FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB2013F

Product name(s): Observer

Chemical active substance:

Zoxamide, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: January 2024

Update: July 2024

MS Finalisation date: 12/2025

Version history

When	What
January 2024	Initial dossier submission by applicant for approval of new product
April 2024	Dossier sent for evaluation
July 2024	Applicant revision 01
September 2024	zRMS finalised evaluation
December 2024	zRMS finalised evaluation after commenting period
December 2025	zRMS finalised evaluation - Efficacy

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

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product containing 450 g/L Zoxamide and formulated as a suspension concentrate (SC).
This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Central zone	Poland, Observer	Czech Republic, Observer Hungary, Observer Ireland, Observer Romania, Observer Slovakia, Observer

0.1.3 Regulatory history of the active(s)

0.1.3.1 Zoxamide

Table 0.1-2: Summary of regulatory history of CAS No: 156052-68-5

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 91/414/EEC as amended by 03/119/EC, Reg. (EU) No 823/2012 and Reg. (EU) 2016/2016 or Reg. (EU) No 540/2011 as amended by Reg. (EU) 2018/84 and Reg. (EU) 2018/692
RMS	LV (The original RMS was UK)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/07/2018
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30/09/2004

Status	
Date of final Commission (re-registration) deadline (Step 2)	31/08/2005
Current expiration of approval	30/06/2033
Low risk substance or Candidate for Substitution?	N/A

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

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

– the protection of groundwater from metabolite RH-141455,
– the protection of bees, aquatic organisms and earthworms.
Conditions of use shall include risk mitigation measures, where appropriate.

The renewal report for zoxamide (SANTE/10052/2018 Rev 2 – 23 March 2018) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 18 August 2017.

Table 0.1-3: Information on minimum purity of zoxamide

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	980 g/kg Equivalence report available: Y RMS: LV

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).
**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

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

Endpoint	**Active Substance**	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
Purity of a.s.	95%	98%

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

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA.

Section 3. Efficacy
Potatoes
The evaluation of the application for GLOB2013F (Observer 0.3 L/ha) resulted in the decision to grant the authorization in North-East EPPO climatic zone (PL) and a decision of cMS in Maritime (IE, CZ) and South- East EPPO climatic zone (HU,RO,SK). ~~All uses applied were authorised except for use(s) on South-East EPPO climatic zone due to lack of appropriate experiments.~~

All requested uses were approved.~~, except for the use(s) in the EPPO South-Eastern Climate Zone due to the lack of appropriate studies~~. Based on the possibility of recognizing the study: "application from the moment of disease symptom onset," this interpretation of the uses of the tested product was applied. The decision to register the tested product GLOB2013F (Observer 0.3 l/ha) against *P.infestans* in the EPPO South-East and Maritime Climate Zones was left to the cMS countries.
The suggestion in Table GAP-alternative for the use of a slightly reduced dose of GLOB2013F (Observer 0.29 L/ha) cannot be accepted due to the lack of efficacy studies for the reduced dose. However, the maintenance of buffer zones can be emphasized and the negative impact on aquatic organisms can be emphasized (in the label).

Grapevine
~~All uses applied weren't authorised for use(s) due to lack of appropriate experiments. The grapevines are qualified as Minor uses in PL and it is accepted in GAP Table but in IE this decision in for cMS.~~

7 fully supportive trials demonstrating high control of infestation of bunches by *P. viticola* obtained after 1 or 2 applications of GLOB2013F(Observer), which provides a basis for full registration of the product intended to protect grapes as a major crop against major pest in Poland. Based on the possibility of recognizing the study: "application from the moment of disease symptom onset," this interpretation of the uses of the tested product was applied. The decision to register the tested product GLOB2013F (Observer 0.3 l/ha) against *Plasmopara viticola* in grapevines in the EPPO South-East and Maritime Climate Zones was left to the cMS countries.
The data provided and the efficacy results obtained are sufficient to register GLOB2013F (Observer) at the 0.23 L/ha 10000m2 tlwa dose for the control of *Plasmopara viticola* in grapevines, in the EPPO North -East (PL) and Maritime (CZ, IE) climate zones (CZ, DE are representative of Poland and the North-east, as neighboring countries) and South-East EPPO climate zone. This is consistent with the intended uses in GAP Table, label, and Uniform Principles. Registration of GLOB2013F (Observer) is appropriate and justified.

