protection products	

Based on the available data Zeppos should be classified as category 1 for eye irritation (H318).

3.4.2 Operator exposure

Operator exposure to Zeppos was not evaluated as part of the EU review of iodosulfuron-methyl-sodium or mesosulfuron-methyl. Therefore all relevant data and risk assessments are provided here and are considered adequate.

The operator exposure was assessed against the AOEL agreed in the EU review of Iodosulfuron-methyl-sodium and mesosulfuron-methyl, and in the DAR of mefenpyr-diethyl. Also for the adjuvant Pottok a risk assessment was carried out based on the AOEL derived from the toxicity trials. Actirob is already on the market for several years. As no AOEL is defined for Actirob, no risk assessment could be performed. No studies were available to determine the dermal absorption, default values as defined in the EFSA guidance on dermal absorption (EFSA 2012; 10(4):2556) were used for the calculations. Operator exposure was modelled using the AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using Zeppos on cereals is acceptable without the use of personal protective equipment. . Given the serious eye damaging potential of Zeppos, eye/face protection should be worn when handling the concentrate.

3.4.3 Worker exposure

Worker exposure to Zeppos was not evaluated as part of the EU review of the active substance nor the safener. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing, when re-entering crops treated with Zeppos. As a standard rule, it could be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

3.4.4 Bystander and resident exposure

Bystander and resident exposure to Zeppos was not evaluated as part of the EU review of both active substance nor the safener. Therefore, all relevant data and risk assessments have been provided and are considered adequate. It is concluded that there is no undue risk to any resident after long-term exposure to Zeppos.

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

3.5.1 Residues

The product contains 2 active substances (iodosulfuron-methyl-sodium and mesosulfuron-methyl) and Mefenpyr-diethyl as a safener.

Storage stability

Iodosulfuron-methyl-sodium

A new stability studies on iodosulfuron-methyl and triazine amine residues in cereals were 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 studies are accepted.

Based on the results obtained, it can be concluded that the residues for iodosulfuron-methyl in wheat (grain and straw), are stable for 190 days when stored in a freezer at or below -20 °C.

The residues for triazine amine in wheat (grain and straw), lettuce and radish (leaves with tops and roots), are stable for 220 days when stored in a freezer at or below -20 °C.

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.

Mefenpyr-diethyl

Additional data are not required.

Metabolism in plants and animals

Iodosulfuron-methyl-sodium

No new data submitted in the framework of this application.

EU Endpoints Plant	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Yes
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not relevant
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016; Reg. (EU) No 289/2014)
Plant residue definition for risk assessment	Sum of iodosulfuron-methyl and its salts, expressed as iodosulfuron-methyl (EFSA, 2012, 2016) Triazine amine (IN-A4098) is a potential candidate for the plant residue definition for risk assessment, and a final decision is pending further clarification regarding the toxicological properties and the related consumer risk. Pending the conclusion on the IN-A4098 toxicity, also the metabolite AE 0031838 (hydroxymethyl triazine amine) observed up to 15% TRR in grain may require a reassessment.
Conversion factor from enforcement to RA	1 (EFSA, 2012, 2016)

Animal	
Animals covered	-
	-

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

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

No further data are required to support the proposed uses.

Mesosulfuron-methyl

No new data submitted in the framework of this application.

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

Animals covered	Ruminant
	Poultry
Time needed to reach a plateau concentration	Egg yolks: day 10; egg whites: day 8;
	Milk : day 5

Animal residue definition for monitoring	Mesosulfuron-methyl (EFSA, 2016; Reg. (EU) No 289/2014)
Animal residue definition for risk assessment	Mesosulfuron-methyl (EFSA, 2016)
Conversion factor	1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	No

No further data are required to support the proposed uses.

Mefenpyr-diethyl

Plant residue definition for monitoring	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Plant residue definition for risk assessment	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.
Conversion factor from enforcement to RA	Not required.

Animal residue definition for monitoring	-
Animal residue definition for risk assessment	Mefenpyr-diethyl (AE F107892) and its metabolites AE F113225 and AE F094270 expressed as mefenpyr-diethyl.

Magnitude of residues in plants

Cereals (winter/spring soft wheat, winter/spring durum wheat, triticale, spelt and winter rye)

Iodosulfuron-methyl-sodium

Proposed GAP: $1 \times 0.0006 - 0.003$ kg as/ha, BBCH 21-32, PHI not relevant, outdoor.

Proposed application rate is less critical than application rate in the EU GAP.

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.

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

New study (4 trials in Northern Europe) on the magnitude of residue has been submitted by the applicant in the framework of this application to support the proposed cGAP. This study is accepted.

Trials GAP: 1×3 g/ha, BBCH 32

The objective of the study was to generate samples for the determination of the residue levels of iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in wheat raw agricultural commodity (RAC) after one foliar application of the formulated product SAP63H (iodosulfuron-methyl-sodium 6 g/kg, mesosulfuron-methyl 30 g/kg, and mefenpyr-diethyl 90 g/kg WG) at the rate of 0.5 kg/ha. The wetting agent HAG 530 01 S was applied in tank mix at

a dose rate of 200 ml/ha.

Results:

E=RA: 4x <0.01 mg/kg

TA: 4x <0.01mg/kg

Sufficient trials wheat are available to support the proposed uses.

Extrapolation from wheat to rye, spelt and triticale is possible (SANTE/2019/12752).

The residues arising from the proposed uses will not exceed the MRLs established for cereals (Commission Regulation (EU) No 289/2014).

Note:

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

Mesosulfuron-methyl

Proposed GAP: 1 × 0.003 – 0.015 kg as/ha, BBCH 21-32, PHI not relevant, outdoor.

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

Wheat

1 × 0.015 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.

Rye

1 × 0.006 kg as/ha, BBCH 20-32, PHI not relevant, outdoor.

GAP on which EU a.s. assessment is based: 1 x 15g as/ha, BBCH 37-47

Residues: E&RA: 9x<0.01 mg/kg

New study (4 trials in Northern Europe) on the magnitude of residue has been submitted by the applicant in the framework of this application to support the proposed cGAP. This study is accepted.

Trials GAP: 1x 15g/ha, BBCH 32

Residues: E&RA: 4x <0.01

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

Extrapolation from wheat to rye, spelt and triticale is possible (SANTE/2019/12752).

The residues arising from the proposed uses will not exceed the MRLs established for cereals (Commission Regulation (EU) No 289/2014).

Note:

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

Mefenpyr-diethyl

Even though no studies assessing mefenpyr-diethyl and its metabolites are required, one study investigating the magnitude of residue has been submitted by the applicant in the framework of this application as additional data.

Trials GAP: 1x45g/ha, BBCH 29-32

Residues: 4x <0.050 mg/kg

Magnitude of residues in livestock

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 livestock were found to be below the threshold intake for the submission of an animal study, 0.004 mg/kg bw/d (using the official spreadsheet “pesticides_mrl_guidelines_animal_model_2017.xls”).

No new data are submitted in the framework of this application

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 GLOB289H / SAP63H.

