

**FINAL** REGISTRATION REPORT

**Part B**

**Section 3**

**Efficacy Data and Information**

Concise summary

Product code: GLOB2013F

Product names: Observer

Chemical active substance:

Zoxamide, 450 g/L

Southern Zone

Zonal Rapporteur Member State: Poland

**CORE ASSESSMENT**

Applicant: Globachem N.V.

Submission date: January 2024

**MS Finalisation date: 12/11/2025**

## Version history

When	What
January 2024	First submission
April 2024	Dossier sent for evaluation
September 2024	zRMS finalised evaluation
December 2024	zRMS finalised evaluation after commenting period
July 2025	Update to fulfil Polish national requirement.
September 2025	Finalised evaluation
November 2025	zRMS finalised evaluation

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### 3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

#### Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text.
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#### 3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

##### Abstract

This document summarises the zonal evaluation and information related to the efficacy data for the authorization of the plant protection product GLOB2013F (Observer) according to Article 33 of Regulation (EC)No1107/2009 of the European Parliament and of the Council of 21 October 2009. Poland is zonal Rapporteur Member State, concern Member States are Czech Republic, Slovakia, Hungary, Romania, Ireland.

Fungicide GLOB2013F (Observer 0.3l/ha) is a SC formulation containing a.s. zoxamide 450 g/l. It is proposed to be used in potato to control *Phytophthora infestans* as foliar spray in 1-3 applications in vegetation season and against *Plasmopara viticola* in grapes in 1-2 applications.

Efficacy evaluation: The assessed dRR did not present any experience in IE and SK accordance with the intended use for the registration of the GLOB2013F(Observer) product.

The analysis of the original research was the basis and allowed the use of experiments that met the requirements, and which provided the basis for assessing the effectiveness of the tested product with high plant infestation of *Phytophthora infestans*.

In order to support the registration of GLOB2013F (Observer 0.3l/ha) for field uses, plot trials were conducted in the countries belonging to Maritime, South-East and North- East EPPO zone between 2021-2023 to demonstrate the effectiveness of tested product against *P. infestans* in potatoes and against *P. viticola* in grapevine.

Preliminary tests to show the benefit of the of Zoxium preparation, containing solo a.s. zoxamide was done in 4 trials in potato, conducted in North- East and Maritime EPPO climatic zone. The submitted results showed that effectiveness of the agent varied but the dose of 0.4l/ha was optimal of used zoxamide individually. For environmental reasons, this dose should not be higher.

Minimum effective dose: Based on available results the proposed application rate 0.3l/ha of GLOB2013F (Observer) for *P. infestans* control in potato and dose rate 0.23l/10000m<sup>2</sup> at LWA correspond to 0,3l/ha in grapevine against *P.viticola* is justified as minimum effective dose.

Effectiveness on potatoes: To demonstrate efficacy of GLOB2013F (Observer 0.3l/ha) 10 experiments were selected with 1-3 applications to obtain clear effect.

The intended use of GLOB2013F (Observer 0.3l/ha) is 1-3 applications during the growing season to protect potatoes against *P. infestans*. Experiments from each zone were selected to analyse the effectiveness of 1-3 applications. The data of dRR complement the confirmation of the effectiveness of GLOB2013F (Observer 0.3l/ha) in combating *P. infestans* in potatoes.

In 10 experiments 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. 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, 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 the **Maritime** EPPO climatic zone, 4 **relevant experiments in two** vegetation seasons are presented. The tested GLOB2013F (Observer 0.3l/ha) agent applied in 3 applications showed an average **effectiveness of 92.5%** against *P. infestans* in potatoes. The reference standards showed an effect at the similar level. In these experiments, the average occurrence of potato late blight amounted to 23.8% of the leaf area. The presentation of results for 4 selected experiments using 3 applications indicates the high effectiveness of GLOB2013F (Observer 0.3l/ha) and the repeatability of the results.

The **dRR presents** the high effectiveness of the tested agent: “first symptoms” - 89.6% (2exp.), 7-10 “days after” - 90.7% (3exp.), 12-16 “days after” - 82.6 % (4exp.). These data can complement the confirmation of the effectiveness of GLOB2013 (Observer 0.3/ha) in combating *P. infestans* in potatoes. The tested product was active at the lower by a few percent of effectiveness of the standard product Revus 0.6l/ha (95.62%).

The presented data **can be accepted** as the basis for registering the GLOB2013F (Observer 0.3l/ha) agent to control *P. infestans* in 3 application in potatoes **in the Maritime EPPO climatic zone. The data provided is not sufficient for GLOB2013F (Observer 0.3l/ha) registration in the South-East EPPO climate zone (HU, RO, SK). In countries of the EPPO South-East climate zone, the decision to register a product for the control of *P. infestans* in potatoes may be made by the CMS.**

Effectiveness on grapes: Experiments carried out in the 3 climate zones of the EPPO to control *P. viticola* on grapevine have the same deficiencies and inaccuracies.

~~Experiments performed in the South East, Maritime (CZ representative for PL, North East) climate EPPO zone did not meet the requirements regarding the intensity of *P. viticola*. The first two applications of the tested product were made only as a preventive measure. The lack of plant infection by *P. viticola* did not provide grounds for assessing the effectiveness of the tested agent used in the first two applications.~~

The provisions in GAP Table have been changed. The status of grapevines in Poland and Ireland is minor crop. Therefore, the grapevine was entered as a minor crop. The Glob2013F(Observer) preparation may be approved for use in grape cultivation as minor uses, in accordance with Art. 51, without testing.

#### Effectiveness on grapes

##### **North-East, Maritime zones:**

The dRR included three additional experiments conducted in the EPPO Maritime climate zone in CZ and DE, which is **representative of the climate EPPO North-East zone**, as these are countries neighbouring **Poland**. 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.

**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.

##### **South -East zone:**

The dRR presents **6 experiments** conducted in Bulgaria and Hungary (in 2021-2022), which are representative of the EPPO South-East climate zone for HU, RO, SK. The effectiveness of the tested

preparation was presented based on the use of 2 applications in the control of *P. viticola* on grapevine bunches.

GLOB2013F (Observer) performed at an average efficacy of 75.5%, while the reference product, Zoxium, showed a similar efficacy of 76.9%. The average efficacy of the other two reference products was higher, at 90.1% for Enervin and 96.7% for Ampexio. The average *P.viticola* infestation of bunches was moderate at 13.8%

6 trials demonstrating control of infestation of bunches by *P. viticola* obtained after 2 applications of GLOB2013F(Observer), which provides a basis for registration of the product intended to protect grapes. A sufficient number of 6 trials demonstrating 75.5 % control of *P. viticola* infection in grapes after two applications of GLOB2013F (Observer) were presented, providing a basis for registration of the product for grapevine protection in the EPPO South-East (HU, RO, SK) climate zone. However, the registration decision remains at the discretion of the cMS.

The anti-resistance strategy is well presented in the dRR and the label. The use of the tested GLOB2013F (Observer 0.3l/ha) agent had a beneficial effect on potato yield and did not cause any adverse effects on the plants. No negative impact of the use of GLOB2013F(Observer) on grapes and grape processing was observed.

#### Final-Potatoes summary

The presented results of GLOB2013F (Observer 0.3l/ha) applied in 1-3 applications in potatoes for the control of *Phytophthora infestans*: 83.5%-92.52 % efficacy, 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 North-East (PL) and Maritime EPPO climate zone (CZ, IE, SK). In countries of the EPPO South-East climate zone (RO,HU,SK), the decision to register a product for the control of *P. infestans* in potatoes may be made by the cMS.

#### Grape summary

~~The data provided are not sufficient for GLOB2013F (Observer at the 0.23 L/ha-10000m2 tlwa dose rate) registration, in the South-East, Maritime (CZ representative for PL, North-East), Mediterranean EPPO climate zone for the control of *Plasmopara viticola* in grape. This is in accordance with the GAP Table, label, and Uniform Principles.~~

#### Final-Grape summary

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) and the South- East EPPO climate zone in Hungary and Romania) 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.

**Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)**

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

PPP (product name/code): GLOB2013F  
Active substance 1: zoxamide  
Applicant: Globachem NV  
Zone(s): Central  
Verified by MS: ~~yes~~/no

Formulation type: SC (suspension concentrate)  
Conc. of as 1: 450 g/L  
Professional use: ☒  
Non professional use: ☐

Field of use: fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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)	zRMS conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	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	CEU PL	Potatoes	F	Phytophthora infestans PHYTIN	Downward spraying	BBCH 21- 79	a) 3 b) 3	5-7	0.3 L/ha	0.135 kg/ha	150-300	7		A
2	CZ, IE, SK	Potatoes	F PHYTIN	Phytophthora infestans PHYTIN	Downward spraying	BBCH 21- 79	a) 3 b) 3	7	0.3 L/ha  150-300	0.135 kg/ha	150-300	7		C
3	HU, RO, SK	Potatoes	F PHYTIN	Phytophthora infestans PHYTIN	Downward spraying	BBCH 21- 79	a) 3 b) 3	7	0.3 L/ha  150-300	0.135 kg/ha	150-300	7		N C
2 4	CZ, HU, IE, PL, RO, SK, IE, 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		N C CZ, HU, RO, SK, IE  A

3 5	CZ, HU, IE, PL, RO, SK, IE, PL	Table and wine grape (VITVI)	F	<i>Plasmopara viticola</i> (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	Maximum 2 apps per season. 0.23 L/10.000 m <sup>2</sup> LWA corresponding to 0.1035kg a.i./10.000 m <sup>2</sup> LWA. For early BBCH stages (13-52), the maximum rate allowed per ha soil is set at 0.3L/ha soil corresponding to 13000 m <sup>2</sup> LWA. For later stages (BBCH53-83), the maximum rate allowed per ha soil is set at 0.368L/ha soil corresponding to 16000 m <sup>2</sup> LWA.  <b>RO, SK, HU:</b> Range from 0.17 to 0.23 L/10.000 m <sup>2</sup> LWA	PL N C CZ, HU, RO, SK, IE A PL
Minor uses according to Article 51														
6	PL, IE	Table and wine grape (VITVI)	F	<i>Plasmopara viticola</i> (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		Maximum 2 apps per season. 0.23 L/10.000 m <sup>2</sup> LWA corresponding to 0.1035kg a.i./10.000 m <sup>2</sup> LWA. For early BBCH stages (13-52), the maximum rate allowed per ha soil is set at 0.3L/ha soil corresponding to 13000 m <sup>2</sup> LWA. For later stages (BBCH53-83), the maximum rate allowed per ha soil is set at 0.368L/ha soil	A-PL C- IR
6-7	PL, IE	Table and wine grape (VITVI)	F	<i>Plasmopara viticola</i> (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			



													corresponding to 16000 m <sup>3</sup> LWA	
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\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

Commentary on the GAP table:

The provisions in GAP Table have been changed. The status of grapevines in Poland and Ireland is minor crop. Therefore, the grapevine was entered as a minor crop.

The Glob2013F(Observer) preparation may be approved for use in grape cultivation as minor uses, in accordance with Art. 51, without testing.

The GAP table shows the intended uses of the GLOB2013F (Observer) agent according to the cMS belonging to the different EPPO's of the climatic zones.

Countries that do not have experiments that meet the registration requirements are marked in the GAP Table — N — not acceptable.

There is no Mediterranean country in the GAP table that applies to register the GLOB2013F(Observer) measure.

Commenting of Label:

The label should include a change to indicate that the grapes are a minor use crop. Therefore, all formal changes should also be introduced.

Additional comment on the GAP table.

The submission of a supplemented dRR with the required number of trials allows for full registration of the Observer/GLOB2013F product for the protection of grapevines as a major crop in Poland. Based on the trials presented in dRR, cMS can make individual decisions regarding the registration of the Obsever/GLOB2013F product in accordance with the formal requirements in their country.

Label Comments

The label should contain information consistent with the GAP Table, of intended uses.

## 3.2 Efficacy data (KCP 6)

### Introduction

This document summarises the information related to the efficacy of the plant protection product GLOB2013F, containing zoxamide. GLOB2013F is used against late blight (*Phytophthora infestans*) on potatoes and against downy mildew (*Plasmopara viticola*) on grapes.

Poland is the zRMS for the Central administrative Zone in this submission. The Czech Republic, Hungary, Ireland, Romania and Slovakia are considered cMS.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zoxamide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

In this overall assessment there are however no efficacy related concerns.

### Description of the active substance

Zoxamide is a broad-spectrum contact fungicide that affects tubulin polymerization and is used to control various fungal diseases on potatoes, grapes and other fruits and vegetables.

### Mode of action

Zoxamide belongs to the chemical group of the toluamides, which affect tubulin polymerization (B3). It is a contact compound that has protective as well as curative activity against oomycetes.

**-Table 3.2-1: Details of the active substance in GLOB2013F**

Active substance	Zoxamide
Concentration	450 g/L
Chemical group	Toluamides
Mode of action	Contact fungicide (B3)
Biological action	Interference with oomycete nuclear division and microtubule cytoskeleton

### Description of the plant protection product

Information on the detailed composition of GLOB2013F can be found in the confidential dossier of this submission (Registration Report - Part C).

GLOB2013F contains 450 g/L zoxamide, and is formulated as a suspension concentrate (SC). It is used against *Phytophthora infestans* (late blight) on potatoes against *Plasmopara viticola* (downy mildew) on grapes. Its technical characteristics are acceptable for a suspension concentration formulation, no particular problems are expected when GLOB2013F is used as recommended.

More information can be found in Part B1, B2 and B4 of this submission.

The classification proposal for GLOB2013F according to Regulation (EC) 1272/2008 (CLP Regulation) can be found in Part A of this submission.

Comments of zRMS:	The description of the active substances and the tested GLOB2013F (Observer) preparation is complete and appropriate and <b>complies with the Uniform Principles</b> .
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**-Table 3.2-2: Simplified table of requested uses for GLOB2013F**

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Potatoes	Late blight ( <i>Phytophthora infestans</i> )	PL, CZ, HU, IE, RO, SK	0.3 L/ha	1-3 applications 7 day interval 7 day PHI
Grapes	Downy mildew ( <i>Plasmopara viticola</i> )	PL, CZ, IE	0.23 L/ha LWA	1-2 applications 8-10 day interval 28 day PHI
		HU, RO, SK	0.17-0.23 L/ha LWA	

Further details are in the table “All intended uses” in Part B - Section 0.

Comments of zRMS:	Regarding Requested uses Tab.3.22: It should be emphasized that the Applicant requests the application of the GLOB2013F (Observer 0.3l/ha) agent 1-3 times during the growing season to control <i>Phytophthora infestans</i> in potato cultivation at 7-days intervals and 1-2 times at 8-10 days intervals to control <i>Plasmopara viticola</i> in grapes but this was <b>not presented in the research</b> .
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### Description of the target pests

GLOB2013F is used as a fungicide against *Phytophthora infestans* on potatoes and against *Plasmopara viticola* on grapes.

**Table 3.2--1: Glossary of pests mentioned in the dossier.**

EPPO code	Scientific name
PHYTIN	<i>Phytophthora infestans</i>
PLASVI	<i>Plasmopara viticola</i>

Comments of zRMS:	The Applicant did not provide a description of the tested pathogen. <b><i>Phytophthora infestans</i></b> is the pathogen that causes the potato late blight.
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	<p>The description of the controlled disease, which is potato late blight, does not contain some particularly important information. It should be emphasized that this pathogen is characterized by high pathogenicity and can potentially easily produce resistance to the plant protection products used.</p> <p>Protecting potatoes against late blight is difficult due to the ease and speed of its spread. The effectiveness of chemical protection is determined by properly selected dates of chemical treatments.</p> <p><b><i>Plasmopara viticola</i></b> is the pathogen that causes vine downy mildew. Currently, this pathogen is found all over the world, wherever it finds hosts. In conditions of high air humidity, a whitish coating of white powder appears on the lower side of the leaf blade. The young organs of the vine are infected. Infected shoots are shorter and thicker, just like leaves, flowers and fruit buds turn brown, wrinkle and die. The occurrence of the disease greatly reduces the quality and size of the grape yield. Fungicide protection treatments should be carried out just before the development of inflorescences and just before flowering and repeated every 2 weeks.</p> <p><i>Plasmopara viticola</i> can cause large losses in the size and quality of the grape yield.</p>
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**Table 3.2--2: Major / minor status of intended uses (for all cMS and zRMS).**

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Potatoes	PL, CZ, HU, IE, RO, <b>SK</b>	<b>SK</b>	Late blight ( <i>Phytophthora infestans</i> )	PL, CZ, HU, IE, RO, SK	-
Grapes	CZ, HU, RO, SK,	PL, IE	Downy mildew ( <i>Plasmopara viticola</i> )	PL, CZ, HU, IE, RO, SK	

### Compliance with the Uniform Principles

All data submitted in this Biological assessment dossier are in compliance with the Uniform Principles.

Comments of zRMS:	<p>The major status for the crop - potatoes, as well as the status for the pathogen <i>Phytophthora infestans</i> for the zRMS and cMS countries is appropriate. <b>Only in SK potatoes have the status of a minor crop.</b></p> <p>The cultivation status was correctly given - the <b>grapevine is a minor crop in Poland</b> and Ireland, the <b>downy mildew</b> of the grapevine has the <b>major status in presented countries.</b></p> <p><b>The status of crops and pathogens are appropriately presented and are complies with the Uniform Principles.</b></p>
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### Information on trials submitted (3.1 Efficacy data)

The list of individual trials is presented under 3.2.3 Efficacy tests.

In total, 36 efficacy trials are included in this submission to support the use on potatoes, all of which were performed between 2021 and 2023. 13 trials were performed in countries of the Maritime EPPO Zone (Czech Republic, Germany, France, the Netherlands, Sweden, the UK), 11 were performed in the

North-East EPPO Zone (Poland and Latvia), 8 were performed in countries of the Mediterranean EPPO Zone (Italy, Spain, Morocco) and 6 in the South-East EPPO Zone (Hungary and Romania).

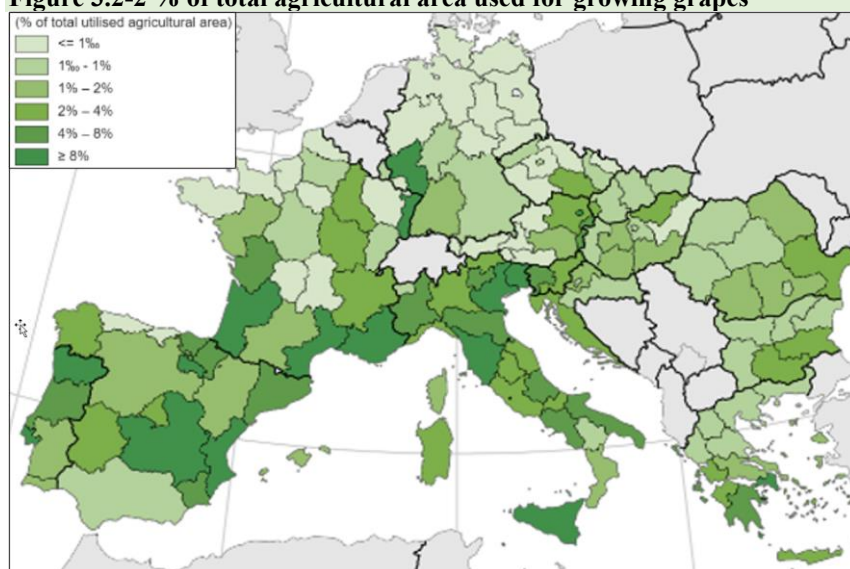
Two confirmatory Moroccan trials (KCP 6.2-117 and 118) were performed in the very North of the country, between the strait of Gibraltar and Rabat (as indicated with the arrow in Figure 1 below). According to EPPO Guideline 1/241(2), this region is also considered the Mediterranean EPPO Zone. However, these trials are presented separately from the rest of the presented data package.

**Figure 1 EPPO Zones according to Guideline 1/241(2)**



The applicant is aware that no trials from the North-East EPPO Zone are submitted to support its registration in Poland, but the crop's minor status makes it difficult to find good trial locations and/or CROs specialized in this crop. According to the data on vineyards in the EU<sup>1</sup> (May 2022), the wine growing area in Poland is below the 500-hectare threshold. The same applies to Belgium, Denmark, Estonia, Ireland, Lithuania, Malta, the Netherlands, Finland, and Sweden. For the remaining EU countries (that have at least 500 hectares of grapes) Figure 3.2-2 provides an overview of the relative growing area used for growing grapes.

**Figure 3.2-2 % of total agricultural area used for growing grapes**



<sup>1</sup> [https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Vineyards\\_in\\_the\\_EU\\_-\\_statistics](https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Vineyards_in_the_EU_-_statistics)

Table 3.2-5 below presents all efficacy trials performed on potatoes.

**Table 3.2-5: Presentation of efficacy trials performed on potatoes**

Crop	Target(s)	Country	Years	Type of trial**	Number of trials per EPPO Zone*				GEP, non-GEP, official***
					MAR	N-E	MED	S-E	
Potatoes	PHYTIN	CZ	2020	P	1				Prelim. trials
		DE	2020	P	1				
		SE	2020	P	1				
		PL	2020	P		1			
		TOTAL			3	1			4
		CZ	2021	E, MED	3				
			2022	E, MED	2				
		DE	2022	E, MED	1				
		FR	2021	E, MED	2				
		NL	2022	E, MED	2				
		SE	2022	E, MED	2				
		UK	2021	E, MED	1				
		PL	2021	E, MED		4			
			2022	E, MED		2			
		LV	2021	E, MED		3			
			2022	E, MED		2			
		IT	2021	E, MED			3		
			2022	E, MED			1		
		ES	2021	E, MED			1		
			2022	E, MED			1		
		HU	2021	E, MED				3	
			2022	E, MED				2	
		RO	2021	E, MED				1	
		MA	2023	E, MED			2		
		TOTAL			13	11	8	6	36

\* MAR: Maritime / N-E: North-East / MED: Mediterranean / S-E: South-East EPPO Zone

\*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

\*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In total, 27 efficacy trials are included in this submission to support the use on grapes, all of which were performed in 2021 and 2022. 11 trials were performed in countries of the Maritime EPPO Zone (Czech Republic, Germany, France), 10 were performed in countries of the Mediterranean EPPO Zone (France, Italy, Spain) and 6 in the South-East EPPO Zone (Bulgaria and Romania).  
Table 3.2-6 below presents all efficacy trials performed on ~~potatoes~~ grapes.

**Table 3.2-6: Presentation of efficacy trials performed on grapes**

Crop	Target(s)	Country	Years	Type of trial**	Number of trials per EPPO Zone*			GEP, non-GEP, official***
					MAR	MED	S-E	
Grapes	PLASVI	CZ	2021	E, MED	1			
			2022	E, MED	3			
		DE	2021	E, MED	1			
			2022	E, MED	2			
		FR	2021	E, MED	1			
			2022	E, MED	3	3		
		ES	2022	E, MED		2		
		IT	2021	E, MED		1		
			2022	E, MED		4		
		BG	2021	E, MED			1	
			2022	E, MED			2	
		HU	2021	E, MED			1	
			2022	E, MED			2	
		<b>TOTAL</b>			<b>11 +3</b>	<b>10</b>	<b>6</b>	<b>27</b>

\* MAR: Maritime / N-E: North-East / MED: Mediterranean / S-E: South-East EPPO Zone

\*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

\*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.



<p>Comments of zRMS:</p>	<p>In the dRR, 4+36 experiments are presented to confirm the effectiveness of the tested agent GLOB2013F (Observer) in controlling <b><i>P. infestans</i> in potatoes.</b></p> <p>Preliminary trials , 2020 - 4 :</p> <p>N-E -PL (1), MAR- SE(1), DE(1), CZ(1) Efficacy trials 2021-2022 3,- MAR – 13- CZ, DE, FR, NL, SE, UK N- E - 11-PL, LV MED - 8 -IT, ES, MA S- E – 6- HU, RO.+ Morocco-2</p> <p>No experiments has been demonstrated in SK and IE, these countries are listed in Table GAP. The applicant presented trials for the Mediterranean EPPO climatic zone, but the GAP table does not include countries from this zone. The additional experiments carried out in Morocco are presented for the Mediterranean EPPO climatic zone. For each zone, the experiments were carried out in two growing seasons.</p> <p>In the presented dRR, 27 experiments are presented to confirm the effectiveness of the tested agent GLOB2013F (Observer) in controlling <i>Plasmopara viticola</i> in <b>grapevines</b>, in two vegetation seasons 2021-2022-<b>2023</b></p> <p>Efficacy trials: MAR- FR(4), DE(3+1 DE), CZ(4 +2) MAR – 13- CZ, DE, FR, NL, SE, UK N- E - 11-PL, LV MED - 8 -IT, ES, MA S- E – 6- HU, BG <del>RO</del></p> <p><b>Ref. to Potatoes</b></p> <p>No experiments has been demonstrated in SK and IE, these countries are listed in Table GAP. The applicant presented trials for the Mediterranean EPPO climatic zone, but the GAP table does not include countries from this zone. The additional experiments carried out in Morocco are presented for the Mediterranean EPPO climatic zone. For each zone, the experiments were carried out in two vegetation seasons. The number of experiments carried out for <i>P. infestans</i> control in potatoes in North-East, Maritime EPPO climate zone is in accordance with the requirements and complies with the Uniform Principles. <b>The number of experiments, localisation and number of test seasons is representative for each climate zone and B-Centre zone for registration of GLOB2013 F(Observer) in potatoes for the control of <i>P.infestans</i>.</b></p> <p><b>Ref. to Grapevine</b></p> <p>In the dRR, 27 experiments are presented to confirm the effectiveness of the tested agent GLOB2013F (Observer) in controlling <i>Plasmopara viticola</i> in grapevine.</p> <p>Efficacy trials , 2021 -2022 : MAR-11, MED -10, S-E- 6.</p> <p>The number of experiments presented for MAR, MED, S-E zones is in accordance with the requirements of EPPO PP1/226(3). However, there is no experiment conducted in the N-E zone. In the GAP table, Poland is listed as the country in which the GLOB2013F(Observer, ) agent is scheduled for registration. The number of experiments carried out in the countries neighbouring Poland is: CZ-3 trials and DE-3 (6) meets requirements .</p> <p><b>The location, number of experiments in two seasons, carried out for <i>Phytophthora infestans</i> control in potatoes in North-East, Maritime, Mediterranean, South-East EPPO climate zone is in accordance with the</b></p>
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	<p><b>requirements and complies with the Uniform Principles.</b></p> <p><b>The location, number of experiments+3 additional trials in two + one (3) seasons, carried out for <i>Plasmopara viticola</i> control in grapevine in Maritime (CZ+DE representative for PL North-East), Mediterranean, South-East EPPO climate zone is in accordance with the requirements and complies with the Uniform Principles.</b></p>
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A list of all reference standards used in the presented trials on potatoes and grapes is given below in Table 3.2-7.-

**Table 3.2--3: Presentation of reference standards used in the efficacy trials**

Crop(s)	Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per trt.)	Comments / Other relevant details on GAPs
					Type	Concentration of a.s.			
Potato	Revus	CZ	4608	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		DE	026221-00	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		DK	1-195	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		ES	25186	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		FR	2080098	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		HU	02.5/2622	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		NL	12969	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		RO	2718/ 25.10.2007	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		SE	4843	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Revus 250 SC	LV	0312	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		PL	R-12/2009	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
		MA	E11-7-039	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Pergado SC	IT	13382	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Revus Top	LV	0453	Mandipropamid Difenoconazole	SC	250 g/L 250 g/L	0.6 L/ha	0.6 L/ha	
	Shirlan	DE	034092-00	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Shirlan Gold	NL	14744	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Frownicide (=Shirlan)	FR	9100636	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Winby (=Shirlan)	PL	R-134/2018	Fluazinam	SC	500 g/L	0.4 L/ha	0.4 L/ha	
	Ranman Top	CZ	4592-0	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		DE	006860-00	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		FR	2110012	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		NL	13467	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
		SE	4995	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	
	Ranman Top 160 SC	PL	R-12/2012 wu	Cyazofamid	SC	160 g/L	0.5 L/ha	0.5 L/ha	

Crop(s)	Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per trt.)	Comments / Other relevant details on GAPs
					Type	Concentration of a.s.			
	Infinito	CZ	4602-2	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		DE	025876-00	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		FR	2090136	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		HU	04.2/3959	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		LV	0302	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		NL	12927	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		SE	5072	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		UK	16335	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
	Infinito 687.5 SC	PL	R-37/2011	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
	Volare	ES	25351	Fluopicolid Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		IT	13592	Fluopicolide Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
		MA	E07-9-018	Fluopicolide Propamocarb	SC	62.5 g/L 625 g/L	1.6 L/ha	1.6 L/ha	
Grape	Enervin SC	BL	11-1337	Ametoctradin	SC	200 g/L	1.5 L/ha	1.5 L/ha	
		CZ	5561-0	Ametoctradin	SC	200 g/L	0.9-1.5 L/ha	0.9-1.5 L/ha	
		DE	008966-00	Ametoctradin	SC	200 g/L	0.6-2.4 L/ha	0.6-2.4 L/ha	
		ES	00524	Ametoctradin	SC	200 g/L	1.5 L/ha	1.5 L/ha	
		IT	015264	Ametoctradin	SC	200 g/L	1.5 L/ha	1.5 L/ha	
	Enervin Active	FR	2140270	Ametoctradin	SC	200 g/L	1.5 L/ha	1.5 L/ha	
	Enervin 560 WG	HU	04.2/2237-1/2011	Ametoctradin Metiram	WG	120 g/kg 440 g/kg	2.5 kg/ha	2.5 kg/ha	
	Zoxium 240 SC	IT	14062	Zoxamide	SC	240 g/L	0.625-0.75 L/ha	0.75 L/ha	
	Ampexio	DE	008314-00	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.16-0.48 kg/ha	0.5 kg/ha	
		FR	2171119	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.5 kg/ha	0.5 kg/ha	
		CZ	36751	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.25-0.5 kg/ha	0.25-0.5 kg/ha	
		DE	008314-00	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.16-0.48 kg/ha	0.16-0.48 kg/ha	

Crop(s)	Reference standard	Countries where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per trt.)	Comments / Other relevant details on GAPs
					Type	Concentration of a.s.			
							kg/ha		
		BL	01522	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.5 kg/ha	0.5 kg/ha	
		HU	04.2/3466-1/2018	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.5 kg/ha	0.5 kg/ha	
		ES	00288	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.5 kg/ha	0.5 kg/ha	
		IT	016288	Mandipropamid Zoxamide	WG	250 g/kg 240 g/kg	0.5 kg/ha	0.5 kg/ha	

Reference standards were appropriately selected to compare the performance of the tested agent GLOB2013F (Observer) in controlling *P.infestans* in potato crops and **complies with the Uniform Principles**.