Section 5. Analytical methods
Please refer to Part B5.

Section 6. Mammalian Toxicology
Classification: Skin Sens. 1, H317 with the additional statement *Contains 1,2-benzisothiazolin-3-one.*
Operator: no PPE. Protective gloves at the M/L step recommended due to the product classification.
Workers: workwear
Resident/Bystander: None (potatoes), 5m of buffer zone (grapes)

Section 7. Metabolism and Residues
The metabolism of zoxamide in plant was investigated in primary and rotational crops. According to the

results of the metabolism and the hydrolysis studies, the residue definition for enforcement in primary, rotational crops, honey and processed commodities can be proposed as zoxamide (sum of constituent isomers) while for risk assessment can be proposed as sum of zoxamide and metabolite RH-141452, expressed as zoxamide. For processed commodities, a separate residue definition for risk assessment for metabolite RH-150721 was also proposed.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.02 mg/kg for zoxamide in potato and 5 mg/kg in table/wine grapes as laid down in Reg. (EU) 396/2005 is not expected.

Studies provided by the Applicant indicate that the applicable MRL for zoxamide in honey (0.05 mg/kg, Reg (EU) 2017/17) is not expected to be exceeded following GLOB2013F applications consistent with the proposed GAP.

The effects of processing on the nature of zoxamide residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

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

The chronic and the short-term intakes of zoxamide residues are unlikely to present a public health concern.

Section 8. Environmental Fate
In accordance with proposed pattern use in potatoes and vines, an exposure assessment for the formulation of GLOB2013F was submitted.
The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

Section 9. Ecotoxicology
In accordance with proposed use pattern, risk assessment to non-target organisms for the formulation of GLOB2013F was sufficient.
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of GLOB2013F as fungicide on: potato (seed potato, ware and starch potato) and table and wine grape poses an acceptable risk to non-target organisms.

Section 10. Assessment of the relevance of metabolites in groundwater
Based on PECgw assessment for metabolites submitted in Section B8, only for the RH-141455 metabolite the trigger value of 0.1 µg/L was exceeded.
The max PECgw = 4.652 µg/L, as the worst case, in Jokioinen scenario was considered below.
The assessment of RH-141455 metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.11 (21 October 2021) was performed by Applicant and accepted.

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

use 1: acceptable; uses 2, 3: to be confirmed by cMS; use ~~7, 8: PL: acceptable, IE: to be confirmed by cMS,~~ 4, 5 – acceptable PL; CZ, HU, RO, SK, IE: to be confirmed by cMS

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

~~3, 4, 5, 6~~

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

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Appendix 1 ALL intended uses

GAP rev. 4.0, date: 13/11/2023

PPP (product name/code):	GLOB2013F	Formulation type:	SC (suspension concentrate)
Active substance 1:	zoxamide	Conc. of as 1:	450 g/L
Applicant:	Globachem NV	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	Yes		

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	~~CZ, HU,~~ ~~IE~~, PL, ~~RO, SK~~	Potatoes Seed, ware and starch potato (SOLTU)	F	*Phytophthora infestans* (PHYTIN)	Downward spraying	BBCH 21-79	a) 3 b) 3	7	a) 0.3 b) 0.9	a) 0.135 b) 0.405	150-300	7	
2	CZ, IE, ~~SK~~	Potatoes Seed, ware and starch potato (SOLTU)	F	*Phytophthora infestans* (PHYTIN)	Downward spraying	BBCH 21-79	a) 3 b) 3	7	a) 0.3 b) 0.9	a) 0.135 b) 0.405	150-300	7	

