FINAL REGISTRATION REPORT
Part A
Risk Management

Product code: GLOB2013F

Product name(s): Observer

Chemical active substance:

Zoxamide, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Globachem NV

Submission date: January 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
September 2024	zRMS finalised evaluation
December 2024	zRMS finalised evaluation after commenting period
May 2025	Updated version of Part A
July 2025	Updated version of Part A
December 2025	zRMS finalised evaluation - Efficacy

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PART A
RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem NV in January 2024.

The application was for approval of GLOB2013F, a suspension concentrate containing 450 g/L zoxamide for use as a fungicide in potato and grape for which Poland was designated zRMS.

1.2 Letters of Access

Vertebrate studies access is currently negotiated with the Notifier.

1.3 Justification for submission of tests and studies

The application is for approval of a new product. It 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.

1.4 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	GLOB2013F
Product name in MS	Observer
Authorization number	-
Function	Fungicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Zoxamide: 450 g/L
Formulation type	Suspension concentrate (SC)
Packaging	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH
Coformulants of concern for national authorizations	None
Restrictions related to identiy	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluator also verified whether the co-formulants contained in plant protection product Observer (Product code: GLOB2013F) are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be

considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.
Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Observer (Product code: GLOB2013F) does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.
According to the current knowledge and available information none of the co-formulants in the plant protection product Observer (Product code: GLOB2013F) meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

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:	Skin Sens. 1, H317 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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:	**GHS07**, **GHS09**
Signal word:	**Warning**
Hazard statement(s):	H317 – May cause an allergic skin reaction. H400 – Very toxic to aquatic life. H410 – Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P261 - Avoid breathing dust/fume/ gas/mist/vapours/spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/ protective clothing/eye protection/face protection. P302+P352 - IF ON SKIN: Wash with plenty of water/… P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P321 - Specific treatment (see on this label). P362+P364 - Take off contaminated clothing and wash it before reuse. P391 – Collect spillage. P501 - Dispose of contents/ container to...
Additional labelling phrases:	**To avoid risks to man and the environment, comply with the instructions for use. [EUH401]**
	Contains 1,2-Benzisothiazolin-3-one (CAS No. 2634-33-5).

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

Further labelling statements under Regulation (EC) No 1272/2008:	
-	-

See Part C for justifications of the classification and labelling proposals.

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	When using in potato to protect aquatic organisms respect a: - 5 m vegetative strip with 5 m no spray buffer zone (VFSMOD) When using in grapes to protect aquatic organisms respect a: - 5 m vegetative strip with 5 m no spray buffer zone with 90 ~~50~~% drift reducing nozzles (VFSMOD) (early application) Or -unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies. - 5 m vegetative strip with 5 m no spray buffer zone with 90% drift reducing nozzles (VFSMOD) (late application) *Or* - unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 75% drift reducing nozzles to surface water bodies. ~~-unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles~~

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:	
	No PPE required. Due to the product classification, it is reccomended to use protective gloves at the M/L step.
Worker protection:	
	No PPE required (workwear)
Integrated pest management (IPM)/sustainable use:	
	/
Environmental protection	
P501	Dispose of contents/container in accordance with local/regional/national regulation.
SP1	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).

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)

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	PL	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	PL	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.
3	PL	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	
~~**Minor uses according to Article 51**~~													
~~2~~	~~PL~~	~~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~~
~~2 3~~	~~PL~~	~~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~~	

													~~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.~~

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

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

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 an opaque, white, free flowing liquid, with a sweet odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of >400 °C. In aqueous solution, it has a pH value around 5.71 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. 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. Its technical characteristics are acceptable for a suspension concentrate formulation.
The intended concentration of use is 0.03% to 0.4%.

3.2 Efficacy (Part B, Section 3)

This application is for the authorization of the fungicide Observer/Explain, containing 450 g/L Zoxamide in an SC formulation. The product is intended as a fungicide to control *Phytophthora infestans* in potatoes and *Plasmopara viticola* in grapevine.