Comments zRMS:	of	Reference standards were appropriately selected to compare the performance of the tested agent GLOB2013F (Observer) in controlling <i>Pytophthora infestans</i> in potato crops and in controlling <i>Plasmopara viticola</i> in grapevine and this is <b>complying with the Uniform Principles</b> .
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### 3.2.1 Preliminary tests (KCP 6.1) – use on potatoes

To test the potential of zoxamide as a solo product for the use on potatoes against *Phytophthora infestans*, Zoxium 240 SC (240 g/L zoxamide, Gowan) was tested, applied at multiple dose rates. This product is registered for use on potatoes in Italy at a dose range from 0.625-0.75 L/ha (150-180 g/ha zoxamide).

The preliminary trial program consisted of 3 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany and Sweden) and 1 trial performed in the North-East EPPO Zone (Poland).

All preliminary tests were performed by GEP certified research institutes in accordance with EPPO Guidelines. Detailed information on these trials is included in the tables describing the regular efficacy trials under section 3.2.3.1.

For individual trial data reference is made to Appendix 3 of the Biological Assessment Dossier – Preliminary trial data.

Pest severity (PESSEV) was assessed multiple times throughout the season. In all trials applications started preventatively, but because of specific weather conditions there was a lot of variation in the time between the start of the applications and the first observation of the disease in the different trials. To demonstrate the impact of the tested treatments on disease development, all assessment data was grouped according to the number of days since the disease was first observed in each trial as follows:

- First symptoms (0 days, first symptoms)
- 1 week after symptoms (7-10 days after first symptoms)
- 2 weeks after symptoms (14 days after first symptoms)
- 3 weeks after symptoms (15-21 days after first symptoms)
- 4 weeks after symptoms (22-28 days after first symptoms)
- 5 weeks after symptoms (31-35 days after first symptoms)
- 6 weeks after symptoms (39-42 days after first symptoms)
- 7 weeks after symptoms (44-49 days after first symptoms)
- 8 weeks after symptoms (55-56 days after first symptoms)

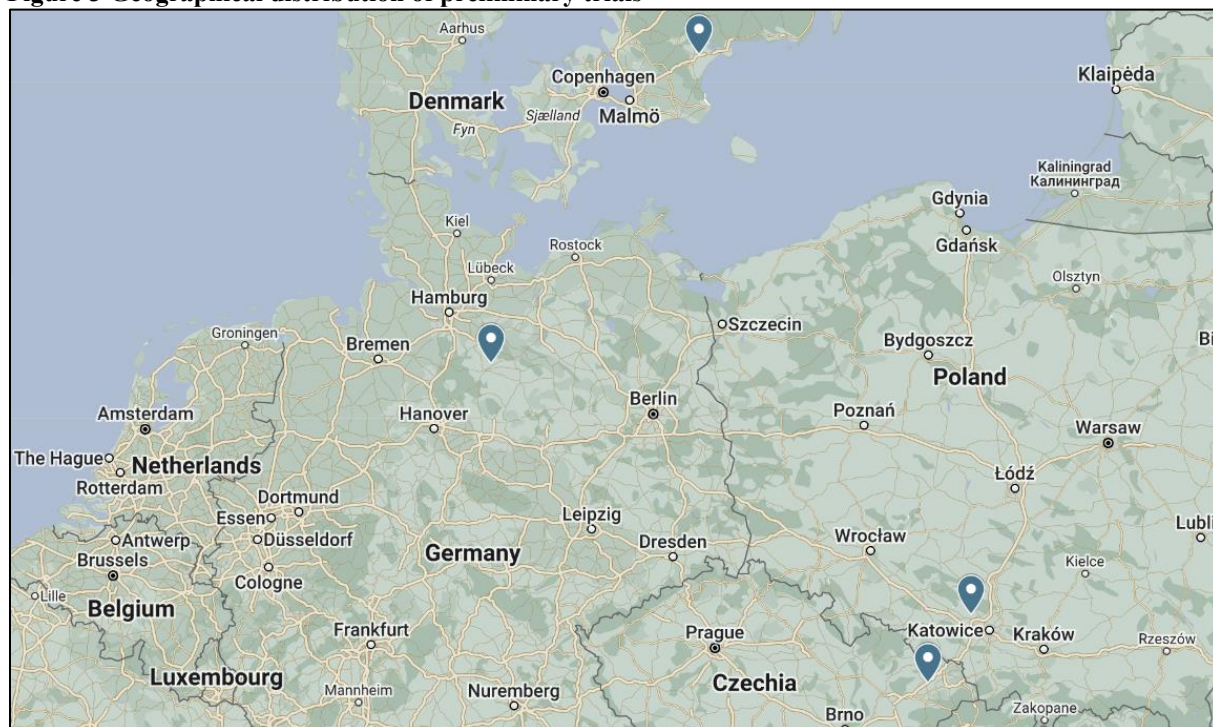
In case the pest severity/incidence was below 5% for the untreated control, the efficacy results for that assessment are **marked in grey** and are not taken into account for any of the summaries.

The Area Under the Disease Progress Curve (AUDPC) is a summarizing value for the efficacy of the treatments across the season. Therefore all AUDPC data is presented together for all trials.

The geographical distribution of the preliminary trials is shown in Figure 3 below.

Because of the limited spread of the trials the applicant ought it acceptable to summarize all gathered data together to be able to draw stronger conclusions, as opposed to splitting the data set according to the EPPO Zone they are performed in.

**Figure 3 Geographical distribution of preliminary trials**



The table below summarizes the efficacy data found in Appendix 3 of the Biological Assessment Dossier – Preliminary trial data.

**Table 3.2–4 Summary of preliminary efficacy trials against *Phytophthora infestans* performed with Zoxium 240 SC**

Number of trials	Number of days after first symptoms	Infestation of the untreated control (unit)		% control					
				Zoxium 240 SC 0.4 L/ha		Zoxium 240 SC 0.62 L/ha		Zoxium 240 SC 0.75 L/ha	
		Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.
2	first symptoms	8.3	8.3 - 8.3	76.2	70.7 - 81.7	83.4	70.7 - 96	85.8	75.5 - 96.0
2	7-10 days	40.8	23.3 - 58.3	70	65.6 - 74.4	80.6	75.6 - 85.6	81.4	80.6 - 82.2
3	15-21 days	54.2	13.3 - 92.5	65	37.3 - 82.3	73	59.5 - 84.0	79.1	63.7 - 92.2
3	22-28 days	77.8	65.0 - 88.3	74.6	69.6 - 79.2	78.1	66.3 - 96.9	80.6	79.9 - 81.2
3	31-35 days	97.8	96.0 - 99.2	42.2	4.2 - 78	55	35.8 - 88.2	57.1	41.0 - 89.2
2	39-42 days	99.5	99.0 - 100	11.9	3.3 - 20.4	18.1	12.5 - 23.6	24.1	12.5 - 35.7
2	44-49 days	100	100 - 100	39.6	0.8 - 78.3	46	4.2 - 87.7	46.3	4.2 - 88.3
2	55-56 days	100	100 - 100	36.7	0.0 - 73.3	42.7	0.0 - 85.3	44.6	0.8 - 88.3
4	whole season	2726.8	1553.9 - 4662.5	54.3	19.6 - 77.8	60.4	37.5 - 89.2	65	38.2 - 87.4

## Conclusion

The results obtained in the preliminary studies demonstrate the good potential of zoxamide as a solo treatment. Very good levels of control were reached at 0.62 L/ha of Zoxium 240 SC (148.8 g/ha zoxamide), but the results obtained with 0.4 L/ha Zoxium 240 SC (96 g/ha zoxamide) seem to indicate the optimal dose rate lies somewhere in between these two rates (96-148.8 g/ha zoxamide).

<p>Comments of zRMS:</p>	<p>The <b>Preliminary trials</b> based on the use Zoxium 240 SC (240 g/L) of the active substance zoxamide, was tested, applied at multiple dose rates. Preliminary studies using a product based on one a.s. zoxamide indicated its effects which can be used in a wider practice of plant production.</p> <p>The active substance has been used as fungicide in potatoes in commercial practice for many years, but only in combination with other active substances. The preliminary trial program consisted of 3 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany and Sweden) and 1 trial performed in the North-East EPPO Zone (Poland). Quite a different level of effectiveness of the tested agent in dose 0.4l/ha was obtained in controlling <i>Phytophthora infestans</i> in potatoes in the range 11.0 % efficacy- assessment 39-45 days after first symptoms to 76.2% after first symptoms.</p> <p>From the submitted trials it is possible to conclude that the preparation Zoxium 240 SC used in a dose 0.4l/ha has a moderate control level of <i>P. infestans</i> in potatoes. For environmental reasons, this dose should not be higher.</p> <p><b>Zoxium 0.4 l/ha gave the moderate effectiveness in controlling <i>P. infestans</i> in potato, but this preparation may find a good place in the policy of using IPM.</b></p>
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### 3.2.2 Minimum effective dose (MED) tests (KCP 6.2)

#### 3.2.2.1 Use on potatoes

Based on the preliminary data presented in section 3.2.1, the applicant estimated the ideal dose rate of zoxamide against *Phytophthora infestans* to lie somewhere in the range of 96-148.8 g/ha of zoxamide. Subsequently a preliminary risk assessment was performed by the applicant, which indicated that in order to avoid additional restrictions (i.e. 20 meter vegetative filter strip), the dose rate could not exceed 135 g/ha. Therefore the target dose rate of GLOB2013F (450 g/L zoxamide) was set to 0.3 L/ha.

In all trials presented in this dossier, a reduced dose rate of 0.18 L/ha GLOB2013F (60% of target rate) was included to confirm 0.3 L/ha as the minimum effective dose against *Phytophthora infestans* on potatoes. These trials were performed in the Maritime EPPO Zone, the North-East EPPO Zone, the Mediterranean EPPO Zone and the South-East EPPO Zone (Hungary). For a complete list of countries reference is made to **Błąd! Nie można odnaleźć źródła odwołania..**

It should be noted that the two Moroccan trials (KCP 6.2-117 and 118) which are considered part of the Mediterranean EPPO Zone package, were not included in the demonstration of the minimum effective dose.

Sites and application details of these trials are presented in the tables under 3.2.3.1.

For individual trial data reference is made to Appendix 4 of the Biological Assessment Dossier – Efficacy data on potatoes

For more information on the presentation of the results in Appendix 4 of the Biological Assessment Dossier reference is made to section 3.2.3.1.

First, the minimum effective dose is demonstrated for all trials presented in this dossier, this demonstrates the minimum effective dose across a wide variety of conditions. Next it is demonstrated for each EPPO Zone separately.



**Table 3.2--5 Minimum effective dose of GLOB2013F against PHYTIN across all EPPO Zones**

Rating type	Part rated	Timing	n	Untreated control		% control GLOB2013F										
						0.18 L/ha					0.3 L/ha					
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	30	1167.5	34.4	3698.5	56.5	19.5	98.5	53.0	21.4	67.2	21.9	98.3	66.5	23.1
PESINC	TUBER	harvest	9	9.9	5.0	16.0	62.7	27.1	100.0	58.8	23.7	75.4	25.0	100.0	79.1	24.8
PESSEV	LEAF	first symptoms	6	12.9	5.3	25.0	68.2	45.0	100.0	63.8	19.5	68.2	47.0	100.0	67.6	20.2
PESSEV	LEAF	5-10 days after symptoms	13	21.1	5.0	82.5	64.4	40.0	96.6	62.2	18.4	76.8	48.2	100.0	73.8	19.3
PESSEV	LEAF	12-16 days after symptoms	16	26.5	5.0	100.0	68.4	27.5	100.0	70.7	23.6	72.4	19.7	100.0	80.1	26.3
PESSEV	LEAF	17-21 days after symptoms	22	31.3	5.0	98.8	62.3	25.2	100.0	57.4	22.5	71.0	32.5	100.0	71.2	23.4
PESSEV	LEAF	23-28 days after symptoms	21	43.8	6.5	100.0	54.6	8.2	100.0	50.0	27.6	62.0	18.8	100.0	47.9	27.5
PESSEV	LEAF	29-36 days after symptoms	19	49.0	9.2	100.0	60.8	0.0	97.8	66.7	26.2	70.5	0.0	100.0	83.3	27.3
PESSEV	LEAF	37-45 days after symptoms	17	45.1	12.4	100.0	44.5	0.0	95.9	42.3	25.8	55.7	0.0	98.8	50.5	27.8
PESSEV	LEAF	46-52 days after symptoms	8	48.0	9.5	100.0	55.0	0.0	98.9	66.3	31.3	66.1	1.3	97.2	71.3	30.0

**Table 3.2--6 Minimum effective dose of GLOB2013F against PHYTIN in the Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control		% control GLOB2013F										
						0.18 L/ha					0.3 L/ha					
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	11	1093.8	104.4	3422.5	68.5	23.6	98.5	68.1	24.9	75.0	31.7	98.3	88.0	23.5
PESINC	TUBER	harvest	3	11.4	9.0	16.0	61.3	44.4	85.2	54.2	21.3	72.2	25.0	100.0	91.5	41.1
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	90.4	80.8	100.0	90.4	13.6	89.6	79.2	100.0	89.6	14.7
PESSEV	LEAF	7-10 days after symptoms	3	51.8	8.0	82.5	67.7	44.3	96.6	62.2	26.6	75.0	52.9	98.4	73.8	22.8
PESSEV	LEAF	12-16 days after symptoms	5	43.3	5.0	100.0	80.3	27.5	99.0	95.0	30.0	86.1	45.0	100.0	96.1	23.3
PESSEV	LEAF	17-21 days after symptoms	6	36.5	5.0	98.8	76.4	32.5	100.0	87.8	28.1	79.9	32.5	100.0	95.8	29.0
PESSEV	LEAF	23-28 days after symptoms	8	41.9	6.5	100.0	62.0	8.8	100.0	65.8	35.5	66.5	18.8	100.0	68.5	33.3
PESSEV	LEAF	29-35 days after symptoms	7	52.8	9.2	100.0	70.1	0.0	97.8	82.5	35.3	74.4	0.0	100.0	89.2	36.6
PESSEV	LEAF	37-45 days after symptoms	5	50.7	13.3	100.0	50.4	0.0	95.9	42.3	38.3	57.9	0.0	98.8	56.3	40.8
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	78.9	66.2	98.9	71.7	17.5	87.7	77.5	97.2	88.5	9.9

**Table 3.2--7 Minimum effective dose of GLOB2013F against PHYTIN in the North-East EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control		% control GLOB2013F										
						0.18 L/ha					0.3 L/ha					
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	10	1567.1	383.9	3698.5	45.9	19.5	73.7	40.6	17.4	57.7	21.9	84.3	55.9	20.1
PESINC	TUBER	harvest	3	9.5	5.0	15.0	58.7	40.4	76.9	58.8	18.3	73.2	50.4	90.0	79.1	20.5
PESSEV	LEAF	first symptoms	2	9.6	5.3	13.8	60.5	55.8	65.2	60.5	6.6	55.6	47.0	64.2	55.6	12.2
PESSEV	LEAF	5-10 days after symptoms	5	12.4	6.4	17.5	66.4	49.2	93.3	64.8	17.0	78.8	48.2	98.8	90.3	22.3
PESSEV	LEAF	12-14 days after symptoms	4	19.1	10.0	30.0	61.3	50.0	86.1	54.5	16.8	70.3	50.0	95.0	68.2	20.7
PESSEV	LEAF	17-21 days after symptoms	8	21.7	5.6	48.8	57.5	40.0	75.9	57.4	11.4	65.2	45.0	91.9	63.6	17.5
PESSEV	LEAF	23-28 days after symptoms	7	36.3	11.6	80.0	49.3	31.4	75.4	54.7	17.1	53.8	33.8	80.4	45.9	18.7
PESSEV	LEAF	29-35 days after symptoms	9	37.8	10.3	100.0	55.1	20.5	80.7	55.0	20.3	63.6	34.6	87.7	68.1	22.7
PESSEV	LEAF	38-42 days after symptoms	9	41.3	16.6	100.0	45.6	17.5	79.9	46.1	20.6	59.5	30.0	85.3	50.5	21.7
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	40.7	0.0	70.0	44.5	29.6	53.1	1.3	85.1	57.5	31.2

**Table 3.2--8 Minimum effective dose of GLOB2013F against PHYTIN in the Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F									
							0.18 L/ha					0.3 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	694.5	34.4	2753.9	55.2	41.2	66.6	57.2	11.2	65.1	28.8	92.5	72.0	27.8
PESINC	TUBER	harvest	2	10.3	5.0	15.5	88.7	77.3	100.0	88.7	16.1	87.8	75.6	100.0	87.8	17.3
PESSEV	LEAF	first symptoms	1	7.5	7.5	7.5	62.3	62.3	62.3	62.3	-	71.0	71.0	71.0	71.0	-
PESSEV	LEAF	7-10 days after symptoms	2	14.7	5.0	24.3	62.5	60.0	65.0	62.5	3.5	80.9	71.7	90.0	80.9	12.9
PESSEV	LEAF	13-13 days after symptoms	3	19.4	5.8	43.8	61.0	41.5	71.2	70.2	16.9	49.3	19.7	80.7	47.6	30.5
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	51.0	25.2	78.3	50.3	22.2	62.4	38.1	85.0	63.2	25.9
PESSEV	LEAF	25-28 days after symptoms	3	40.8	7.2	91.3	55.5	41.8	78.6	46.2	20.1	53.9	34.2	86.5	40.9	28.5
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	61.3	61.3	61.3	61.3	-	68.8	68.8	68.8	68.8	-
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	21.5	15.0	27.9	21.5	9.1	29.0	17.5	40.5	29.0	16.3

**Table 3.2--9 Minimum effective dose of GLOB2013F against PHYTIN in the South-East EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F									
							0.18 L/ha					0.3 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	4	962.1	290.5	1652.5	51.3	35.0	77.4	46.3	18.7	72.0	51.8	96.0	70.0	22.7
PESINC	TUBER	harvest	1	6.0	6.0	6.0	27.1	27.1	27.1	27.1	-	66.7	66.7	66.7	66.7	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	45.0	45.0	45.0	45.0	-	47.5	47.5	47.5	47.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	59.1	40.0	88.3	48.9	25.7	72.4	57.2	100.0	60.0	23.9
PESSEV	LEAF	14-15 days after symptoms	4	18.5	5.0	42.5	66.1	41.0	100.0	61.8	27.4	74.5	46.9	100.0	75.6	28.6
PESSEV	LEAF	21-21 days after symptoms	3	48.9	10.5	80.0	69.9	43.8	100.0	66.0	28.3	86.9	62.5	100.0	98.2	21.2
PESSEV	LEAF	28-28 days after symptoms	3	69.3	17.5	98.0	45.9	8.2	85.0	44.5	38.4	77.0	38.8	97.1	95.2	33.1
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	53.3	36.7	69.8	53.3	23.4	88.6	83.3	93.8	88.6	7.4
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	51.7	51.7	51.7	51.7	-	63.8	63.8	63.8	63.8	-

## Summary

The data presented above clearly demonstrates the benefit of using GLOB2013F at the requested dose rate of 0.3 L/ha, with higher and most consistent levels of control of *Phytophthora* infestans compared to the 0.18 L/ha (60%) dose rate. This is most obvious when comparing the AUDPC (Area Under the Disease Pressure Curve) values for both dose rates, which summarize the observed pest severity on leaves during the season. On average the 0.3 L/ha dose rate provides about 10% better control of the disease.

### 3.2.2.2 Use on grapes

In the trials presented in this dossier, GLOB2013F was tested at multiple dose rates for the efficacy against *Plasmopara viticola* on grapes; 0.1 L/ha lwa, 0.17 L/ha lwa and 0.23 L/ha lwa.

These trials were performed in the Maritime EPPO Zone, the Mediterranean EPPO Zone and the South-East EPPO Zone. For a complete list of countries reference is made to **Błąd! Nie można odnaleźć źródła odwołania..**

Sites and application details of all trials are presented in the tables under 3.2.3.2.

For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Efficacy data on grapes.

For more information on the presentation of the results in Appendix 5 of the Biological Assessment Dossier reference is made to section 3.2.3.2.

First, the minimum effective dose is demonstrated for all trials presented in this dossier, this demonstrates the minimum effective dose across a wide variety of conditions. Next it is demonstrated for each EPPO Zone separately.

**Table 3.2--10 Minimum effective dose of GLOB2013F against PLASVI across all EPPO Zones**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F														
							0.1 L/ha lwa					0.17 L/ha lwa					0.23 L/ha lwa				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	16	18.8	5.4	36.7	73.1	29.7	93.6	77.5	17.8	80.8	58.6	97.9	84.8	13.8	84.8	61.9	98.8	88.3	13.0
PESINC	LEAF	BBCH 75 - 85	19	51.6	6.3	100.0	58.2	21.2	79.6	63.0	17.8	68.9	23.3	100.0	70.3	21.5	73.9	30.8	100.0	72.7	20.3
PESSEV	BUNCH	BBCH 79 - 85	15	20.1	3.4	87.6	71.5	29.3	98.7	77.8	22.8	79.9	32.8	99.1	85.9	18.7	84.2	43.1	99.4	88.1	15.5
PESINC	BUNCH	BBCH 78 - 85	20	43.2	5.0	100.0	57.0	0.0	87.8	66.6	24.7	69.5	19.3	100.0	75.6	25.2	74.1	24.0	100.0	80.7	24.5

**Table 3.2--11 Minimum effective dose of GLOB2013F against PLASVI in the Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F														
							0.1 L/ha lwa					0.17 L/ha lwa					0.23 L/ha lwa				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 79 - 85	3	23.5	5.4	35.9	88.4	80.5	93.0	91.7	6.9	95.5	94.2	97.9	94.5	2.1	97.9	97.0	98.8	97.9	0.9
PESINC	LEAF	BBCH 79 - 85	6	34.5	6.3	74.5	72.5	63.2	77.7	73.1	5.3	91.5	73.1	100.0	94.3	10.8	93.8	81.7	100.0	95.2	7.0
PESSEV	BUNCH	BBCH 79 - 83	2	31.9	30.9	32.8	97.3	95.9	98.7	97.3	2.0	98.4	97.7	99.1	98.4	1.0	98.2	97.0	99.4	98.2	1.7
PESINC	BUNCH	BBCH 79 - 85	7	84.9	21.2	100.0	66.2	13.5	87.8	68.1	24.9	84.3	33.0	100.0	90.3	23.3	87.3	28.2	100.0	100.0	26.4

**Table 3.2--12 Minimum effective dose of GLOB2013F against PLASVI in the Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F														
							0.1 L/ha lwa					0.17 L/ha lwa					0.23 L/ha lwa				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	8	19.3	6.7	36.7	64.7	29.7	93.6	63.0	20.6	76.2	60.2	96.4	74.3	14.4	79.3	61.9	98.3	79.0	14.5
PESINC	LEAF	BBCH 75 - 85	8	59.9	41.5	100.0	44.2	21.2	79.6	40.6	18.7	55.3	23.3	85.9	57.2	18.9	59.7	30.8	89.2	63.3	19.9
PESSEV	BUNCH	BBCH 79 - 85	8	21.1	3.4	87.6	65.6	40.8	96.1	57.0	21.3	77.5	62.7	96.9	73.3	13.9	82.7	67.6	96.7	83.7	10.7
PESINC	BUNCH	BBCH 78 - 85	8	53.4	22.5	100.0	48.9	0.0	77.4	56.0	27.0	58.7	19.3	87.9	66.5	27.1	65.2	24.0	86.9	71.4	21.9

**Table 3.2--13 Minimum effective dose of GLOB2013F against PLASVI in the South-East EPPO Zone**

Rating type	Part rated	Timing	n	Untreated control			% control GLOB2013F														
							0.1 L/ha lwa					0.17 L/ha lwa					0.23 L/ha lwa				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 81 - 83	5	15.1	8.9	31.3	77.4	65.6	86.2	78.4	8.6	79.2	58.6	87.3	84.2	11.8	85.8	71.4	93.1	87.6	8.5
PESINC	LEAF	BBCH 81 - 83	5	58.7	50.5	77.3	63.3	56.5	74.7	63.0	7.5	63.6	45.3	71.8	70.3	11.4	72.8	58.4	83.6	72.4	9.8
PESSEV	BUNCH	BBCH 81 - 83	5	13.9	4.5	40.4	70.6	29.3	94.6	77.8	25.0	76.5	32.8	95.4	87.1	26.1	81.1	43.1	99.2	91.3	23.0
PESINC	BUNCH	BBCH 81 - 83	5	50.3	27.0	81.0	57.2	34.8	78.3	63.2	20.6	66.0	45.4	84.0	75.0	17.3	69.8	45.5	93.9	79.2	21.7

## Summary

For the assessment data presented above it should be noted that assessments of pest severity (PESSEV) provide the best indication of effective disease control, because pest incidence (PESINC) is merely the percentage of infested leaves/bunches; it does not take into account the severity of the infestation. The data presented above clearly demonstrates the benefit of using GLOB2013F at the requested dose rate of 0.23 L/ha lwa, with higher and most consistent levels of control of *Plasmopara viticola* compared to the 0.1 and 0.17 L/ha lwa dose rates.

Comments of zRMS:	<p>The results obtained in experiments presented in dRR indicate that the GLOB2013F (Observer) dose of 0.3l/ha is the appropriate minimum dose for controlling <b><i>P. infestans</i> in potatoes</b>. The preliminary risk assessment was performed by the applicant, which indicated that in order to avoid additional restrictions (i.e. 20-meter vegetative filter strip), the dose rate could not exceed 135 g/ha. Therefore, the target dose rate of GLOB2013F (450 g/L zoxamide) was set to 0.3 L/ha.</p> <p>In all trials presented in this dossier, a reduced dose rate of 0.18 L/ha GLOB2013F (60% of target rate) was included to confirm 0.3 L/ha as the minimum effective dose against <b><i>Phytophthora infestans</i></b> on potatoes. The tested preparation GLOB2013F (Observer) at a dose of 0.3 l/ha showed clearly better effectiveness than when used at a dose of 0.18 l/ha. These trials (36) were performed in the Maritime EPPO Zone, the North-East, the Mediterranean and the South-East EPPO climatic zone.</p> <p>Overall field trials (27) to control <b><i>Plasmopara viticola</i></b> on grapevine were carried across 3 EPPO climatic zones: Maritime, Mediterranean and the South-East EPPO zone.</p> <p>The data presented in dRR clearly demonstrates the benefit of using GLOB2013F at the requested dose rate of <b>0.23L/ha Lwa</b> (0.23 L/ha10000m2Lwa), with higher and most consistent levels of control of <b><i>Plasmopara viticola</i></b> compared to the 0.1 and 0.17 L/ha lwa dose rates.</p>
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	<p>The proposed application rate of 0.3 l/ha of GLOB2013F (Observer) for potato protection against <i>Phytophthora infestans</i> and against <i>Plasmopara viticola</i> on grapevine at the requested dose rate of 0.23 L/ha10000m2 lwa (correspond to 0.3L/ha) in the field is justified as minimum effective dose.</p>
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### 3.2.3 Efficacy tests (KCP 6.2)

#### 3.2.3.1 Use on potatoes

GLOB2013F is used on potatoes for the control of a late blight (*Phytophthora infestans*) at a dose rate of 0.3 L/ha.

The trials presented in this dossier were conducted by contractor companies and official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Trials were conducted across a wide range of sites. The trials are therefore representative of a wide range of environmental conditions likely to be encountered in practice in the area of proposed use.

It should be noted that all trials performed for this project are included in this submission, this includes trials performed in the Maritime, North-East, Mediterranean and South-East EPPO Zone (ref. **Błąd! Nie można odnaleźć źródła odwołania.**). The applicant is aware that not all submitted data is accepted by the countries where registration is requested, however data from other EPPO Zones can be considered confirmatory data that demonstrates the performance of GLOB2013F under a wide range of climatic and edaphic conditions.

The trials package of GLOB2013F includes 13 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany, France, the Netherlands, Sweden and the UK), 11 trials performed in the North-East EPPO Zone (Poland and Latvia), 6 trials performed in the Mediterranean EPPO Zone (Italy and Spain) and 6 trials performed in the South-East EPPO Zone (Hungary and Romania). All trials were performed in 2021 and 2022.