The use of Zeppos in a mixture with adjuvants, e.g. Actirob 842 EC has been accepted

3.5.2 Consumer exposure

Consumer risk assessment was performed using EFSA PRIMo-rev. 3 model. For chronic risk assessment, MRLs as set in Reg. (EU) No. 289/2014 were used as input values. Since the calculations (EFSA PRIMo v 3.0) for iodosulfuron-methyl-sodium and mesosulfuron methyl demonstrate a sufficient margins of safety, it was not deemed necessary to perform recalculations using EFSA PRIMo rev. 3.1 version.

Table 3.5-1: Consumer risk assessment iodosulfuron-methyl-sodium

TMDI (% ADI) according to EFSA PRIMo	6% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Assessment not required.
IESTI (% ARfD) according to EFSA PRIMo*	Wheat: 0.0 % (for all the groups tested)
NTMDI (% ADI) **	Assessment not required.
NEDI (% ADI)**	Assessment not required.
NESTI (% ARfD) **	Assessment not required.

* 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 Zeppos do not represent unacceptable acute and chronic risks for the consumer.

Table 3.5-2: Consumer risk assessment mesosulfuron-methyl

TMDI (% ADI) according to EFSA PRIMo	0.2% (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Assessment not required.
IESTI (% ARfD) according to EFSA PRIMo*	Assessment not required.
NTMDI (% ADI) **	Assessment not required.
NEDI (% ADI)**	Assessment not required.
NESTI (% ARfD) **	Assessment not required.

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

** if national model is available

The proposed uses of mesosulfuron-methyl in Zeppos do not represent unacceptable chronic risks for the consumer.

According with the European information available, mefenpyr-diethyl is not an active substance and has not been reviewed under Directive 91/414/EEC or under Regulation (EC) No 1107/2009.

Furthermore, there is no data available for the applicant indicating in which crops mefenpyr is authorised. Hence, a risk assessment cannot be properly carried out.

However, no values above the LOQ have been found in any of the trials performed in grain. Taking this into account, it can be considered that the proposed uses of mefenpyr-diethyl in Zeppos do not represent unacceptable chronic and acute risks for the consumer.

Combined exposure and risk assessment

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues.

Acute consumer risk assessment from combined exposure: not required

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

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

The PEC of iodosulfuron-methyl-sodium, mesosulfuron-methyl, mefenpyr-diethyl and their metabolites in soil have been assessed with the FOCUS model and the DT₅₀ values established in the EU review / DAR. Based on the intended use, the maximum initial predicted environmental concentration in soil (PECs) of the active substances, safener and the formulation are provided in the table below.

Table 3.7-1: Maximum PEC_{soil} values

Compound	Maximum PECs (mg/kg)	PEC _{plateau} (5cm) after year 1	PEC _{accumulation} (PEC _{act} + PEC _{plateau})
Iodosulfuron-methyl-sodium	0.0032	-	-
AE F075736	0.00204	-	-
AE F161778	0.00032	-	-
AE F059411	0.00035	0.0002	0.0005
AE F145740	0.00026	-	-
AE F145741	0.00021	-	-
AE 0000119	0.00022	0.000	0.0002
BCS-CW81253	0.00073	0.0001	0.0008
AE 0002166	0.00048	-	-
Mesosulfuron-methyl	0.016	0.0039	0.0199
Mesosulfuron	0.00252	0.0011	0.0036
AE F160459	0.00138	0.0003	0.0017
AE F099095	0.00185	0.0011	0.0030
AE F092944	0.00050	-	-
AE F160460	0.00133	-	-
AE F140584	0.00073	-	-
AE F1447447	0.00060	0.0017	0.0023
Mefenpyr-diethyl	0.02880	-	-
AE F113225	0.01958	-	-
AE F094270	0.02517	0.0429	0.0777
AE 2211046	0.00579	-	-

The results for PEC soil for the active substances, safener and their metabolites were used for the ecotoxicological risk assessment.

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

The PEC_{gw} of iodosulfuron-methyl-sodium, mesosulfuron-methyl, mefenpyr-diethyl and their metabolites has been determined with the standard FOCUS scenarios to obtain outputs from the FOCUS PELMO

5.5.3 and FOCUS PEARL 4.4.4 models.

When the dose of 0.5 kg/ha Zeppos was considered, the relevant trigger of 0.1 µg/L mesosulfuron-methyl is slightly exceeded (0.104 µg/L) in the Okehampton scenario if modelled with PELMO 5.5.3. No exceedance is observed in PEARL 4.4.4. Since Okehampton is not considered a relevant scenario for Poland, the risk is considered acceptable. 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 0.5 µg/L. Nevertheless, these metabolites are considered non-relevant according to Sanco/221/2000 –rev.10- final. Besides, the relevance of these, has been evaluated under dRR B10 and the RAR of mesosulfuron-methyl. The risk to groundwater is therefore low.

No exceedance of the relevant trigger of 0.1 µg/L iodosulfuron-methyl-sodium, mefenpyr-diethyl or their metabolites is expected for any of the proposed uses.

No risk for groundwater is to be expected for the requested uses of Zeppos.

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

The PEC_{sw} values of iodosulfuron-methyl-sodium, mesosulfuron-methyl, mefenpyr-diethyl and their metabolites have been assessed further to drift, run-off and drainage events according to the intended use. The PEC_{sw} of Zeppos was also assessed for drift events.

Calculations for iodosulfuron-methyl-sodium and metabolite AE F075736 were performed at STEP 1, STEP 2 and STEP 3. All other metabolites showed an acceptable risk in STEP 1.

Calculations for mesosulfuron-methyl and metabolite BCS-CV14885 were performed at STEP 1, STEP 2 and STEP 3. All other metabolites showed an acceptable risk in STEP 1.

Calculations for mefenpyr-diethyl and metabolites were performed at STEP 1.

The resulting PEC_{sw} values for the active substances, the safener, metabolites and formulation were used for the ecotoxicological risk assessment.

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

The fate and behaviour of iodosulfuron-methyl-sodium and mesosulfuron-methyl in air was evaluated during the EU review. No additional studies have been performed.

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

Mefenpyr-diethyl has negligible volatility as concluded from its low vapour pressure of 6.3 x 10⁻⁶ Pa at 20°C. This was confirmed in an experimental test showing low volatility on soil and plant surfaces. Calculation of the photo-oxidative degradation in air according Atkinson methodology (AOPWIN) resulted in a DT₅₀ value of 1.96 d for standard OH radical concentration of 1.5 × 10⁶ radicals/cm³ and a daytime frame of 12 hours.

Vapour pressure does not exceed FOCUS Air trigger values for volatilisation potential (i.e. V_p ≥ 10⁻⁴ Pa at 20°C for volatilisation from soil. and V_p ≥ 10⁻⁵ Pa at 20°C for volatilisation from plants). and atmospheric half-life does not exceed FOCUS Air trigger for possibility of long range transport (i.e. DT₅₀ > 2 days). Concluded from both contributing factors. there is no risk of atmospheric long-range transport of mefenpyr-diethyl; PEC calculations are therefore not required.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The TER_a and TER_{lt} values exceed the triggers of 10 and 5 for the acute and long-term exposure respectively at the screening step, indicating that iodosulfuron-methyl-sodium, mesosulfuron-methyl and mefenpyr-diethyl do not pose an acute or long-term risk to wild birds and mammals. In addition, the combined effect of simultaneous exposure was considered. Also for the combined exposure, the trigger of 10 for the acute exposure was exceeded, indicating an acceptable risk for the use of GLOB289H according to the intended GAP.

