FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: GLOB2007bF

Product name: Observer Pro

Chemical active substances:

Zoxamide, 67.5 g/L
Propamocarb-HCl, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Globachem NV

Submission date: November 2023

Update: July 2024

MS Finalisation date: 31/10/2024

Version history

When	What
November 2023	Initial dossier submission by applicant for approval of new product
March 2024	Dossier sent for evaluation
July 2024	Applicant revision 01 to address zRMS initial comments
July 2024	zRMS finalised evaluation
October 2024	zRMS finalised evaluation after commenting period

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

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product containing 67.5 g/L Zoxamide and 450 g/L Propamocarb-HCl 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.

The Annex II data for propamocarb-HCl are out of data protection.
The Annex II data on zoxamide are matched.
The Annex III data used for GLOB2007bF are owned by Globachem NV.

The intended sources of the active substances have been positively evaluated in the EU.

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 Pro	Czech Republic, Observer Pro Hungary, Observer Pro Ireland, Observer Pro Romania, Observer Pro Slovakia, Observer Pro, Netherlands, Observer Pro, Belgium, Observer Pro, Germany, Obsever Pro

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
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%
K_{foc} (mL/g)/K_{fom}	Arithmetic mean Zoxamide: 1207/700 RH – 127450 669/388	Geometric mean Zoxamide: 1179/684 RH – 127450 593/344
K_{foc} (mL/g)/K_{fom}	Arithmetic mean Propamocarb-HCl 535.56	Geometric mean Propamocarb-HCl 263.65

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

0.1.3.2 Propamocarb-HCl

Table 0.1-4: Summary of regulatory history of CAS No: 25606-41-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 91/414/EEC Commission Implementing Regulation (EU) No 540/2011 Commission Implementing Regulation (EU) No 2020/869 Commission Implementing Regulation (EU) No 2021/745 Commission Implementing Regulation (EU) No 2022/708
RMS	IE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/10/2007
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/03/2008
Date of final Commission (re-registration) deadline (Step 2)	30/09/2011
Current expiration of approval	15/06/2025
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 operators and workers safety. Conditions of use should include protective measures, where appropriate;

- the transfer of soil residues for rotating and succeeding crops;
- the protection of surface and groundwater in vulnerable zones;
- the protection of birds, mammals and aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Propamocarb (SANCO/10057/2006 final) 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 5 July 2006.

Table 0.1-5: Information on minimum purity of propamocarb-HCl

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 *, **
920 g/kg	920 ~~950~~ g/kg Equivalence report available: Y RMS: DE

* 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.	92%	95%

* 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

Missing storage stability study at ambient temperature – study is ongoing (3 years storage stability study at ambient temperature). It is required to set a shelf-life for the PPP from real time storage test at ambient temperature and may be evaluated in post-registration at national level.

Section 3. Efficacy

~~The suggestion in Table GAP alternative for the use of a slightly reduced dose of GLOB2007bF (Observer Pro 2.0 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).~~
~~The evaluation of the application for GLOB2007bF (Observer Pro 2 L/ha) resulted in the decision to grant the authorization in North-East EPPO climatic zone and Maritime – decision of cMS. All uses applied were authorised except for use(s) on South-East EPPO climatic zone due to lack of appropriate experiments.~~
After a detailed analysis of the data on the efficacy of GLOB2007bF (Observer Pro 2l/ha) and the assessment of the minimum effective dose and the data from EPPO PP1/307(2) it was decided that the use of a slightly reduced dose 1.9l/ha of GLOB2007bF (Observer Pro 2.0 L/ha) can be accepted. According to EPPO PP1/307(2) the content of a.s. in the preparation may be lower by 10%. That is, a reduction of the a.s. content by 5% is permissible. Observer Pro agent indicates its good effectiveness, which should be maintained when using a dose 5% lower.
The suggestion in Table GAP-alternative for the use of a slightly reduced dose of GLOB2007bF (Observer Pro 2.0 L/ha) can be accepted. However, the maintenance of buffer zones can be emphasized and the negative impact on aquatic organisms can be emphasized (in the label).
The evaluation of the application for GLOB2007bF (Observer Pro 2 L/ha) resulted in the decision to grant the authorization in North-East EPPO climatic zone and decision of cMS on national level in Maritime EPPO zone. The South-East EPPO climatic zone that authorization of Observer Pro can be recognized at the national level or as conditional registration if official regulations at the national level allow it. Conditional registration may be accepted provided that additional experimental data are provided.

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

Section 7. Metabolism and Residues
The proposed uses of propamocarb-HCl and zoxamide in the formulation GLOB2007bF do not represent unacceptable acute and chronic risks for the consumer.
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.3 mg/kg for propamocarb-HCl and 0.01 mg/kg for zoxamide in potato as laid down in Reg. (EU) 396/2005 is not expected.
According to available data, no specific mitigation measures should apply.

Section 8. Environmental Fate
In accordance with proposed pattern use in potatoes, an exposure assessment for the formulation of GLOB2007bF 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 GLOB2007bF was sufficient.
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of GLOB2007bF as fungicide in potato (seed potato, ware and starch potato) poses an acceptable risk to non-target organisms (uses 1-2).

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:

No 1, 2

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

~~No 2~~

Appendix 1 ALL intended uses

GAP rev. 2.2 date: 2022-03-03

PPP (product name/code):	GLOB2007bF	Formulation type:	SC [a, b]
Active substance 1:	zoxamide	Conc. of as 1:	67.5 g/L [c]
Active substance 2:	propamocarb	Conc. of as 2:	450 g/L [c]
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)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CZ, ~~HU,~~ HU, IE, PL, ~~RO,~~ RO, SK ~~DE, NL,~~ DE, NL, BE	~~Seed, ware and starch potato (SOLTU)~~ Potato	F	*Phytophthora infestans* (PHYTIN)	Downwards spraying	BBCH 21-79	a) 3 b) 3	7	a) 2 b) 6	a) 135 Zoxamide + 900 Propamocarb-HCl b) 405 Zoxamide + 2700 Propamocarb-HCl	150-300	7	/
~~2~~	~~CZ, HU, IE, PL, RO, SK DE, NL~~	~~Potato~~	~~F~~	~~PHYTIN~~	~~Downwards spraying~~	~~BBCH 21-79~~	~~a) 3 b) 3~~	~~7~~	~~a) 1.9 b) 5.7~~	~~a) 130 Zoxamide + 855 Propamocarb b) 390 Zoxamide + 2565 Propamocarb~~	~~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~~
2	CZ,~~,~~ HU, IE, PL, RO, SK DE, NL, BE	Potato	F	PHYTIN	Downwards spraying	BBCH 21-79	a) 3 b) 3	7	a) 1.9 b) 5.7	~~a)~~ 130 Zoxamide + 855 Propamocarb b) 390 Zoxamide + 2565 Propamocarb	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

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