It is important to note that more than the requested number of applications were performed in the submitted trials, applications were continued at a 5-10 day interval until harvest. Assessments were made before every new application to assess the efficacy of each application.

In Table 3.2-14 the trial methodology used in the trials is shown.

**Table 3.2-14: Details on trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)
	Specific guidelines	EPPO PP 1/2 (4)
<b>Experimental design</b>	Plot design	RCBD
	Plot size	18-30 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop (varieties)	<b>All submitted data:</b> 36 trials (27 varieties) <b>Maritime EPPO Zone</b> 13 trials (12 varieties) <b>North-East EPPO Zone</b> 11 trials (7 varieties) <b>Mediterranean EPPO Zone:</b> 6 trials (5 varieties) <b>South-East EPPO Zone:</b> 6 trials (5 varieties)
<b>Application</b>	Crop stage at first application	BBCH 13-70
	Pest stage at first application	First application was preventative or at the latest at the start of the disease.
	First application-Final application	<b>Maritime EPPO Zone</b> June 13 <sup>th</sup> – September 20 <sup>th</sup> <b>North-East EPPO Zone</b> June 14 <sup>th</sup> – September 22 <sup>nd</sup> <b>Mediterranean EPPO Zone</b> March 29 <sup>th</sup> – November 20 <sup>th</sup> <b>South-East EPPO Zone</b> June 17 <sup>th</sup> – October 14 <sup>th</sup>
	Application interval	Applications were continued at 5-10 day interval until one week before harvest
	Spray volumes	150-300 L/ha
<b>Assessment</b>	Assessment types	Pest severity: from start of trial Phytotoxicity; from 7 DA-A Yield: total weight, weight per class, total number of tubers, number of tubers per class, starch concentration Pest incidence on tubers after 4-8 weeks in storage
	e.g. Field / Greenhouse...	Field trials

### Assessment methods

The following assessments were made in accordance with EPPO Guideline 1/2 (5):

- Phytotoxicity (and description of the symptoms) was assessed by visual estimation of the intensity on an overall plot basis on a percentage scale 0-100% (0% = no damage).
- The assessment of efficacy in the treated plots was made in relation to the untreated plot on an overall plot basis (scale 0-100%, 0% = no efficacy). Efficacy was recorded by estimation of the intensity (severity) of the disease on the leaves during the growing season and the frequency (incidence) of the disease on the tubers after harvest.

### Area Under the Disease Progress Curve (AUDPC)

At the end of the growing season the AUDPC is calculated from the individual assessment data (pest severity at several time points). This value summarizes the plant disease infestation over the trials.

Because of the discrete nature of assessments in an efficacy trial, the AUDPC is estimated using the trapezoidal method. In this method the total surface area under the curve between adjacent assessments is calculated.

### Statistical analysis

Data were analysed using a two-way analysis of variance (ANOVA). The probability of no significant differences occurring between treatment means is calculated as the F probability value (Prob(F)). Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob(F) < 0.05) and these are indicated by the LSD-value and by a letter-test. The ANOVA data and the plot data are included in the appendices of the study reports.

Comments of zRMS:	<p><b>Trials methodology:</b></p> <p>The Specific guidelines EPPO PP 1/2 (4) is used in dRR but the current specific guidelines applicable from 2020 is EPPO PP1/002(5).</p> <p>Experiment – design is EPPO compliant, The countries where the experiments were located should be listed Crop - no indication of the crop on which the experiments were carried out, -no pest name Application- no indication of the number of applications, -it is not indicated how many days after application the assessments were made -there are no rules for presenting the effectiveness of the tested agent after 1, 2 or 3 applications Assessment types-no data on which plant organs the assessment was performed, and no units in which the assessment was performed. (this information is provided only in the text: <b>Assessment methods</b>). Appropriate methods of assessing plant damage and statistical analysis methods were used. The applicant should complete the missing data. The Methodology presented in dRR will be appropriate after the Applicant completes the above-mentioned data.</p>
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### Trial results

For individual trial data reference is made to Appendix 4 of the Biological Assessment Dossier – Efficacy data on potatoes.

It should be noted that the results of all trials included in this dossier are presented together, regardless of the EPPO Zone they were performed in. An overall summary is provided, followed by a summary for each EPPO Zone separately.



In the presentation of the data, the colour of the KCP numbers is used to indicate the EPPO Zone each trial was performed in:

Maritime EPPO Zone:		+	
Czech/German trials:			
North-East EPPO Zone:			
Mediterranean EPPO Zone:			
South-East EPPO Zone:			

For every assessment the absolute value (AUDPC/PESSEV/PESINC) for the untreated control is given, the efficacy of the treatments is then shown as %UNCK.

The Area Under the Disease Progress Curve (AUDPC) and the pest incidence (PESINC) on tubers are only assessed once in every trial, therefore all assessment data is presented together.

Pest severity (PESSEV) was assessed multiple times throughout the season. Applications started preventatively, but because of specific weather conditions there was a lot of variation in the time between the start of the applications and the first observation of the disease in the different trials.

In the efficacy trials presented in this dossier the days after first application at which the first symptoms were observed are shown below:

Maritime EPPO Zone:	7-57 DA-A	(average of 28 days, 19 days stdev.)
Czech/German trials:	7-24 DA-A	(average of 15 days, 8 days stdev.)
North-East EPPO Zone:	5-30 DA-A	(average of 13 days, 8 days stdev.)
Mediterranean EPPO Zone:	8-57 DA-A	(average of 30 days, 22 days stdev.)
South-East EPPO Zone:	18-35 DA-A	(average of 26 days, 8 days stdev.)

This means that if the assessment data were to be sorted by the number of days after first application this would result in highly variable results. Because of the different stages of disease development between the trials at a given time after trial initiation this would make it impossible to demonstrate the impact of the tested treatments on disease progression. Therefore, in order to have the best presentation of the impact of tested treatments on the disease development, the moment of first observation was used as the reference point for the grouping of the data.

The individual assessment data (pest severity) for all trials was grouped by the number of days after the first symptoms of *Phytophthora infestans* infection were observed, indicated in the tables by 'Days after symptoms'. The following groupings were made based on the number days after the first observation of symptoms:

0 days		first observation of symptoms
5-10 days	~	1 week after symptoms
12-16 days	~	1-2 weeks after symptoms
17-21 days	~	2-3 weeks after symptoms
22-28 days	~	3-4 weeks after symptoms
29-36 days	~	4-5 weeks after symptoms
37-45 days	~	5-6 weeks after symptoms
46-52 days	~	6-7 weeks after symptoms

In case the pest severity/incidence was below 5% for the untreated control, the efficacy results for that assessment were not taken into account for any of the summaries. These results are **marked in grey** in the presented data.

The tables below summarize the results obtained in the presented efficacy trials. First, summaries are provided for all EPPO Zones combined, followed by separate summaries per EPPO Zone.

### All EPPO Zones

To provide an overview of all obtained efficacy data, Table 3.2-15 below summarizes the efficacy of GLOB2013F at the 0.3 L/ha dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.3 L/ha to the reference products Revus (Table 3.2-16) and Infinito/Volare (Table 3.2-17), separately.

**Table 3.2-15 Efficacy of GLOB2013F against PHYTIN - All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	35	1126.5	34.4	3698.5	69.3	21.9	100.0	72.0	22.4	77.7	36.7	100.0	77.6	19.7
PESINC	TUBER	harvest	10	11.9	5.0	30.0	75.8	25.0	100.0	79.2	23.5	79.6	32.4	100.0	87.6	21.2
PESSEV	LEAF	first symptoms	8	11.4	5.3	25.0	76.1	47.0	100.0	75.1	22.5	85.0	57.5	100.0	91.7	17.0
PESSEV	LEAF	5-10 days after symptoms	16	20.3	5.0	82.5	80.7	48.2	100.0	90.2	19.2	85.0	45.7	100.0	92.3	16.9
PESSEV	LEAF	12-16 days after symptoms	19	25.5	5.0	100.0	75.0	19.7	100.0	80.7	25.2	83.1	46.9	100.0	93.4	18.5
PESSEV	LEAF	17-21 days after symptoms	26	31.7	5.0	98.8	73.3	32.5	100.0	77.6	22.6	75.5	37.5	100.0	77.9	21.7
PESSEV	LEAF	23-28 days after symptoms	26	42.2	6.5	100.0	67.3	18.8	100.0	71.7	27.4	75.5	23.5	100.0	82.5	23.5
PESSEV	LEAF	29-36 days after symptoms	22	49.9	9.2	100.0	68.9	0.0	100.0	81.1	28.1	80.1	5.0	100.0	83.9	21.5
PESSEV	LEAF	37-45 days after symptoms	19	44.5	12.4	100.0	55.8	0.0	98.8	50.5	26.3	74.0	27.5	100.0	73.3	20.9
PESSEV	LEAF	46-52 days after symptoms	8	48.0	9.5	100.0	66.1	1.3	97.2	71.3	30.0	80.9	42.5	100.0	90.9	23.4

**Table 3.2-16 Orthogonal comparison between GLOB2013F and Revus against PHYTIN - All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	28	1279.9	59.3	3698.5	69.4	21.9	100.0	73.4	23.6	74.0	36.7	100.0	72.8	19.7
PESINC	TUBER	harvest	7	12.9	5.0	30.0	69.8	25.0	100.0	75.6	25.5	72.4	29.8	100.0	85.2	25.5
PESSEV	LEAF	first symptoms	8	11.4	5.3	25.0	76.1	47.0	100.0	75.1	22.5	83.5	45.8	100.0	91.7	20.0
PESSEV	LEAF	5-10 days after symptoms	14	22.3	5.0	82.5	82.0	48.2	100.0	91.6	19.0	85.2	55.0	100.0	88.1	14.6
PESSEV	LEAF	12-16 days after symptoms	18	26.7	5.0	100.0	73.6	19.7	100.0	80.1	25.2	78.4	41.0	100.0	87.1	20.3
PESSEV	LEAF	17-21 days after symptoms	22	34.2	5.5	98.8	73.8	32.5	100.0	84.2	23.3	74.9	37.5	100.0	79.2	22.3
PESSEV	LEAF	23-28 days after symptoms	22	43.4	6.5	100.0	69.0	18.8	100.0	79.5	28.4	76.8	13.3	100.0	88.4	25.3
PESSEV	LEAF	29-36 days after symptoms	18	56.7	9.2	100.0	67.9	0.0	100.0	80.1	29.6	79.3	2.5	100.0	85.2	24.8
PESSEV	LEAF	37-45 days after symptoms	14	51.4	12.4	100.0	50.8	0.0	98.8	45.1	28.0	73.9	27.5	100.0	78.6	24.0
PESSEV	LEAF	46-52 days after symptoms	6	49.2	9.5	100.0	64.5	1.3	97.2	71.3	34.2	63.4	40.1	89.5	67.5	19.0

**Table 3.2-17 Orthogonal comparison between GLOB2013F and Infinito/Volare against PHYTIN - All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	26	840.4	34.4	2852.5	71.8	28.8	100.0	75.7	21.2	75.5	31.6	100.0	73.4	22.2
PESINC	TUBER	harvest	7	11.3	5.0	30.0	77.2	25.0	100.0	79.3	26.0	78.4	32.4	100.0	89.6	25.2
PESSEV	LEAF	first symptoms	4	9.7	6.3	13.8	77.9	47.5	100.0	82.1	26.4	82.5	57.5	100.0	86.3	21.1
PESSEV	LEAF	5-10 days after symptoms	9	81.7	45.7	100.0	83.3	52.9	100.0	92.9	19.8	81.7	45.7	100.0	92.9	20.4
PESSEV	LEAF	12-16 days after symptoms	11	16.6	5.0	42.5	75.6	19.7	100.0	90.0	27.6	81.8	50.4	100.0	90.9	20.4
PESSEV	LEAF	17-21 days after symptoms	18	27.8	5.0	90.0	71.5	32.5	100.0	70.7	23.9	72.1	35.5	100.0	71.7	23.4
PESSEV	LEAF	23-28 days after symptoms	20	37.5	6.5	100.0	70.0	32.5	100.0	76.5	26.5	69.4	23.5	100.0	69.9	26.8
PESSEV	LEAF	29-36 days after symptoms	15	39.8	9.2	100.0	74.6	15.0	100.0	85.6	26.4	76.5	5.0	100.0	78.6	26.3
PESSEV	LEAF	37-45 days after symptoms	14	35.3	12.4	93.8	64.6	38.8	98.8	59.7	21.3	70.1	21.0	100.0	72.2	23.7
PESSEV	LEAF	46-52 days after symptoms	6	42.4	9.5	100.0	77.1	56.8	97.2	81.3	16.7	79.8	37.5	100.0	96.1	28.7

### Summary

The results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.3 L/ha dose rate.

## Maritime EPPO Zone

Table 3.2-18 below summarizes the efficacy of GLOB2013F at the 0.3 L/ha dose rate (including efficacy data extrapolated from the 1.9 L/ha dose rate) and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.3 L/ha to the reference products Revus (Table 3.2-19) and Infinito/Volare (Table 3.2-20), separately.

**Table 3.2-18 Efficacy of GLOB2013F against PHYTIN - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1112.7	104.4	3422.5	75.2	31.7	98.3	82.9	22.5	85.2	47.9	100.0	95.9	18.4
PESINC	TUBER	harvest	3	11.4	9.0	16.0	72.2	25.0	100.0	91.5	41.1	57.3	32.4	85.2	54.4	26.5
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	89.6	79.2	100.0	89.6	14.7	95.0	90.0	100.0	95.0	7.1
PESSEV	LEAF	7-10 days after symptoms	4	41.4	8.0	82.5	81.3	52.9	100.0	86.1	22.4	85.4	45.7	100.0	97.9	26.5
PESSEV	LEAF	12-16 days after symptoms	5	43.3	5.0	100.0	86.1	45.0	100.0	96.1	23.3	96.7	94.0	100.0	95.0	3.0
PESSEV	LEAF	17-21 days after symptoms	7	34.9	5.0	98.8	82.2	32.5	100.0	96.0	27.1	84.7	50.1	100.0	100.0	23.1
PESSEV	LEAF	23-28 days after symptoms	9	40.0	6.5	100.0	69.7	18.8	100.0	89.0	32.6	82.4	42.5	100.0	90.0	21.9
PESSEV	LEAF	29-35 days after symptoms	8	52.4	9.2	100.0	75.1	0.0	100.0	87.1	34.0	84.9	60.0	100.0	92.5	17.7
PESSEV	LEAF	37-45 days after symptoms	6	50.6	13.3	100.0	56.6	0.0	98.8	53.2	36.6	73.9	27.5	100.0	81.2	30.8
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	87.7	77.5	97.2	88.5	9.9	100.0	99.9	100.0	100.0	0.1

**Table 3.2-19 Orthogonal comparison between GLOB2013F and Revus against PHYTIN - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	10	1193.1	104.4	3422.5	79.3	31.7	98.3	89.5	22.1	80.6	57.1	100.0	80.0	16.8
PESINC	TUBER	harvest	2	12.5	9.0	16.0	58.3	25.0	91.5	58.3	47.0	57.5	29.8	85.2	57.5	39.2
PESSEV	LEAF	first symptoms	2	19.7	14.3	25.0	89.6	79.2	100.0	89.6	14.7	95.0	90.0	100.0	95.0	7.1
PESSEV	LEAF	7-10 days after symptoms	3	52.5	10.0	82.5	90.7	73.8	100.0	98.4	14.7	98.6	97.6	100.0	98.1	1.3
PESSEV	LEAF	12-16 days after symptoms	4	52.8	5.0	100.0	82.6	45.0	99.2	93.1	25.3	94.6	90.0	99.8	94.2	4.0
PESSEV	LEAF	17-21 days after symptoms	5	36.8	6.3	98.8	84.0	32.5	100.0	96.0	29.0	88.5	52.5	100.0	100.0	20.6
PESSEV	LEAF	23-28 days after symptoms	7	34.7	6.5	100.0	78.2	18.8	100.0	96.0	32.1	89.2	47.5	100.0	99.5	19.1
PESSEV	LEAF	29-35 days after symptoms	8	52.4	9.2	100.0	75.1	0.0	100.0	87.1	34.0	83.9	52.5	100.0	92.4	19.4
PESSEV	LEAF	37-45 days after symptoms	5	54.7	13.3	100.0	56.6	0.0	98.8	50.0	40.9	76.2	27.5	100.0	99.8	33.8
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	87.7	77.5	97.2	88.5	9.9	58.3	40.1	69.3	65.6	15.9

**Table 3.2-20 Orthogonal comparison between GLOB2013F and Infinito/Volare against PHYTIN - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	10	731.5	104.4	1440.8	77.8	45.9	98.3	82.9	19.1	81.8	31.6	100.0	99.8	25.7
PESINC	TUBER	harvest	2	9.2	9.0	9.3	62.5	25.0	100.0	62.5	53.0	43.4	32.4	54.4	43.4	15.6
PESSEV	LEAF	7-10 days after symptoms	2	72.9	45.7	100.0	76.5	52.9	100.0	76.5	33.3	72.9	45.7	100.0	72.9	38.4
PESSEV	LEAF	12-16 days after symptoms	3	9.2	5.0	17.5	96.4	90.0	100.0	99.2	5.6	98.3	95.0	100.0	99.9	2.9
PESSEV	LEAF	17-21 days after symptoms	6	24.2	5.0	55.0	80.6	32.5	100.0	97.9	29.4	82.5	45.0	100.0	100.0	27.1
PESSEV	LEAF	23-28 days after symptoms	8	32.5	6.5	100.0	76.1	32.5	100.0	92.5	28.3	74.6	32.5	100.0	82.2	28.7
PESSEV	LEAF	29-35 days after symptoms	6	36.6	9.2	95.3	86.0	52.5	100.0	92.1	18.0	83.0	38.3	100.0	99.8	27.1
PESSEV	LEAF	37-45 days after symptoms	5	40.7	13.3	93.8	67.9	40.2	98.8	56.3	26.7	76.7	21.0	100.0	100.0	35.1
PESSEV	LEAF	48-52 days after symptoms	3	21.7	9.5	35.5	87.7	77.5	97.2	88.5	9.9	100.0	99.9	100.0	100.0	0.1

## Summary

The results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.3 L/ha dose rate.

### **North-East EPPO Zone**

Table 3.2-21 below summarizes the efficacy of GLOB2013F at the 0.3 L/ha dose rate (including efficacy data extrapolated from the 1.9 L/ha dose rate) and allow comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.3 L/ha to the reference products Revus (Table 3.2-22) and Infinito/Volare (

Table 3.2-23), separately.

**Table 3.2-21 Efficacy of GLOB2013F against PHYTIN - North-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1513.7	383.9	3698.5	60.2	21.9	84.3	65.8	19.1	68.3	36.7	94.6	69.9	16.4
PESINC	TUBER	harvest	4	14.6	5.0	30.0	74.7	50.4	90.0	79.2	17.0	85.2	71.0	94.1	87.9	10.0
PESSEV	LEAF	first symptoms	3	8.5	5.3	13.8	70.4	47.0	100.0	64.2	27.0	74.6	57.5	100.0	66.4	22.4
PESSEV	LEAF	5-10 days after symptoms	6	15.3	6.4	30.0	81.1	48.2	98.8	91.6	20.8	80.6	61.7	100.0	81.6	15.0
PESSEV	LEAF	12-14 days after symptoms	5	23.8	10.0	42.5	75.1	50.0	95.0	79.5	20.9	77.2	62.5	99.2	65.5	17.6
PESSEV	LEAF	17-21 days after symptoms	10	27.4	5.6	90.0	68.8	45.0	95.9	70.7	18.2	70.5	49.3	95.7	69.6	17.2
PESSEV	LEAF	23-28 days after symptoms	9	40.6	11.2	100.0	60.0	33.8	90.8	67.2	20.8	67.8	38.4	95.9	70.0	18.9
PESSEV	LEAF	29-35 days after symptoms	11	41.5	10.3	100.0	60.7	15.0	87.7	68.1	25.8	72.0	5.0	95.5	78.6	23.9
PESSEV	LEAF	38-42 days after symptoms	10	40.2	16.6	100.0	59.8	30.0	85.3	56.8	20.5	72.7	41.3	93.5	72.2	14.8
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	53.1	1.3	85.1	57.5	31.2	69.4	42.5	92.3	73.5	22.8

### +Czech+German trials

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	17	1410.5	215.3	3698.5	63.3	21.9	92.8	63.5	18.1	71.5	36.7	100.0	70.5	16.6
PESINC	TUBER	harvest	6	13.9	5.0	30.0	69.2	25.0	91.5	79.2	26.2	65.5	0.0	94.1	85.2	35.7
PESSEV	LEAF	first symptoms	5	9.4	5.3	14.3	76.4	47.0	100.0	71.0	23.2	83.4	57.5	100.0	93.3	20.1
PESSEV	LEAF	5-10 days after symptoms	8	20.9	6.4	65.0	85.6	48.2	100.0	93.7	19.5	85.2	61.7	100.0	88.7	15.3
PESSEV	LEAF	12-15 days after symptoms	8	27.2	5.0	88.8	82.7	50.0	100.0	92.2	19.2	84.4	62.5	100.0	93.9	16.7
PESSEV	LEAF	17-21 days after symptoms	14	29.2	5.0	98.8	72.0	32.5	100.0	71.2	22.2	74.8	49.3	100.0	71.7	19.3
PESSEV	LEAF	23-28 days after symptoms	13	33.0	8.8	100.0	63.1	33.8	96.0	67.2	21.9	70.8	38.4	100.0	70.0	18.9
PESSEV	LEAF	29-35 days after symptoms	15	44.1	10.3	100.0	65.0	15.0	89.2	80.0	24.3	73.9	5.0	100.0	78.6	22.0
PESSEV	LEAF	38-45 days after symptoms	13	44.3	16.6	100.0	57.3	30.0	85.3	50.5	18.7	72.5	41.3	100.0	71.0	16.3
PESSEV	LEAF	46-52 days after symptoms	5	63.9	28.0	100.0	53.1	1.3	85.1	57.5	31.2	69.4	42.5	92.3	73.5	22.8

**Table 3.2-22 Orthogonal comparison between GLOB2013F and Revus against PHYTIN - North-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	8	2003.5	434.7	3698.5	55.2	21.9	76.5	55.9	19.1	64.4	36.7	94.6	67.7	18.4
PESINC	TUBER	harvest	2	19.3	8.5	30.0	64.9	50.4	79.3	64.9	20.4	78.6	71.0	86.1	78.6	10.7
PESSEV	LEAF	first symptoms	3	8.5	5.3	13.8	70.4	47.0	100.0	64.2	27.0	70.7	45.8	100.0	66.4	27.4
PESSEV	LEAF	5-10 days after symptoms	6	15.3	6.4	30.0	81.1	48.2	98.8	91.6	20.8	79.5	55.0	100.0	81.6	16.8
PESSEV	LEAF	12-14 days after symptoms	5	23.8	10.0	42.5	75.1	50.0	95.0	79.5	20.9	75.3	56.3	99.2	65.2	19.5
PESSEV	LEAF	17-21 days after symptoms	8	32.7	9.6	90.0	70.1	45.0	95.9	71.0	20.1	69.9	44.3	95.7	66.7	18.4
PESSEV	LEAF	23-28 days after symptoms	7	48.9	11.2	100.0	55.5	33.8	90.8	45.9	21.6	68.2	31.7	95.9	70.0	21.7
PESSEV	LEAF	29-35 days after symptoms	7	54.2	16.1	100.0	53.5	15.0	86.0	50.0	25.8	66.3	2.5	95.5	70.5	30.2
PESSEV	LEAF	38-42 days after symptoms	6	50.7	22.5	100.0	51.1	30.0	84.7	45.1	19.7	69.9	41.3	93.5	70.8	18.4
PESSEV	LEAF	46-52 days after symptoms	3	76.7	30.0	100.0	41.3	1.3	65.0	57.5	34.8	68.5	42.5	89.5	73.5	23.9

### +Czech+German trials

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	12	1778.1	215.3	3698.5	61.0	21.9	92.8	61.9	19.4	69.4	36.7	100.0	67.7	19.3
PESINC	TUBER	harvest	4	15.9	8.5	30.0	61.6	25.0	91.5	64.9	29.8	68.0	29.8	86.1	78.1	26.4
PESSEV	LEAF	first symptoms	5	9.4	5.3	14.3	76.4	47.0	100.0	71.0	23.2	81.1	45.8	100.0	93.3	24.1
PESSEV	LEAF	5-10 days after symptoms	8	20.9	6.4	65.0	85.6	48.2	100.0	93.7	19.5	84.4	55.0	100.0	88.7	16.9
PESSEV	LEAF	12-15 days after symptoms	7	30.4	5.0	88.8	80.3	50.0	96.1	90.0	19.3	80.1	56.3	99.2	90.0	18.0
PESSEV	LEAF	17-21 days after symptoms	11	35.6	6.3	98.8	71.0	32.5	96.0	71.5	23.2	72.9	44.3	100.0	69.1	19.7
PESSEV	LEAF	23-28 days after symptoms	10	38.8	8.8	100.0	62.1	33.8	96.0	57.4	24.0	71.2	31.7	100.0	72.4	22.5
PESSEV	LEAF	29-35 days after symptoms	11	53.1	16.1	100.0	61.9	15.0	89.2	68.1	24.9	70.3	2.5	100.0	71.7	26.4
PESSEV	LEAF	38-45 days after symptoms	8	56.0	22.5	100.0	49.6	30.0	84.7	45.1	17.1	71.6	41.3	100.0	70.8	20.2
PESSEV	LEAF	46-52 days after symptoms	3	76.7	30.0	100.0	41.3	1.3	65.0	57.5	34.8	68.5	42.5	89.5	73.5	23.9

**Table 3.2-23 Orthogonal comparison between GLOB2013F and Infinito/Volare against PHYTIN - North-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	9	1138.2	383.9	2852.5	65.4	42.6	84.3	70.8	16.6	68.6	43.4	89.4	69.2	12.6
PESINC	TUBER	harvest	3	16.7	5.0	30.0	82.8	79.1	90.0	79.3	6.2	89.4	84.4	94.1	89.6	4.9
PESSEV	LEAF	first symptoms	2	10.1	6.3	13.8	82.1	64.2	100.0	82.1	25.3	78.8	57.5	100.0	78.8	30.1
PESSEV	LEAF	5-10 days after symptoms	3	75.1	61.7	92.9	83.1	62.1	94.4	92.9	18.2	75.1	61.7	92.9	70.6	16.1
PESSEV	LEAF	12-14 days after symptoms	2	31.9	21.3	42.5	75.6	56.8	94.4	75.6	26.6	78.2	65.5	90.9	78.2	18.0
PESSEV	LEAF	17-21 days after symptoms	7	26.8	5.6	90.0	68.5	48.7	95.9	70.5	17.7	68.9	49.3	94.4	70.1	15.0
PESSEV	LEAF	23-28 days after symptoms	6	38.0	11.2	100.0	65.5	35.3	90.8	71.7	21.7	65.4	38.4	87.9	69.9	18.7
PESSEV	LEAF	29-35 days after symptoms	8	35.1	10.3	100.0	63.6	15.0	87.7	81.1	29.4	68.8	5.0	84.8	76.3	26.1
PESSEV	LEAF	38-42 days after symptoms	8	34.9	16.6	69.7	65.5	38.8	85.3	69.3	18.5	69.3	38.8	89.3	72.2	14.5
PESSEV	LEAF	46-52 days after symptoms	3	63.1	28.0	100.0	66.5	56.8	85.1	57.5	16.1	59.6	37.5	92.3	49.1	28.9

#### +Czech+German trials

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	13	1034.0	215.3	2852.5	65.4	42.6	84.3	69.5	14.2	68.3	31.6	100.0	69.2	17.4
PESINC	TUBER	harvest	4	14.8	5.0	30.0	68.4	25.0	90.0	79.2	29.3	75.1	32.4	94.1	87.0	28.8
PESSEV	LEAF	first symptoms	2	10.1	6.3	13.8	82.1	64.2	100.0	82.1	25.3	78.8	57.5	100.0	78.8	30.1
PESSEV	LEAF	5-10 days after symptoms	4	81.3	61.7	100.0	87.4	62.1	100.0	93.7	17.1	81.3	61.7	100.0	81.8	18.1
PESSEV	LEAF	12-15 days after symptoms	4	18.5	5.0	42.5	85.3	56.8	100.0	92.2	19.4	87.9	65.5	100.0	93.0	15.4
PESSEV	LEAF	17-21 days after symptoms	10	22.4	5.0	90.0	70.8	32.5	100.0	70.7	23.3	72.7	45.0	100.0	71.7	20.3
PESSEV	LEAF	23-28 days after symptoms	10	29.2	8.8	100.0	67.4	35.3	96.0	71.7	22.2	64.7	32.5	100.0	64.8	21.3
PESSEV	LEAF	29-35 days after symptoms	11	35.0	10.3	100.0	66.4	15.0	89.2	80.1	26.5	68.1	5.0	100.0	74.9	26.0
PESSEV	LEAF	38-45 days after symptoms	11	41.2	16.6	93.8	61.0	38.8	85.3	56.3	17.7	67.0	21.0	100.0	71.0	21.8
PESSEV	LEAF	46-52 days after symptoms	3	63.1	28.0	100.0	66.5	56.8	85.1	57.5	16.1	59.6	37.5	92.3	49.1	28.9

#### Summary

The results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.3 L/ha dose rate.