3.2.1 Efficacy data

Preliminary studies performed on potatoes showed the good potential of zoxamide as a solo treatment against *Phytophthora infestans* at an estimated dose rate in the range between 96 g/ha and 148 g/ha. Subsequently, a preliminary risk assessment was performed which indicated that in order to avoid unwanted restrictions (i.e. <20 vegetative filter strip) the maximum dose rate could not exceed 135 g/ha, therefore this was set as the target rate (0.3 L/ha of GLOB2013F).
The Minimum Effective Dose (MED) rate of 0.3 L/ha was confirmed on potatoes by including a reduced dose rate of 0.18 L/ha (60%) in all submitted trials.
For the use on grapes, GLOB2013F was tested at multiple dose rates: 0.1 L/ha lwa 0.17 L/ha lwa and 0.23 L/ha lwa in all submitted trials. The provided data confirms 0.23 L/ha lwa as the Minimum Effective Dose (MED) rate for the control of *Plasmopara viticola* in grapevine, with better and more consistent levels of control compared to the lower dose rates. Although it should be noted that in many instances effective control could already be reached at a dose rate of 0.17 L/ha lwa.

In summary, it can be concluded that concerning the number of trials, the data provided is considered sufficient to support each major use requested for GLOB2013F.

Potatoes
In 10 **experiments** (consistent with the requirements), analyzed generally, conducted in the **North-East** EPPO climate zone + **CZ**, in 2021- 2022, the tested GLOB2007bF (Observer 0.3l/ha) agent showed an average **effectiveness of 83.5%** against *P. infestans* in potatoes.
This is the average **effectiveness obtained using 1-3 applications,** that were performed "from the moment of disease symptoms onset," (BBCH 21-79). This interpretation of the uses of the tested product was applied.
In these selected experiments, the average occurrence of potato late blight amounted to 15% of the leaf area. The tested agent and reference standards showed an effect at the similar level.
The presented results in dRR (analyzed generally), based on assessment dates only can be considered as a protection program using the tested agent:" from first symptoms" for preventative application to "harvest". The obtained results may allow for the assessment of trends in the protection of potatoes against *P. infestans*.
~~The data presented meet the criteria required for registration of the product in the North-East EPPO climate zone in PL.~~

The data presented from selected trials and the general assessment of all trials in the dRR complement each other and meet the criteria required for product registration in the North- eastern EPPO climate zone, in Poland against *P. infestans* in potatoes.

The presented results of GLOB2013F (Observer 0.3 L/ha) applied in 1-3 applications in potatoes for the control (83.5%-92.52 % efficacy) of *Phytophthora infestans* indicate compliance with the GAP table and with label of the measure tested and Uniform principles. It is justified to claim the registration of GLOB2013F (Observer) for 3 applications in dose 0.3 L/ha for the control of *P. infestans* in potatoes crop in the Poland, North-East EPPO climatic zone. ~~and Maritime EPPO climate zone (CZ, IE, SK).~~

~~Mediterranean~~
~~The dRR presents the results of experiments on the control of *P. infestans* in potatoes in the Mediterranean EPPO climate zone, but in the GAP Table there is no country from this zone listed for registration. Therefore, no interpretation of the test results was presented.~~
~~South-East~~
~~Experiments performed in the South-East EPPO climate zone did not meet the requirements regarding the intensity of *P. infestans*. The first three applications of the tested product were made only as a preventive measure. The lack of plant infection by *P. infestans* did not provide grounds for assessing the effectiveness of the tested agent used in the first three applications. In the dRR Table 3.232-234 too few experiments were also presented (1-5).~~
~~The data provided is not sufficient for GLOB2013F (Observer 0.3 l/ha) registration in the South-East EPPO climate zone (HU,RO, SK).~~

Grapevine
~~The Applicant in dRR presented the effectiveness of the GLOB2013F (Observer 0.3l/ha) agent based on assessment dates only and not application dates. The term of use of GLOB2013F (Observer 0.3 l/ha) and the number of applications were not given. The presented results can be considered as a protection program using the tested agent. The obtained results may allow for the assessment of trends in the protection of grapes against *P. viticola*.~~
~~The decision that it was impossible to draw conclusions on the basis of the data provided in the dRR was made after the analysis of the course of experiments included in the reports.~~
~~The data provided are not sufficient for GLOB2013F (Observer 0.3 l/ha) registration in the North-East, South-East, Maritime (CZ+DE representative for PL, North- East), Mediterranean EPPO climate zone for the control of *Plasmopara viticola* in a grape.~~
~~The GLOB preparation may be introduced in Poland for use in the control of *Plasmopara viticola* in grapes, which has the status of minor crop in accordance with Article 51.~~