The ratio of the effective application rate to the acute and long term toxicity endpoint is less than 50 for the less sorptive substances iodosulfuron-methyl-sodium and mesosulfuron-methyl. For the more sorptive substance mefenpyr-diethyl, the trigger of 3000 is not exceeded. Therefore it is considered that there is low risk of acute/long term toxicity to birds and mammals from the uptake of contaminated drinking water and no further assessment is required.

Iodosulfuron-methyl-sodium and mesosulfuron-methyl both have a log Pow value < 3. Therefore no assessment of secondary poisoning was considered necessary. Mefenpyr-diethyl has a log Pow value > 3, a risk assessment for secondary poisoning was therefore considered necessary.

Earthworm-eating birds

With a TER of 311.8 which largely exceeds the trigger of 5, there is a large safety margin so the risk for earthworm-eating birds due to exposure to mefenpyr-diethyl via bioaccumulation in earthworms is considered acceptable.

Fish-eating birds

The TER of 212 largely exceeds the trigger value of 5, so the risk for fish-eating birds due to exposure to mefenpyr-diethyl via bioaccumulation in fish is considered acceptable.

Earthworm-eating mammals

With a TER of 216.6 which largely exceeds the trigger of 5, there is a large safety margin so the risk for earthworm-eating mammals due to exposure to mefenpyr-diethyl via bioaccumulation in earthworms is considered acceptable.

Fish-eating mammals

The TER of 198.7 largely exceeds the trigger value of 5, so the risk for fish-eating mammals due to exposure to mefenpyr-diethyl via bioaccumulation in fish is considered acceptable.

3.7.2 Effects on aquatic species

An acceptable acute and long-term risk to aquatic organisms is identified for the intended use of Zeppos (+ adjuvant) in winter and spring cereals when 5 meter buffer zone to surface water bodies is applied.

Sp3: To protect aquatic organism respect 5 meter buffer zone to surface water bodies.

3.7.3 Effects on bees

Although the guidance document is not yet approved, the evaluation of the risk for honeybees was performed in accordance with the recommendations of the “EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombis* spp. and solitary bees)”, EFSA Journal 2013; 11(7):3295.

The hazard quotient after acute contact exposure was 2.5, which is below the trigger value of 42. It can therefore be concluded that the intended use of GLOB289H gives a low acute contact risk to honey bees. For the acute oral exposure, an ETR of 0.02 was calculated. This is below the trigger of 0.2, indicating an acceptable risk.

The chronic ETRs for adult honeybees and honeybee larvae are 0.033 and 0.07 respectively, exceeding the respective trigger values of 0.03 and 0.2, indicating an acceptable risk.

In general, there is no concern for honeybees when the product (+ adjuvant) is applied according the GAP. No mitigation measures are necessary.

3.7.4 Effects on other arthropod species other than bees

Considering the acceptable risk to *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Crysoperla carnea* and *Aleochara bilineata* from the glass plate and extended laboratory studies, the product complies with the trigger values recommended by ESCORT 2. It is therefore concluded that the risk to non-target arthropods following the recommended uses of the product (+adjuvant) will be negligible. No mitigation measures are necessary.

3.7.5 Effects on soil organisms

All the long-term TER values calculated in the earthworms and other non-target soil organisms risk assessment largely exceed the trigger value of 5. Based on these results can be concluded that GLOB289H (+ adjuvant) poses low long-term risk to earthworms, collembola and predatory mites.

The maximum concentrations with an effect $\leq 25\%$ are higher than the maximum PEC_{soil} of iodosulfuron-methyl-sodium, mesosulfuron-methyl, their relevant metabolites and GLOB289H (+ adjuvant) from the intended use so the risk is acceptable.

The use of GLOB289H according to the proposed use pattern in cereals will not have unacceptable effects on soil micro-organisms. No mitigation measures necessary.

3.7.6 Effects on non-target terrestrial plants

effects on considering risk mitigation measures are used. Following combinations offer an acceptable risk:

Winter cereals – 0.5 kg/ha

- 1m buffer zone combined with 90% drift reducing nozzles
- 5m buffer zone combined with 50% drift reducing nozzles
- 10m buffer zone

Winter and spring cereals – 0.3 kg/ha

- 1m buffer zone combined with 90% drift reducing nozzles
- 5 m buffer zone.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.8 Relevance of metabolites (Part B, Section 10)

Metabolites AE F160459, AE F160460, AE F147447 and BCS-CV14885 are predicted to occur in groundwater at concentrations above 0.1 $\mu\text{g/L}$ (see dRR Part B8). Assessment of the relevance of this these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 was therefore required. Based on this assessment could be concluded that none of the metabolites should be considered as relevant.

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

Neither iodosulfuron-methyl-sodium nor mesosulfuron-methyl are candidates for substitution. A comparative assessment was therefore not considered necessary.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

Appendix 1 Copy of the product authorization

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

Appendix 2 Copy of the product label

Sekcja pozostałości i toksykologii: brak uwag.

Projekt etykiety ZEPPOS

Posiadacz zezwolenia:

Globachem N.V., Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint-Truiden, Królestwo Belgii, tel.: +32-11 785717, e-mail: globachem@globachem.com

ZEPPOS

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

jodosulfuron metylosodowy (związek z grupy pochodnych sulfonilomocznika) - **6 g/kg**,

mezosulfuron metylowy (związek z grupy pochodnych sulfonilomocznika) - **30 g/kg**.

Zezwolenie MRiRW nr R-



Uwaga

H318 – Powoduje poważne uszkodzenie oczu

H410– Działa bardzo toksycznie na organizmy wodne powodując długotrwałe skutki

P280 – Stosować rękawice ochronne/odzież ochronna/ochronę oczu/ochronę twarzy.

P310 - Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem/...

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.

~~P273 – Nie wypuszczać do środowiska. (Unikać uwalniania do środowiska.)~~

P391 – Zebrać wyciek

OPIS DZIAŁANIA

Środek chwastobójczy, granulat do sporządzania zawiesin wodnych, stosowany nalistnie, przeznaczony do powschodowego zwalczania chwastów jednoliściennych i niektórych dwuliściennych w pszenicy ozimej, pszenżycie ozimym i życie. Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych.

DZIAŁANIE NA CHWASTY

Środek pobierany jest poprzez liście, także poprzez korzenie chwastów i przemieszczany w roślinie, co powoduje zahamowanie rozwoju i wzrostu chwastów. Najskuteczniej niszczy chwasty jednoroczne intensywnie rosnące, znajdujące się w fazie 2-3 liści. 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 zamie-

ranie chwastów następuje w 4-6 tygodni po zabiegu. Skuteczności działania sprzyja ciepła i wilgotna pogoda.