## Mediterranean EPPO Zone

Table 3.2-24 below summarizes the efficacy of GLOB2013F at the 0.3 L/ha dose rate (including efficacy data extrapolated from the 1.9 L/ha dose rate) and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.3 L/ha to the reference products Revus (Table 3.2-25) and Infinito/Volare (Table 3.2-26), separately.

**Table 3.2-24 Efficacy of GLOB2013F against PHYTIN - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	6	639.9	34.4	2753.9	70.9	28.8	100.0	80.1	28.7	82.5	55.0	100.0	89.3	18.5
PESINC	TUBER	harvest	2	10.3	5.0	15.5	87.8	75.6	100.0	87.8	17.3	94.5	89.0	100.0	94.5	7.8
PESSEV	LEAF	first symptoms	2	7.5	7.5	7.5	85.5	71.0	100.0	85.5	20.5	96.7	93.3	100.0	96.7	4.7
PESSEV	LEAF	7-10 days after symptoms	3	13.1	5.0	24.3	87.2	71.7	100.0	90.0	14.4	95.9	91.7	100.0	96.0	4.2
PESSEV	LEAF	13-13 days after symptoms	4	17.6	5.8	43.8	62.0	19.7	100.0	64.2	35.5	81.2	60.2	100.0	82.3	18.3
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	62.4	38.1	85.0	63.2	25.9	72.2	40.3	94.4	77.1	23.2
PESSEV	LEAF	25-28 days after symptoms	4	34.6	7.2	91.3	65.4	34.2	100.0	63.7	32.7	74.7	48.4	100.0	75.2	25.9
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	68.8	68.8	68.8	68.8	-	92.3	92.3	92.3	92.3	-
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	29.0	17.5	40.5	29.0	16.3	71.1	51.8	90.3	71.1	27.2

**Table 3.2-25 Orthogonal comparison between GLOB2013F and Revus against PHYTIN - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	761.0	59.3	2753.9	66.6	28.8	100.0	72.0	29.8	77.1	55.0	92.8	85.8	16.4
PESINC	TUBER	harvest	2	10.3	5.0	15.5	87.8	75.6	100.0	87.8	17.3	94.5	89.0	100.0	94.5	7.8
PESSEV	LEAF	first symptoms	2	7.5	7.5	7.5	85.5	71.0	100.0	85.5	20.5	96.7	93.3	100.0	96.7	4.7
PESSEV	LEAF	7-10 days after symptoms	2	17.1	9.9	24.3	85.9	71.7	100.0	85.9	20.0	85.9	80.1	91.7	85.9	8.2
PESSEV	LEAF	13-13 days after symptoms	4	17.6	5.8	43.8	62.0	19.7	100.0	64.2	35.5	76.8	58.4	92.4	78.2	14.8
PESSEV	LEAF	18-20 days after symptoms	4	24.6	5.5	71.3	62.4	38.1	85.0	63.2	25.9	72.2	40.3	94.4	77.1	23.2
PESSEV	LEAF	25-28 days after symptoms	4	34.6	7.2	91.3	65.4	34.2	100.0	63.7	32.7	71.6	48.4	93.7	72.2	22.4
PESSEV	LEAF	35-35 days after symptoms	1	100.0	100.0	100.0	68.8	68.8	68.8	68.8	-	92.3	92.3	92.3	92.3	-
PESSEV	LEAF	41-42 days after symptoms	2	56.2	12.4	100.0	29.0	17.5	40.5	29.0	16.3	71.1	51.8	90.3	71.1	27.2

**Table 3.2-26 Orthogonal comparison between GLOB2013F and Infinito/Volare against PHYTIN - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	4	256.6	34.4	367.0	66.3	28.8	100.0	68.2	35.3	72.7	44.4	100.0	73.3	29.9
PESINC	TUBER	harvest	1	5.0	5.0	5.0	100.0	100.0	100.0	100.0	-	100.0	100.0	100.0	100.0	-
PESSEV	LEAF	first symptoms	1	7.5	7.5	7.5	100.0	100.0	100.0	100.0	-	100.0	100.0	100.0	100.0	-
PESSEV	LEAF	7-10 days after symptoms	2	98.0	96.0	100.0	95.0	90.0	100.0	95.0	7.1	98.0	96.0	100.0	98.0	2.8
PESSEV	LEAF	13-13 days after symptoms	3	8.9	5.8	12.4	55.8	19.7	100.0	47.6	40.8	70.2	50.4	100.0	60.2	26.3
PESSEV	LEAF	18-20 days after symptoms	2	10.4	5.5	15.3	40.0	38.1	41.8	40.0	2.6	40.9	35.5	46.2	40.9	7.6
PESSEV	LEAF	25-28 days after symptoms	3	15.7	7.2	23.9	58.4	34.2	100.0	40.9	36.2	61.8	41.3	100.0	44.1	33.1
PESSEV	LEAF	41-42 days after symptoms	1	12.4	12.4	12.4	40.5	40.5	40.5	40.5	-	44.5	44.5	44.5	44.5	-

## Summary

The results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.3 L/ha dose rate.

## Confirmatory Mediterranean trials performed in Morocco

In addition to the trials summarized above, two efficacy trials (KCP 6.2-117 and 118) were performed in the very North of Morocco, between the strait of Gibraltar and Rabat. According to EPPO Guideline 1/241(2), this region is also considered the Mediterranean EPPO Zone. The efficacy data gathered in these trials can be found in Appendix 4 of the Biological Assessment Dossier. All data is summarized in Table 3.2-27 below. These trials support that the 0.3 L/ha dose rate of GLOB2013F can provide good control throughout the growing season.

**Table 3.2-27 Efficacy of GLOB2013F against PHYTIN in Moroccan trials - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control					
							GLOB2013F 0.3 L/ha			Best reference		
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
AUDPC	LEAF	season	2	1414.6	1408.0	1421.1	82.5	74.1	90.9	95.4	93.5	97.2
PESSEV	LEAF	5-8 days after symptoms	2	9.1	6.8	11.3	56.4	46.9	65.8	84.8	76.3	93.3
PESSEV	LEAF	12-15 days after symptoms	2	13.8	11.3	16.3	66.4	48.8	84.0	83.4	75.0	91.7
PESSEV	LEAF	18-22 days after symptoms	2	21.9	20.0	23.8	73.5	57.5	89.5	87.2	79.0	95.3
PESSEV	LEAF	27-30 days after symptoms	2	45.7	33.8	57.5	84.8	78.1	91.5	96.5	94.6	98.4
PESSEV	LEAF	37-38 days after symptoms	2	74.4	50.0	98.8	87.4	82.2	92.6	98.5	98.0	98.9



### South-East EPPO Zone

Table 3.2-28 below summarizes the efficacy of GLOB2013F at the 0.3 L/ha dose rate (including efficacy data extrapolated from the 1.9 L/ha dose rate) and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.3 L/ha to the reference products Revus (Table 3.2-29) and Infinito/Volare (Table 3.2-30), separately.

**Table 3.2-28 Efficacy of GLOB2013F against PHYTIN - South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	74.9	51.8	96.0	86.6	20.7	76.4	46.7	99.6	90.1	27.3
PESINC	TUBER	harvest	1	6.0	6.0	6.0	66.7	66.7	66.7	66.7	-	93.8	93.8	93.8	93.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	47.5	47.5	47.5	47.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	72.4	57.2	100.0	60.0	23.9	82.7	68.1	100.0	80.0	16.1
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	74.3	46.9	100.0	73.3	24.8	76.9	46.9	100.0	84.7	25.5
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	86.1	62.5	100.0	91.0	17.3	84.6	50.0	100.0	94.3	23.7
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	80.1	38.8	97.1	92.3	27.7	78.2	23.5	100.0	94.7	36.8
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	88.6	83.3	93.8	88.6	7.4	99.6	99.1	100.0	99.6	0.6
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	63.8	63.8	63.8	63.8	-	92.8	92.8	92.8	92.8	-

**Table 3.2-29 Orthogonal comparison between GLOB2013F and Revus against PHYTIN - South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Revus 0.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	5	814.4	223.6	1652.5	74.9	51.8	96.0	86.6	20.7	73.2	39.3	99.5	82.1	28.6
PESINC	TUBER	harvest	1	6.0	6.0	6.0	66.7	66.7	66.7	66.7	-	45.8	45.8	45.8	45.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	47.5	47.5	47.5	47.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	3	9.3	5.0	15.8	72.4	57.2	100.0	60.0	23.9	82.7	68.1	100.0	80.0	16.1
PESSEV	LEAF	14-15 days after symptoms	5	15.9	5.0	42.5	74.3	46.9	100.0	73.3	24.8	69.7	41.0	100.0	60.4	28.6
PESSEV	LEAF	21-21 days after symptoms	4	39.3	10.5	80.0	86.1	62.5	100.0	91.0	17.3	79.9	43.8	100.0	87.9	26.6
PESSEV	LEAF	28-28 days after symptoms	4	58.2	17.5	98.0	80.1	38.8	97.1	92.3	27.7	75.6	13.3	100.0	94.5	41.8
PESSEV	LEAF	35-36 days after symptoms	2	60.7	23.8	97.5	88.6	83.3	93.8	88.6	7.4	99.4	98.7	100.0	99.4	0.9
PESSEV	LEAF	42-42 days after symptoms	1	28.8	28.8	28.8	63.8	63.8	63.8	63.8	-	92.8	92.8	92.8	92.8	-

**Table 3.2-30 Orthogonal comparison between GLOB2013F and Infinito/Volare against PHYTIN - South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.3 L/ha					Infinito / Volare 1.6 L/ha				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
AUDPC	LEAF	season	3	1088.5	223.6	1652.5	78.7	53.4	96.0	86.6	22.4	78.8	46.8	99.6	90.1	28.1
PESINC	TUBER	harvest	1	6.0	6.0	6.0	66.7	66.7	66.7	66.7	-	93.8	93.8	93.8	93.8	-
PESSEV	LEAF	first symptoms	1	11.3	11.3	11.3	47.5	47.5	47.5	47.5	-	72.5	72.5	72.5	72.5	-
PESSEV	LEAF	7-7 days after symptoms	2	84.1	68.1	100.0	78.6	57.2	100.0	78.6	30.3	84.1	68.1	100.0	84.1	22.6
PESSEV	LEAF	14-15 days after symptoms	3	21.6	5.3	42.5	74.8	52.8	98.3	73.3	22.8	79.1	52.8	99.9	84.7	24.0
PESSEV	LEAF	21-21 days after symptoms	3	48.9	10.5	80.0	81.5	62.5	98.2	83.7	18.0	79.5	50.0	99.9	88.6	26.2
PESSEV	LEAF	28-28 days after symptoms	3	71.7	24.6	98.0	74.4	38.8	95.2	89.3	31.0	71.0	23.5	99.6	89.8	41.4
PESSEV	LEAF	35-36 days after symptoms	1	97.5	97.5	97.5	93.8	93.8	93.8	93.8	-	99.1	99.1	99.1	99.1	-

The analysis was the basis and allowed the use of experiments that met the requirements, and which provided the basis for assessing the effectiveness of the tested product

### Summary

The results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.3 L/ha dose rate.

Comments of zRMS:	<p>According to Simplified table (3.22) of requested uses for GLOB2013F(Observer 0.3 l/ha), table GAP and project of label the preparation is intended for use in one to three applications to protect potatoes against <i>P. infestans</i> during the growing season. The assessed dRR did not present any experience in accordance with the intended use for the registration of the GLOB2013F (Observer) product. The analysis of the original research allowed the use of experiments that met the requirements and compiled them in tables, which provided the basis for assessing the effectiveness of the tested product.</p> <p>However, the Applicant presented results for the use of many applications of the tested product from first symptoms to harvest. Such a summary of results only allows for the assessment of the effectiveness of the entire protection program. Therefore, the evaluator prepared the <b>tables 1, 2</b> (and Tab.3 for Mediterranean data – unnecessarily) of the obtained effectiveness of the tested agent for 1-3 number of treatments.</p> <p><b>North-East</b> Table 1: Efficacy - experiments for the EPPO climatic zone <b>North-East + CZ</b></p>
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Trial No	Assessment data	Infestation in the untreated control (%)	% Efficacy					
			GLOB2013F - 0,18 l/ha	GLOB2013F - 0,3 l/ha	GLOB2013F - 0,33 l/ha	Propamocarb 722 SL - 1.4 l/ha REF. STD	Bevus 250 SC - 0.8 l/ha REF. STD	Infinita - 1.6 l/ha REF. STD
FE- KCP 6.2-21 FE-21-A- GLOB2013F- 2106F-2007F- LV02	19.07.2021 (after 2 applications)	6.36	64.8	90.3	88.7	69.5	78.8	-
	26.07.2021 (after 3 applications)	15.03	56.5	79.5	83.6	63.3	65.2	-
FE- KCP 6.2-22 FE-21-A- GLOB2013F- 2106F-2007F- PL03	02.07.2021 (after 3 applications)	5.25	65.18	46.96	76.43	71.61	66.43	-
FE- KCP 6.2-23 FE-21-A- GLOB2013F- 2106F-2007F- PL04	30.07.2021 (after 3 applications)	17.5	93.3	98.8	98.8	95.8	100.0	-
FE- KCP 6.2-25 FE-21-B- GLOB2013F- 2106F- 2007FCZ02	20.07.2021 (after 2 applications)	14.0	100.0	100.0	100.0	-	100.0	-
	27.07.2021 (after 3 applications)	65.0	96.6	98.4	99.3	-	98.1	-
FE- KCP 6.2-33 FE-21-C- GLOB2013F- 2106F-2007F- CZ01	12.08.2021 (after 3 applications)	10.0	100.0	100.0	100.0	100.0	100.0	100.0
FE- KCP 6.2-39 FE-21-C- GLOB2013F- 2106F-2007F- PL07	19.07.2021 (after 2 applications)	6.25	100.0	100.0	100.0	100.0	100.0	100.0
	26.07.2021 (after 3 applications)	30.0	92.9	94.8	97.3	91.7	92.9	92.9
FE- KCP 6.2-43 FE-21-D- GLOB2013F- 2106F-2007F- LV04	31.07.2021 (after 3 applications)	5.60	57.3	56.4	57.8	-	-	53.1
FE- KCP 6.2-45 FE-21-D- GLOB2013F- 2106F-2007F- PL06	19.07.2021 (after 3 applications)	6.00	66.2	70.8	76.4	-	-	70.1
FE- KCP 6.2-52 FE-22-B- GLOB2013F- 2106F-2007F- CZ02	18.07.2022 (after 3 applications)	5.00	85.0	85.0	-	-	90.0	95.0
FE- KCP 6.2-57 FE-22-B- GLOB2013F- 2106F-2007F- PL08	06.07.2022 (after 3 applications)	13.75	55.83	64.17	-	-	45.83	57.50
Mean	-	15.4	79,5	83,5	88,9	84,6	85,2	81,2

In **10 experiments** conducted in the **North-East** EPPO climate zone + **CZ**, in seasons 2021-2022. The tested GLOB2013F (Observer 0.3l/ha) agent showed an average **effectiveness of 83.5 %** against *Phytophthora infestans* in potatoes. The experiments from Czech Republic have been added to increase the representativeness of the research. Tab.1. The German experiment was not included because the plant infestation was 0%. Table 1. shows the average effectiveness obtained using **2-3 applications** of the tested preparation. Only experiments where disease infestation was more than 5% in the untreated control **were selected for analysis**. In these experiments, the average occurrence of potato late blight amounted to 9.96 % of the leaf area.

The tested agent presented an effectiveness level of **83.5%** and reference standards showed an effect at the similar level: for Propamocarb 722SL (1.4l/ha) - 84.6%,

Revus 250SC (0.6l/ha) -85.2% and Infinito (1.6l/ha)- 81.2% in controlling *P. infestans*.

**The data presented meet the criteria required for registration of the product in the North-East EPPO climate zone.**

**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:” from first symptoms” to “harvest”. The obtained results may allow for the assessment of trends in the protection of potatoes against *P. infestans*.

**The effectiveness 83.5% of GLOB2013F (Observer 0.3l/ha) action of 1-3 applications is confirmed by the results of the effectiveness of programs presented in the dRR: “first symptoms” to 5-10 “days after and “12-15 “day after symptoms is appropriately : 76.4% (5 experiments) -85.6% (8 exp.)-80.3% (7 exp.) and Revus 0,6l/ha-reference standard is - 81.1 %-84.4%-80.1% efficacy.**

The effectiveness of the tested agent is the highest in the first three assessments. These results are presented in dRR ,Table No 3.225-3.226, Efficacy of GLOB2013F (Observer 0.3l/ha) against PHYTIN - North-East EPPO climate Zone+CZ.

The tested preparation shows effectiveness 83.5% that qualifies it to control *P. infestans* in potato crops in the 1- 3 applications in North-East climatic EPPO zone. The experiments are appropriately representative for North-East EPPO climate Zone+CZ.

**Maritime**

Table.2.: Efficacy - experiments for the **Maritime** EPPO climate zone.

Trial No	Assessment data	Infestation in the untreated control (%)	% Efficacy					
			GLOB2013F- 0,18 l/ha	GLOB2013F - 0,3 l/ha	GLOB2013F - 0,33 l/ha	Propamocarb 722 SL - 1.4 l/ha REF. STD	Revus 250 SC - 0.6 l/ha REF. STD	Infinito - 1.6 l/ha REF. STD
FE- KCP 6.2-21 FE-21-A- GLOB2013F- 2106F-2007F- LV02	19.07.2021 (after 2 applications)	6.36	64.8	90.3	88.7	69.5	78.8	-
	26.07.2021 (after 3 applications)	15.03	56.5	79.5	83.6	63.3	65.2	-
FE- KCP 6.2-22 FE-21-A- GLOB2013F- 2106F-2007F- PL03	02.07.2021 (after 3 applications)	5.25	65.18	46.96	76.43	71.61	66.43	-
FE- KCP 6.2-23 FE-21-A- GLOB2013F- 2106F-2007F- PL04	30.07.2021 (after 3 applications)	17.5	93.3	98.8	98.8	95.8	100.0	-
FE- KCP 6.2-39 FE-21-C- GLOB2013F- 2106F-2007F- PL07	19.07.2021 (after 2 applications)	6.25	100.0	100.0	100.0	100.0	100.0	100.0
	26.07.2021 (after 3 applications)	30.0	92.9	94.8	97.3	91.7	92.9	92.9
FE- KCP 6.2-43 FE-21-D- GLOB2013F- 2106F-2007F- LV04	31.07.2021 (after 3 applications)	5.60	57.3	56.4	57.8	-	-	53.1
FE- KCP 6.2-45 FE-21-D- GLOB2013F- 2106F-2007F- PL06	19.07.2021 (after 3 applications)	6.00	66.2	70.8	76.4	-	-	70.1
FE- KCP 6.2-57 FE-22-B- GLOB2013F- 2106F-2007F- PL08	06.07.2022 (after 3 applications)	13.75	55.83	64.17	-	-	45.83	57.50
Mean	-	9,96	72,4	78,0	84,9	82,0	78,5	74,7

### Efficacy

In the **Maritime** EPPO climatic zone, **4 relevant (selected)** experiments in **two** vegetation seasons 2021-2022 are presented in Table 2. The tested GLOB2013F (Observer 0.3l/ha) agent applied in **3 applications** showed an average **effectiveness of 92.52%** against *P. infestans* in potatoes. The reference standards showed an effect at the slightly higher level: for Propamocarb 722 SL(1.4l/ha) – 100 %, Revus 250 SC (0.6l/ha) -95.62 % and Infinito (1.6l/ha)- 97.5% in controlling *P. infestans* in 3 applications. In these experiments, the average occurrence of potato late blight amounted to 23.8 % of the leaf area. Only experiments where disease infestation was more than 5% in the untreated control were selected for analysis.

In the Maritime climate zone, the criteria for presenting an appropriate number of 6 experiments for registration of the product are not met. However, the presentation of results for **4 experiments** using 2- 3 applications indicates the high effectiveness of GLOB2007bF (Observer 0.3l/ha) and the repeatability of the results.

The **dRR presents** research results (Table, 3.222-224) in which the effectiveness of the agent is presented as the results of assessments without indicating the number and dates of application. However, the effectiveness of the tested agent is high, especially in the first three assessments and amounts to: “**first symptoms**” - **89.6% (2 exp.)**, **7-10 “days after** “**90.7 % (3exp.)**, **12-16 “days after” -82.6% (4 exp.)**. These data can complement the confirmation of the effectiveness of GLOB2007bF (Observer 0.3l/ha) in combating *P. infestans* in potatoes. The tested product was active at a lower

level of effectiveness of the standard product Revus 0.6l/ha: 95.0 %, 98.6 %, 94.6 % of efficacy.

dRR experiments:

The justification for supplementing the data from dRR is in the North-East EPPO climatic zone, section.

The number of experiments amounting to: 4 selected and 2-7 supplementary with dRR may constitute the required number of **experiments**.

In the opinion of the evaluator, the presented data can be accepted as the basis for registering the GLOB2013F (Observer 0.3l/ha) agent to control *P. infestans* in 3 application in potatoes in the Maritime EPPO climate zone.

**The number of experiments 4+ dRR 2-7 performed in two vegetation seasons and the achieved effectiveness of 92.52% and dRR -89.6%-90.7%- 82.6% meet the requirements for registration of the agent GLOB2013F (Observer) 0.3l/ha for the protection of potato crops against *Phytophthora infestans* in the Maritime EPPO climate zone.**

**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. However, cMS may make an individual decision on registration.**

#### Summary

The representativeness of the experiments selected for analysis and presented in the dRR is appropriate in terms of location and the large number of potato varieties tested.

**North-East (PL) and Maritime EPPO climate zone (CZ, IE, ~~SK~~).**

**The presented results of GLOB2013F (Observer 0.3l/ha) applied in 1-3 applications to control *P. infestans* in potatoes crop indicate 83.5%-92.52 % efficacy and demonstrate 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 *Phytophthora infestans* in potatoes crop in the North-East (PL) 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**

**The data provided is not sufficient for GLOB2013F (Observer 0.3 l/ha) registration in the South-East EPPO climate zone. However, cMS SK,HU,RO may make an individual decision on registration.**

### 3.2.3.2 Use on grapes

GLOB2013F is used on grapes for the control of downy mildew (*Plasmopara viticola*) at a dose rate of 0.23 L/ha lwa.

The trials presented in this dossier were conducted by contractor companies and official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Trials were conducted across a wide range of sites. The trials are therefore representative of a wide range of environmental conditions likely to be encountered in practice in the area of proposed use.

It should be noted that all trials performed for this project are included in this submission, this includes trials performed in the Maritime, Mediterranean and South-East EPPO Zone (ref. **Błąd! Nie można odnaleźć źródła odwołania.**). The applicant is aware that not all submitted data is accepted by the countries where registration is requested, however data from other EPPO Zones can be considered confirmatory data that demonstrates the performance of GLOB2013F under a wide range of climatic and edaphic conditions.

The trials package of GLOB2013F includes 11 trials performed in the Maritime EPPO Zone (the Czech Republic, Germany and France), 10 trials performed in the Mediterranean EPPO Zone (France, Italy and Spain) and 6 trials performed in the South-East EPPO Zone (Bulgaria and Hungary). All trials were performed in 2021 and 2022.

It is important to note that more than the requested number of applications were performed in the submitted trials, applications were continued at a 7-14 day interval until harvest (except trials KCP 6.2-88 and 112, which only had a 5 day interval between their first and second applications, but continued at a longer interval). Assessments were made before every new application to assess the efficacy of each application.

In Table 3.2-31 the trial methodology used in the trials is shown.

**Table 3.2-31: Details on trial methodology**

<b>Guidelines</b>	General guidelines	EPPO PP 1/152 (4), 1/135 (4), 1/181 (4)
	Specific guidelines	EPPO PP 1/31 (3)
<b>Experimental design</b>	Plot design	RCBD
	Plot size	9.6 – 32.0 m <sup>2</sup>
	Number of replications	4
<b>Crop</b>	Trials per crop (varieties)	<b>All submitted data:</b> 27 trials (21 varieties) <b>Maritime EPPO Zone</b> 13 trials (8 varieties) <b>Mediterranean EPPO Zone:</b> 10 trials (9 varieties) <b>South-East EPPO Zone:</b> 6 trials (5 varieties)
<b>Application</b>	Crop stage at first application	<b>Maritime EPPO Zone:</b> BBCH 13-65 <b>Mediterranean EPPO Zone:</b> BBCH 12-65 <b>South-East EPPO Zone:</b> BBCH 13-65
	Pest stage at first application	First application was preventative or at the latest at the start of the disease.
	First application-Final application	<b>Maritime EPPO Zone</b> May 5 <sup>th</sup> – June 8 <sup>th</sup> <b>Mediterranean EPPO Zone</b> April 29 <sup>th</sup> – June 1 <sup>st</sup> <b>South-East EPPO Zone</b> May 15 <sup>th</sup> – June 4 <sup>th</sup>
	Application interval	Applications were continued at 7-14 day interval. The only exceptions are trial KCP 6.2-88 and 6.2-112, where the interval between the first and second application was 5 days.
	Spray volumes	<b>Maritime EPPO Zone</b> 125 – 800 L/ha <b>Mediterranean EPPO Zone</b> 200 - 1139 L/ha <b>South-East EPPO Zone</b> 200 - 1000 L/ha
<b>Assessment</b>	Assessment types	Pest severity/incidence on leaves/bunches: from start of trial Phytotoxicity; from 7 DA-A
	e.g. Field / Greenhouse...	Field trials

<p>Comments of zRMS:</p>	<p><b>Trials methodology:</b> The Specific guidelines EPPO PP 1/31 (3) is used in dRR Experiment – design is EPPO compliant, The countries where the experiments were located should be listed Crop - no indication of the crop on which the experiments were carried out, -no pest name Application- no indication of the number of applications, Assessment types-no data on which plant organs the assessment was performed, and no units in which the assessment was performed. (this information is provided only in the text: <b>Assessment methods</b>). Appropriate methods of assessing plant damage and statistical analysis methods were used. The applicant should complete the missing data. The Methodology presented in dRR will be appropriate after the Applicant completes the above-mentioned data. The presented dRR includes three additional studies on the control of <i>P. viticola</i> in grapevines. The studies were conducted in the EPPO Maritime climate zone, in Czech Republic and Germany. These studies are also representative of Poland, as these are neighboring countries. Added trials: KCP6.2-119, KCP6.2-120, KCP6.2 - 121.</p>
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### Assessment methods

The following assessments were made in accordance with EPPO Guideline 1/2 (5):

- Phytotoxicity (and description of the symptoms) was assessed by visual estimation of the intensity on an overall plot basis on a percentage scale 0-100% (0% = no damage).
- The assessment of efficacy in the treated plots was made in relation to the untreated plot on an overall plot basis (scale 0-100%, 0% = no efficacy). Efficacy was recorded by estimation of the intensity (severity) and frequency (incidence) of the disease on the leaves and the bunches.





### Statistical analysis

Data were analysed using a two-way analysis of variance (ANOVA). The probability of no significant differences occurring between treatment means is calculated as the F probability value (Prob(F)). Student-Newman-Keuls test was then applied to separate any treatment differences that may be implied by the ANOVA TEST (Prob(F) < 0.05) and these are indicated by the LSD-value and by a letter-test. The ANOVA data and the plot data are included in the appendices of the study reports.

### Trial results

For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Efficacy data on grapes.

It should be noted that the results of all trials included in this dossier are presented together, regardless of the EPPO Zone they were performed in. An overall summary is provided, followed by a summary for each EPPO Zone separately. In the presentation of the data, the colour of the KCP numbers is used to indicate the EPPO Zone each trial was performed in:

Maritime EPPO Zone:  +   
Mediterranean EPPO Zone:   
South-East EPPO Zone: 

For every assessment the absolute value (PESSEV/PESINC) for the untreated control is given, the efficacy of the treatments is then shown as %UNCK.

In case the pest severity/incidence was below 5% for the untreated control, the efficacy results for that assessment were not taken into account for any of the summaries. These results are **marked in grey** in the presented data.

## Presentation of the results applicable to Poland

During the evaluation of the core dossier, zRMS Poland has requested an alternative presentation of the efficacy trials submitted to support the use of GLOB2013F against *Plasmopara viticola* on grapes. Therefore, this section provides an alternative analysis of the efficacy data in support of the Polish registration on grapes.

The applicant requests the Polish evaluators to decide on the acceptability of the submitted efficacy trials based on this analysis, but to allow the cMS to decide on the acceptability of the initially proposed approach in the following sections.

It should be noted that grapes are considered a minor crop in Poland, however, because grapes are a major crop in the cMS, it is crucial that the zRMS performs a complete evaluation.

**Instead of summarizing the final assessments in every trial, each trial is discussed separately to identify the assessment that best reflects the efficacy that can be expected when GLOB2013F is applied according to the requested GAP (one or two applications). The counting of the number of applications starts from the final application before disease appearance (on the assessed plant part). Earlier applications are simply discarded, because the disease did not appear and the efficacy of the treatment is lost by the time of the next application.**

**Following this approach, the corresponding summary of the efficacy data will be more representative of the intended use of GLOB2013F.**

All trials performed in the Czech Republic and Germany, which are applicable to Poland, are discussed separately. All assessment data gathered on bunches and leaves is presented to allow for the most representative assessments to be identified.

To demonstrate the efficacy of the test treatments to control downy mildew, the assessments on the bunches, are considered the most relevant.

Assessments that can be used to support the efficacy after 1 application are coloured green.