In the dRR a total of **7** representative **experiments (2021-2023 seasons)** are presented, the number of these experiments is appropriate. The presented experiments allowed for the evaluation of the effectiveness of the GLOB2013F (Observer) agent used in one or two applications in the vineyard against infection by *P. viticola*.
The average effectiveness of the tested product in **one application** was **92.7%** and was higher than the effectiveness of the reference product Ampexio, which was **87.3%**, with an average level of bunches **infestation** in the untreated control of **10.8%** of the surface.
The efficacy of the product in **two applications** was **94.3%,** which was higher than the efficacy of the Ampexio **reference product**, which was **87.3%,** with an average level of **bunch infestation** in the UTC of **13.6%** of the area.
This is the average **effectiveness obtained using 1-2 applications,** that were performed "from the moment of disease symptoms onset," (BBCH 21-79). This interpretation of the uses of the tested product was applied.
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.
The data provided and the efficacy results obtained are sufficient to register GLOB2013F (Observer) at the 0.23 L/ha 10000m2 tlwa dose, 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) EPPO climate zone for the control of *Plasmopara viticola* in grapevines.
This is consistent with the intended uses in GAP Table, label, and Uniform Principles.
Registration of GLOB2013F (Observer) in Poland is appropriate and justified.

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

In an unrestricted use pattern, the resistance risk is unacceptable. However, if the resistance management strategy is respected, resistance can be kept under control as seen in the yearly reports of the FRAC.

Any fungus population may contain individuals naturally less sensitive to zoxamide. Resistant individuals can dominate the fungus population over time if zoxamide is used repeatedly and exclusively in programs. To delay the onset (and spread) of fungicide resistance it is in the best interest of all those involved in recommending and using these fungicides that they are utilized in such a way that their effectiveness is maintained.

3.2.3 Adverse effects on treated crops

No signs of phytotoxicity were observed in any of the submitted efficacy studies on potatoes.
In accordance with EPPO Guideline 1/135(1) yield amount was assessed in efficacy trials performed on potatoes. Yield quantity and quality was recorded, indicating no negative impact following treatment with GLOB2013F.

No signs of phytotoxicity were observed in any of the submitted efficacy studies on grapevine.
Yield effects were not investigated in the efficacy trials performed on grapes as this is not required according to EPPO Guideline 1/135(1).

3.2.4 Observations on other undesirable or unintended side-effects

The product is considered safe because there are no adverse effects on succeeding crops expected after application of the product. Also any adverse effects on adjacent crops seems to be unlikely.
No specific trials for assessment of beneficial organisms and non-target organisms according to EPPO were submitted, but no negative effects were noted during the course of efficacy trials.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of zoxamide in GLOB2013F were not evaluated as part of the EU review of the active substance. Therefore all relevant data are provided here and are considered adequate. An HPLC-PDA method was submitted to analyze zoxamide in the formulation. The method of analysis of active substance content has been validated in compliance with Document SANCO/3030/99 – rev 5. The acceptance criteria are met for all the validation parameters.

3.3.2 Analytical methods for residues

All analytical methods are active substance data and were provided in the EU review of zoxamide.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

No vertebrate studies were performed. The toxicological classification of GLOB2013F was based on theoretical calculations according to Regulation 1272/2008. GLOB2013F must be classified for skin sensitisation.

3.4.2 Operator exposure

	Result	PPE / Risk mitigation measures
Operators	Acceptable	No PPE (work wear - arms , body and legs covered) Due to the product classification (Skin Sens. 1, H317), it is reccomended to use protective gloves at the M/L step.
Workers	Acceptable	No PPE (work wear - arms , body and legs covered)
Residents	Acceptable	None (potatoes), 5m of buffer zone (grapes)
Bystanders	Acceptable	None (potatoes), 5m of buffer zone (grapes)

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary. 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.

3.4.3 Worker exposure

Please refer to 3.4.2.

3.4.4 Bystander and resident exposure

Please refer to 3.4.2.

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

3.5.1 Residues

For the applied use of GLOB2013F in potatoes and grapes, reference is made to existing studies submitted at EU level as well as new trials. The evaluated GAP is covering the one intended for GLOB2013F.

Compliance with the EU MRLs of zoxamide is met for the intended uses of GLOB2013F.

3.5.2 Consumer exposure

Based on PRIMO rev. 3.1 calculations made to estimate the risk for consumer through diet and other means, it can be concluded that the proposed use of zoxamide in the product GLOB2013F does not lead to an unacceptable risk for consumers.

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

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

The PECs values of zoxamide and relevant metabolites were calculated for the intended uses. These were then used for the ecotoxicological risk assessment.