Chwasty wrażliwe w dawce 0,2 kg/ha np: ~~miotła zbożowa, maruna bezwonna, gwiazdnica pospolita, wyczyniec polny, tasznik pospolity~~

Chwasty wrażliwe w dawce 0,3 kg/ha np: ~~miotła zbożowa, gwiazdnica pospolita, mak polny, przytulia czepna, wiechlina roczna, wyczyniec polny, tasznik pospolity, maruna nadmorska~~

Chwasty wrażliwe w dawce 0,4 kg/ha np: ~~miotła zbożowa, gwiazdnica pospolita, owies gluchy, przytulia czepna, wiechlina roczna, wyczyniec polny, mak polny, tasznik pospolity, maruna nadmorska~~

Chwasty średnio wrażliwe w dawce 0,2 kg/ha np: ~~miotła zbożowa, wiechlina roczna, gwiazdnica pospolita, przetacznik perski, mak polny, maruna nadmorska~~

Chwasty średnio wrażliwe w dawce 0,3 kg/ha np: ~~wyczyniec polny, przytulia czepna, przetacznik perski~~

Chwasty średnio wrażliwe w dawce 0,4 kg/ha np: ~~wyczyniec polny, przytulia czepna, przetacznik perski, fiołek polny~~

Chwasty średnio odporne w dawce 0,2 kg/ha np: ~~wyczyniec polny, przytulia czepna, fiołek polny~~

Chwasty średnio odporne w dawce 0,3 kg/ha np: ~~fiołek polny~~

STOSOWANIE ŚRODKA

Pszenica ozima i jara, pszenżyto jare i ozime, pszenica twarda, orkisz, żyto

Maksymalna dawka dla jednorazowego zastosowania: 0,4 kg/ha.

Zalecana dawka dla jednorazowego zastosowania: 0,2 – 0,4 kg/ha.

Termin stosowania:

Zabieg wykonać wiosną po rozpoczęciu wegetacji roślin do początku strzelania w źdźbło.

Wyższą z zalecanych dawek stosować w przypadku intensywnego zachwaszczenia i na chwasty bardziej zaawansowane w rozwoju.

Srodek należy stosować z dodatkiem środka zwiększającego przyczepność cieczy roboczej np. Actirob 842 EC . W przypadku stosowania dawki 0,2 kg/ha środka stosować ilość Actirob 842 EC w dawce 0,4 l/ha; w przypadku stosowania dawki 0,3 kg/ha dodać 0,6 l/ha Actirob 842 EC a w przypadku stosowania środka Zeppos w ilości 0,4 kg/ha zastosować Actirob 842 EC w ilości 0,8 l/ha.

Zalecana ilość wody: **100-400 l/ha.**

Zalecane opryskiwanie: **średniokropliste.**

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

NASTĘPSTWO ROŚLIN

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

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Środek zawiera w swoim składzie dwie substancje czynne z grupy pochodnych sulfonilomocznika. Z uwagi na możliwość wystąpienia odporności niektórych gatunków chwastów

- należy unikać corocznego stosowania herbicydów z grupy pochodnych sulfonilomocznika na tym samym polu.
2. 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.
 3. Środka nie stosować:
 - na rośliny osłabione lub uszkodzone przez choroby, szkodniki czy przymrozki,
 - przed spodziewanym silnym przymrozkiem,
 - w zbożach z wsiewką roślin motylkowatych.
 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.
 5. **Należy unikać nakładania się oprysku, zwłaszcza w przypadku żyta opryskiwacza ozimego/jarego. Wrażliwość odmian powinna zostać zbadana lub skonsultowana z posiadaczem zezwolenia.**

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wsypać 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 wleciu 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

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe 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.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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.

Środki ostrożności dla osób stosujących środek:

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 roboczej oraz w trakcie wykonywania zabiegu.

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.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 4- 5 m od zbiorników i cieków wodnych.

W celu ochrony roślin lądowych niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości:

Zboża ozime w dawce 0.5 kg/ha

- 1 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% lub
- 10 m lub
- 5 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50%.

- Zboża ozime i jare w dawce 0.3 kg /ka

- 1 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% lub
- 5 m

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.

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

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny przeznaczone na paszę do dnia w którym zwierzęta mogą być karmione tymi roślinami (okres karencji dla pasz):

Nie dotyczy

Okres od ostatniego zastosowania środka na rośliny do dnia w którym można siać lub sadzić rośliny uprawiane następnie:

Należy uwzględnić NASTĘPSTWO ROŚLIN.

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.

Okres ważności 1 rok ~~-2 lata~~

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letter of access submitted.

Appendix 4 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1-2.11	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) – Physical, chemical and technical properties of the plant protection product EF/298/19 Ascenza Agro S.A. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.2.1	Dornhagen J.	2019	SAP63H – Explosive properties PS20190222-2 Siemens A.G. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.2.2	Dornhagen J.	2019	SAP63H – Oxidizing properties of solids O.1 PS20190222-3 Siemens A.G. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.3.2	Dornhagen J.	2019	SAP63H – Flammability (solids) N.1 PS20190222-1 Siemens A.G. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.3.3	Dornhagen J.	2019	SAP63H – Relative self-ignition temperature for solids (Grewer-oven)	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			PS20190222-4 Siemens A.G. GLP Not published				
KCP 2.9.1-01	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with vegetal oil adjuvant – Evaluation of physical compatibility PC/09/2019 Ascenza Agro S.A. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.1-02	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with non-ionic surfactant – Evaluation of physical compatibility PC/08/2019 Ascenza Agro S.A. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.2-01	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with vegetal oil adjuvant – Physical, chemical and technical properties of the plant protection product EF/300/19 Ascenza Agro S.A. GLP Not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 2.9.2-02	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) with non-ionic surfactant – Physical,	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			chemical and technical properties of the plant protection product EF/299/19 Ascenza Agro S.A. GLP Not published				
KCP 6.2-1	Jim Scholey	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-UK01 Lab: OAT GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-3	Henk de Vries	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-NL03 Lab: Zwaagdijk GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-4	Terzieff Frédéric	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-FR04 Lab: Promo-Vert GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-5	Jean-Pierre Rivet	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-FR05 Lab: Essais+ GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.
KCP 6.2-6	Jean-Pierre Rivet	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-FR06	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Lab: Essais+ GEP, not published				
KCP 6.2-7	Xavier Bourgeois	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds, Belgium 2017 Report number: HE-17-GLOB289H-BE07 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-8	Vladimira Bauer	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds, Czech Republic 2017 Report number: HE-17-GLOB289H-CZ08 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-9	Lukasz Kmiecik	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds, Poland 2017 Report number: HE-17-GLOB289H-PL09 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-11	Sören Hötzel	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-DE11-156-V2 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-12	Ulrich Ströbele	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-DE12-156-V3 Lab: Quintus GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-13	Lukasz Kmiecik	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds, Poland 2017	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: ASO-17-29960-PL06 KBI Lab: Staphyt GEP, not published				
KCP 6.2-14	Honorata Dziubek	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: S17-03160-01 Lab: Eurofins GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-15	Mateusz Świtkowski	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-PL15 Lab: Syntech GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-16	Grzegorz Piotrowski	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-PL16 Lab: Syntech GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-17	Henk de Vries	2017	Efficacy of GLOB289H in winter cereals against mono and dicotyledonous weeds. Report number: HE-17-GLOB289H-BE17 Lab: Proeftuin Zwaagdijk GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-18	Eltje Weiß	2018	Efficacy and selectivity of GLOB289H against ALOMY applied post-emergence in winter cereals 2018. Report number: HE-18-A-GLOB289H-DE01 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-19	Eltje Weiß	2018	Efficacy and selectivity of GLOB289H against ALOMY applied post-emergence in winter cereals 2018. Report number: HE-18-A-GLOB289H-DE02 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-20	Katrin Torkler	2018	Efficacy and selectivity of GLOB289H against ALOMY applied post-emergence in winter cereals.2018 Report number: HE-18-A-GLOB289H-DE03 Lab: Quintus GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-21	Andrew Hunt	2018	Efficacy and selectivity of GLOB289H against ALOMY applied post-emergence in winter cereals.2018 Report number: HE-18-A-GLOB289H-UK04 Lab: OAT GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-22	Veronika Gezova	2018	Efficacy and selectivity of GLOB289H against ALOMY applied post-emergence in winter cereals.2018 Report number: HE-18-A-GLOB289H-CZ05 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-23	Eltje Weiß	2018	Efficacy and selectivity of GLOB289H against POAAN applied post-emergence in winter cereals.2018 Report number: HE-18-B-GLOB289H-DE01 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-24	Uwe Gerdau	2018	Efficacy and selectivity of GLOB289H against POAAN applied post-emergence in winter cereals.2018 Report number: HE-18-B-GLOB289H-DE02 Lab: Agrartest	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP, not published				
KCP 6.2-25	Andy Hunt	2018	Efficacy and selectivity of GLOB289H against POAAN applied post-emergence in winter cereals.2018 Report number: HE-18-B-GLOB289H-UK03 Lab: OAT GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-26	Andrew Hunt	2018	Efficacy and selectivity of GLOB289H against POAAN applied post-emergence in winter cereals.2018 Report number: HE-18-B-GLOB289H-UK04 Lab: OAT GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-27	Jana Konvalinkova	2018	Efficacy and selectivity of GLOB289H against POAAN applied post-emergence in winter cereals.2018 Report number: HE-18-B-GLOB289H-CZ05 Lab: ZS Rymarov GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-28	Wladyslaw Slezak	2018	Evaluation of efficacy of GLOB289H against weeds in winter wheat, applied on early spring. Report number: S18-04316-01 Lab: Eurofins GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-29	Grzegorz Piotrowski	2018	Efficacy and selectivity of GLOB289H against non-restant ALOMY applied post-emergence in winter cereals.2018 Report number: HE-18-C-GLOB289H-PL02 Lab: Syntech GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-30	Adam Kreczmer	2018	Efficacy and selectivity of GLOB289H against APESV and AVEFA applied post-emergence in winter cere-	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			als.2018 Report number: HE-18-D-GLOB289H-PL01 Lab: FRS GEP, not published				
KCP 6.2-31	Dariusz Gajek	2018	Efficacy and selectivity of GLOB289H against APESV and AVEFA applied post-emergence in winter cereals.2018 Report number: HE-18-D-GLOB289H-PL02 Lab: ARC GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-32	Dariusz Gajek	2018	Efficacy and selectivity of GLOB289H against APESV and AVEFA applied post-emergence in winter cereals.2018 Report number: HE-18-D-GLOB289H-PL03 Lab: ARC GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-33	Hélène Venard	2019	Efficacy and visual selectivity of GLOB289H against ALOMY and dicots applied post-emergence in winter wheat. Report number: HE-19-A-GLOB289H-BE01 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-34	Eltje Weiß	2019	Field study to evaluate the efficacy of GLOB289H against Poa annua and dicotyledonous weeds applied post-emergence in winter wheat in Germany. Report number: HE-19-A-GLOB289H-DE02 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-35	Ulrich Ströbele	2019	Efficacy and selectivity of GLOB289H against ALOMY and dicots applied post-emergence in winter wheat.2019	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: HE-19-A-GLOB289H-DE03 Lab: Quintus GEP, not published				
KCP 6.2-36	Antonin Ruzicka	2019	Efficacy and selectivity of GLOB289H against APESV and dicots applied post-emergence in winter wheat 2019 Report number: HE-19-B-GLOB289H-CZ01 Lab: ZS Rymarov GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.2-37	Jaroslav Subr	2019	Efficacy and selectivity of GLOB289H against APESV and dicots applied post-emergence in winter wheat 2019 Report number: HE-19-B-GLOB289H-CZ02 Lab: ZS Trutnov GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-1	Eltje Weiß	2017	Selectivity of GLOB289H in cereals. Report number: HS-17-GLOB289H-DE01 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-2	Eltje Weiß	2017	Selectivity of GLOB289H in cereals. Report number: HS-17-GLOB289H-DE02 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-3	Eltje Weiß	2017	Selectivity of GLOB289H in cereals. Report number: HS-17-GLOB289H-DE03 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-4	Jordan Corentin	2017	Selectivity of GLOB289H in cereals. Report number: 17F HCEGLO FR08	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Lab: Promo-Vert GEP, not published				
KCP 6.4-5	Terzieff Frédéric	2017	Selectivity of GLOB289H in cereals. Report number: 17F HCEGLO FR11 Lab: Promo-Vert GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-6	Cheneval-Pallud Sylvie	2017	Selectivity of GLOB289H in cereals. Report number: 17F HCEGLO FR12 Lab: Promo-Vert GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-7	Frédéric Terzieff	2017	Selectivity of GLOB289H in cereals. Report number: 17F HCEGLO FR09 Lab: Promo-Vert GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-8	David Julien	2017	Selectivity of GLOB289H in cereals. Report number: 17F HCEGLO FR11 Lab: Promo-Vert GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-9	Mike Turner	2017	Selectivity of GLOB289H in cereals, United Kingdom 2017 Report number: HS-17-GLOB289H-UK09 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-10	Xavier Bourgeois	2017	Selectivity of GLOB289H in cereals, Belgium 2017 Report number: HS-17-GLOB289H-BE10 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-11	Vladimira Bauer	2017	Selectivity of GLOB289H in cereals, Czech Republic 2017 Report number: HS-17-GLOB289H-CZ11 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-12	Vladimira Bauer	2017	Selectivity of GLOB289H in cereals, Czech Republic 2017 Report number: HS-17-GLOB289H-CZ12 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-13	Vladimira Bauer	2017	Selectivity of GLOB289H in cereals, Czech Republic 2017 Report number: HS-17-GLOB289H-CZ13 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-14	Vladimira Bauer	2017	Selectivity of GLOB289H in cereals, Czech Republic 2017 Report number: HS-17-GLOB289H-CZ14 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-15	Vladimira Bauer	2017	Selectivity of GLOB289H in cereals, Czech Republic 2017 Report number: HS-17-GLOB289H-CZ15 Lab: Staphyt GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-16	Annika Land	2018	Selectivity of GLOB289H applied post-emergence on winter rye. 2018 Report number: HS-18-A-GLOB289H-DE01 Lab: FRS	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP, not published				
KCP 6.4-17	Katrin Torkler	2018	Selectivity of GLOB289H applied post-emergence on winter triticale. 2018 Report number: HS-18-A-GLOB289H-DE02 Lab: Quintus GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-18	Adam Kreczmer	2018	Selectivity of GLOB289H applied post-emergence on winter wheat. 2018 Report number: HS-18-B-GLOB289H-PL01 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-19	Adam Kreczmer	2018	Selectivity of GLOB289H applied post-emergence on winter wheat. 2018 Report number: HS-18-B-GLOB289H-PL02 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-20	Paweł Taraska	2018	Selectivity of GLOB289H applied post-emergence on winter cereals. 2018 Report number: HS-18-B-GLOB289H-PL03 Lab: Anadiag GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-21	Łukasz Sasin	2018	Selectivity of GLOB289H applied post-emergence on winter cereals. 2018 Report number: HS-18-B-GLOB289H-PL04 Lab: Anadiag GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-22	Piotr Trzaskowski	2018	Selectivity of GLOB289H applied post-emergence on winter cereals. 2018	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: HS-18-B-GLOB289H-PL05 Lab: Anadiag GEP, not published				
KCP 6.4-23	Eltje Weiß	2016	Evaluation of the selectivity of GLOB288H and GLOB289H when applied on rye and triticale in spring. Report number: FRS130-16-V1 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-24	Malte Selig	2016	Evaluation of the selectivity of GLOB288H and GLOB289H when applied on rye and triticale in spring. Report number: FRS130-16-V2 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-25	Shemsi Greku	2016	Evaluation of the selectivity of GLOB288H and GLOB289H when applied on rye and triticale in spring. Report number: FRS131-16-V1 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-26	Shemsi Greku	2016	Evaluation of the selectivity of GLOB288H and GLOB289H when applied on rye and triticale in spring. Report number: FRS131-16-V2 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-27	Jörg Fahning	2016	Evaluation of the selectivity of GLOB288H, GLOB289H, Fluflo 102.5 SE and Florasulam 50 SC when applied on winter wheat in spring. Report number: FRS132-16-V1 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-28	Karsten Franke	2016	Evaluation of the selectivity of GLOB288H, GLOB289H, Fluflo 102.5 SE and Florasulam 50 SC when applied on winter wheat in spring. Report number: FRS132-16-V2 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.4-29	Eltje Weiß	2016	Evaluation of the selectivity of GLOB288H, GLOB289H, Fluflo 102.5 SE and Florasulam 50 SC when applied on winter wheat in spring. Report number: FRS132-16-V3 Lab: FRS GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.5-1	Catherine Davies	2018	GLOB289H (Iodosulfuron + Mesosulfuron + Mefenpyr (0.6% + 3% + 9%) WG) GLP Seedling Emergence and Seedling Growth Test Terrestrial Non Target Plant Species following soil incorporation Report number: STC/18/E1158 Lab: Stockbridge Research Centre GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.5-2	Bénédicte Trouslard	2017	Evaluate the impact of an application of post-emergence wheat herbicide, applied at N and 2N on the development and the growth of 4 succeeding crops, GEP Trial, FRANCE, 2017 Report number: BTD-17-29868-FR01 Lab: Staphyt France GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.5-3	Mélanie Gressard	2017	Evaluate the impact of an application of postemergence wheat herbicide, applied at N and 2N, on the development and the growth of 4 succeeding crops: OSR, winter barley, maize and potatoes. Evaluate any impact of 2 types of soil cultivation.	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report number: QUALI17129H06 Lab: Qualiphyt GEP, not published				
KCP 6.5-4	Catherine Davies	2017	GLOB289H GLP Vegetative Vigour Test Terrestrial Non Target Plants Report number: STC/17/E1118 Lab: Stockbridge Research Centre GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.5-5	Sona Silva	2019	IODOSULFURON-METHYL-SODIUM 0.6 % + MESOSULFURON-METHYL 3.0 % + MEFENPYR-DIETHYL 9.0 % WG (SAP63H) with NON-IONIC SURFACTANT: Effectiveness of Cleaning procedure Report number: EF-303-19 Lab: Ascenza Agro, SA GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 6.5-6	Sona Silva	2019	IODOSULFURON-METHYL-SODIUM 0.6 % + MESOSULFURON-METHYL 3.0 % + MEFENPYR-DIETHYL 9.0 % WG (SAP63H) with VEGETAL OIL ADJUVANT: Effectiveness of Cleaning procedure Report number: EF-304-19 Lab: Ascenza Agro, SA GEP, not published	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.1.1	Silva S.	2019	Iodosulfuron-methyl-sodium 0.6% + Mesosulfuron-methyl 3.0% + Mefenpyr-diethyl 9.0% WG (SAP63H) – Physical, chemical and technical properties of the plant protection product. EF/298/19 Ascenza Agro, S.A. GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.1.2-01	Arias A.	2019	Validation of the analytical method for the determination of mesosulfuron-methyl, mefenpyr-diethyl and its metabolites (AE F113225 and AE F094270) in wheat (grain and straw) and iodosulfuron-methyl in straw. VAL25/18 Ascenza Laboratorio de Residuos GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.1.2-02	Gordo J.	2018	Validation of the analytical method for the determination of triazine amine (AE F059411) residues in barley, wheat, lettuce and radish. VAL02/18 SAPEC Agro - Laboratorio de Residuos GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.1.2-03	Morias F.F.	2018	Cross validation of an extraction method based on Quechers Method vs. an extraction method applied in 14C-metabolism studies for the determination of iodosulfuron-methyl in wheat (green material). VAL48/17 SAPEC Agro - Laboratorio de Residuos GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.1.2-04	Arias A.	2018	Cross validation of an extraction method based on Quechers Method vs. an extraction method applied in 14C-metabolism studies for the determination of mesosulfuron-methyl in wheat (green material). VAL19/18 Ascenza Laboratorio de Residuos GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 5.2-01 (submitted as KCP 10.2-01)	Renner, P.	2018a	Acute toxicity of GLOB289H to <i>Daphnia magna</i> in a 48-hour static test. 18 48 ADL 0008 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-02 (submitted as KCP 10.2-02)	Renner, P.	2018b	Effects of GLOB289H on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test. 18 48 AAL 0019 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-03 (submitted as KCP 10.2-03)	Renner, P.	2018c	Effects of GLOB289H on <i>Lemna gibba</i> in a growth inhibition test under semi-static conditions – Appendix 3: Analytical phase report 18 48 ALE 0006 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-04 (submitted as KCP 10.2-04)	Renner P.	2019a	Effects of GLOB289H and Actirob B on <i>Lenma gibba</i> in a growth inhibition test under semi-static test conditions – Appendix 3: Analytical phase report 19 48 ALE 0004 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-05 (submitted as KCP 10.2-05)	Renner P.	2019b	Effects of Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + mefenpyr-diethyl (6+30+90) g/kg WG (SAP63H) and the adjuvant (Pottok) on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions – Appendix 3:	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Analytical phase report 19 48 ALE 0007 BioChem Agrar GLP Unpublished				
KCP 5.2-06 (submitted as KCP 10.3.1.2-01)	Kleebaum K.	2018	GLOB289H – Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (<i>in vitro</i>) 17 48 BLC 0089 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-07 (submitted as KCP 10.3.1.2-02)	Ruhland S.	2018	Chronic toxicity of Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (0.6 + 3 + 9)% WG to the honey bee <i>Apis mellifera</i> L. under laboratory conditions 17 48 BAC 0055 BioChem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-08	Andrews G. Bills K.	2019	Method validation – Analytical method for the determination of iodosulfuron-methyl in body fluid and tissue FH/19/002 Batelle UK GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 5.2-09	Knop M.	2018	Validation of the analytical method for the determination of mesosulfuron-methyl in body fluids and animal matrices. S17-7891 Eurofins	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 5.2-10	Andrews G. Pearson J.	2018	Independent method validation – determination of residues of mesosulfuron-methyl in body fluid FH/18/004 Batelle GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 7.2.3/01a	Perny, A.	2019	Generation of samples for the determination of Iodosulfuron-methyl-sodium, Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) residues in wheat following foliar application with SAP63H under field conditions in Northern and Southern Europe in 2018. Perny, A., 2019. Report n° R B8019. GLP, unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 7.2.3/01b	Arias, A.	2019	Determination of residues of Iodosulfuron-methyl (and its metabolite Triazine Amine), Mesosulfuron-methyl and Mefenpyr-diethyl (and its metabolites AE F113225 and AE F094270) in wheat after one foliar application of SAP63H in Northern and Southern Europe. Report n° QUT20/18 GLP, unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 7.2.1/01 (KCA 6.1)	Gordo, J.	2019	Stability Study of Iodosulfuron-methyl Residues in Wheat Stored Under Deep Freezing Conditions. Report n° EST51/18 GLP, unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 7.2.1/02 (KCA 6.1)	Gordo, J.	2019	Stability Study of Triazine amine (AE F059411) Residues in Wheat, Lettuce and Radish Stored Under Deep Freezing Conditions. Report n°	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			EST50/18 GLP, unpublished				
KCP 7.4.1/01 (KCA 6.1)	Gaffney, V.	Ongoing	Stability study of Mefenpyr-diethyl and its Metabolites AE F113225 and AE F094270 Residues in Wheat (Grain and Straw) Stored Under Deep Freezing Conditions. Study Plan Report n° EST16/19 GLP, unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 9.2.4	Baré B.	2019	GLOB289H/SAP63H Report PEC _{GW} calculations Globachem GMP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 9.2.5	Baré B.	2019	GLOB289H/SAP63H Report PEC _{SW} and PEC _{SED} calculations Globachem GMP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-01	Renner P.	2018a	Acute toxicity of GLOB289H to <i>Daphnia magna</i> in a 48-hour static test 18 48 ADL 0008 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-02	Renner P.	2018b	Effects of GLOB289H on <i>Pseudokirchneriella subcapitata</i> in an algal growth inhibition test 18 48 ADL 0019 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-03	Renner P.	2018c	Effects of GLOB289H on <i>Lemna gibba</i> in a growth rate inhibition test under semi-static test conditions.	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			18 48 ALE 0006 Biochem agrar GLP Unpublished				
KCP 10.2-04	Renner P.	2019a	Effects of GLOB289H and Actirob B on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions. 19 48 ALE 0004 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-05	Renner P.	2019b	Effects of Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (6 + 30 + 90) g/kg WG (SAP63H) and the adjuvant (Pottok) on <i>Lemna gibba</i> in a growth inhibition test under semi-static test conditions 19 48 ALE 0007 Biocem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_01 (also submitted as KCA 8.2.7_08-01)	Dill, M.	2018a	Mesosulfuron-methyl technical: Growth inhibition of <i>Nasturtium officinale</i> in a water/sediment system S18-00146 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_02 (also submitted as KCA	Dill, M.	2018b	Mesosulfuron-methyl technical: Growth inhibition of <i>Hottonia palustris</i> in a water/sediment system S18-00147 Eurofins GLP	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
8.2.7_08-02)			Unpublished				
KCP 10.2-06_03 (also submitted as KCA 8.2.7_08-03)	Dill, M.	2018c	Mesosulfuron-methyl technical: Growth inhibition of <i>Myriophyllum sibiricum</i> in a water/sediment system S18-00148 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_04 (also submitted as KCA 8.2.7_08-04)	Dill, M.	2018d	Mesosulfuron-methyl technical: Growth inhibition of <i>Ceratophyllum demersum</i> in a water/sediment system S18-00149 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_05 (also submitted as KCA 8.2.7_08-05)	Dill, M.	2018e	Mesosulfuron-methyl technical: Growth inhibition of <i>Vallisneria spiralis</i> in a water/sediment system S18-00150 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_06 (also submitted as KCA 8.2.7_08-0f)	Dill, M.	2018f	Mesosulfuron-methyl technical: Growth inhibition of <i>Glyceria maxima</i> in a water/sediment system S18-00151 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-	Dill, M.	2018g	Mesosulfuron-methyl technical: Growth inhibition	N	Y	Data / study never submitted to	Ascenza Agro S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
06_07 (also submitted as KCA 8.2.7_08-07)			of <i>Elodea canadensis</i> in a water/sediment system S18-00152 Eurofins GLP Unpublished			Poland before	Globachem N.V
KCP 10.2-06_08 (also submitted as KCA 8.2.7_08-08)	Dill, M.	2018h	Mesosulfuron-methyl technical: Growth inhibition of <i>Wolffia arrhiza</i> in a water/sediment system S18-00153 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-06_09 (also submitted as KCA 8.2.7_08-09)	Dill, M.	2018i	Mesosulfuron-methyl technical: Growth inhibition of <i>Spirodela polyrhiza</i> in a water/sediment system S18-00154 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.2-07 (also submitted as KCA 8.2.7_09)	Lang, C.	2018	Mesosulfuron-methyl technical: Toxicity to the Duckweed <i>Lemna gibba</i> under laboratory conditions (acute test – static) S18-00164 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.1-01	Sipos K.	2018	Acute contact and oral toxicity of Iodosulfuron + Mesosulfuron (0.6% + 3%) WG on honey bees (<i>apis mellifera</i>) 17/173-116MT Citoxlab	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.3.1-02	Franke M.	2019a	Acute contact toxicity of GLOB289H + Actirob (adjuvant) to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. 19 48 BAA 0019 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.1-03	Marin M.	2019b	Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (6 + 30 + 90) g/kg WG (SAP63H) + adjuvant (Pottok) – Acute contact toxicity to the honey bee, <i>Apis mellifera</i> L. under laboratory conditions S19-00809 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.1-04	Franke M.	2019c	Acute oral toxicity of GLOB289H + Actirob (adjuvant) to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. 19 48 BAA 0089 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.1-05	Franke M.	2019d	Acute oral toxicity of GLOB289H + Pottok (adjuvant) to the honeybee <i>Apis mellifera</i> L. under laboratory conditions. 19 48 BAA 0088 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.2-01	Kleebaum K.	2018	GLOB289H – Repeated exposure of honey bee (<i>Apis mellifera</i> L.) larvae under laboratory conditions (<i>in vitro</i>) 17 48 BLC 0089 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.1.2-02	Ruhland S.	2018	Chronic toxicity of Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (0.6+3+9)% WG to the honey bee <i>Apis mellifera</i> L under laboratory conditions. 17 48 BAC 0055 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.2-01	Röhlig U.	2017a	Effects of Iodosulfuron + Mesosulfuron (0.6+3) % WG on predatory mite <i>Typhlodromus pyri</i> Scheuten in a laboratory test 17 48 NTL 0008 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.2-02	Röhlig U.	2017b	Effects of Iodosulfuron + Mesosulfuron (0.6+3) % WG on the parasitic wasp <i>Aphidius rhopalosiphii</i> (destefani-perez) in a laboratory test 17 48 NAL 0009 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.2-03	Röhlig U.	2019a	Effects of GLOB289H + Actirob B on the predatory mite <i>Typhlodromus pyri</i> Scheuten in a laboratory test	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			19 48 NTL 0002 Biochem Agrar GLP Unpublished				
KCP 10.3.2-04	Röhlig U.	2009b	Effects of GLOB289H + Actirob B on the parasitic wasp <i>Aphidius rhopalosiphii</i> (DeStefani-Perez) in an extended laboratory test 19 48 NAE 0009 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.2-05	Röhlig U.	2009c	Effects of GLOB289H + Actirob B on the green lacewing <i>Chrysoperla carnea</i> Steph. in an extended laboratory test 19 48 NCE 0010 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.3.2-06	Röhlig U.	2019d	Effects of GLOB289H + Actirob B on the rove beetle <i>Aleochara bilineata</i> Gyll. in an extended laboratory test 19 48 NKE 0006 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KPC 10.3.2-07	Luna F.	2019	Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (6 + 30 + 90) g/kg WG (SAP63H) + adjuvant (Pottok) – Toxicity to the parasitoid <i>Aphidius rhopalosiphii</i> De Stefani Perez (Hymenoptera, Braconidae) under extended laboratory conditions S19-02623	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Eurofins GLP Unpublished				
KCP 10.4-01	Friedrich S.	2018a	Effects of Iodosulfuron + Mesosulfuron (0.6+3)% WG on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil 17 48 TEC 0043 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.4-02	Friedrich S.	2019a	Effects of GLOB289H + Actirob B on the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil 19 48 TEC 0063 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.4-03	Friedrich S.	2019b	Effects of GLOB289H + Pottok in the reproduction of the earthworm <i>Eisenia andrei</i> in artificial soil 19 48 TEC 0064 Biochem Agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.4-04	Friedrich S	2018b	Effects of Iodosulfuron + Mesosulfuron (0.6+3) % WG on the reproduction of the collembolan <i>Folsomia candida</i> 17 48 TCC 0043 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.4-	Schulz L.	2018a	Effects of Iodosulfuron + Mesosulfuron (0.6+3) %	N	Y	Data / study never submitted to	Ascenza Agro S.A.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
05			WG on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> 17 48 THC 0038 Biochem agrar GLP Unpublished			Poland before	Globachem N.V
KCP 10.5-01	Schulz L.	2018b	Effects of Iodsulfuron + Mesosulfuron (0.6 + 3) % WG on the activity of soil microflora (Nitrogen transformation test) 17 48 SMN 0050 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.5-02	Persdorf M.	2019a	Effects of Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (6 + 30 + 90) g/kg WG (GLOB289H) and the adjuvat (Pottok) on the activitiy of soil microflora (Nitrogen transformation test) 19 48 SMN 0054 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.5-03	Persdorf M.	2019b	Effects of GLOB289H + Actirob B on the activity of soil microflora (Nitrogen transformation test) 19 48 SMN 0053 Biochem agrar GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.6-01	Davies C.	2018	GLOB289H GLP Vegetative vigour test terrestrial non-target plants STC/17/E1118 Stockbridge technology centre Ltd	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP Unpublished				
KCP 10.6-02	Stead A.	2018	GLP Seedling emergence and seedling growth test terrestrial non-target plants STC/17/E1119 Stockbridge technology centre Ltd GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.6-03	Davies C.	2019	GLOB289H + Actirob B GLP Vegetative Vigour test terrestrial non-target plants (based on OECD guideline 227) – 2019 STC/19/E1233 Stockbridge technology centre Ltd GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V
KCP 10.6-04	Huerta F.	2019	Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl (6 + 30 + 90) g/kg WG (SAP63H) + adjuvant (Pottok): Effects on the Vegetative Vigour of six non-target terrestrial plant species under greenhouse conditions S19-00811 Eurofins GLP Unpublished	N	Y	Data / study never submitted to Poland before	Ascenza Agro S.A. Globachem N.V

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA 7.1.1/01	xxx	2013a	Acute oral toxicity study of HAG 530 01 S study in rats xxx Report-no. 29035 GLP: yes Published: no	Y			HELM AG BELCHIM SAPEC
KIIIA 7.1.2/01	xxx	2013b	Acute dermal toxicity study of HAG 530 01 S study in CD rats xxx Report-no. 29034 GLP: yes Published: no	Y			HELM AG BELCHIM SAPEC
KIIIA 7.1.3/01	xxx	2013	EPI Suite Results For CAS 103818-93-5 xxx Report-no. n.a. GLP: n.a. Published: no	Y			HELM AG BELCHIM SAPEC
KIIIA 7.1.4/01	xxx	2013a	Acute dermal irritation/corrosion test (patch test) of HAG 530 01 S in rabbits xxx Report-no. 29031 GLP: yes Published: no	Y			HELM AG BELCHIM SAPEC
KIIIA 7.1.5/01	xxx	2013b	Acute eye irritation/corrosion test of HAG 530 01 S in rabbits xxx Report-no. 29033 GLP: yes Published: no	Y			HELM AG BELCHIM SAPEC
KIIIA 7.1.6/01	xxx	2013c	HAG 530 01 S Skin sensitisation: local lymph node assay in NMRI mice xxx	Y			HELM AG BELCHIM SAPEC

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Report-no. 29032 GLP: yes Published: no				
KIIIA 7.2/01	xxx	2013	Mutagenicity study of HAG 530 01 S in the <i>Salmonella typhimurium</i> reverse mutation assay (<i>in vitro</i>) xxx Report-no. 29030 GLP: yes Published: no	N			HELM AG BELCHIM SAPEC

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