3	~~HU, RO~~ HU, RO, SK	~~Seed, ware and starch potato (SOLTU)~~ Potatoes Seed, ware and starch potato (SOLTU)	~~F~~ F	~~*Phytophthora infestans* (PHYTIN)~~ *Phytophthora infestans (PHYTIN)*	~~Downward spraying~~ Downward spraying	~~BBCH 21-79~~ BBCH 21-79	~~a) 3 b) 3~~ a) 3 b) 3	~~7~~ 7	~~a) 0.3 b) 0.9~~ a) 0.3 b) 0.9	~~a) 0.135 b) 0.405~~ a) 0.135 b) 0.405	~~150-300~~ 150-300	~~7~~ 7	
~~2~~ 4	~~CZ, HU, IE, PL, RO, SK~~ CZ, HU, RO, SK, IE, PL	~~Table and wine grape (VITVI)~~ Table and wine grape (VITVI)	~~F~~ F	~~*Plasmopara viticola* (PLASVI)~~ *Plasmopara viticola* (PLASVI~~)~~	~~Air assisted~~ Air assisted	~~BBCH 13-52~~ BBCH 13-52	~~a) 2 b) 2~~ ~~a)~~ 2 b) 2	~~8~~ 8	~~a) 0.3 b) 0.6~~ a) 0.3 b) 0.6	~~a) 0.135 b) 0.270~~ a) 0.135 b) 0.270	~~100-1000~~ 100-1000	~~28~~ 28	C CZ, HU, RO, SK, IE A PL
~~3~~ 5	~~CZ, HU, IE, PL, RO, SK~~ CZ, HU, RO, SK, IE, PL	~~Table and wine grape (VITVI)~~ Table and wine grape (VITVI)	~~F~~ F	~~*Plasmopara viticola* (PLASVI)~~ *Plasmopara viticola* (PLASVI)	~~Air assisted~~ Air assisted	~~BBCH 53-83~~ BBCH 53-83	~~a) 2 b) 2~~ a) 2 b) 2	~~8~~ 8	~~a) 0.368 b) 0.736~~ a) 0.368 b) 0.736	~~a) 0.166 b) 0.332~~ a) 0.166 b) 0.332	100-1000 100-1000	~~28~~ 28	Maximum 2 apps per season. 0.23 L/10.000 m² LWA corresponding to 0.1035kg a.i./10.000 m² LWA. For early BBCH stages (13-52), the maximum rate allowed per ha soil is set at 0.3L/ha soil corresponding to 13000 m2 LWA. For later stages (BBCH53-83), the maximum rate allowed per ha soil is set at 0.368L/ha soil corresponding to 16000 m2 LWA. RO, SK, HU: Range from 0.17 to 0.23 L/10.000 m² LWA
4 6	~~CZ, HU, IE, PL, RO, SK~~	~~Seed, ware and starch potato (SOLTU)~~	~~F~~	~~*Phytophthora infestans* (PHYTIN)~~	~~Downwards spraying~~	~~BBCH 21-79~~	~~a) 3 b) 3~~	~~7~~	~~a) 0.29 b) 0.87~~	~~a) 0.130 b) 0.390~~	~~150-300~~	~~7~~	~~Alternative GAP with a slightly lower dose rate in order to maintain a mitigation of maximum 10 m VFS only where~~

													necessary
Minor uses according to Article 51													
7	PL, IE	Table and wine grape (VITVI)	F	*Plasmopara viticola* (PLASVI)	Air assisted	BBCH 13-52	a) 2 b) 2	8-10	a) 0.3 b) 0.6	a) 0.135 b) 0.270	100-1000	28	Maximum 2 apps per season. 0.23 L/10.000 m² LWA corresponding to 0.1035kg a.i./10.000 m² LWA. For early BBCH stages (13-52), the maximum rate allowed per ha soil is set at 0.3L/ha soil corresponding to 13000 m² LWA. For later stages (BBCH53-83), the maximum rate allowed per ha soil is set at 0.368L/ha soil corresponding to 16000 m² LWA. A-PL C- IE
7 8	PL, IE	Table and wine grape (VITVI)	F	*Plasmopara viticola* (PLASVI)	Air assisted	BBCH 53-83	a) 2 b) 2	8-10	a) 0.368 b) 0.736	a) 0.166 b) 0.332	100-1000	28	

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions