

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

Product code: GLOB2007bF

Product name(s): Observer Pro

Chemical active substances:

Zoxamide, 67.5 g/L

Propamocarb-HCl, 450 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland  
(authorization)

Applicant: Globachem NV

Submission date: November 2023

MS Finalisation date: 31/10/2024

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## Version history

| When          | What  |
|---------------|---|
| November 2023 | Initial dossier submission by applicant for approval of new product |
| March 2024    | Dossier sent for evaluation   |
| July 2024     | zRMS finalised evaluation   |
| October 2024  | zRMS finalised evaluation after commenting period                   |

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## PART A

### RISK MANAGEMENT

#### 1 Details of the application

##### 1.1 Application background

This application was submitted by Globachem NV in November 2023.

The application was for approval of GLOB2007bF, a suspension concentrate containing 67.5 g/L zoxamide and 450 g/L propamocarb-HCl for use as a fungicide in potatoes for which Poland was designated zRMS.

##### 1.2 Letters of Access

Vertebrate studies access is currently negotiated with the Notifier. The negotiation e-mail exchange was already sent to all MSs with the data matching package.

##### 1.3 Justification for submission of tests and studies

The application is for approval of a new product. It follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

##### 1.4 Data protection claims

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

#### 2 Details of the authorization decision

##### 2.1 Product identity

|  |  |
|--|--|
| Product code   | GLOB2007bF   |
| Product name in MS                                     | Observer Pro   |
| Authorization number                                   | -  |
| Function   | Fungicide  |
| Applicant  | Globachem NV   |
| Active substance(s)<br>(incl. content)                 | Zoxamide: 67.5 g/L<br>Propamocarb-HCl: 450 g/L                                     |
| Formulation type                                       | Suspension concentrate (SC)  |
| Packaging  | 0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L HDPE, HDPE/PA, HDPE/F,<br>HDPE/EVOH |
| Coformulants of concern for<br>national authorizations | None   |
| Restrictions related to identity                       | None   |
| Mandatory tank mixtures                                | None   |
| Recommended tank mixtures                              | None   |

##### 2.2 Conclusion

The evaluator also verified whether the co-formulants contained in plant protection product Observer Pro

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(Product code: GLOB2007bF) are listed in Annex III to Regulation (EC) No 1107/2009 and/or could be considered unacceptable based on the criteria indicated in the Annex to the Commission Implementing Regulation (EU) 2023/574 of 13 March 2023.

Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product Observer Pro (Product code: GLOB2007bF) does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 amending Annex III to Regulation (EC) No 1107/2009.

According to the current knowledge and available information none of the co-formulants in the plant protection product Observer Pro (Product code: GLOB2007bF) meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products. Taking this into account, none of the co-formulants/ingredients in this product is considered to be a candidate for inclusion in Annex III of Regulation (EU) 1107/2009.

### 2.3 Substances of concern for national monitoring

There are no substances of concern for national monitoring.

### 2.4 Classification and labelling

#### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

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

|                               |  |
|-------------------------------|--|
| Hazard class(es), categories: | Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1 |
|-------------------------------|--|

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

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

|  |  |
|--|--|
| Special rule for labelling of plant protection product (PPP):    |  |
| EUH401   | To avoid risks to man and the environment, comply with the instructions for use. |
| Further labelling statements under Regulation (EC) No 1272/2008: |  |

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|  |  |
|--|--|
|  | Contains 1,2-Benzisothiazolin-3-one (CAS No. 2634-33-5). |
|--|--|

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

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

|      |   |
|------|---|
| SP 1 | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| SPe3 | When using in potato to protect aquatic organisms respect a:<br>- 5 m vegetative strip with 5 m no spray buffer zone (VFSSMOD)  |

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

|   |   |
|---|---|
| - | - |
|---|---|

## 2.5 Risk management

### 2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

|   |   |
|---|---|
| Operator protection:                              |   |
|   | No PPE required. Due to the product classification, it is recommended to use protective gloves at the M/L step.   |
| Worker protection:                                |   |
|   | No PPE required (workwear)  |
| Integrated pest management (IPM)/sustainable use: |   |
|   | /   |
| Environmental protection                          |   |
| P501  | Dispose of contents/container in accordance with local/regional/national regulation.  |
| SP1   | Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads). |
| Other specific restrictions                       |   |
| EUH401  | To avoid risks to man and the environment, comply with the instructions for use.  |

The authorization of the PPP is linked to the following conditions (voluntary labelling):

|   |   |
|---|---|
| Integrated pest management (IPM)/sustainable use: |   |
| -   | - |

### 2.5.2 Specific restrictions linked to the intended uses

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

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

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|   |   |   |
|---|---|---|
| - | - | - |
|---|---|---|



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## 2.6 Intended uses (only NATIONAL GAP)

GAP rev. 2.2 date: 2022-03-03

PPP (product name/code): GLOB2007bF  
Active substance 1: zoxamide  
Active substance 2: propamocarb  
Applicant: Globachem NV  
Zone(s): Central  
Verified by MS: yes

Formulation type: SC <sup>(a, b)</sup>  
Conc. of as 1: 67.5 g/L <sup>(c)</sup>  
Conc. of as 2: 450 g/L <sup>(c)</sup>  
Professional use: ☒  
Non professional use: ☐

Field of use: Fungicide

| 1  | 2                  | 3  | 4   | 5   | 6                     | 7  | 8   | 9  | 10   | 11  | 12                             | 13            | 14  |
|--|--------------------|--|---|---|-----------------------|--|---|--|--|---|--------------------------------|---------------|---|
| Use-No.<br>(e)   | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application           |  |   |  | Application rate   |   |                                | PHI<br>(days) | Remarks:<br><br>e.g. g<br>safener/synergist<br>per ha<br>(f)  |
|  |                    |  |   |   | Method /<br>Kind      | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product / ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season              | Water<br>L/ha<br><br>min / max |               |   |
| Zonal uses (field or outdoor uses, certain types of protected crops) |                    |  |   |   |                       |  |   |  |  |   |                                |               |   |
| 1  | PL                 | Seed, ware and<br>starch potato<br>(SOLTU)<br>Potato                     | F   | Phytophthora infestans<br>(PHYTIN)  | Downwards<br>spraying | BBCH 21-79                                   | a) 3<br>b) 3  | 7  | a) 2<br>b) 6   | a) 135 Zoxamide +<br>900 Propamocarb-<br>HCl<br>b) 405 Zoxamide +<br>2700 Propamocarb-<br>HCl | 150-300                        | 7             | /   |
| 2  | PL                 | Potato   | F   | PHYTIN  | Downwards<br>spraying | BBCH<br>21-79                                | a) 3<br>b) 3  | 7  | a) 1.9<br>b) 5.7   | a) 130 Zoxamide +<br>855 Propamocarb<br>b) 390 Zoxamide +<br>2565 Propamocarb                 | 150-300                        | 7             | Alternative GAP<br>with a slightly<br>lower dose rate<br>in order to<br>maintain a<br>mitigation of |

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| 1              | 2                  | 3  | 4   | 5   | 6                | 7  | 8   | 9  | 10   | 11   | 12                             | 13            | 14   |
|----------------|--------------------|--|---|---|------------------|--|---|--|--|--|--------------------------------|---------------|--|
| Use-No.<br>(e) | Member<br>state(s) | Crop and/<br>or situation<br><br>(crop destination /<br>purpose of crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application      |  |   |  | Application rate   |  |                                | PHI<br>(days) | Remarks:<br><br>e.g. g<br>safener/synergist<br>per ha<br>(f) |
|                |                    |  |   |   | Method /<br>Kind | Timing / Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product / ha<br>a) max. rate<br>per appl.<br>b) max. total<br>rate per<br>crop/season | g or kg as/ha<br><br>a) max. rate per appl.<br>b) max. total rate per<br>crop/season | Water<br>L/ha<br><br>min / max |               |  |
|                |                    |  |   |   |                  |  |   |  |  |  |                                |               | maximum 10 m<br>VFS only where<br>necessary                  |

**Remarks table heading:**

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)  
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008  
(c) g/kg or g/l

(d) Select relevant  
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1  
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

**Remarks columns:**

1 Numeration necessary to allow references  
2 Use official codes/nomenclatures of EU Member States  
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)  
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.  
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application  
8 The maximum number of application possible under practical conditions of use must be provided.  
9 Minimum interval (in days) between applications of the same product  
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.  
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  
13 PHI - minimum pre-harvest interval  
14 Remarks may include: Extent of use/economic importance/restrictions

### **3 Background of authorization decision and risk management**

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

Overall summary: The product GLOB2007bF is a suspension concentrate. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a liquid with a separate brown liquid layer on the top but without sediment on the bottom (no cake), homogeneous after gentle shaking, with a chemical odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 398 °C. In aqueous solution, it has a pH value of 2.15 at 24°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE (High Density PolyEthylene), HDPE-F (Fluorinated High Density PolyEthylene), HDPE-EVOH and HDPE/PA. Its technical characteristics are acceptable for a suspension concentrate formulation.

The intended concentration of use is 0.67% to 1.33%.

No tank mixtures were proposed for this formulation.

#### **3.2 Efficacy (Part B, Section 3)**

All submitted data supports that requested dose rate of 2 L/ha is effective for the control of late blight (*Phytophthora infestans*) on potatoes and is safe.

##### **3.2.1 Efficacy data**

The trials package of GLOB2007bF 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.

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 GLOB2007bF under a wide range of climatic and edaphic conditions.

zRMS note to Alternative GAP:

The suggestion in Table GAP-alternative for the use of a slightly reduced dose (1.9 l/ha) of GLOB2007bF (Observer Pro 2.0l/ha) cannot be accepted due to the lack of efficacy studies for the reduced dose. However, the maintenance of buffer zones can be emphasized and the negative impact on aquatic organisms can be emphasized (in the label).

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

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

Although resistance to both active substances is very unlikely to occur, resistant individuals can eventually dominate the fungus population if these fungicides are 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.

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The applicant suggests the following the general FRAC guidelines stated in the Biological Assessment Dossier.

### **3.2.3 Adverse effects on treated crops**

No phytotoxic effects, and no negative impact on yield amount or quality was observed in any of the efficacy trials presented in this dossier.

### **3.2.4 Observations on other undesirable or unintended side-effects**

Samples of two efficacy trials submitted in this dossier were sent over to the National Institute of Horticultural Research (InHort) in Poland for organoleptic testing.

The evaluation was carried out for the quality parameters characterizing the smell, colour and texture of boiled and fried potatoes. It was concluded there are no major differences between the tested samples.

## **3.3 Methods of analysis (Part B, Section 5)**

### **3.3.1 Analytical method for the formulation**

Analytical methods for the determination of zoxamide and propamocarb-HCl in GLOB2007bF were not evaluated as part of the EU review of these active substances. Therefore all relevant data are provided here and are considered adequate. An HPLC-UV method was submitted to analyze zoxamide in the formulation. An HPLC-UV method as well, was submitted to analyze propamocarb-HCl in the formulation. The methods of analysis of active substances content has been validated in compliance with Document SANCO/3030/99 – rev 5. The acceptance criteria are met for all the validation parameters.

### **3.3.2 Analytical methods for residues**

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

## **3.4 Mammalian toxicology (Part B, Section 6)**

### **3.4.1 Acute toxicity**

No vertebrate studies were performed. The toxicological classification of GLOB2007bF was based on theoretical calculations according to Regulation 1272/2008. GLOB2007bF must be classified for skin sensitisation.

### **3.4.2 Operator exposure**

|            | <b>Result</b> | <b>PPE / Risk mitigation measures</b>  |
|------------|---------------|--|
| Operators  | Acceptable    | No PPE (work wear - arms , body and legs covered)<br>Due to the product classification (Skin Sens. 1, H317), it is recommended to use protective gloves at the M/L step. |
| Workers    | Acceptable    | No PPE (work wear - arms , body and legs covered)  |
| Residents  | Acceptable    | None   |
| Bystanders | Acceptable    | None   |

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary. As a standard rule, it could be mentioned on the label that treated crops should not be re-entered before spray deposits on leaf surfaces have completely dried.

### **3.4.3 Worker exposure**

Please refer to 3.4.2.

### **3.4.4 Bystander and resident exposure**

Please refer to 3.4.2.

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

### **3.5.1 Residues**

For the applied use of GLOB2007bF in potatoes, reference is made to existing studies submitted at EU level. The evaluated GAP is covering the one intended for GLOB2007bF.

Compliance with the EU MRLs of zoxamide and propamocarb-HCl is met for the intended use of GLOB2007bF.

### **3.5.2 Consumer exposure**

Based on PRIMO rev. 3.1 calculations made to estimate the risk for consumer through diet and other means, it can be concluded that the proposed use of zoxamide and propamocarb-HCl in the product GLOB2007bF does not lead to an unacceptable risk for consumers.

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

### **3.6.1 Predicted environmental concentrations in soil (PEC<sub>soil</sub>)**

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

### **3.6.2 Predicted environmental concentrations in groundwater (PEC<sub>gw</sub>)**

In PEC<sub>gw</sub> assessment the geometric mean of K<sub>foc</sub> for both active substances and their metabolites was used (in accordance with EFSA, 2014 guidance and national requirements) as it represents a worse case. Zoxamide. The maximum PEC<sub>gw</sub> values for active substance and their metabolites, except RH-141455, were below the trigger value of 0.1 µg/L. Only the metabolite RH-141455 is predicted to occur in groundwater at concentrations above 0.1 µg/L (between 0.75 µg/L and 10 µg/L). A relevance assessment has therefore been provided.

Propamocarb-HCl. The maximum PEC<sub>gw</sub> values for active substance were below the trigger value of 0.1 µg/L. no relevant metabolites were identified.

### **3.6.3 Predicted environmental concentrations in surface water (PEC<sub>sw</sub>)**

In PEC<sub>gw</sub> assessment the geometric mean of K<sub>foc</sub> for both active substances and their metabolites was used (in accordance with EFSA, 2014 guidance and national requirements) as it represents a worse case.

Zoxamide. The PEC values (PEC<sub>sw</sub> and PEC<sub>sed</sub>) resulting from the FOCUS STEP 1 to 4 of zoxamide and relevant metabolites were calculated for the intended use. In Step 4 the VFSmod was also used. The mitigation measures of 5 m, 10 m non-sprayed buffer strips and vegetative buffer zones were proposed. Propamocarb-HCl. The PEC values (PEC<sub>sw</sub> and PEC<sub>sed</sub>) resulting from the FOCUS STEP 1 to 2 of propamocarb-HCl were calculated for the intended use.

The relevant PEC<sub>sw</sub> and PEC<sub>sed</sub> values were used for the ecotoxicological risk assessment.

### **3.6.4 Predicted environmental concentrations in air (PEC<sub>air</sub>)**

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

### **3.7 Ecotoxicology (Part B, Section 9)**

#### **3.7.1 Effects on terrestrial vertebrates**

The TER<sub>a</sub> value is greater than the Annex VI trigger of 10, indicating low acute risk to birds from zoxamide and metabolites following application of GLOB2007bF at the intended GAP. The TER<sub>lt</sub> value for zoxamide and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2007bF presents no unacceptable long-term risk to birds when applied according to the proposed GAP.

The risk assessment for secondary poisoning, required for zoxamide and its metabolites, showed that the risk for earthworm-eating and fish-eating birds is acceptable following use of GLOB2007bF according to the proposed use pattern.

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

The risk assessments for mammals indicated that the TER<sub>a</sub> and TER<sub>lt</sub> values are greater than the Annex VI trigger of 10 or 5 respectively, indicating that the use of GLOB2007bF in potato according to the proposed GAP poses a low acute and long-term risk to mammals.

The risk assessment for secondary poisoning, required for zoxamide and its metabolites, showed that the risk for earthworm-eating and fish-eating mammals is acceptable following use of GLOB2007bF according to the proposed use pattern.

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

Tests on other terrestrial vertebrate wildlife (reptiles and amphibians) are not required.

#### **3.7.2 Effects on aquatic species**

An acceptable risk for the formulation GLOB2007bF in potato is acceptable with the following mitigation measures:

- 5 m no spray buffer zone including a 5 m vegetated filter strip. (VFSSMOD)

#### **3.7.3 Effects on bees**

The risk for non-target arthropods is acceptable when using GLOB2007bF according to the intended uses. No risk mitigation measures are needed.

#### **3.7.4 Effects on other arthropod species other than bees**

The risk for non-target arthropods is acceptable when using GLOB2007bF according to the intended uses. No risk mitigation measures are needed.

#### **3.7.5 Effects on soil organisms**

The TER values indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2007bF.

The EU review for zoxamide and propamocarb-HCl and the test on the formulation show that there are no effects on soil microbial activity at dose rates much higher than the corresponding PEC<sub>soil</sub> of the intended use. Therefore, it is concluded that there is no unacceptable risk on soil microbial activity for GLOB2007bF.

#### **3.7.6 Effects on non-target terrestrial plants**

First tier risk assessment indicates that there is no unacceptable risk from GLOB2007bF for non-target plants when applied according to the proposed use rates.

#### **3.7.7 Effects on other terrestrial organisms (Flora and Fauna)**

Tests on other non-target species are not required.

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### 3.8 Relevance of metabolites (Part B, Section 10)

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

## Appendix 1 Copy of the product authorization

## Appendix 2 Copy of the product label

### Uwagi do etykiety:

Fizykochemia – zaakceptowano 2-letni okres trwałości środka.

Toksykologia – wprowadzono zmiany w akapitach „PIERWSZA POMOC” i „Środki ostrożności dla osób stosujących środek”.

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – brak uwag do etykiety.

Ekotoksykologia – dodano zwrot P501, usunięto zwrot P273. Wyznaczono strefę ochronną dla organizmów wodnych.

Skuteczność działania – brak uwag do etykiety.

### Posiadacz zezwolenia:

Globachem N.V., Brustem Industriepark, Lichtenberglaan 2019, B-3800 Sint-Truiden, Królestwo Belgii, tel.: xxxxxxxxxxxx, e-mail: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

# OBSERVER PRO

## Środek przeznaczony do stosowania przez użytkowników profesjonalnych

### Zawartość substancji czynnej:

chlorowodorek propamokarbu (związek z grupy pochodnych kwasu karbaminowego)–  
450 g/l

zoksamid (związek z grupy benzamidów) – 67,5 g/l

zawiera : 1,2-Benzisothiazolin-3-one (CAS No. 2634-33-5)

Zezwolenie MRiRW nr R –



### Niebezpieczeństwo

H317 - Może powodować reakcję alergiczną skóry

H410 - Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki



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EUH 401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

P280 - Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy.

P302+352 - W PRZYPADKU KONTAKTU ZE SKÓRĄ: umyć dużą ilością wody z mydłem.

P391 - Zebrać wyciek.

P501 - Zawartość/pojemnik usuwać do specjalny punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi.

## OPIS DZIAŁANIA

Observer Pro jest środkiem grzybobójczym w formie rozpuszczalnego koncentratu do sporządzania zawiesiny wodnej o działaniu kontaktowym i układowym do stosowania zapobiegawczego i interwencyjnego w ochronie upraw ziemniaków.

Środek zawiera propamokarb (wg.FRAC grupa 28) oraz zoksamid, (wg FRAC grupa 22)

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

## STOSOWANIE ŚRODKA

### Ziemniak

#### Zaraza ziemniaka

**Maksymalna/zalecana dawka dla jednorazowego zastosowania: 2 l/ha**

*Termin zabiegu:*

*Pierwszy zabieg wykonać zgodnie z sygnalizacją lub:*

*- na plantacjach odmian wczesnych w okresie wystąpienia pierwszych objawów choroby,*

*- na plantacjach odmian późnych w okresie wystąpienia pierwszych objawów choroby na odmianach wczesnych.*

*Środek stosować od początku fazy rozwoju pierwszych rozgałęzień ziemniaków nad i pod powierzchnią gleby do fazy dojrzewania jagód (BBCH 21 - 79).*

*Odstęp między opryskami: co najmniej 7 dni*

*Zalecana ilość wody: 150 - 300 l/ha*

*Zalecane opryskiwanie: drobnokropliste.*

*Ilość cieczy użytkowej dostosować do zagęszczenia plantacji.*

*Maksymalna liczba zastosowań w sezonie wegetacyjnym: 3*

## ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ

1. Środek stosować przemienne z fungicydami należącymi do innych grup chemicznych, o odmiennym mechanizmie działania.

2. Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

3. Warunkiem skuteczności zabiegu jest dokładne pokrycie roślin uprawnych cieczą roboczą. Wielokrotne stosowanie środków grzybobójczych zawierających substancje czynne o podobnym mechanizmie działania może przyczynić się do wyselekcjonowania w populacji sprawcy choroby form odpornych i w konsekwencji do obniżenia skuteczności zabiegów. Z tego też względu w ramach strategii antyodpornościowej zaleca się stosowanie środka: – wyłącznie w zalecanej dawce, – maksymalnie trzykrotnie w sezonie wegetacyjnym, – tylko jako część programu ochrony, do którego włączone są inne środki grzybobójcze, zawierające substancje czynne o innych mechanizmach działania (stosowanie środków przemienne lub sekwencyjne).

## **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszałem) i uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w mieszało hydrauliczne ciecz w zbiorniku mechanicznie wymieszać. Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową. W przypadku przerw w opryskiwaniu przed ponownym przystąpieniem do pracy, dokładnie wymieszać ciecz użytkową w zbiorniku opryskiwacza.

## **POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY**

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

- po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, jeżeli jest to możliwe, lub,
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub,
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

## **WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA**

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

### **Środki ostrożności dla osób stosujących środek:**

Nie jeść, nie pić ani nie palić podczas używania produktu.

Stosować rękawice ochronne, ochronę oczu, ochronę twarzy oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Zanieczyszczoną odzież zdjąć i wyprać przed ponownym użyciem.

Zanieczyszczonej odzieży ochronnej nie wносить poza miejsce pracy.

### **Środki ostrożności związane z ochroną środowiska naturalnego:**

Nie zanieczyszczać wód produktem lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

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

**Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):**

nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

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

Ziemniak – 7 dni

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## **WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA**

Chronić przed dziećmi.

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, w temperaturze nieprzekraczającej 0°C - 30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

## **PIERWSZA POMOC**

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.

W PRZYPADKU POŁKNIECIA: W przypadku złego samopoczucia skontaktować się z OŚRODKIEM ZATRUĆ lub z lekarzem.

W PRZYPADKU KONTAKTU ZE SKÓRĄ: Umyć dużą ilością wody z mydłem.

W przypadku utrzymywania się działania drażniącego na oczy: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii -

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### **Appendix 3   Lists of data considered for national authorization**

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

Please refer to the reference list.

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

Please refer to the reference list.