Assessments in support of 2 applications are coloured blue.

Instances where the pest pressure in the untreated was below 4.5% for the identified assessment timings, the results are coloured grey.

### **Low-severity assessments on bunches and the impact on the corresponding assessment of pest incidence**

Some representative assessments of pest incidence (PESINC) on bunches are identified where the incidence in the untreated control was above the 4.5% threshold value, meaning the results -in theory- are valid. However, if for the corresponding assessment of pest severity (PESSEV) on bunches the minimum requirement was not met for the untreated control, this can impact the statistical reliability of the pest incidence assessment for the following reasons:

1. Limited biological relevance: not a representation of moderate or high disease pressure, which is more relevant to growers.
2. Increased chance of sampling errors (false positives/false negatives), combined with a relatively low percentage of bunches infected can exaggerate or obscure effects. Small absolute differences between treatments can lead to large relative differences in calculated incidence control.

Therefore, when all representative assessments are presented at the end of this section, two summaries are made for the assessments on pest incidence (PESINC):

1. First, all assessments where pest incidence in the untreated control reached the 4.5% threshold are summarized.
2. Next, all assessments where the corresponding pest severity in the untreated control was below 4.5% are left out of the summary.

### KCP 6.2-81

The first observation of downy mildew in the trial occurred on leaves at 4 DA-E. At this time the disease was not present on bunches, where it was first observed at 7 DA-H. Therefore, application H is considered the first application that can be used to demonstrate the efficacy of the test treatments on bunches.

22 DA-H: efficacy after one application (not enough disease pressure at 7 DA-H).

No applications were made after application H.

**Table 3.2-32 Assessments on bunches in trial KCP 6.2-81**

Rating Date	15-7-2021	31-7-2021	17-8-2021	1-9-2021	15-7-2021	31-7-2021	17-8-2021	1-9-2021
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	71-75	78-79	83-85	85-85	71-75	78-79	83-85	85-85
Days after First Application	44	60	77	92	44	60	77	92
Days After Last Application	4	10	7	22	4	10	7	22
Treatment Appl. Interval	4 DA-E	10 DA-F	7 DA-H	22 DA-H	4 DA-E	10 DA-F	7 DA-H	22 DA-H
Untreated	0.0	0.0	1.8	7.0	0.0	0.0	0.1	1.0
GLOB2013F 0.1 L/ha lwa	0.0 a	0.0 a	100.0 a	74.4 a	0.0 a	0.0 a	100.0 a	90.0 a
GLOB2013F 0.17 L/ha lwa	0.0 a	0.0 a	100.0 a	85.0 a	0.0 a	0.0 a	100.0 a	93.6 a
GLOB2013F 0.23 L/ha lwa	0.0 a	0.0 a	100.0 a	100.0 a	0.0 a	0.0 a	100.0 a	100.0 a
GLOB2013F 0.4 L/ha	0.0 a	0.0 a	100.0 a	100.0 a	0.0 a	0.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	0.0 a	0.0 a	100.0 a	81.7 a	0.0 a	0.0 a	100.0 a	92.2 a
Zoxium 240 SC 0.75 L/ha	0.0 a	0.0 a	100.0 a	76.7 a	0.0 a	0.0 a	100.0 a	93.7 a

**Table 3.2-33 Assessments on leaves in trial KCP 6.2-81**

Rating Date	15-7-2021	31-7-2021	17-8-2021	1-9-2021	15-7-2021	31-7-2021	17-8-2021	1-9-2021
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	71-75	78-79	83-85	85-85	71-75	78-79	83-85	85-85
Days after First Application	44	60	77	92	44	60	77	92
Days After Last Application	4	10	7	22	4	10	7	22
Treatment Appl. Interval	4 DA-E	10 DA-F	7 DA-H	22 DA-H	4 DA-E	10 DA-F	7 DA-H	22 DA-H
Untreated	18.8	26.8	44.3	46.0	1.5	3.8	5.3	5.4
GLOB2013F 0.1 L/ha lwa	96.1 a	97.0 a	76.4 c	71.0 b	98.4 a	99.1 a	86.4 b	80.5 b
GLOB2013F 0.17 L/ha lwa	96.7 a	99.0 a	91.6 ab	88.5 a	98.8 a	99.8 a	97.2 a	94.5 a
GLOB2013F 0.23 L/ha lwa	100.0 a	100.0 a	95.4 a	93.5 a	100.0 a	100.0 a	98.8 a	97.9 a
GLOB2013F 0.4 L/ha	91.4 a	85.9 ab	91.2 ab	91.3 a	97.1 a	93.4 a	94.8 a	95.5 a
Enervin SC 0.9-1.5 L/ha	86.7 a	90.0 ab	82.9 bc	82.9 a	92.7 a	96.1 a	92.9 ab	91.4 a
Zoxium 240 SC 0.75 L/ha	58.8 b	70.6 b	75.8 c	69.4 b	73.3 b	87.3 a	86.9 b	77.8 b

It should be noted that at 22 DA-H, the pest severity on bunches in the untreated was below the 4.5% threshold, therefore the corresponding assessment of pest incidence should be handled with care.

### KCP 6.2-88

The first observation of downy mildew in the trial occurred on leaves at 11 DA-D. At this time no assessment was performed on bunches, so we cannot say for sure the disease was not present on bunches. Therefore, application D is considered the first application that can be used to demonstrate the efficacy of the test treatments.

11 DA-D: efficacy after one application (no assessment on bunches).

9 DA-E: efficacy after two applications.

**Table 3.2-34 Assessments on bunches in trial KCP 6.2-88**

Rating Date	16-7-2021	23-7-2021	28-7-2021	5-8-2021	16-7-2021	23-7-2021	28-7-2021	5-8-2021	24-8-2021
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-77	77-78	77-79	79-81	75-77	77-78	77-79	79-81	81-83
Days after First Application	49	56	61	69	49	56	61	69	88
Days After Last Application	9	4	9	17	9	4	9	17	36
Treatment Appl. Interval	9 DA-E	4 DA-F	9 DA-F	17 DA-F	9 DA-E	4 DA-F	9 DA-F	17 DA-F	36 DA-F
Untreated	32.3	64.8	97.5	99.3	5.4	19.4	62.8	67.4	72.5
GLOB2013F 0.23 L/ha lwa	85.9 ab	82.6 b	76.9 bc	73.3 b	85.9 a	89.7 a	96.0 ab	93.4 a	90.6 a
Ampexio 0.24-0.48 kg/ha	78.4 b	80.8 b	69.0 c	62.2 c	83.6 a	89.4 a	90.3 b	86.2 b	88.9 a

Rating Date	6-7-2021	16-7-2021	23-7-2021	28-7-2021	5-8-2021	6-7-2021	16-7-2021	23-7-2021	28-7-2021	5-8-2021	24-8-2021
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	73-75	75-77	77-78	77-79	79-81	73-75	75-77	77-78	77-79	79-81	81-83
Days after First Application	39	49	56	61	69	39	49	56	61	69	88
Days After Last Application	11	9	4	9	17	11	9	4	9	17	36
Treatment Appl. Interval	11 DA-D	9 DA-E	4 DA-F	9 DA-F	17 DA-F	11 DA-D	9 DA-E	4 DA-F	9 DA-F	17 DA-F	36 DA-F
Untreated	9.8	70.3	90.8	93.5	96.0	1.1	8.3	45.3	53.4	58.2	77.5
GLOB2013F 0.23 L/ha Iwa	26.5 b	63.6 c	49.7 b	45.2 bc	42.0 b	27.2 b	78.4 b	52.4 b	75.3 b	68.6 c	70.3 b
Amplexio 0.24-0.48 kg/ha	73.9 a	69.1 bc	45.2 b	38.2 c	36.7 b	78.4 ab	83.2 ab	47.2 b	66.0 b	62.6 c	70.7 b

**KCP 6.2-90**

## 10 DA-D: efficacy after one application

Unfortunately, no assessments were made between applications E and F, which could serve to support the efficacy after two applications.

Rating Date	6-7-2022	16-7-2022	3-8-2022	13-8-2022	27-8-2022	6-7-2022	16-7-2022	3-8-2022	13-8-2022	27-8-2022
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-75	77-77	79-81	83-85	85-85	75-75	77-77	79-81	83-85	85-85
Days after First Application	30	40	58	68	82	30	40	58	68	82
Days After Last Application	10	10	9	10	14	10	10	9	10	14
Treatment Appl. Interval	10 DA-C	10 DA-D	9 DA-F	10 DA-G	14 DA-H	10 DA-C	10 DA-D	9 DA-F	10 DA-G	14 DA-H
Untreated	0.0	38.8	5.0	5.0	5.0	0.0	18.3	1.0	1.4	1.5
GLOB2013F 0.1 L/ha lwa	0.0 a	67.2 b	74.3 c	74.3 c	65.8 b	0.0 a	88.9 a	87.1 b	89.9 b	84.5 a
GLOB2013F 0.17 L/ha lwa	0.0 a	77.0 ab	100.0 a	100.0 a	100.0 a	0.0 a	92.3 a	100.0 a	100.0 a	100.0 a
GLOB2013F 0.23 L/ha lwa	0.0 a	86.2 a	100.0 a	100.0 a	100.0 a	0.0 a	97.4 a	100.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	0.0 a	87.3 a	100.0 a	100.0 a	100.0 a	0.0 a	97.8 a	100.0 a	100.0 a	100.0 a
Ampexio 0.25-0.5 kg/ha	0.0 a	85.6 a	100.0 a	100.0 a	100.0 a	0.0 a	96.6 a	100.0 a	100.0 a	100.0 a

[illegible]

### KCP 6.2-91

The first observation of downy mildew in the trial occurred at 10 DA-D, this is when the disease appeared on bunches as well as leaves. Therefore, application D is considered the first application that can be used to demonstrate the efficacy of the test treatments.

10 DA-D: efficacy after one application.

10 DA-E: efficacy after two applications.

**Table 3.2-38 Assessments on bunches in trial KCP 6.2-91**

Rating Date	10-7-2022	20-7-2022	8-8-2022	18-8-2022	10-7-2022	20-7-2022	8-8-2022	18-8-2022
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-77	77-77	77-81	81-85	75-77	77-77	77-81	81-85
Days after First Application	40	50	69	79	40	50	69	79
Days After Last Application	10	10	10	10	10	10	10	10
Treatment Appl. Interval	10 DA-D	10 DA-E	10 DA-F	10 DA-G	10 DA-D	10 DA-E	10 DA-F	10 DA-G
Untreated	4.8	17.8	5.5	5.5	0.5	6.4	1.0	1.0
GLOB2013F 0.1 L/ha lwa	86.4 a	62.9 b	76.3 a	68.1 b	88.4 a	92.4 b	87.1 a	79.9 b
GLOB2013F 0.17 L/ha lwa	100.0 a	82.6 a	100.0 a	100.0 a	100.0 a	96.3 a	100.0 a	100.0 a
GLOB2013F 0.23 L/ha lwa	100.0 a	88.2 a	100.0 a	100.0 a	100.0 a	98.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	100.0 a	91.5 a	100.0 a	100.0 a	100.0 a	98.8 a	100.0 a	100.0 a
Ampexio 0.25-0.5 kg/ha	100.0 a	85.2 a	100.0 a	100.0 a	100.0 a	97.8 a	100.0 a	100.0 a

**Table 3.2-39 Assessments on leaves in trial KCP 6.2-91**

Rating Date	10-7-2022	20-7-2022	8-8-2022	18-8-2022	10-7-2022	20-7-2022	8-8-2022	18-8-2022
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-77	77-77	77-81	81-85	75-77	77-77	77-81	81-85
Days after First Application	40	50	69	79	40	50	69	79
Days After Last Application	10	10	10	10	10	10	10	10
Treatment Appl. Interval	10 DA-D	10 DA-E	10 DA-F	10 DA-G	10 DA-D	10 DA-E	10 DA-F	10 DA-G
Untreated	2.0	2.0	4.8	6.3	0.1	0.1	0.7	0.7
GLOB2013F 0.1 L/ha lwa	100.0 a	100.0 a	100.0 a	74.7 b	100.0 a	100.0 a	100.0 a	74.0 a
GLOB2013F 0.17 L/ha lwa	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
GLOB2013F 0.23 L/ha lwa	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
Ampexio 0.25-0.5 kg/ha	100.0 a	100.0 a	100.0 a	92.9 ab	100.0 a	100.0 a	100.0 a	90.9 a

It should be noted that at 10 DA-D, the pest severity on bunches in the untreated was far below the 4.5% threshold, therefore the corresponding assessment of pest incidence should be handled with care.

### KCP 6.2-92

The first observation of downy mildew in the trial occurred at 10 DA-C, this is when the disease appeared on bunches as well as leaves. Therefore, application C is considered the first application that can be used to demonstrate the efficacy of the test treatments.

10 DA-C: efficacy after one application.

10 DA-D: efficacy after two applications.

It should be noted that at 10 DA-C, the pest incidence as well as pest severity on bunches was far below the 4.5% threshold, therefore no assessment data can be used to support the efficacy of one application.

**Table 3.2-40 Assessments on bunches in trial KCP 6.2-92**

Rating Date	6-7-2022	16-7-2022	7-8-2022	17-8-2022	27-8-2022	6-7-2022	16-7-2022	7-8-2022	17-8-2022	27-8-2022
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-75	77-79	79-83	83-85	85-85	75-75	77-79	79-83	83-85	85-85
Days after First Application	28	38	60	70	80	28	38	60	70	80
Days After Last Application	10	10	10	10	10	10	10	10	10	10
Treatment Appl. Interval	10 DA-C	10 DA-D	8 DA-F	10 DA-G	10 DA-H	10 DA-C	10 DA-D	8 DA-F	10 DA-G	10 DA-H
Untreated	2.0	33.0	7.3	7.3	7.3	0.2	13.1	1.2	1.2	1.2
GLOB2013F 0.1 L/ha lwa	100.0 a	65.2 b	68.8 b	68.8 b	67.4 b	100.0 a	91.0 b	85.2 b	85.2 b	78.3 b
GLOB2013F 0.17 L/ha lwa	100.0 a	80.5 a	90.3 ab	90.3 ab	90.3 ab	100.0 a	92.4 ab	96.1 a	96.1 a	96.1 a
GLOB2013F 0.23 L/ha lwa	100.0 a	87.5 a	100.0 a	100.0 a	100.0 a	100.0 a	96.4 a	100.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	100.0 a	89.1 a	100.0 a	100.0 a	100.0 a	100.0 a	97.5 a	100.0 a	100.0 a	100.0 a
Ampexio 0.25-0.5 kg/ha	100.0 a	85.2 a	87.5 ab	87.5 ab	87.5 ab	100.0 a	94.8 ab	97.2 a	97.2 a	96.3 a

**Table 3.2-41 Assessments on leaves in trial KCP 6.2-92**

Rating Date	6-7-2022	16-7-2022	7-8-2022	17-8-2022	27-8-2022	6-7-2022	16-7-2022	7-8-2022	17-8-2022	27-8-2022
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	75-75	77-79	79-83	83-85	85-85	75-75	77-79	79-83	83-85	85-85
Days after First Application	28	38	60	70	80	28	38	60	70	80
Days After Last Application	10	10	10	10	10	10	10	10	10	10
Treatment Appl. Interval	10 DA-C	10 DA-D	8 DA-F	10 DA-G	10 DA-H	10 DA-C	10 DA-D	8 DA-F	10 DA-G	10 DA-H
Untreated	4.0	3.8	13.5	13.0	10.8	0.5	0.4	1.0	1.0	1.3
GLOB2013F 0.1 L/ha lwa	51.3 b	68.8 b	75.7 b	80.5 b	76.8 a	76.3 b	68.8 b	76.6 b	75.8 b	87.4 b
GLOB2013F 0.17 L/ha lwa	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
GLOB2013F 0.23 L/ha lwa	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
Enervin SC 0.9-1.5 L/ha	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a	100.0 a
Ampexio 0.25-0.5 kg/ha	100.0 a	100.0 a	94.5 a	98.1 a	100.0 a	100.0 a	100.0 a	94.6 a	97.2 a	100.0 a

It should be noted that at 10 DA-C, the pest incidence as well as the pest severity on bunches in the untreated were far below the 4.5% threshold, therefore no data from this trial can be used to support one application.

### KCP 6.2-94

The first observation of downy mildew in the trial occurred on bunches at 8 DA-H. Therefore, application H is considered the first application that can be used to demonstrate the efficacy of the test treatments.

8 DA-H: efficacy after one application.

12 DA-I: efficacy after two applications.

**Table 3.2-42 Assessments on bunches in trial KCP 6.2-94**

Rating Date	18-7-2022	27-7-2022	9-8-2022	24-8-2022	18-7-2022	27-7-2022	9-8-2022	24-8-2022
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	79	79	83	85	79	79	83	85
Days after First Application	53	62	75	90	53	62	75	90
Days After Last Application	5	5	8	12	5	5	8	12
Treatment Appl. Interval	5 DA-F	5 DA-G	8 DA-H	12 DA-I	5 DA-F	5 DA-G	8 DA-H	12 DA-I
Untreated	0.0	0.0	8.3	14.5	0.0	0.0	0.4	1.9
GLOB2013F 0.1 L/ha lwa	0.0 a	0.0 a	21.9 a	13.5 a	0.0 a	0.0 a	35.0 a	30.9 a
GLOB2013F 0.17 L/ha lwa	0.0 a	0.0 a	22.5 a	33.0 a	0.0 a	0.0 a	38.5 a	49.5 a
GLOB2013F 0.23 L/ha lwa	0.0 a	0.0 a	2.5 a	28.2 a	0.0 a	0.0 a	19.2 a	40.3 a
Enervin SC 0.6-2.4 L/ha	0.0 a	0.0 a	7.5 a	25.2 a	0.0 a	0.0 a	23.3 a	40.6 a
Ampexio 0.16-0.48 kg/ha	0.0 a	0.0 a	11.3 a	26.5 a	0.0 a	0.0 a	22.2 a	44.7 a

**Table 3.2-43 Assessments on leaves in trial KCP 6.2-94**

Rating Date	18-7-2022	9-8-2022	24-8-2022	18-7-2022	9-8-2022	24-8-2022
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV
Crop Stage	79	79	79	79	79	79
Days after First Application	53	62	90	53	62	90
Days After Last Application	5	5	12	5	5	12
Treatment Appl. Interval	5 DA-F	5 DA-G	12 DA-I	5 DA-F	5 DA-G	12 DA-I
Untreated	0.0	0.8	6.8	0.0	0.1	1.0
GLOB2013F 0.1 L/ha lwa	0.0 a	0.0 -	71.4 a	0.0 a	0.0 -	71.9 a
GLOB2013F 0.17 L/ha lwa	0.0 a	100.0 -	100.0 a	0.0 a	100.0 -	100.0 a
GLOB2013F 0.23 L/ha lwa	0.0 a	66.7 -	96.9 a	0.0 a	60.0 -	97.9 a
Enervin SC 0.6-2.4 L/ha	0.0 a	100.0 -	71.4 a	0.0 a	100.0 -	81.9 a
Ampexio 0.16-0.48 kg/ha	0.0 a	66.7 -	97.2 a	0.0 a	60.0 -	98.2 a

It should be noted that at 8 DA-H and 12 DA-I, the pest severity on bunches in the untreated was far below the 4.5% threshold, therefore the corresponding assessment of pest incidence should be handled with care.

The performance of all test treatments was far below the expectations. Even the reference products weren't able to reach an adequate level of efficacy.

## KCP 6.2-116

The first observation of downy mildew in the trial occurred on leaves at 8 DA-D. At this time no assessment was performed on bunches, so we cannot say for sure the disease was not present on bunches. Therefore, application D is considered the first application that can be used to demonstrate the efficacy of the test treatments.

8 DA-D: efficacy after one application (no assessment on bunches).

14 DA-E: efficacy after two applications.

**Table 3.2-44 Assessments on bunches in trial KCP 6.2-116**

Rating Date	15-7-2022	26-7-2022	3-8-2022	29-8-2022	15-7-2022	26-7-2022	3-8-2022	29-8-2022
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	78-79	79-81	80-81	83-85	78-79	79-81	80-81	83-85
Days after First Application	59	70	78	104	59	70	78	104
Days After Last Application	3	14	8	20	3	14	8	20
Treatment Appl. Interval	3 DA-E	14 DA-E	8 DA-F	20 DA-G	3 DA-E	14 DA-E	8 DA-F	20 DA-G
Untreated	5.8	7.8	19.8	24.3	0.6	1.0	2.4	4.6
GLOB2013F 0.23 L/ha lwa	59.7 a	53.2 ab	69.1 c	50.5 e	79.7 a	77.2 a	84.9 ab	75.6 c
Ampexio 0.5 kg/ha	87.5 a	87.5 ab	91.0 ab	81.7 ab	82.5 a	90.0 a	94.9 a	94.9 ab
Ampexio 0.24-0.48 kg/ha	100.0 a	100.0 a	96.4 a	77.3 abc	100.0 a	100.0 a	97.7 a	95.0 ab
Enervin SC 1.2 L/ha lwa	90.9 a	80.3 ab	69.1 c	61.9 d	92.7 a	88.6 a	75.4 b	78.5 c

**Table 3.2-45 Assessments on leaves in trial KCP 6.2-116**

Rating Date	6-7-2022	15-7-2022	26-7-2022	3-8-2022	29-8-2022	6-7-2022	15-7-2022	26-7-2022	3-8-2022	29-8-2022
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	77-78	78-79	79-81	80-81	83-85	77-78	78-79	79-81	80-81	83-85
Days after First Application	50	59	70	78	104	50	59	70	78	104
Days After Last Application	8	3	14	8	20	8	3	14	8	20
Treatment Appl. Interval	8 DA-D	3 DA-E	14 DA-E	8 DA-F	20 DA-G	8 DA-D	3 DA-E	14 DA-E	8 DA-F	20 DA-G
Untreated	4.5	13.0	15.0	32.5	37.5	0.6	1.9	2.7	6.0	9.3
GLOB2013F 0.23 L/ha lwa	55.0 a	68.0 a	60.6 a	72.9 a	55.8 c	59.9 a	62.0 a	57.3 a	70.8 a	64.7 d
Ampexio 0.5 kg/ha	86.7 a	78.5 a	76.1 a	80.0 a	78.2 ab	74.2 a	81.5 a	78.5 a	86.1 a	89.5 ab
Ampexio 0.24-0.48 kg/ha	90.8 a	71.7 a	73.6 a	83.8 a	76.8 ab	95.8 a	80.0 a	82.5 a	88.4 a	89.4 ab
Enervin SC 1.2 L/ha lwa	38.3 a	52.6 a	48.0 a	63.5 a	56.4 c	67.5 a	46.6 a	51.6 a	68.0 a	67.9 cd

It should be noted that at 14 DA-E, the pest severity on bunches in the untreated was far below the 4.5% threshold, therefore the corresponding assessment of pest incidence should be handled with care.

Alternatively, if we were to assume no disease was present on bunches at 8 DA-D, but that the disease first appeared on bunches on 3 DA-E. This would mean the assessment at 8 DA-F would demonstrate the efficacy after two applications: with a disease pressure of 19.8%, GLOB2013F showed 91% control.

## KCP 6.2-119

The first observation of downy mildew in the trial occurred on leaves at 9 DA-B. At this time the disease was not present on bunches, where it was first observed at 5 DA-D. Therefore, application D is considered the first application that can be used to demonstrate the efficacy of the test treatments on bunches.

10 DA-D: efficacy after one application (not enough disease pressure at 5 DA-D).

Unfortunately, no assessments were made between applications E and F, which could serve to support the efficacy after two applications.

**Table 3.2-46 Assessments on bunches in trial KCP 6.2-119**

Rating Date	19-6-2023	3-7-2023	8-7-2023	4-8-2023	19-6-2023	3-7-2023	8-7-2023	4-8-2023
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	57-61	69-71	71-73	79-81	57-61	69-71	71-73	79-81
Days after First Application	18	32	37	64	18	32	37	64
Days After Last Application	9	5	10	8	9	5	10	8
Treatment Appl. Interval	9 DA-B	5 DA-D	10 DA-D	8 DA-G	9 DA-B	5 DA-D	10 DA-D	8 DA-G
Untreated	0.0	3.0	18.5	28.3	0.0	0.3	8.1	17.0
GLOB2013F 0.17 L/ha lwa	0.0 a	100.0 a	51.4 b	60.3 a	0.0 a	100.0 a	40.5 b	72.0 b
GLOB2013F 0.23 L/ha lwa	0.0 a	100.0 a	80.9 a	76.0 a	0.0 a	100.0 a	84.7 a	93.7 a
Enervin SC 0.9-1.5 L/ha	0.0 a	100.0 a	73.7 a	68.0 a	0.0 a	100.0 a	76.8 a	88.0 a
Ampexio 0.25-0.5 kg/ha	0.0 a	100.0 a	75.3 a	72.0 a	0.0 a	100.0 a	76.0 a	88.2 a



**Table 3.2-47 Assessments on leaves in trial KCP 6.2-119**

Rating Date	19-6-2023	3-7-2023	8-7-2023	4-8-2023	19-6-2023	3-7-2023	8-7-2023	4-8-2023
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	57-61	69-71	71-73	79-81	57-61	69-71	71-73	79-81
Days after First Application	18	32	37	64	18	32	37	64
Days After Last Application	9	5	10	8	9	5	10	8
Treatment Appl. Interval	9 DA-B	5 DA-D	10 DA-D	8 DA-G	9 DA-B	5 DA-D	10 DA-D	8 DA-G
Untreated	2.5	11.8	16.0	19.5	0.2	0.9	1.5	2.0
GLOB2013F 0.17 L/ha lwa	100.0 a	68.7 b	59.9 b	69.7 a	100.0 a	65.5 a	47.7 a	80.7 a
GLOB2013F 0.23 L/ha lwa	100.0 a	77.7 ab	76.3 a	81.9 a	100.0 a	73.3 a	68.2 a	86.5 a
Enervin SC 0.9-1.5 L/ha	100.0 a	82.5 a	77.9 a	79.2 a	100.0 a	87.6 a	75.0 a	77.1 a
Ampexio 0.25-0.5 kg/ha	100.0 a	67.9 b	68.6 ab	84.9 a	100.0 a	69.7 a	60.6 a	85.2 a

Although the assessment data gathered at 8 DA-G cannot be used to support this registration, it should be noted that GLOB2013F still had 76% control of the disease, where products typically lose performance as the disease progresses. GLOB2013F outperformed the reference products by more than 5%, on average.

### KCP 6.2-120

The first observation of downy mildew in the trial occurred on leaves at 9 DA-C. At this time the disease was not present on bunches, where it was first observed at 10 DA-E. Therefore, application E is considered the first application that can be used to demonstrate the efficacy of the test treatments on bunches.

10 DA-E: efficacy after one application

Unfortunately, no assessments were made between applications F and G, which could serve to support the efficacy after two applications.

**Table 3.2-48 Assessments on bunches in trial KCP 6.2-120**

Rating Date	28-6-2023	8-7-2023	18-7-2023	4-8-2023	28-6-2023	8-7-2023	18-7-2023	4-8-2023
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	71-73	73-75	75-77	81-83	71-73	73-75	75-77	81-83
Days after First Application	27	37	47	64	27	37	47	64
Days After Last Application	9	10	10	8	9	10	10	8
Treatment Appl. Interval	9 DA-C	10 DA-D	10 DA-E	8 DA-G	9 DA-C	10 DA-D	10 DA-E	8 DA-G
Untreated	0.0	0.0	8.5	13.0	0.0	0.0	6.1	7.2
GLOB2013F 0.17 L/ha lwa	0.0 a	0.0 a	64.9 a	52.8 a	0.0 a	0.0 a	87.8 a	68.4 b
GLOB2013F 0.23 L/ha lwa	0.0 a	0.0 a	82.3 a	73.7 a	0.0 a	0.0 a	95.9 a	95.4 a
Enervin SC 0.9-1.5 L/ha	0.0 a	0.0 a	70.5 a	64.2 a	0.0 a	0.0 a	92.2 a	91.3 a
Ampexio 0.25-0.5 kg/ha	0.0 a	0.0 a	67.7 a	65.0 a	0.0 a	0.0 a	89.7 a	90.7 a

**Table 3.2-49 Assessments on leaves in trial KCP 6.2-120**

Rating Date	28-6-2023	8-7-2023	18-7-2023	4-8-2023	28-6-2023	8-7-2023	18-7-2023	4-8-2023
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV	PESSEV
Crop Stage	71-73	73-75	75-77	81-83	71-73	73-75	75-77	81-83
Days after First Application	27	37	47	64	27	37	47	64
Days After Last Application	9	10	10	8	9	10	10	8
Treatment Appl. Interval	9 DA-C	10 DA-D	10 DA-E	8 DA-G	9 DA-C	10 DA-D	10 DA-E	8 DA-G
Untreated	1.3	6.5	7.5	9.0	0.1	0.5	0.6	0.9
GLOB2013F 0.17 L/ha lwa	100.0 a	62.8 a	67.5 a	67.5 a	100.0 a	68.6 a	66.0 a	66.4 a
GLOB2013F 0.23 L/ha lwa	100.0 a	78.1 a	80.2 a	83.5 a	100.0 a	85.6 a	81.8 a	90.9 a
Enervin SC 0.9-1.5 L/ha	100.0 a	82.9 a	76.6 a	65.8 a	100.0 a	88.3 a	76.4 a	56.1 a
Ampexio 0.25-0.5 kg/ha	100.0 a	66.0 a	62.3 a	73.1 a	100.0 a	76.5 a	60.8 a	75.5 a

Although the assessment data gathered at 8 DA-G cannot be used to support this registration, it should be noted that GLOB2013F still had 73.7% control of the disease, where products typically lose performance as the disease progresses. GLOB2013F outperformed the reference products by more than 8%, on average.



## KCP 6.2-121

The first observation of downy mildew in the trial occurred at 5 DA-D, this is when the disease appeared on bunches as well as leaves. Therefore, application D is considered the first application that can be used to demonstrate the efficacy of the test treatments.

5 DA-D: efficacy after one application.

8 DA-E: efficacy after two applications.

**Table 3.2-50 Assessments on bunches in trial KCP 6.2-121**

Rating Date	20-6-2023	6-7-2023	18-7-2023	20-6-2023	6-7-2023	18-7-2023
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV
Crop Stage	71-73	77-78	79-80	71-73	77-78	79-80
Days after First Application	34	50	62	34	50	62
Days After Last Application	5	8	8	5	8	8
Treatment Appl. Interval	5 DA-D	8 DA-E	8 DA-F	5 DA-D	8 DA-E	8 DA-F
Untreated	8.3	44.5	73.3	0.6	29.3	57.0
GLOB2013F 0.23 L/ha lwa	91.9 a	83.4 a	60.6 b	97.9 a	96.8 a	87.1 ab
Enervin SC 1.2 L/ha lwa	46.9 b	27.7 c	14.9 d	65.0 a	50.2 b	27.3 d
Ampexio 0.5 kg/ha	84.7 a	66.5 b	50.3 c	92.6 a	89.5 a	74.9 bc
Ampexio 0.24-0.48 kg/ha	90.6 a	65.5 b	45.3 c	96.8 a	89.4 a	71.8 c

**Table 3.2-51 Assessments on leaves in trial KCP 6.2-121**

Rating Date	20-6-2023	6-7-2023	18-7-2023	20-6-2023	6-7-2023	18-7-2023
Part Rated	LEAF	LEAF	LEAF	LEAF	LEAF	LEAF
Rating Type	PESINC	PESINC	PESINC	PESSEV	PESSEV	PESSEV
Crop Stage	71-73	77-78	79-80	71-73	77-78	79-80
Days after First Application	34	50	62	34	50	62
Days After Last Application	5	8	8	5	8	8
Treatment Appl. Interval	5 DA-D	8 DA-E	8 DA-F	5 DA-D	8 DA-E	8 DA-F
Untreated	35.3	37.8	67.5	2.2	16.0	37.6
GLOB2013F 0.23 L/ha lwa	89.4 a	47.8 a	62.3 ab	92.0 a	70.3 a	76.8 abc
Enervin SC 1.2 L/ha lwa	33.5 b	3.4 c	30.5 d	40.0 b	22.1 c	42.6 d
Ampexio 0.5 kg/ha	74.5 a	29.3 b	51.5 bc	82.0 a	46.8 b	70.9 bc
Ampexio 0.24-0.48 kg/ha	87.3 a	39.7 ab	43.2 c	91.3 a	66.5 a	69.1 c

It should be noted that at 5 DA-D, the pest severity on bunches in the untreated was far below the 4.5% threshold, therefore the corresponding assessment of pest incidence should be handled with care.

## Summary

This section provides an overview of all assessments performed on bunches that can be used to support the registration of GLOB2013F for up to 2 applications.

The tables below present all assessment data that can be used to support the efficacy of a single application and two applications of GLOB2013F. For assessments of pest severity (PESSEV) it should be noted that instances where the pest severity in the untreated was below the 4.5% threshold are indicated in grey. None of these assessments were included in the summaries of pest severity results.

As already noted in the trial-by-trial analysis, assessments of pest incidence (PESINC) on bunches where the corresponding assessment of pest severity was far below the 4.5% threshold should be handled with care. Therefore, two separate summaries are made for the assessments of pest incidence: one for all assessments (no matter the corresponding pest severity in the untreated), and another without the (low pest severity) trials where the pest severity in the untreated was below the 4.5% threshold.

**Table 3.2-52 Assessment data on bunches in support of a single application**

Trial ref.	KCP 6.2-81	KCP 6.2-90	KCP 6.2-91	KCP 6.2-94	KCP 6.2-119	KCP 6.2-120	KCP 6.2-121		
Rating Date	1-9-2021	16-7-2022	10-7-2022	9-8-2022	8-7-2023	18-7-2023	20-6-2023		
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESINC	PESINC	PESINC	PESINC
Crop Stage	85-85	77-77	75-77	83	71-73	75-77	71-73	all trials	excl. low PESSEV trials
Days after First Application	92	40	40	75	37	47	34		
Days After Last Application	22	10	10	8	10	10	5		
Treatment Appl. Interval	22 DA-H	10 DA-D	10 DA-D	8 DA-H	10 DA-D	10 DA-E	5 DA-D	n Mean Min Max	n Mean Min Max
Untreated	7.0	38.8	4.8	8.3	18.5	8.5	8.3	7 13.5 4.8 38.8	3 21.9 8.5 38.8
GLOB2013F 0.1 L/ha lwa	74.4 a	67.2 b	86.4 a	21.9 a				4 62.5 21.9 86.4	1 67.2 67.2 67.2
GLOB2013F 0.17 L/ha lwa	85.0 a	77.0 ab	100.0 a	22.5 a	51.4 b	64.9 a		6 66.8 22.5 100.0	3 64.4 51.4 77.0
GLOB2013F 0.23 L/ha lwa	100.0 a	86.2 a	100.0 a	2.5 a	80.9 a	82.3 a	91.9 a	7 77.7 2.5 100.0	3 83.1 80.9 86.2
GLOB2013F 0.4 L/ha	100.0 a							1 100.0 100.0 100.0	
Enervin SC 1.2 L/ha lwa							46.9 b	1 46.9 46.9 46.9	
Enervin SC 0.9-1.5 L/ha	81.7 a	87.3 a	100.0 a		73.7 a	70.5 a		5 82.6 70.5 100.0	3 77.2 70.5 87.3
Enervin SC 0.6-2.4 L/ha				7.5 a				1 7.5 7.5 7.5	
Ampexio 0.16-0.48 kg/ha				11.3 a				1 11.3 11.3 11.3	
Ampexio 0.24-0.48 kg/ha							90.6 a	1 90.6 90.6 90.6	
Ampexio 0.25-0.5 kg/ha		85.6 a	100.0 a		75.3 a	67.7 a		4 82.2 67.7 100.0	3 76.2 67.7 85.6
Ampexio 0.5 kg/ha							84.7 a	1 84.7 84.7 84.7	
Zoxium 240 SC 0.75 L/ha	76.7 a							1 76.7 76.7 76.7	
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	
Rating Type	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	
Treatment Appl. Interval	22 DA-H	10 DA-D	10 DA-D	8 DA-H	10 DA-D	10 DA-E	5 DA-D	n Mean Min Max	
Untreated	1.0	18.3	0.5	0.4	8.1	6.1	0.6	3 10.8 6.1 18.3	
GLOB2013F 0.1 L/ha lwa	90.0 a	88.9 a	88.4 a	35.0 a				1 88.9 88.9 88.9	
GLOB2013F 0.17 L/ha lwa	93.6 a	92.3 a	100.0 a	38.5 a	40.5 b	87.8 a		3 73.5 40.5 92.3	
GLOB2013F 0.23 L/ha lwa	100.0 a	97.4 a	100.0 a	19.2 a	84.7 a	95.9 a	97.9 a	3 92.7 84.7 97.4	
GLOB2013F 0.4 L/ha	100.0 a								
Enervin SC 1.2 L/ha lwa							65.0 a		
Enervin SC 0.9-1.5 L/ha	92.2 a	97.8 a	100.0 a		76.8 a	92.2 a		3 88.9 76.8 97.8	
Enervin SC 0.6-2.4 L/ha				23.3 a					
Ampexio 0.16-0.48 kg/ha				22.2 a					
Ampexio 0.24-0.48 kg/ha							96.8 a		
Ampexio 0.25-0.5 kg/ha		96.6 a	100.0 a		76.0 a	89.7 a		3 87.4 76.0 96.6	
Ampexio 0.5 kg/ha							92.6 a		
Zoxium 240 SC 0.75 L/ha	93.7 a								

**Table 3.2-53 Assessment data on bunches in support of two applications**

Trial ref.	KCP 6.2-88	KCP 6.2-91	KCP 6.2-92	KCP 6.2-94	KCP 6.2-116	KCP 6.2-121			
Rating Date	16-7-2021	20-7-2022	16-7-2022	24-8-2022	26-7-2022	6-7-2023			
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH		BUNCH	BUNCH
Rating Type	PESINC	PESINC	PESINC	PESINC	PESINC	PESINC		PESINC	PESINC
Crop Stage	75-77	77-77	77-79	85	79-81	77-78		all trials	excl. low PESSEV trials
Days after First Application	49	50	38	90	70	50			
Days After Last Application	9	10	10	12	14	8			
Treatment Appl. Interval	9 DA-E	10 DA-E	10 DA-D	12 DA-I	14 DA-E	8 DA-E		n Mean Min Max	n Mean Min Max
Untreated	32.3	17.8	33.0	14.5	7.8	44.5		6 25.0 7.8 44.5	4 31.9 17.8 44.5
GLOB2013F 0.1 L/ha lwa		62.9 b	65.2 b	13.5 a				3 47.2 13.5 65.2	2 64.1 62.9 65.2
GLOB2013F 0.17 L/ha lwa		82.6 a	80.5 a	33.0 a				3 65.4 33.0 82.6	2 81.6 80.5 82.6
GLOB2013F 0.23 L/ha lwa	85.9 ab	88.2 a	87.5 a	28.2 a	53.2 ab	83.4 a		6 71.1 28.2 88.2	4 86.3 83.4 88.2
Enervin SC 1.2 L/ha lwa					80.3 ab	27.7 c		2 54.0 27.7 80.3	1 27.7 27.7 27.7
Enervin SC 0.9-1.5 L/ha		91.5 a	89.1 a					2 90.3 89.1 91.5	2 90.3 89.1 91.5
Enervin SC 0.6-2.4 L/ha				25.2 a				1 25.2 25.2 25.2	
Ampexio 0.16-0.48 kg/ha				26.5 a				1 26.5 26.5 26.5	
Ampexio 0.24-0.48 kg/ha	78.4 b				100.0 a	65.5 b		3 81.3 65.5 100.0	2 72.0 65.5 78.4
Ampexio 0.25-0.5 kg/ha		85.2 a	85.2 a					2 85.2 85.2 85.2	2 85.2 85.2 85.2
Ampexio 0.5 kg/ha					87.5 ab	66.5 b		2 77.0 66.5 87.5	1 66.5 66.5 66.5
Part Rated	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH	BUNCH		BUNCH	
Rating Type	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV	PESSEV		PESSEV	
Treatment Appl. Interval	9 DA-E	10 DA-E	10 DA-D	12 DA-I	14 DA-E	8 DA-E		n Mean Min Max	
Untreated	5.4	6.4	13.1	1.9	1.0	29.3		4 13.6 5.4 29.3	
GLOB2013F 0.1 L/ha lwa		92.4 b	91.0 b	30.9 a				2 91.7 91.0 92.4	
GLOB2013F 0.17 L/ha lwa		96.3 a	92.4 ab	49.5 a				2 94.4 92.4 96.3	
GLOB2013F 0.23 L/ha lwa	85.9 a	98.0 a	96.4 a	40.3 a	77.2 a	96.8 a		4 94.3 85.9 98.0	
Enervin SC 1.2 L/ha lwa					88.6 a	50.2 b		1 50.2 50.2 50.2	
Enervin SC 0.9-1.5 L/ha		98.8 a	97.5 a					2 98.2 97.5 98.8	
Enervin SC 0.6-2.4 L/ha				40.6 a					
Ampexio 0.16-0.48 kg/ha				44.7 a					
Ampexio 0.24-0.48 kg/ha	83.6 a				100.0 a	89.4 a		2 86.5 83.6 89.4	
Ampexio 0.25-0.5 kg/ha		97.8 a	94.8 ab					2 96.3 94.8 97.8	
Ampexio 0.5 kg/ha					90.0 a	89.5 a		1 89.5 89.5 89.5	

The table below provides an orthogonal comparison between GLOB2013F at the requested dose rate of 0.23 L/ha lwa and the reference products Enervin SC and Ampexio. It should be noted that the reference products were tested at several dose rates, but always in accordance with the local product registration. For simplicity, all tested dose rates of the reference products are summarized together in the table below. For trial-specific information on the tested dose rates, reference is made to the tables above.

**Table 3.2-54 Orthogonal comparison between GLOB2013F and the reference products**

Target	Part assessed	Assessment type	#appl*	No. of trials	Infestation in the untreated control (%)			% control						No of trials where product is >, <, = compared to standard
								GLO2013FF 0.23 L/ha lwa			Enervin SC			
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
PLASVI	BUNCH	PESINC	1	7	13.5	4.8	38.8	77.7	2.5	100.0	66.8	7.5	100.0	6x =, 1x >
		PESSEV	1	3	10.8	6.1	18.3	92.7	84.7	97.4	88.9	76.8	97.8	3x =
		PESINC	2	5	23.5	7.8	44.5	68.1	28.2	88.2	62.8	25.2	91.5	1x >, 4x =
		PEESEV	2	3	16.3	6.4	29.3	97.1	96.4	98.0	82.2	50.2	98.8	1x >, 2x =
Target	Part assessed	Assessment type	#appl*	No. of trials	Infestation in the untreated control (%)			% control						No of trials where product is >, <, = compared to standard
								GLO2013FF 0.23 L/ha lwa			Ampexio			
					Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	
PLASVI	BUNCH	PESINC	1	6	14.5	4.8	38.8	74.0	2.5	100.0	70.8	11.3	100.0	6x =
		PESSEV	1	3	10.8	6.1	18.3	92.7	84.7	97.4	87.4	76.0	96.6	3x =
		PESINC	2	6	25.0	7.8	44.5	71.1	28.2	88.2	73.5	26.5	100.0	2x >, 3x =, 1x <
		PESSEV	2	4	13.6	5.4	29.3	94.3	85.9	98.0	91.4	83.6	97.8	1x >, 3x =

\*1: data in support of a single application / 2: data in support of two applications

The comparison shown above clearly demonstrates that GLOB2013F provides as much control of downy mildew as the reference products Enervin SC and Ampexio at their registered dose rates. In many instances GLOB2013F even outperforms the references and provides more consistent control (higher minimal efficacy).

## Conclusion for Poland

From the presented efficacy data it is clear that GLOB2013F, applied at 0.23 L/ha lwa, offers good control of downy mildew on grapes. The efficacy results presented in Table 3.2-52 and Table 3.2-53 can be summarized as follows.

### Efficacy of a single application

Pest incidence control: 83.1% control (3 trials\*)

Pest severity control: 92.7% control (3 trials\*)

\*High reliability trials<sup>2</sup> in support of a single application: KCP 6.2-90, 119, 120

### Efficacy of two applications

Pest incidence control: 86.3% control (4 trials\*)

Pest severity control: 94.4% control (4 trials\*)

\*High reliability trials<sup>3</sup> in support of a single application: KCP 6.2-88, 91, 92, 121

In total, 7 fully supportive reliable trials have been submitted which demonstrate full (>80%) control (pest incidence and severity) of downy mildew is achieved in grapes after 1 or 2 applications of GLOB2013F at 0.23 L/ha lwa.

This therefore supports the registration of GLOB2013F for use on grapes as a major crop in Poland.

<b>Final Comments of zRMS:</b>	<p>In response to the assessments contained in the assessed RR, the Applicant submitted an updated Registration Report. The attached studies are precise, complete and clearly commented.</p> <p>-The Applicant presented three additional researches conducted on the control of <i>Plasmopara viticola</i> in grapes, located in the Czech Republic and Germany. The results obtained in these experiments are representative for the EPPO Maritime climate zone (CZ, IE) and for the EPPO North-East climate zone, including Poland, as they were located in countries neighbouring Poland (KCP 6.2-119: KCP 6.2-120, KCP 6.2-121)</p> <p>The effectiveness results of the tested agent Observer/GLOB2013F(Zoxamide, 450 g/L) used at a dose of 0.23l/10000m2 LWA( are presented below, which showed average effectiveness after one application and after two applications.</p> <p><b><u>EPPO Maritime climate zone (CZ, IE) and for the EPPO North-East climate zone, including Poland</u></b></p> <p><b><u>1 application:</u></b></p> <p>KCP 6.2-90 (2022 – Czech Republic) - <b>97.4%</b></p> <p>KCP 6.2-119 – (2023 – Czech Republic ) - <b>95.9%</b></p> <p>KCP 6.2-120 – (2023 – Czech Republic) - <b>84.7%</b></p> <p><b>Summary :</b></p> <p>Average level of bunch infection by <i>P. viticola</i> in the untreated control: <b>10.8%</b>(in each trial higher than the 5% threshold)</p> <p>Average effectiveness: <b>92.7%</b></p> <p>Average effectiveness of the comparative fungicide Ampexio: <b>87.3%.</b></p> <p><b><u>2 applicatinos :</u></b></p> <p>KCP 6.2-88 (2021 -Germany) - <b>85.9%</b></p> <p>KCP 6.2-91 (2022 – Czech Republic) - <b>98.0%</b></p> <p>KCP 6.2-92 (2022 – Czech Republic) - <b>96.4%</b></p>
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<sup>2</sup> Trials where both pest incidence and pest severity in the untreated were above 4.5% at the representative assessment timing.

**KCP 6.2-121 – (2023 -Czech Republic) - 96.8%**

**Summary :**

Average level of bunch infection by *P. viticola* in the untreated control: **13.6%**( in each trial higher than the 5% threshold)

Average effectiveness: **94.3%**

Average effectiveness of the comparative fungicide Ampexio: **91.4%**.

The applicant submitted an appropriate number (7) of representative, appropriately located trials (DE,CZ) for the EPPO Maritime climatic zone (CZ, IE) and for the North-East zone (PL). *Plasmopara viticola* occurrence levels averaged 11-14% of the bunches area. This level of infestation is appropriate for assessing disease control effectiveness.

The evaluations conducted in the presented trials allowed for the assessment of the effectiveness of Observer/GLOB2013F after one and two applications in protecting grapes against *P. viticola* infection.

The tested product, Obsever/GLOB2013F, demonstrated an effectiveness of 85-97% after a single application from the pathogen's appearance, while the reference product, Ampexio, demonstrated an effectiveness of 87%. Two applications of Observer/GLOB2013F resulted in an effectiveness of 86-98% in grapevine protection. The reference product, Ampexio, demonstrated an average effectiveness of 91%. The study product Observer/GLOB2013F performed at a similar or higher level of effectiveness than the reference product Ampexio.

**The researches presented in the dRR meets the requirements for representativeness and appropriate effectiveness (1 application 84% and 2 applications 94%, at a similar or higher level of the reference product Ampexio) in controlling *Plasmopara viticola* in grapevines, which justifies the full registration of the Observer/GLOB2013F(Zoxamide, 450 g/L) product used at a dose of 0.23l/10000m<sup>2</sup> tLWA in Poland for the control of major pests in grape as a major crops. This is consistent with label, the GAP table: intended uses and justifies the registration of this product.**

-The Applicant presented 6 researches conducted on the control of *Plasmopara viticola* in grapes, located in the Bulgaria and Hungary. The results obtained in these experiments are representative for the EPPO South-East climate zone (HU, SK, RO).

The effectiveness results of the tested agent Observer/GLOB2013F(Zoxamide, 450 g/L) used at a dose of 0.23l/10000m<sup>2</sup> tLWA are presented below, which showed average effectiveness after two applications.

**EPPO South-East climate Zone HU, RO, SK**

**2 applications:**

KCP 6.2-84 (2021 – Bulgaria) – bunch infest. -38.5%, effectiveness - **95.4%**

KCP 6.2-87 (2021 – Bulgaria) - bunch infest. -6.2%, - effectiveness -**38.6%**

KCP 6.2-89 (2022 – Bulgaria) – bunch infest.-12.9%, effectiveness - **71.4%**

KCP 6.2-100 (2022 – Hungary) – bunch infest.-9.2% , effectiveness - **99.1%**

KCP 6.2-111 (2022 – Hungary) – bunch infest.-12.6%, effectiveness - **58.2%**

KCP 6.2-101(2022 – Bulgaria)–**bunch infest. 2.8%, inc. 33.5 % , effect.90%**

	<p>- <i>Comment to KCP6.2-101</i>: After two applications from the appearance of disease symptoms, the infection level was <b>2.8%</b>, but incidence was high-<b>33,5%</b>, the efficacy was <b>90.2%</b>, the efficacy of the reference fungicide Enervin SC was <b>96.6%</b>, and the Ampexio was <b>92.8%</b>.</p> <p>- <i>Comment to table</i>: Bunch infestation by <i>P.viticola</i> in the untreated control.</p> <p><b>Summary:</b> Average infection level from 6 trials: <b>13.8%</b> Average efficacy from 6 trials: <b>75.5%</b> Average efficacy of the reference fungicide Enervin SC: <b>90.1%</b> (KCP 6.2-84, KCP 6.2-87, KCP 6.2-100) Average efficacy of the reference fungicide Zoxium 240 SC: <b>76.9%</b> (KCP 6.2-84, KCP 6.2-87) Average efficacy of the reference fungicide Ampexio: <b>96.7%</b> (KCP 6.2-89, KCP 6.2-100, KCP 6.2-111)</p> <p>The presented results from 6 experiments meet the requirements. One experiment with a lower level of bunch infestation (approx. 3%) but with a frequent occurrence of 33.5% bunches was also considered as representative for the evaluation of the effect of the agent Observer/GLOB2013F. The trials were appropriately located in Bulgaria and Hungary, corresponding to the EPPO South-East climatic zone.</p> <p>The tested preparation Observer/GLOB 2013F showed from 38% to 99% (average 75.5%) of effectiveness in controlling <i>P. viticola</i> on grapevines. The reference preparations had a similar effect - Zoxium 76.9% and a higher effect - Enervin SC 90% and Ampexio 96.7%.</p> <p><b>The researches presented in the dRR meets the requirements for representativeness and appropriate effectiveness of 2 applications 76.9%, at a similar or lower level of the reference product (Zoxium 240 SC, Enervin SC, Ampexio ) in controlling <i>Plasmopara viticola</i> in grapevines, which justifies the registration of the Observer/GLOB2013F(Zoxamide, 450 g/L) product used at a dose of 0.23l/10000m<sup>2</sup> tLWA in two applications.</b></p> <p><b>This is consistent with the GAP table: intended uses and justifies the registration of this product in countries of the EPPO South-East climate zone. Individual decisions on the registration of Obsever/GLOB2013F belong to the cMS countries, which is consistent with their formal requirements.</b></p>
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## Presentation of reesults for cMS

The tables below summarize the results obtained in the presented efficacy trials. First, summaries are provided for all EPPO Zones combined, followed by separate summaries per EPPO Zone.

### All EPPO Zones

To provide an overview of all obtained efficacy data, Table 3.2-55 below summarizes the efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.23 L/ha lwa and the reference products Enervin SC (Table 3.2-56) and Ampexio (Table 3.2-57) at their respective registered dose rate(s) (for more information on the country-specific registrations please refer to A list of all reference standards used in the presented trials on potatoes and grapes is given below in Table 3.2-7.-

Table 3.2--3.

**Table 3.2-55 Efficacy of GLOB2013F against PLASVI- All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	22	20.6	5.4	58.2	83.8	61.9	98.8	87.5	12.6	90.3	62.6	100.0	94.1	10.2
PESINC	LEAF	BBCH 75 - 85	26	55.0	6.3	100.0	70.0	28.3	100.0	71.0	20.7	79.5	28.3	100.0	81.9	18.9
PESSEV	BUNCH	BBCH 78 - 85	22	26.8	3.4	92.3	82.3	43.1	99.4	84.4	14.1	89.7	62.6	100.0	94.7	11.5
PESINC	BUNCH	BBCH 78 - 85	27	51.1	5.0	100.0	69.6	10.8	100.0	77.2	25.6	78.6	24.4	100.0	85.2	20.9

**Table 3.2-56 Orthogonal comparison between GLOB2013F and Enervin SC against PLASVI - All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Enervin SC				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	18	18.4	5.4	36.7	84.2	61.9	98.8	88.2	13.3	85.7	34.2	98.7	92.5	17.3
PESINC	LEAF	BBCH 75 - 85	22	51.8	6.3	100.0	72.8	30.8	100.0	72.2	19.2	71.4	0.0	100.0	76.1	24.2
PESSEV	BUNCH	BBCH 78 - 85	18	23.4	3.4	87.6	81.4	43.1	99.4	83.7	14.3	81.2	0.0	99.3	90.8	26.1
PESINC	BUNCH	BBCH 78 - 85	22	46.6	5.0	100.0	70.5	24.0	100.0	77.7	24.1	75.4	4.5	100.0	83.5	24.5

**Table 3.2-57 Orthogonal comparison between GLOB2013F and Ampexio against PLASVI - All EPPO Zones**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Ampexio				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	18	21.1	6.7	58.2	82.1	61.9	98.8	87.1	13.2	87.5	62.6	100.0	88.6	11.1
PESINC	LEAF	BBCH 75 - 85	22	54.8	6.3	100.0	68.8	28.3	100.0	70.9	21.9	76.1	28.3	100.0	83.3	21.6
PESSEV	BUNCH	BBCH 78 - 85	20	26.0	3.4	92.3	81.6	43.1	99.4	84.1	14.4	82.9	0.0	100.0	90.1	22.9
PESINC	BUNCH	BBCH 78 - 85	23	51.1	5.0	100.0	68.6	10.8	100.0	73.3	26.4	74.2	24.4	100.0	83.2	24.2

### Summary

The efficacy results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate on grapes. The amount of control on leaves and bunches was calculated from pest severity data (PESSEV: the percentage of total leaf/bunch surface infested) and pest incidence data (PESINC: the percentage of infested leaves/bunches).

It should be noted that pest incidence does not take into account how much of the affected leaf/bunch is covered; therefore the amount of control calculated from pest severity data (PESSEV) provides the most accurate representation of a product's efficacy. The level of control (PESSEV) offered by GLOB2013F at the 0.23 L/ha lwa dose rate was always in excess of 80%, therefore it can be stated that GLOB2013F effectively controls PLASVI on grapes.

From the orthogonal comparisons to Enervin SC and Ampexio it is clear that GLOB2013F provides highly similar levels of control, with only minor differences in efficacy and can therefore be considered an equivalent product.

It should be noted that although 0.23 L/ha lwa was demonstrated to be the minimum effective dose to acquire good, consistent control of PLASVI under a wide variety of conditions, it is clear from the Minimum Effective Dose (MED) results presented in section 3.2.2.2 that good efficacy (>80% control) can already be achieved at a dose rate of 0.17 L/ha lwa in many of the presented trials. Overall, close to 80% efficacy was reached, which further supports this statement. Reference is made to the individual trial results in Appendix 5 of the Biological Assessment Dossier (BAD). Therefore,



in countries that prefer to have a dose range on the label (HU, RO, SK), the applicant requests registration of the 0.17-0.23 L/ha lwa dose range.

## Maritime EPPO Zone

Table 3.2-58 below summarizes the efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.23 L/ha lwa and the reference products Enervin SC (Table 3.2-59) and Ampexio (Table 3.2-60), at their respective registered dose rate(s) (for more information on the country-specific registrations please refer to A list of all reference standards used in the presented trials on potatoes and grapes is given below in Table 3.2-7.- Table 3.2--3.

**Table 3.2-58 Efficacy of GLOB2013F against PLASVI - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 79 - 85	7	27.6	5.4	58.2	85.5	64.7	98.8	90.2	14.3	87.6	62.6	98.8	91.4	13.1
PESINC	LEAF	BBCH 79 - 85	10	52.8	6.3	100.0	77.3	28.3	100.0	87.6	25.9	79.3	28.3	100.0	89.7	25.7
PESSEV	BUNCH	BBCH 79 - 84	6	46.4	4.6	92.3	82.7	67.2	99.4	81.9	14.2	88.8	62.6	98.5	93.7	13.7
PESINC	BUNCH	BBCH 79 - 85	11	46.3	5.0	100.0	72.9	10.8	100.0	88.7	32.1	75.1	24.4	100.0	81.7	27.5

**Table 3.2-59 Orthogonal comparison between GLOB2013F and Enervin SC against PLASVI - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Enervin SC				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 79 - 85	4	19.9	5.4	35.9	89.6	64.7	98.8	97.5	16.6	86.4	67.9	98.6	89.5	13.1
PESINC	LEAF	BBCH 79 - 85	7	34.9	6.3	74.5	88.4	55.8	100.0	93.5	15.7	80.5	56.4	100.0	82.9	17.5
PESSEV	BUNCH	BBCH 79 - 84	4	31.6	4.6	58.2	85.2	68.6	99.4	86.3	15.4	68.8	0.0	98.5	88.3	46.8
PESINC	BUNCH	BBCH 79 - 85	8	26.3	5.0	77.5	82.7	28.2	100.0	97.2	27.7	80.9	25.2	100.0	89.4	26.0

**Table 3.2-60 Orthogonal comparison between GLOB2013F and Ampexio against PLASVI - Maritime EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Ampexio				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 79 - 85	6	31.4	9.3	58.2	83.4	64.7	98.8	85.6	14.4	86.9	62.6	98.8	92.1	14.2
PESINC	LEAF	BBCH 79 - 85	9	53.5	6.3	100.0	75.5	28.3	100.0	84.5	26.8	77.9	28.3	100.0	89.1	26.5
PESSEV	BUNCH	BBCH 79 - 84	6	46.4	4.6	92.3	82.7	67.2	99.4	81.9	14.2	88.6	62.6	98.5	93.7	13.5
PESINC	BUNCH	BBCH 79 - 85	10	50.2	5.0	100.0	70.2	10.8	100.0	81.0	32.4	72.9	24.4	100.0	84.6	27.7

## Summary

The efficacy results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate on grapes. The amount of control on leaves and bunches was calculated from pest severity data (PESSEV: the percentage of total leaf/bunch surface infested) and pest incidence data (PESINC: the percentage of infested leaves/bunches).

It should be noted that pest incidence does not take into account how severely the leaves/bunches are affected (% coverage); therefore the amount of control calculated from pest severity data (PESSEV) provides the most accurate representation of a product's efficacy. The level of control (PESSEV) offered by GLOB2013F at the 0.23 L/ha lwa dose rate was always in excess of 80%, therefore it can be stated that GLOB2013F effectively controls PLASVI on grapes. From the orthogonal comparisons to Enervin SC and Ampexio it is clear that GLOB2013F provides highly similar levels of control, with only minor differences in efficacy and can therefore be considered an equivalent product.

It should be noted that although 0.23 L/ha lwa was demonstrated to be the minimum effective dose to acquire good, consistent control of PLASVI under a wide variety of conditions, it is clear from the Minimum Effective Dose (MED) results presented in section 3.2.2.2 that good efficacy (>80% control) can already be achieved at a dose rate of 0.17 L/ha lwa in many of the presented trials. Overall, close to 80% efficacy was reached, which further supports this statement. Reference is made to the individual trial results in Appendix 5 of the Biological Assessment Dossier (BAD). Therefore, in countries that prefer to have a dose range on the label (HU, RO, SK), the applicant requests registration of the 0.17-0.23 L/ha lwa dose range.

## Mediterranean EPPO Zone

Table 3.2-61 below summarizes the efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.23 L/ha lwa and the reference products Enervin SC (Table 3.2-62) and Ampexio (Table 3.2-63), at their respective registered dose rate(s) (for more information on the country-specific registrations please refer to A list of all reference standards used in the presented trials on potatoes and grapes is given below in Table 3.2-7.- Table 3.2--3.

**Table 3.2-61 Efficacy of GLOB2013F against PLASVI - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	9	19.4	6.7	36.7	80.1	61.9	98.3	86.6	13.7	88.5	68.7	98.7	90.1	10.0
PESINC	LEAF	BBCH 75 - 85	10	57.7	6.8	100.0	60.9	30.8	89.2	66.0	17.8	74.9	53.6	100.0	74.1	14.8
PESSEV	BUNCH	BBCH 78 - 85	10	22.0	3.4	87.6	83.9	67.6	96.7	84.4	9.9	88.2	65.8	99.5	92.6	12.0
PESINC	BUNCH	BBCH 78 - 85	10	54.9	22.0	100.0	66.1	24.0	94.4	71.4	22.7	78.9	49.1	96.8	86.0	16.6

**Table 3.2-62 Orthogonal comparison between GLOB2013F and Enervin SC against PLASVI - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Enervin SC				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	9	19.4	6.7	36.7	80.1	61.9	98.3	86.6	13.7	80.9	34.2	98.7	90.1	22.3
PESINC	LEAF	BBCH 75 - 85	9	63.3	41.5	100.0	60.7	30.8	89.2	68.5	18.9	65.8	23.0	92.5	72.6	21.2
PESSEV	BUNCH	BBCH 78 - 85	9	23.9	3.4	87.6	82.9	67.6	96.7	84.0	10.0	82.9	35.9	99.3	90.9	21.2
PESINC	BUNCH	BBCH 78 - 85	9	58.5	22.5	100.0	62.9	24.0	86.9	65.5	21.6	70.6	4.5	96.8	73.7	29.3

**Table 3.2-63 Orthogonal comparison between GLOB2013F and Ampexio against PLASVI - Mediterranean EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Ampexio				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 78 - 85	8	18.8	6.7	36.7	79.2	61.9	98.3	78.6	14.4	84.8	68.7	98.4	86.7	9.1
PESINC	LEAF	BBCH 75 - 85	9	58.4	6.8	100.0	60.0	30.8	89.2	63.5	18.6	69.1	51.0	100.0	68.9	17.2
PESSEV	BUNCH	BBCH 78 - 85	9	21.2	3.4	87.6	83.9	67.6	96.7	84.8	10.5	84.1	65.8	99.5	87.4	12.2
PESINC	BUNCH	BBCH 78 - 85	9	54.8	22.0	100.0	64.9	24.0	94.4	65.5	23.7	70.0	27.8	96.6	74.2	22.9

## Summary

The efficacy results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate on grapes. The amount of control on leaves and bunches was calculated from pest severity data (PESSEV: the percentage of total leaf/bunch surface infested) and pest incidence data (PESINC: the percentage of infested leaves/bunches).

It should be noted that pest incidence does not take into account how much of the affected leaf/bunch is covered; therefore the amount of control calculated from pest severity data (PESSEV) provides the most accurate representation of a product's efficacy. The level of control (PESSEV) offered by GLOB2013F at the 0.23 L/ha lwa dose rate was always in excess of 80%, therefore it can be stated that GLOB2013F effectively controls PLASVI on grapes. From the orthogonal comparisons to Enervin SC and Ampexio it is clear that GLOB2013F provides highly similar levels of control, with only minor differences in efficacy and can therefore be considered an equivalent product.

It should be noted that although 0.23 L/ha lwa was demonstrated to be the minimum effective dose to acquire good, consistent control of PLASVI under a wide variety of conditions, it is clear from the Minimum Effective Dose (MED) results presented in section 3.2.2.2 that good efficacy (>80% control) can already be achieved at a dose rate of 0.17 L/ha lwa in many of the presented trials. Overall, close to 80% efficacy was reached, which further supports this statement. Reference is made to the individual trial results in Appendix 5 of the Biological Assessment Dossier (BAD). Therefore, in countries that prefer to have a dose range on the label (HU, RO, SK), the applicant requests registration of the 0.17-0.23 L/ha lwa dose range.

### South-East EPPO Zone

Table 3.2-64 below summarizes the efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate and allows comparison to the best performing reference product within each trial. This table is followed by an orthogonal comparison between GLOB2013F at the 0.23 L/ha lwa and the reference products Enervin SC (Table 3.2-65) and Ampexio (Table 3.2-66), at their respective registered dose rate(s) (for more information on the country-specific registrations please refer to A list of all reference standards used in the presented trials on potatoes and grapes is given below in Table 3.2-7.- Table 3.2--3.

**Table 3.2-64 Efficacy of GLOB2013F against PLASVI - South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Best reference				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 81 - 83	6	14.3	8.9	31.3	87.3	71.4	95.0	89.1	8.5	87.3	71.4	95.0	89.1	8.5
PESINC	LEAF	BBCH 81 - 83	6	54.4	33.0	77.3	72.7	58.4	83.6	72.2	8.7	87.3	77.3	99.0	86.7	9.6
PESSEV	BUNCH	BBCH 81 - 83	6	15.2	4.5	40.4	79.5	43.1	99.2	83.9	20.9	93.0	74.6	100.0	96.9	9.5
PESINC	BUNCH	BBCH 81 - 83	6	53.6	27.0	81.0	69.3	45.5	93.9	73.0	19.5	84.7	65.2	100.0	88.1	14.3

**Table 3.2-65 Orthogonal comparison between GLOB2013F and Enervin SC against PLASVI - South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Enervin SC				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 81 - 83	5	15.4	9.6	31.3	87.2	71.4	95.0	90.5	9.4	87.2	71.4	95.0	90.5	9.4
PESINC	LEAF	BBCH 81 - 83	6	54.4	33.0	77.3	72.7	58.4	83.6	72.2	8.7	69.1	0.0	91.4	79.1	34.6
PESSEV	BUNCH	BBCH 81 - 83	5	15.9	4.5	40.4	75.5	43.1	95.6	76.4	20.7	88.1	69.1	97.1	90.7	11.2
PESINC	BUNCH	BBCH 81 - 83	5	57.6	27.0	81.0	64.3	45.5	82.2	66.7	17.1	74.9	65.2	91.0	67.9	12.2

**Table 3.2-66 Orthogonal comparison between GLOB2013F and Ampexio - against PLASVI South-East EPPO Zone**

Rating type	Part rated	Timing	n	Infestation in the untreated			% control									
							GLOB2013F 0.23 L/ha lwa					Ampexio				
				Mean	Min	Max	Mean	Min	Max	Med.	Stdev	Mean	Min	Max	Med.	Stdev
PESSEV	LEAF	BBCH 81 - 83	4	10.5	8.9	12.9	86.1	71.4	95.0	89.1	10.3	86.1	71.4	95.0	89.1	10.3
PESINC	LEAF	BBCH 81 - 83	4	49.7	33.0	60.8	73.5	58.4	83.6	75.9	11.1	87.6	63.5	99.0	94.0	16.4
PESSEV	BUNCH	BBCH 81 - 83	5	10.1	4.5	21.6	76.3	43.1	99.2	76.4	21.7	74.1	0.0	100.0	96.6	42.6
PESINC	BUNCH	BBCH 81 - 83	4	45.2	27.0	70.0	72.7	48.0	93.9	74.5	19.9	87.0	60.6	100.0	93.6	18.0

### Summary

The efficacy results shown in the tables above confirm the good efficacy of GLOB2013F at the 0.23 L/ha lwa dose rate on grapes. The amount of control on leaves and bunches was calculated from pest severity data (PESSEV: the percentage of total leaf/bunch surface infested) and pest incidence data (PESINC: the percentage of infested leaves/bunches).

It should be noted that pest incidence does not take into account how much of the affected leaf/bunch is covered; therefore the amount of control calculated from pest severity data (PESSEV) provides the most accurate representation of a product's efficacy. The level of control (PESSEV) offered by GLOB2013F at the 0.23 L/ha lwa dose rate was always in excess of 80%, therefore it can be stated that GLOB2013F effectively controls PLASVI on grapes.

From the orthogonal comparisons to Enervin SC and Ampexio it is clear that GLOB2013F provides highly similar levels of control, with only minor differences in efficacy and can therefore be considered an equivalent product.

It should be noted that although 0.23 L/ha lwa was demonstrated to be the minimum effective dose to acquire good, consistent control of PLASVI under a wide variety of conditions, it is clear from the Minimum Effective Dose (MED) results presented in section 3.2.2.2 that good efficacy (>80% control) can already be achieved at a dose rate of 0.17 L/ha lwa in many of the presented trials. Overall, close to 80% efficacy was reached, which further supports this statement. Reference is made to the individual trial results in Appendix 5 of the Biological Assessment Dossier (BAD). Therefore, in countries that prefer to have a dose range on the label (HU, RO, SK), the applicant requests registration of the 0.17-0.23 L/ha lwa dose range.

Comments of zRMS:	<b>Grapes</b>  Experiments carried out in the 3 climatic zones of the EPPO have the same deficiencies and inaccuracies.
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	<p>Experiments performed in the South-East, Maritime - (CZ+DE representative for PL, North- East), Mediterranean climate EPPO zone did not meet the requirements regarding the intensity of <i>Plasmopara viticola</i>. The first two applications of the tested product were made only as a preventive measure. The lack of plant infection by <i>P. viticola</i> did not provide grounds for assessing the effectiveness of the tested agent used in the first two applications.</p> <p>Only experiments where disease infestation was more than 5% in the untreated control <b>were selected for analysis.</b></p> <p><b>The Applicant in dRR presented</b> the effectiveness of the GLOB2013F (Observer 0.3l/ha) agent based on <b>assessment dates only</b> 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 <i>P. viticola</i>.</p> <p>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.</p> <p><b>The data provided are not sufficient for GLOB2013F (Observer at the 0.23 L/ha10000m2tlwa dose rate) registration in the South-East, Maritime - (CZ representative for PL, North- East), Mediterranean EPPO climate zone for the control of <i>Plasmopara viticola</i> in a grape. This is in accordance with the GAP Table, the label and the uniform Principles. Conditional registration of the tested product is possible if the Applicant provides 3 additional representative experiments consistent with the label assumptions. One experiment for each zone.</b></p>
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### **3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)**

#### **3.3.1 Inherent risk of active substance**

Zoxamide is the only fungicide in the group of the benzamides, which inhibit tubulin polymerization (B3, FRAC Code 22) which destroys the microtubule cytoskeleton, thereby arresting nuclear division. According to the FRAC, group 22 fungicides are considered low to medium risk.

Interestingly, most attempts to induce zoxamide resistance in laboratory studies have failed<sup>3</sup>, suggesting that the risk of a highly resistant pathogen population developing rapidly in the field is low.

#### **3.3.2 Inherent risk of target pathogen**

*Phytophthora infestans* was first considered a pathogen with a high risk of developing resistance, because it quickly developed resistance to phenylamide fungicides. However, although there is full cross-resistance among all members of the phenylamide (PA) fungicides there is no cross-resistance between PA fungicides and any of the other chemical classes, including carbamates. This resulted in a re-classification of *P. infestans*, making it a medium risk pathogen for all modes of action<sup>4</sup>. This means it poses a much lower risk than initially thought, because resistance is not a major problem or has been slow to develop.

*Plasmopara viticola* is considered a pathogen with a high risk of developing resistance, it has developed resistance to many of the currently used fungicide classes used and constitutes one of the most important threats for grapevine production.

#### **3.3.3 Evidence of resistance**

Zoxamide-resistance has been observed in *Phytophthora capsica*, which infests a wide range of Cucurbitaceae and Solanaceae hosts, in China and the US. It should be noted that these isolates' EC<sub>50</sub> values weren't dramatically higher than baseline sensitivity<sup>5</sup>.

In the EU, zoxamide has been extensively used on a wide range of crops since its introduction in 2003 without any resistance cases ([https://resistance.eppo.int/database/cases\\_list](https://resistance.eppo.int/database/cases_list)).

#### **3.3.4 Cross resistance**

It is very unlikely there's cross-resistance between zoxamide and other fungicides. It is the only member of toluamide fungicides and the only EU registered B3 fungicide. A 2016 study by Cai *et al.* confirmed that zoxamide resistant mutants (lab-created) of *Phytophthora sojae* show no cross-resistance to other fungicides<sup>6</sup>.

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<sup>3</sup> Young DH, Spiewak SL, Slaweki RA. Laboratory studies to assess the risk of development of resistance to zoxamide. Pest Manag Sci. 2001 Nov;57(11):1081-7. doi: 10.1002/ps.399. PMID: 11721527.

<sup>4</sup> Pathogen Risk List, FRAC, September 2019

<sup>5</sup> Bi Y, Chen L, Cai M, Zhu S, Pang Z, Liu X. Two non-target recessive genes confer resistance to the anti-oomycete microtubule inhibitor zoxamide in *Phytophthora capsici*. PLoS One. 2014 Feb 20;9(2):e89336. doi: 10.1371/journal.pone.0089336. PMID: 24586697; PMCID: PMC3930715.

<sup>6</sup> Cai M, Miao J, Song X, Lin D, Bi Y, Chen L, Liu X and Tyler BM (2016) C239S Mutation in the  $\beta$ -Tubulin of *Phytophthora sojae* Confers Resistance to Zoxamide. Front. Microbiol. 7:762. doi: 10.3389/fmicb.2016.00762

### 3.3.5 Sensitivity data

No information on the baseline sensitivity of *Phytophthora infestans* and/or *Plasmopara viticola* to zoxamide is available to the applicant.

### 3.3.6 Use pattern

The use pattern is detailed in the GAP table.

### 3.3.7 Acceptability of the resistance risk

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.

### 3.3.8 Resistance management strategy

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 utilised in such a way that their effectiveness is maintained.

The applicant suggests the following general guidelines;

- When multiple applications are required in a single growing season, use mixtures or alternate (in block sprays or in sequence) with effective non-cross-resistant fungicides.
- If performance of carbamates declines and less sensitive forms of the pathogen are detected, carbamates should only be used in mixture or alternated with effective non-cross-resistant fungicides.
- Avoid exclusive repeated use of fungicides from the same fungicide group code. Alternate with products from different fungicide group codes
- Complementary use of other fungicide classes with different modes of action should be maximised.
- Use as recommended on the label. Do not use reduced doses. This ensures good performance and reduces the risk of resistance development.
- Integrate other control methods (chemical, cultural, biological) into disease control programmes.
- Use other measures such as resistant varieties, good agronomic practice, plant hygiene.

Comments of zRMS:	<p><b>Resistance</b></p> <p>The GLOB2013F (Obsever 0.3l/ha) preparation contains one a.s. zoxamide. The active substance zoxamide is registered in Poland and Europe in many agents intended for application to control diseases in plants as a <i>Phytophthora infestans</i> on potatoes, tomatoes and against <i>Plasmopara viticola</i> on grapevines and others during the vegetation season.</p> <p>According to FRAC's information, fungus <i>Phytophthora infestans</i> developed resistance quite rapidly to phenylamide fungicides but not at all to CAA fungicides and Carbamates and other.</p> <p>FRAC re-classified <i>P. infestans</i> as a medium risk pathogen for all modes of action. However, the grapevine pathogen <i>Plasmopara viticola</i> is listed in FRAC, Pathogen Risk List in Table 1 as a plant pathogen showing a high risk of development of resistance to fungicide.</p> <p>According to FRAC's target site and code B3, FRAC code 22: Chemical group benzamides, common name <b>zoxamide</b> is in group of low to medium risk of resistance but resistance management is required.</p> <p>Currently, there is no risk of pathogens resistance to zoxamide, but with very frequent use this phenomenon may occur. Adequate policy should be followed and</p>
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	<p>zoxamide should not be applied more than three times per season on one crop.</p> <p><u>Information from the FRAC</u></p> <p>Information is provided about the risk of pathogens to develop resistance to fungicides under specific agronomic conditions.</p> <p>The risk increases when a pathogen undergoes many and short disease cycles per season.</p> <p>When the dispersal through spores over time and space is high.</p> <p>Furthermore, the risk is considered as high when resistance evolved already after few years of product use.</p> <p>Therefore, we consider the pathogen risk as medium to high only if resistance was reported in commercial situations for more than one fungicide class.</p> <p><b>The Applicant</b> in section 3.3 has provided current data on pathogen resistance to a.s. zoxamide.</p> <p>An appropriate EPPO PP 1/213 guidelines (4)-compatible resistance policy should be presented.</p> <p><b>The Applicant included the appropriate indications in dRR and on the label for the use of an anti-immune strategy for GLOB2013F (Obsever ) 0,3l/ha for <i>Phytophthora infestance</i> control and 0.23 L/ha10000m<sup>2</sup> tLwa dose rate preparation for <i>Plasmopara viticola</i> on grape control.</b></p> <p>There should also be a wide information campaign among the producers of potatoes and grapevines.</p>
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### 3.4 Adverse effects on treated crops (KCP 6.4)

#### 3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Plant protection products containing zoxamide have been applied to a wide variety of vegetables in different countries for many years without any reports of damage symptoms to the crops. The active substance is considered safe.

In accordance with EPPO PP 1/135 (4), crop safety assessments were made in the efficacy trials presented in this dossier (3.2.3). This guideline states that for fungicides it is considered sufficient to demonstrate the crop safety at the N dose rate when no phytotoxicity is expected.

The tables below summarize the phytotoxicity observed in the efficacy trials included in this submission, performed on potatoes and grapes, separately.

##### Use on potatoes

Number of trials with...		Efficacy trials (36 trials)	
		GLOB2013F	Reference products
		0.3/0.33 L/ha	N
<b>Maximum of phytotoxicity recorded during the trials</b>	0% to 5%	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		
<b>Level of symptoms at the last assessments</b>	0% to 5%	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials	13 Maritime trial (6 CZ/DE) 11 North-East trials 6 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		

##### Conclusion

No significant adverse effects were recorded at the proposed dose rate, nor at higher tested dose rates (0.33 L/ha = 110%). Therefore GLOB2013F can be considered safe for use on potatoes.

Comments of zRMS:	<p>The Applicant did not present separate experiments on phytotoxicity - in the case of fungicides, it is in accordance with EPPO guidelines. Phytotoxicity was assessed in all efficacy experiments 13 Maritime EPPO Zone trials (the Czech Republic, Germany, France, the Netherlands, Sweden and the UK), 11 North-East EPPO Zone trials (Poland and Latvia), 6 Mediterranean EPPO Zone trials (Italy and Spain), 6 South-East EPPO Zone trials (Hungary and Romania). Additionally, the results of two experiments conducted in Morocco are presented.</p> <p>Observer (GLOB2013F) fungicide was used in 2020, 2021, 2022 and 2023 at a dose 0.3 l/ha.</p> <p>The number of trials is sufficient and their location is appropriate for evaluation. The methods used in the presented experiments were appropriate, and the studies presented for evaluation are satisfactorily representative of the potato crop.</p> <p><b>In connection with the fact that no phytotoxic effects were observed in any of the efficacy trials presented in this dossier it can be concluded that fungicide Observer (GLOB2013F) is selective for potato crop.</b></p>
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### Use on grapes

Number of trials with...		Efficacy trials (27 trials)	
		GLOB2013F	Reference products
		0.23 L/ha lwa	0.23 L/ha lwa N
Maximum of phytotoxicity recorded during the trials	0% to 5%	11 Maritime trial (7 CZ/DE+3) 10 Mediterranean trials 6 South-East trials	11 Maritime trial (7 CZ/DE+3) 10 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		
Level of symptoms at the last assessments	0% to 5%	11 Maritime trial (7 CZ/DE+3) 10 Mediterranean trials 6 South-East trials	11 Maritime trial (7 CZ/DE+3) 10 Mediterranean trials 6 South-East trials
	>5% to 10%		
	>10% to 15%		
	>15 %		

### Conclusion

No significant adverse effects were recorded at the proposed dose rate. Therefore GLOB2013F can be considered safe for use on grapes

Comments of zRMS:	<p>The Applicant did not present separate experiments on phytotoxicity - in the case of fungicides, it is in accordance with EPPO guidelines. Phytotoxicity was assessed in all efficacy experiments 11 +3 Maritime EPPO Zone trials (the Czech Republic, Germany and France), 10 Mediterranean EPPO Zone trials (France, Italy and Spain), 6 South-East EPPO Zone trials (Bulgaria and Hungary).</p> <p>Observer (GLOB2013F) fungicide was used in in 2021 and 2022 at a dose 0.17 L/10000m<sup>2</sup> LWA l/ha and 0.23 L/10000m<sup>2</sup> LWA l/ha.</p> <p>The number of trials is sufficient, and their location is appropriate for evaluation. The methods used in the presented experiments were appropriate, and the studies presented for evaluation are satisfactorily representative of the grape crop.</p> <p><b>In connection with the fact that no phytotoxic effects were observed in any of the efficacy trials presented in this dossier it can be concluded that fungicide Observer (GLOB2013F) is selective for grape crop.</b></p>
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### 3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

#### Use on grapes

Yield effects were not investigated in the efficacy trials performed on grapes as this is not required according to EPPO Guideline 1/135(1).

Comments of zRMS:	According to EPPO guidelines PP 1/31(3), yield assessment in experiments concerning the efficacy evaluation of fungicides against <i>Plasmopara viticola</i> , is not obligatory. Zoxamide is used in many countries to control various fungal diseases on potatoes, grapes and other fruits and vegetables and moreover no significant visual damage has been observed in effectiveness trials a on grape, in connection with this, according to EPPO PP 1/135 (4), further evidence of crop safety (including yield assessments) they are not required.
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#### Use on potatoes

I In accordance with EPPO Guideline 1/135(1) yield amount was assessed in all efficacy trials performed on potatoes presented in section 3.2.3 except KCP 6.2-53 and 61, performed in Germany (Maritime EPPO Zone) and Spain KCP 6.2-61 (Mediterranean EPPO Zone), respectively.

Plots were harvested individually and the recorded yield was then converted to metric tons per ha. The number of tubers per plot was also recorded. The absolute yield amount (t/ha and number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control (%UNCK).

For individual trial data reference is made to Appendix 6 of the Biological Assessment Dossier – Crop safety data.

It should be noted that the results of all presented trials are presented together, regardless of the EPPO Zone they were performed in. An overall summary is provided, followed by a summary for each EPPO Zone separately.

In the presentation of the data, the colour of the KCP numbers is used to indicate the EPPO Zone each trial was performed in:

Maritime EPPO Zone:

Czech/German trials:

North-East EPPO Zone:

Mediterranean EPPO Zone:

South-East EPPO Zone:

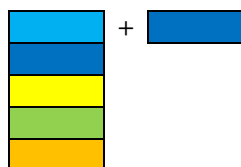


Table 3.4-1 below summarizes the recorded yield amounts expressed in tons per hectare, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes.

The absolute yield amount (t/ha) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

**Table 3.4-1 Summary of yield amount (tons per hectare)**

Rating Type Rating Unit			SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
			YIELD (T-MET)						YIELD (T-MET)						YIELD (T-MET)					
			n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (t/ha)			34	29.1	6.3	72.0	28.1	13.6	12	36.9	6.8	72.0	35.5	15.1	11	28.5	16.9	42.4	26.8	9.6
GLOB2013F	0.18	L/ha	29	119.4	89.3	207.0	113.9	23.4	11	123.8	89.3	207.0	116.9	31.6	9	113.0	99.4	129.5	112.1	8.5
GLOB2013F	0.3	L/ha	34	127.3	100.9	260.4	119.4	29.3	12	132.0	105.8	260.4	119.4	42.0	11	121.8	108.4	145.7	115.9	11.4
GLOB2013F	0.33	L/ha	27	131.5	101.7	251.0	123.3	35.4	8	134.4	103.0	242.0	123.1	45.3	8	122.8	109.0	138.8	122.5	9.8
Infinito	1.6	L/ha	22	121.2	99.9	151.9	116.3	14.6	10	118.8	106.1	147.4	112.6	14.5	8	124.8	107.5	151.9	121.1	15.1
Volare	1.6	L/ha	3	118.9	109.2	138.1	109.5	16.6												
Revus 250 SC	0.6	L/ha	24	135.9	99.5	325.4	125.5	53.1	10	132.7	99.5	273.8	120.0	51.2	8	127.8	103.8	156.6	130.4	17.9
Pergado SC	0.6	L/ha	3	126.2	113.6	135.4	129.6	11.3												
Revus Top	0.6	L/ha	1	125.7	125.7	125.7	125.7	-							1	125.7	125.7	125.7	125.7	-

[illegible]

Table 3.4-2 below summarizes the recorded yield amounts expressed in number of tubers per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes. The absolute yield amount (number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

**Table 3.4-2 Summary of yield amount (number of tubers per plot)**

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type		YIELD (# TUBERS)						YIELD (# TUBERS)						YIELD (# TUBERS)					
Rating Unit		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		34	460.5	76.0	1101.3	375.4	257.6	12	591.5	216.3	1101.3	526.2	304.3	11	487.0	222.0	913.5	421.8	225.1
GLOB2013F	0.18 L/ha	29	110.0	84.3	191.4	102.8	21.1	11	111.7	84.3	191.4	102.6	29.0	9	108.9	94.0	140.2	102.8	14.4
GLOB2013F	0.3 L/ha	34	118.9	95.6	239.6	110.6	26.8	12	121.5	98.0	239.6	107.5	38.6	11	114.9	100.8	139.0	111.0	11.2
GLOB2013F	0.33 L/ha	27	121.0	94.1	251.4	108.3	36.3	8	125.6	98.8	222.1	114.9	40.6	8	109.9	96.7	135.0	104.1	13.4
Infinito	1.6 L/ha	22	111.5	93.5	137.6	108.4	11.8	10	110.5	93.5	126.3	108.4	10.5	8	111.7	99.8	131.3	107.5	10.6
Volare	1.6 L/ha	3	119.5	98.4	131.9	128.1	18.3												
Revus 250 SC	0.6 L/ha	24	123.5	92.6	263.7	112.5	44.3	10	124.0	93.9	261.3	106.9	49.5	8	118.1	106.1	137.6	115.3	10.9
Pergado SC	0.6 L/ha	3	113.9	100.9	120.4	120.3	11.2												
Revus Top	0.6 L/ha	1	111.5	111.5	111.5	111.5	-							1	111.5	111.5	111.5	111.5	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type		YIELD (# TUBERS)						YIELD (# TUBERS)						YIELD (# TUBERS)					
Rating Unit		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		16	501.2	222.0	913.5	443.5	205.7	5	271.6	76.0	329.0	318.3	109.6	6	307.2	163.0	527.5	307.2	128.9
GLOB2013F	0.18 L/ha	13	106.4	92.3	140.2	102.1	13.2	4	114.2	97.3	145.7	106.9	22.3	5	104.9	92.7	120.7	106.7	12.2
GLOB2013F	0.3 L/ha	16	111.5	98.0	139.0	108.4	10.8	5	130.8	100.3	178.0	134.5	31.5	6	110.9	95.6	123.8	112.1	12.1
GLOB2013F	0.33 L/ha	11	109.4	96.7	135.0	103.7	13.2	5	134.4	94.1	251.4	101.4	66.6	6	118.3	98.8	144.0	119.8	17.7
Infinito	1.6 L/ha	12	109.7	93.5	131.3	107.5	10.7							4	113.6	95.6	137.6	110.6	19.3
Volare	1.6 L/ha							3	119.5	98.4	131.9	128.1	18.3						
Revus 250 SC	0.6 L/ha	12	113.2	93.9	137.6	114.8	13.0	1	263.7	263.7	263.7	263.7	-	5	103.3	92.6	116.4	103.0	10.0
Pergado SC	0.6 L/ha							3	113.9	100.9	120.4	120.3	11.2						
Revus Top	0.6 L/ha	1	111.5	111.5	111.5	111.5	-												

## Conclusion

From the results presented above, it can be concluded that GLOB2013F has a positive effect on yield amount on potatoes compared to the untreated control. Furthermore, the results are highly comparable to the reference products. Overall these results fully support the authorization of GLOB2013F at the requested dose rate.