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

The PECgw assessment was provided for two values of Kfoc: the agreed at the EU level (arithmetic mean) and recalculated geometric mean required in accordance with EFSA, 2014 and both models FOCUS PEARL and FOCUS PELMO.
Only the metabolite RH-141455 is predicted to occur in groundwater at concentrations above 0.1 µg/L (between 0.75 µg/L and 10 µg/L) with max value of 4.652 µg/L. A relevance assessment has therefore been provided.

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

The PECsw assessment was provided for two values of Kfoc: the agreed at the EU level (arithmetic mean) and recalculated geometric mean required in accordance with EFSA, 2014 and modelling.
In accordance with national requirements, the surrogate crop for vines was used.

The PEC values (PEC_{sw} and PEC_{sed}) resulting from the FOCUS STEP 1 to 4 of zoxamide and relevant metabolites were calculated for the intended uses. Mitigation measures were proposed in accordance with Lanscape & Mitigation guidance and using VFSmod. The latter method is accepted in Poland and relevant mitigation were proposed.
These were then used for the ecotoxicological risk assessment.

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

The fate and behaviour in air of zoxamide was evaluated during the EU review of the active substance. No additional studies have been performed.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to birds and mammals from zoxamide and metabolites following application of GLOB2013F at the intended GAP. The TER_{lt} value for zoxamide and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2013F presents no unacceptable long-term risk to birds and mammals when applied according to the proposed GAP.

The risk assessment for secondary poisoning, required for zoxamide and its metabolites, showed that the risk for earthworm-eating and fish-eating birds and mammals is acceptable following use of GLOB2013F according to the proposed use pattern.

Furthermore, the risk assessment for exposure to zoxamide *via* drinking water also showed an acceptable risk.

3.7.2 Effects on aquatic species

An acceptable risk for the formulation GLOB2013F in potato and grape is acceptable with the following mitigation measures:

SPe3: For potato use, to protect aquatic organisms respect an unsprayed buffer zone of 5 m including a 5 m vegetated filter strip to surface water bodies

SPe3: For grape use a 5 m no spray buffer zone including a 5 m vegetated filter strip with 90% ~~50%~~ drift reducing nozzles (early application) (VFSMOD).
or
- For grape use (early application) unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.

SPe3: For grape use a 5 m no spray buffer zone including a 5 m vegetated filter strip with 90% drift reducing nozzles (late application) (VFSMOD).
Or
- For grape use (late application) unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 75% drift reducing nozzles to surface water bodies.

~~- For grape use (late application) unsprayed buffer zone of 10 m including a 10 m vegetated filter strip with 50% drift reducing nozzles to surface water bodies.~~

3.7.3 Effects on bees

The risk for bees is acceptable when using GLOB2013F according to the intended uses. No risk mitigation measures are needed.

3.7.4 Effects on other arthropod species other than bees

The risk for non-target arthropods is acceptable when using GLOB2013F according to the intended uses. No risk mitigation measures are needed.

3.7.5 Effects on soil organisms

The TER values indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2013F.
The EU review for zoxamide and the test on the formulation show that there are no effects on soil microbial activity at dose rates far higher than the corresponding PEC_{soil} of the intended use. Therefore, it is concluded that there is no unacceptable risk on soil microbial activity for GLOB2013F.

3.7.6 Effects on non-target terrestrial plants

First tier risk assessment indicates that there is no unacceptable risk from GLOB2013F for non-target plants when applied according to the proposed use rates.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Tests on other non-target species are not required.

3.8 Relevance of metabolites (Part B, Section 10)

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PEC_{gw}	4.652 µg/L (potato)
			Based on	FOCUS PEARL 5.5.5, Jokioinen
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No fungicidal activity
		Stage 2	Genotoxic properties of metabolite	Unlikely to be genotoxic
		Stage 3	Toxic properties of metabolite;	Less toxic than the parent compound
			Classification of parent	Skin Sens. 1, H317 (CLP)
			Classification of metabolite	Not classified
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Not acceptable (> 0.75 µg/L)
	STEP 5		Refined risk assessment	Acceptable
			Predicted exposure (% of ADI)	0.03% of ADI adult 0.09% of ADI child 0.14% of ADI infant
			ADI based on	ADI parent compound (SANTE/10052/2018 Rev.2, 23 March 2018)

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Uwagi do etykiety:
Fizykochemia – zaakceptowano 2-letni okres trwałości środka.
Toksykologia – dodano zapis „Zawiera 1,2-benzisothiazolin-3-on (CAS 2634-33-5).”, wykreślono zwrot EUH208, dodano zwroty P261 i P333 + P313, dodano zapis „Winnice: W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.”
Pozostałości – w zakresie stosowania na winorośli dodano zapis obecny w tabeli GAP tj.: Winorośl – maksymalnie 2 zabiegi w sezonie.
Los i zachowanie w środowisku – brak uwag do etykiety.
Ekotoksykologia – dodano zwrot P501, wyznaczono strefy ochronne dla organizmów wodnych.
Skuteczność działania – ~~zastosowanie środka w winoroślach (BBCH 53-83) należy uważać jako zastosowanie małoobszarowe.~~ środek zwalcza zarazę ziemniaka i mączniaka rzekomego winorośli.

Zezwolenie MRiRW nr R - z dnia

Posiadacz zezwolenia:
Globachem nv, Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint Truiden, Belgia,
tel.: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

OBSERVER

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:
zoksamid (związek z grupy benzamidów i tiazolo-karboksamidów) – 450 g/l (%)

Zawiera 1,2-benzisothiazolin-3-on (CAS 2634-33-5).

Zezwolenie MRiRW nr R- z dnia

Uwaga	
H317 H410	Może powodować reakcję alergiczną skóry. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P261 P280 P302 + P352	Unikać wdychania rozpylonej cieczy. Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy. W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem.

P333 + P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać zgodnie z regulacjami krajowymi lub lokalnymi.

OPIS DZIAŁANIA

FUNGICYD w postaci koncentratu w formie stężonej zawiesiny do rozcieńczania wodą (SC) o działaniu powierzchniowym do stosowania zapobiegawczego.
Zgodnie z klasyfikacją FRAC substancja czynna zoksamid zaliczana jest do grupy 22 (inhibitory mitozy – inhibitory powstawania mikrotubuli,).

STOSOWANIE ŚRODKA
Środek przeznaczony do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego lub sadowniczego.

Ziemniak
Zaraza ziemniaka
Maksymalna/zalecana dawka dla jednorazowego zastosowania: 0,3 l/ha
Termin stosowania: Środek stosować zapobiegawczo od początku fazy gdy widoczny jest pierwszy pęd boczny, do końca fazy gdy prawie wszystkie jagody w owocostanie osiągnęły typową wielkość lub opadły (BBCH 21-79).
Liczba zabiegów: 3
Odstęp między zabiegami: 7 dni
Zalecana ilość wody: 150-300 l/ha
Zalecane opryskiwanie: drobnokropliste

~~**Stosowanie środka ochrony roślin w uprawach i zastosowaniach małoobszarowych**~~

~~*Odpowiedzialność za skuteczność działania i fitotoksyczność środka ochrony roślin stosowanego w uprawach małoobszarowych ponosi wyłącznie jego użytkownik*~~

~~**Winorośl – maksymalnie 2 zabiegi w sezonie**~~

~~**Winorośl (winnice o powierzchni ściany liści (LWA) do 13 000 m^2)**~~
~~*Mączniak rzekomy winorośli*~~
~~Maksymalna /zalecana dawka dla jednorazowego zastosowania: 0,23 l/10 000 m^2 powierzchni ściany liści (LWA) (maksymalna LWA = 13 000 m^2, co odpowiada dawce środka 0,3 l na 1 ha)~~

~~Termin stosowania: Środek stosować zapobiegawczo od fazy rozwiniętego 3 liścia do fazy rozwoju kwiatostanów (BBCH 13-52).~~
~~Liczba zabiegów: 2~~
~~Odstęp między zabiegami: 8 dni~~
~~Zalecana ilość wody: 100-1000 l/ha~~
~~Zalecane opryskiwanie: drobnokropliste~~

Winorośl (winnice o powierzchni ściany liści (LWA) do 13 000 m^2)
Mączniak rzekomy winorośli
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 0,23 l/10 000 m^2 powierzchni ściany liści (LWA) (maksymalna LWA = 13 000 m^2, co odpowiada dawce środka 0,3 l na 1 ha)

Termin stosowania: Środek stosować zapobiegawczo od fazy rozwiniętego 3 liścia do fazy rozwoju kwiatostanów (BBCH 13-52).
Liczba zabiegów: 2
Odstęp między zabiegami: 8 dni
Zalecana ilość wody: 100-1000 l/ha
Zalecane opryskiwanie: drobnokropliste

Winorośl (winnice o powierzchni ściany liści (LWA) powyżej 13 000 m^2)
~~*Mączniak prawdziwy winorośli*~~
Mączniak rzekomy winorośli
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 0,3 l/10 000 m^2 powierzchni ściany liści (LWA) (maksymalna LWA = 16 000 m^2, co odpowiada dawce środka 0,368 l na 1 ha).

Termin stosowania: Środek stosować zapobiegawczo od początku fazy kwitnienia do fazy wybawiania się jagód (BBCH 53-83).
Liczba zabiegów: 2
Odstęp między zabiegami: co najmniej 8 dni
Zalecana ilość wody: 100-1000 l/ha
Zalecane opryskiwanie: drobnokropliste

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Ziemniak – 7 dni
Winorośl – 28 dni
1. Zabieg wykonywać dokładnie, aby wszystkie części rośliny były pokryte cieczą użytkową.
2. Podczas stosowania środka nie dopuścić do:
− znoszenia cieczy użytkowej na sąsiednie rośliny uprawne,
− nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.
3. Środek zawiera substancję czynną zoksamid z grupy inhibitorów mitozy (grupa FRAC 22).
W ramach strategii antyodpornościowej należy m. in. stosować środek wyłącznie w zalecanej dawce.
Zaleca się również włączenie do przyjętego programu ochrony środków grzybobójczych, zawierających substancje czynne z innych grup chemicznych, o odmiennym mechanizmie działania (stosowanie przemienne).
4. Zalecana dawka środka w ochronie winorośli odniesiona jest do faktycznego obiektu opryskiwania, czyli bocznej powierzchni rzędu nasadzeń, określanej jako „powierzchnia ściany liści" - LWA:

$$\text{Powierzchnia ściany liści [m}^2\text{/ha]} = \frac{2 \text{ x wysokość ściany liści [m]}}{\text{rozstawa rzędów [m]}} \text{ x } 10\,000 \text{ [m}^2\text{/ha]}$$

Obliczenie ilości środka potrzebnego na 1 ha uprawy (kg/ha) w celu sporządzenia cieczy użytkowej:

$$\text{Ilość środka [kg/ha]} = \frac{\text{zalecana dawka środka na opryskiwaną powierzchnię ściany liści [kg/10 000 m}^2\text{] x powierzchnia ściany liści [m}^2\text{/ha]}}{10\,000 \text{ [m}^2\text{/ha]}}$$

NASTĘPSTWO ROŚLIN

Środek nie stwarza zagrożenia dla roślin uprawianych następczo nawet w przypadku wcześniejszej likwidacji uprawy.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać 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 i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:
– jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, 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.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne, odzież ochronną, ochronę oczu oraz ochronę twarzy zabezpieczające przed oddziaływaniem środków ochrony roślin w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.
Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.
Zanieczyszczonej odzieży ochronnej nie wynosić poza miejsce pracy.
Unikać zanieczyszczenia skóry i oczu.
Dokładnie umyć ręce i twarz po użyciu.

Winnice: W czasie oprysku należy zastosować co najmniej 5 m strefę ochronną od zabudowań mieszkalnych/siedlisk oraz osób postronnych.

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.

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.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

Uprawa ziemniaka

W celu ochrony organizmów wodnych konieczne jest wyznaczenie 5 m strefy ochronnej w tym zadarnionej na szerokości 5 m od zbiorników i cieków wodnych.

Zastosowanie wczesne w uprawie winorośli
W celu ochrony organizmów wodnych konieczne jest wyznaczenie 5 m strefy ochronnej w tym zadarnionej na szerokości 5 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% ~~50%~~ od zbiorników i cieków wodnych.

Zastosowanie późne w uprawie winorośli
W celu ochrony organizmów wodnych konieczne jest wyznaczenie 5 m strefy ochronnej w tym zadarnionej na szerokości 5 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% od zbiorników i cieków wodnych.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:
- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C - 30°C
- w dobrze wentylowanym pomieszczeniu.

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.
W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody/ mydłem.
Wskazówki dla lekarza: leczenie symptomatyczne (dekontaminacja, funkcje witalne). Płukanie żołądka.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....

Appendix 3 Lists of data considered for national authorization

List of data submitted by the applicant and relied on

Please refer to the reference list.

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

Please refer to the reference list.