Comments of zRMS:	<p><u>Maritime EPPO Zone</u></p> <p>Yield assessment was carried out in all efficacy experiments except KCP 6.2-53, performed in Germany.</p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 5 to 13 times at a dose of 0.3 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer (GLOB2013F) fungicide.</p> <p><b>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 5-13 applications, it will not have a negative impact on potato yield after three applications.</b></p> <p><u>North-East EPPO Zone</u></p> <p>Yield assessment was carried out in all efficacy experiments.</p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 6 to 10 times at a dose of 0.3 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer (GLOB2013F) fungicide.</p> <p><b>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 6-10 applications, it will not have a negative impact on potato yield after three applications.</b></p> <p><u>North-East EPPO Zone + Cz</u></p> <p>Yield assessment was carried out in all efficacy experiments.</p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 5 to 10 times at a dose of 0.3 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer (GLOB2013F) fungicide.</p> <p><b>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 5-10 applications, it will not have a negative impact on potato yield after three applications.</b></p> <p><u>South-East EPPO Zone</u></p> <p>Yield assessment was carried out in all efficacy experiments.</p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 7 to 8 times at a dose 0.3 l/ha significantly increases yield, at least to the same level as standard products.</p> <p>The applicant requests three applications of the Observer (GLOB2013F) fungicide.</p> <p><b>The presented results do not allow the conclusion that this fungicide applied three times increases the yield. However, it can be stated that if the fungicide did not have a negative impact on yield after 7-8 applications, it will not have a negative impact on potato yield after three applications.</b></p>
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### 3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

#### Use on grapes

Yield effects were not investigated in the efficacy trials performed on grapes as this is not required according to EPPO Guideline 1/135(1).

However, 2 separate trials (KCP 6.4-01 and 6.4-02) were performed to investigate the potential impact of GLOB2013F on treated grapes. Sensory analysis was performed on fresh berries and processed products (dry raisins) by a panel of judges. All samples were prepared in order to reproduce consumer use conditions. No significant differences ( $P < 0.05$ ) were found between samples treated GLOB2013F and the standard reference product (Ampexio, 0.5 kg/ha).

In addition to the above, yield per treated plot, sugar content, and pH of the juice were measured at harvest. No statistical differences ( $P < 0.05$ ) were found for any of the tested parameters.

Comments of zRMS:	<p>Despite the fact that the effects on yield were not investigated in the effectiveness studies conducted on grapes, the Applicant presented the results of two additional experiments conducted in Greece in 2023. Observer fungicide (GLOB2013F) was applied twice at a dose of 0.23 L/10,000 m<sup>2</sup> LWA.</p> <p>There was no effect of Observer fungicide (GLOB2013F) on the pH value and sugar content in grape juice. In these experiments, sensory analysis of fresh berries and processed products, i.e. dry raisins, was carried out. No significant differences were found between samples treated with GLOB2013F and the standard reference product (Ampexio, 0.5 kg/ha).</p> <p><b>The presented results indicate that Observer (GLOB2013F) fungicide applied twice at a dose of 0.23 L/10,000 m<sup>2</sup> LWA, it will be safe for grape crop.</b></p>
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#### Use on potatoes

Yield quality was assessed in all efficacy trials presented in section 3.2.3 except KCP 6.2-53 and 61, performed in Germany (Maritime EPPO Zone) and Spain (Mediterranean EPPO Zone), respectively.

In each trial the yield distribution was calculated as a % of total weight and as a percentage of total number of tubers.

The weight and amount of malformed tubers was also recorded.

For individual trial data reference is made to Appendix 6 of the Biological Assessment Dossier – Crop safety data on potatoes.

It should be noted that the results of all presented trials are presented together, regardless of the EPPO Zone they were performed in. An overall summary is provided, followed by a summary for each EPPO Zone separately.

In the presentation of the data, the colour of the KCP numbers is used to indicate the EPPO Zone each trial was performed in:







Maritime EPPO Zone:		+	
Czech/German trials:			
North-East EPPO Zone:			
Mediterranean EPPO Zone:			
South-East EPPO Zone:			

Table 3.4-3 below summarizes the yield distribution data according to weight, gathered in the efficacy trials presented in section 3.2.3.

Because the sizing of potatoes is dependent on crop variety, no meaningful overall summary can be made from the percentages. However, the applicant calculated for each treatment the difference in percentage from the untreated. These ‘percent difference to untreated’ values were summarized in order to draw conclusions on possible shifts in yield distribution. For individual trial data (including the ‘percent difference to untreated’) reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes.

**Table 3.4-3 Summary yield distribution differences (%) to untreated control based on weight**

[illegible]

			SUMMARY NORTH-EAST									SUMMARY NORTH-EAST + CZ/DE										
			Difference in yield distribution based on weight									Difference in yield distribution based on weight										
			COMPR1			COMPR2			COMPR3			COMPR1			COMPR2			COMPR3				
			n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	n	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
UNTREATED (%)			11	15.8	1.1	38.8	53.9	15.0	78.9	30.3	8.1	83.9	16	14.0	1.1	38.8	56.0	15.0	80.5	30.0	6.1	83.9
GLOB2013F	0.18	L/ha	9	-0.2	-8.7	9.1	-3.7	-9.8	5.6	3.9	-2.2	11.0	13	-1.0	-8.7	9.1	-1.6	-9.8	6.4	2.7	-6.2	11.0
GLOB2013F	0.3	L/ha	11	-0.1	-8.2	8.6	-2.4	-9.0	8.4	2.5	-7.5	13.4	16	-0.5	-8.2	8.6	-0.9	-9.0	8.4	1.4	-7.5	13.4
GLOB2013F	0.33	L/ha	8	-0.1	-10.4	13.2	-1.7	-11.3	4.4	1.7	-2.0	6.9	11	0.1	-10.4	13.2	-0.1	-11.3	6.5	0.1	-6.3	6.9
Infinito	1.6	L/ha	8	-2.1	-9.4	6.0	-2.1	-9.3	9.1	4.2	-3.3	13.2	12	-1.6	-9.4	6.0	-0.5	-9.3	9.1	2.2	-7.9	13.2
Volare	1.6	L/ha	0	-	0.0	0.0	-	0.0	0.0	0.0	-	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0	-	0.0	0.0
Revus 250 SC	0.6	L/ha	8	1.6	-5.1	10.2	-5.1	-11.7	4.5	3.5	-4.9	13.6	12	0.8	-5.1	10.2	-2.9	-11.7	4.5	2.2	-4.9	13.6
Pergado SC	0.6	L/ha	0	-	0.0	0.0	-	0.0	0.0	0.0	-	0.0	0.0	-	0.0	0.0	0.0	0.0	0.0	-	0.0	0.0
Revus Top	0.6	L/ha	1	-1.0	-1.0	-1.0	-7.9	-7.9	-7.9	8.9	8.9	8.9	1	-1.0	-1.0	-1.0	-7.9	-7.9	-7.9	8.9	8.9	8.9

[illegible]



Table 3.4-4 below summarizes the yield distribution data according to the number of tubers, gathered in the efficacy trials presented in section 3.2.3.

Because the sizing of potatoes is dependent on crop variety, no meaningful overall summary can be made from the percentages. However, the applicant calculated for each treatment the difference in percentage from the untreated. These ‘percent difference to untreated’ values were summarized in order to draw conclusions on possible shifts in yield distribution. For individual trial data (including the ‘percent difference to untreated’) reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes

**Table 3.4-4 Summary of yield distribution differences (%) to untreated control based on number of tubers**

[illegible]

			SUMMARY NORTH-EAST									SUMMARY NORTH-EAST + CZ/DE										
			Difference in yield distribution based on number of tubers									Difference in yield distribution based on number of tubers										
			n	COMPR1			COMPR2			COMPR3			n	COMPR1			COMPR2			COMPR3		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max		
UNTREATED (%)			10	27.4	6.5	68.0	51.8	23.6	68.3	20.9	3.0	57.0	15	23.5	0.5	68.0	53.3	23.6	79.3	23.1	1.1	64.9
GLOB2013F	0.18	L/ha	9	-1.2	-8.0	6.1	-0.4	-5.6	5.9	1.6	-3.6	5.2	13	-1.2	-10.2	6.1	0.3	-5.6	8.0	1.0	-3.7	5.2
GLOB2013F	0.3	L/ha	10	-2.4	-8.1	7.7	0.6	-10.5	8.4	1.7	-8.3	11.1	15	-1.8	-8.1	7.7	1.5	-10.5	15.0	0.4	-14.1	11.1
GLOB2013F	0.33	L/ha	7	-1.3	-7.4	7.7	-0.2	-8.1	4.8	1.5	0.3	3.0	10	-1.1	-7.4	7.7	1.7	-8.1	11.0	-0.6	-10.8	3.0
Infinito	1.6	L/ha	7	-4.5	-9.6	2.1	1.5	-5.1	7.2	3.0	-3.1	11.7	11	-3.4	-9.6	2.1	2.5	-5.1	9.5	1.0	-9.2	11.7
Volare	1.6	L/ha																0.0	-	0.0	0.0	
Revus 250 SC	0.6	L/ha	7	-0.7	-10.8	6.7	-1.3	-10.5	7.0	1.9	-8.0	12.2	11	-0.5	-10.8	6.7	-1.0	-10.5	7.0	1.5	-8.0	12.2
Pergado SC	0.6	L/ha																0.0	-	0.0	0.0	
Revus Top	0.6	L/ha	1	-0.5	-0.5	-0.5	-4.7	-4.7	-4.7	5.2	5.2	5.2	1	-0.5	-0.5	-0.5	-4.7	-4.7	-4.7	5.2	5.2	5.2

[illegible]

Pergado SC	0.6	L/ha	3	-5.4	-10.8	2.9	7.7	6.4	9.7	-2.3	-10.0	4.4					
Revus Top	0.6	L/ha															

Table 3.4-5 below summarizes the recorded amount of malformed tubers expressed in kg weight per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes. The absolute yield amount (kg per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

**Table 3.4-5 Summary of amount of malformed tubers (weight per plot)**

			SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type			MAMDEF (kg)						MAMDEF (kg)						MAMDEF (kg)					
Rating Unit	n	Mean	Min	Max	Med.	Stdev.		n	Mean	Min	Max	Med.	Stdev.		n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)			34	2.1	0.0	29.9	0.9	5.1	12	1.6	0.0	6.5	0.8	2.1	11	0.7	0.0	1.9	0.8	0.5
GLOB2013F	0.18	L/ha	29	62.8	0.0	155.6	69.2	56.6	11	53.7	0.0	146.8	6.2	63.5	9	77.5	0.0	155.6	75.0	56.5
GLOB2013F	0.3	L/ha	34	63.8	0.0	221.1	56.3	64.2	12	59.6	0.0	216.7	12.6	76.0	11	81.8	0.0	221.1	75.0	67.6
GLOB2013F	0.33	L/ha	27	52.6	0.0	125.0	58.9	45.8	8	53.7	0.0	125.0	31.5	60.4	8	54.2	0.0	100.0	58.3	37.7
Infinito	1.6	L/ha	22	62.8	0.0	259.1	32.4	75.9	10	67.5	0.0	259.1	7.4	91.9	8	72.3	0.0	200.0	72.5	63.4
Volare	1.6	L/ha	3	73.5	52.2	112.2	56.3	33.5												
Revus 250 SC	0.6	L/ha	24	47.5	0.0	288.9	23.6	66.9	10	27.3	0.0	133.3	1.5	44.2	8	94.0	0.0	288.9	83.9	88.2
Pergado SC	0.6	L/ha	3	95.6	49.2	143.9	93.8	47.4												
Revus Top	0.6	L/ha	1	200.0	200.0	200.0	200.0	-							1	200.0	200.0	200.0	200.0	-

			SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type			MAMDEF (kg)						MAMDEF (kg)						MAMDEF (kg)					
Rating Unit	n	Mean	Min	Max	Med.	Stdev.		n	Mean	Min	Max	Med.	Stdev.		n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)			16	1.1	0.0	6.5	0.8	1.5	5	7.4	0.0	29.9	1.6	12.6	6	1.2	0.0	3.5	0.7	1.5
GLOB2013F	0.18	L/ha	13	72.7	0.0	155.6	75.0	58.4	4	75.0	0.0	143.9	78.1	59.4	5	46.6	0.0	103.8	60.0	45.6
GLOB2013F	0.3	L/ha	16	80.8	0.0	221.1	62.5	75.2	5	67.5	0.0	126.8	73.2	45.3	6	35.8	0.0	107.7	19.2	44.9
GLOB2013F	0.33	L/ha	11	50.9	0.0	125.0	50.0	45.3	5	60.9	0.0	114.6	58.9	41.3	6	42.0	0.0	103.8	35.7	47.3
Infinito	1.6	L/ha	12	70.4	0.0	200.0	72.5	65.1							4	31.7	0.0	126.9	0.0	63.5
Volare	1.6	L/ha							3	73.5	52.2	112.2	56.3	33.5						
Revus 250 SC	0.6	L/ha	12	75.9	0.0	288.9	64.5	82.2	1	0.0	0.0	0.0	0.0	-	5	22.9	0.0	68.6	0.0	32.4
Pergado SC	0.6	L/ha							3	95.6	49.2	143.9	93.8	47.4						
Revus Top	0.6	L/ha	1	200.0	200.0	200.0	200.0	-							1	200.0	200.0	200.0	200.0	-

Table 3.4-6 below summarizes the recorded amount of malformed tubers expressed in number of tubers per plot, gathered in the efficacy trials presented in section 3.2.3. For individual trial data reference is made to Appendix 5 of the Biological Assessment Dossier – Crop safety data on potatoes. The absolute yield amount (number of tubers per plot) is given for the untreated control. The results for the different treatments are given as a percentage of the untreated control.

**Table 3.4-6 Summary of amount of malformed tubers (number of tubers per plot)**

		SUMMARY ALL						SUMMARY MARITIME						SUMMARY NORTH-EAST					
Rating Type	Rating Unit	MAMDEF (#)						MAMDEF (#)						MAMDEF (#)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		33	13.0	0.0	99.3	8.3	19.4	11	6.9	0.0	23.3	3.0	8.6	10	7.5	1.8	12.5	8.1	3.5
GLOB2013F	0.18 L/ha	30	58.3	0.0	188.9	66.2	52.6	11	37.8	0.0	131.8	0.0	51.4	9	78.4	19.2	188.9	66.7	53.6
GLOB2013F	0.3 L/ha	33	61.5	0.0	248.0	55.6	63.9	11	37.3	0.0	146.0	5.4	50.9	10	88.7	6.4	248.0	75.6	74.5
GLOB2013F	0.33 L/ha	26	49.1	0.0	110.7	56.0	42.4	7	42.5	0.0	105.7	2.7	52.4	7	51.9	3.8	108.0	59.1	38.6
Infinito	1.6 L/ha	21	55.8	0.0	220.7	42.2	66.3	9	48.1	0.0	171.4	0.0	72.5	7	79.3	6.4	220.7	62.2	68.4
Volare	1.6 L/ha	3	73.6	46.6	118.8	55.4	39.4												
Revus 250 SC	0.6 L/ha	23	46.7	0.0	347.8	23.0	75.4	10	22.9	0.0	120.0	0.0	40.7	7	107.2	23.0	347.8	76.0	108.1
Pergado SC	0.6 L/ha	3	88.6	47.6	135.1	83.0	44.0												
Revus Top	0.6 L/ha	1	189.7	189.7	189.7	189.7	-							1	189.7	189.7	189.7	189.7	-

		SUMMARY NORTH-EAST + CZ/DE						SUMMARY MEDITERRANEAN						SUMMARY SOUTH-EAST					
Rating Type	Rating Unit	MAMDEF (#)						MAMDEF (#)						MAMDEF (#)					
		n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.	n	Mean	Min	Max	Med.	Stdev.
UNTREATED (#)		15	7.7	0.0	18.5	7.8	5.0	5	39.1	0.0	99.3	23.5	38.7	6	11.2	0.0	35.3	5.8	14.4
GLOB2013F	0.18 L/ha	14	64.1	0.0	188.9	66.2	53.4	4	75.0	0.0	144.5	77.7	59.2	5	47.1	0.0	100.0	46.2	47.5
GLOB2013F	0.3 L/ha	15	84.5	0.3	248.0	59.1	76.7	5	65.9	0.0	139.4	64.2	49.4	6	34.5	0.0	100.0	21.7	41.9
GLOB2013F	0.33 L/ha	10	47.7	0.0	110.7	46.2	43.9	5	58.6	0.0	94.4	64.8	36.3	6	35.2	0.0	91.3	22.7	41.3
Infinito	1.6 L/ha	11	67.5	0.0	220.7	62.2	64.0							4	29.3	0.0	117.4	0.0	58.7
Volare	1.6 L/ha							3	73.6	46.6	118.8	55.4	39.4						
Revus 250 SC	0.6 L/ha	11	79.3	0.0	347.8	72.2	97.8	1	0.0	0.0	0.0	0.0	-	5	19.0	0.0	50.2	0.0	26.1
Pergado SC	0.6 L/ha							3	88.6	47.6	135.1	83.0	44.0						
Revus Top	0.6 L/ha	1	189.7	189.7	189.7	189.7	-												

## Conclusion

The results summarized in above in Table 3.4-3 and Table 3.4-4 confirm GLOB2013F has no impact on yield distribution.

Table 3.4-5 demonstrated that, based on weight, there is an overall trend towards lowered amounts of malformed tubers for all tested treatments.

The number of malformed tubers (Table 3.4-6) is very similar between all tested treatments, which on average all have a slight increase compared to the untreated control. However, the numbers of malformed tubers is less important than the weight of malformed tubers.

Taken together, all results presented above confirm that GLOB2013F is safe at the requested dose rate.

Comments of zRMS:	<u>Maritime EPPO Zone</u> The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 5 to 13 times at a dose 0.3 l/ha did not show a significant negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers.
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	<p><b>Based on this, it can be concluded that if we apply the Observer (GLOB2013F) fungicide three times at a dose of 0.3 l/ha, it will be safe for potato crop.</b></p> <p><u>North-East EPPO Zone</u></p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 6 to 10 times at a dose of 0.3 l/ha did not show a significant negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers.</p> <p><b>Based on this, it can be concluded that if we apply the Observer (GLOB2013F) fungicide three times at a dose of 0.3 l/ha, it will be safe for potato crop.</b></p> <p><u>North-East EPPO Zone + Cz</u></p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 5 to 10 times at a dose of 0.3 l/ha did not show a significant negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers.</p> <p><b>Based on this, it can be concluded that if we apply the Observer (GLOB2013F) fungicide three times at a dose of 0.3 l/ha, it will be safe for potato crop.</b></p> <p><u>South-East EPPO Zone</u></p> <p>The results presented by the applicant indicate that the Observer (GLOB2013F) fungicide applied 7 to 8 times at a dose of 0.3 l/ha did not show a significant negative effect on yield distribution, the number of malformed tubers and reduced the weight of deformed tubers.</p> <p><b>Based on this, it can be concluded that if we apply the Observer (GLOB2013F) fungicide three times at a dose of 0.3 l/ha, it will be safe for potato crop.</b></p>
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### 3.4.4 Effects on transformation processes (KCP 6.4.4)

According to EPPO Guideline PP 1/243 (2) potato is not subjected to transformation processes, therefore no transformation studies were performed.

Specific vinification trials on GLOB2013F are not available and are not deemed necessary, because other zoxamide products are already registered on grapes since many years. Zoxamide has not shown to have any influence on the vinification process. The applicant refers to unprotected data from old products like Amaline Flow (AMM: 2090132) or Electis Pro (AMM: 2020110).

Comments of zRMS:	In the EU, fungicides containing zoxamide are registered for grape cultivation. The Evaluator agrees with the Applicant's opinion that if old products such as Amaline Flow (AMM: 2090132) or Electis Pro (AMM: 2020110) do not affect the vinification process fungicide Observer (GLOB2013F) has also no influence on this process.
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### 3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Zoxamide is an old, well-characterized active substance that has been used on potatoes in the following products. Therefore it can be considered safe.

Crop(s)	Reference standard	Countries where the product is registered	Active substance(s)	Formulation		Dose rate	Amount of zoxamide applied per application	Number of application per season	Amount of zoxamide applied per growing season
				Type	Concentration of a.s.				
Potato	Presidium	CZ, HU, RO, PL, UK, FR, IT	dimethomorph zoxamide	SC	180 g/L 180 g/L	1 L/ha	180 g/ha	5	900 g/ha
	Lieto, Carlito, Reboot	CZ, HU, RO, PL, SK, IE, UK, FR, IT	cymoxanil zoxamide	WG	330 g/kg 330 g/kg	0.45 kg/ha	148.5 g/ha	6	891 g/ha
	Zoxium 240 SC	IT	zoxamide	SC	240 g/L	0.625-0.75 L/ha	180 g/ha	5	900 g/ha

Comments of zRMS:	The applicant did not submit additional studies aimed at transformation processes and determining the impact on treated plants or plant products to be used for propagation. Considering that the selectivity studies showed no negative effects on potato crop and the fact that zoxamide is a known active substances, it can be concluded that <b>Observer (GLOB2013F) has no negative effect on parts of plants used for transformation processes and propagating purposes.</b>
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### 3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

Samples of harvested potatoes from two efficacy trials submitted in this dossier (FE-22-B-GLOB2013F-2106F-2007F-CZ02 and FE-22-B-GLOB2013F-2106F-2007F-DE04, KCP 6.2-52 and 53, respectively) were sent over to the National Institute of Horticultural Research (InHort) in Poland for organoleptic testing. It should be noted there was no infestation in trial KCP 6.2-53.

The evaluation was carried out for the quality parameters characterizing the smell, colour and texture of boiled and fried potatoes. The results of the evaluation can be found in KCP 6.5.1-01 and 02 respectively and are shown below.

**Table 3.5-1 Results of sensory analysis of boiled potatoes**

Trial	Treatment	Dose rate	Odour of boiled potatoes	Off-odour	Colour	Consistency	Flavour of boiled potatoes	Sweet taste	Bitter taste	Off-flavour	Overall quality
			0-none 10-very intense	0-none 10-very intense	0-bright 10-yellow	0-loose 10-floury	0-none 10-very intense	0-none 10-very intense	0-none 10-very intense	0-none 10-very intense	0-low quality 10-high quality
FE-22-B-GLOB2013F-2106F-2007F-CZ02	Untreated		6.7	0	7.9	7.4	6.6	0.8	0	0.1	7.6
Efficacy trial KCP 6.2-52	GLOB2013F	0.3 L/ha	6.7	0.3	8.3	7.9	7.7	1.1	0.1	0	8.5
Variety: Red Sonia	GLOB2106cF	1.9 L/ha	6.4	0.1	7.8	7.3	6.9	0.9	0.1	0	7.3
InHort Report 098/2022	GLOB2007bF	2 L/ha	6.4	0.1	8.2	7.7	6.8	1.1	0.1	0.1	6.6
KCP 6.5-01	GLOB178F	2 L/ha	6.2	0.2	8.4	7.8	7.4	1.2	0	0.1	8.1
	Revus 250 SC	0.6 L/ha	6.8	0.2	7.9	7.8	7.5	0.9	0.1	0.1	7.8
FE-22-B-GLOB2013F-2106F-2007F-DE04	Untreated		7.1	0.5	6.9	6.1	7	0.9	0.3	0.3	6.8
Efficacy trial KCP 6.5-54	GLOB2013F	0.3 L/ha	7.6	0.2	7.3	6.8	7.5	2.7	0.1	0	7.1
Variety: Antonia	GLOB2106cF	1.9 L/ha	6.6	0.1	7.1	6.6	7.7	0.7	0.1	0.1	7.1
InHort Report 099/2022	GLOB2007bF	2 L/ha	7	0.4	7.6	6.2	7.5	1.5	0.3	0.2	7.2
KCP 6.5-02	GLOB178F	2 L/ha	6.2	0.2	7.7	6.6	7	2.2	0.1	0.4	7.5
	Revus 250 SC	0.6 L/ha	7.1	0.1	7.8	6.5	6.9	1.3	0.2	0.1	7.4

**Table 3.5-2 Results of sensory evaluation of fried potatoes**

Trial	Treatment	Dose rate	Odour of boiled potatoes	Off-odour	Colour	Crunchiness	Hardness	Flavour	Off-flavour	Overall quality
			0-none 10-very intense	0-none 10-very intense	0-light golden 10-dark brown	0-not crunchy 10-very crunchy	0-soft 10-hard	0-none 10-very intense	0-none 10-very intense	0-low quality 10-high quality
FE-22-B-GLOB2013F-2106F-2007F-CZ02	Untreated		7.1	0	4.9	6.2	4.8	7.3	0.1	7.1
Efficacy trial KCP 6.2-52	GLOB2013F	0.3 L/ha	7.4	0.4	3.5	4.9	3.5	6.9	0.3	7.8
Variety: Red Sonia	GLOB2106cF	1.9 L/ha	7.4	0	4.1	5.8	4.1	7.2	0	7.1
InHort Report 098/2022	GLOB2007bF	2 L/ha	7.2	0.1	4.1	5.9	4.4	7.2	0	7.6
KCP 6.5-01	GLOB178F	2 L/ha	7.4	0	3.2	5.6	3.2	7.4	0.1	8.2
	Revus 250 SC	0.6 L/ha	7.6	0.2	3.2	6	3.4	7.3	0.1	7.7
FE-22-B-GLOB2013F-2106F-2007F-DE04	Untreated		7.5	0	3.9	7.7	6.3	7.7	0.1	8.1
Efficacy trial KCP 6.5-54	GLOB2013F	0.3 L/ha	7.8	0.1	4.1	6.7	5.9	8.1	0.1	8.5
Variety: Antonia	GLOB2106cF	1.9 L/ha	7.4	0.1	3.6	5.4	5.6	8	0.1	7.9
InHort Report 099/2022	GLOB2007bF	2 L/ha	6.9	0.1	4	7.2	5.7	7.4	0.1	7.9
KCP 6.5-02	GLOB178F	2 L/ha	7	0.1	4.2	6.8	6.1	7.4	0.1	7.4
	Revus 250 SC	0.6 L/ha	7.7	0.1	3.4	6.2	5.4	7.7	0.1	7.6

It's important to note that even though there is some variance in the scores for the different parameters when comparing different treatments, all scores were very similar. Overall only minor differences were observed between the tested samples.

## Conclusion

Treatment with GLOB2013F has no negative impact on the taste of boiled or fried treated potatoes

Comments of zRMS:	The results of two sensory evaluation tests for evaluation of cooked potatoes and fried potatoes in the form of fries presented by the applicant show that the Observer (GLOB2013F) fungicide does not affect the taste attributes of boiled potatoes and fried potatoes.
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### 3.5.1 Impact on other plants including adjacent crops (KCP 6.5.2)

As mentioned in section 3.4.5 products containing zoxamide have been used in fungicide programs against *Phytophthora infestans* on potatoes for many years at dose rates similar to the currently requested dose rate for GLOB2013F. Fungicides are generally considered safe to plants.

The RAR of zoxamide of June 2016 includes a glasshouse screening study that tested the effects of zoxamide, applied at doses up to 500 g/ha, on broad-leaved weeds, grass weeds and crop plants. Applications were made pre- and post-emergence. No adverse effects were seen on any species at any dose, therefore no further studies on seedling emergence and vegetative vigour were required.

As the above-mentioned threshold values are identical to those used in section **Błąd! Nie można odnaleźć źródła odwołania.**, reference is made to the worst-case approach used in section **Błąd! Nie można odnaleźć źródła odwołania.**

**Table 3.5-1 Total dose of a.i. per season for GLOB2013F – worst case approach**

GLOB2013F		Dose per application	Applications per season	Total dose per season
Zoxamide	450 g/L	0.3 L/ha	3	405 g/ha

#### Conclusion

From the above worst-case calculations it can be concluded that the amount of active substance in the soil would still be below the safe concentrations mentioned in the RAR of zoxamide (500 g/ha).

Comments of zRMS:	The reasoning presented by the Applicant is correct and confirms that the Observer (GLOB2013F) fungicide is safe for adjacent crops.
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### 3.5.2 Effects on beneficial and other non-target organisms (KCP 6.5.3)

There are no known effects of on non-target organisms.

### 3.6 Other/special studies

No other studies were carried out.

### 3.7 List of test facilities including the corresponding certificates

**Table 3.7-1: List of test facilities**

Test facility	Potato trials	Grape trials	Address	Certificate (Yes or No)
Reference is made to the Biological Assessment Dossier				

## Appendix 1      Lists of data considered in support of the evaluation

### List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Company GLP or GEP status Published or not	Data protected (Y/N)	Owner
Reference is made to the Biological Assessment Dossier.					