

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: GLOB2106cF

Product name: Revus Pro

Chemical active substances:

Propamocarb-HCl, 450 g/L

Mandipropamid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Globachem NV

Submission date: March 2023

MS Finalisation date: 06/03/2024

Version history

When	What
March 2023	Initial submission by applicant for approval of new product
July 2023	Dossier sent for evaluation
November 2023	zRMS evaluation of dRR
March 2024	Final version prepared by zRMS after Commenting period

Table of Contents

1	Details of the application	5
1.1	Application background	5
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorization decision	5
2.1	Product identity	5
2.2	Conclusion	5
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	7
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorization decision and risk management	10
3.1	Physical and chemical properties (Part B, Section 2)	10
3.2	Efficacy (Part B, Section 3)	10
3.2.1	Efficacy data	10
3.2.2	Information on the occurrence or possible occurrence of the development of resistance	11
3.2.3	Adverse effects on treated crops	11
3.2.4	Observations on other undesirable or unintended side-effects	11
3.3	Methods of analysis (Part B, Section 5)	11
3.3.1	Analytical method for the formulation	11
3.3.2	Analytical methods for residues	11
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity	12
3.4.2	Operator exposure	12
3.4.3	Worker exposure	12
3.4.4	Bystander and resident exposure	12
3.5	Residues and consumer exposure (Part B, Section 7)	13
3.5.1	Residues	13
3.5.2	Consumer exposure	13
3.6	Environmental fate and behaviour (Part B, Section 8)	13
3.6.1	Predicted environmental concentrations in soil (PEC _{soil})	13
3.6.2	Predicted environmental concentrations in groundwater (PEC _{gw})	13
3.6.3	Predicted environmental concentrations in surface water (PEC _{sw})	13
3.6.4	Predicted environmental concentrations in air (PEC _{air})	13
3.7	Ecotoxicology (Part B, Section 9)	13

3.7.1	Effects on terrestrial vertebrates	13
3.7.2	Effects on aquatic species	14
3.7.3	Effects on bees	14
3.7.4	Effects on other arthropod species other than bees.....	15
3.7.5	Effects on soil organisms	15
3.7.6	Effects on non-target terrestrial plants	15
3.7.7	Effects on other terrestrial organisms (Flora and Fauna).....	16
4	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization	16
Appendix 1	Copy of the product authorization	16
Appendix 2	Copy of the product label.....	16
Appendix 3	Letter of Access	20
Appendix 4	Lists of data considered for national authorization.....	20

PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

This application was submitted by Globachem NV in March 2023.

The application was for approval of GLOB2106cF, a suspension concentrate containing 450 g/L Propamocarb-HCl and 75 g/L Mandipropamid for use as a fungicide in potatoes for which Poland was designated zRMS.

1.2 Letters of Access

A Letter of Access/Supply for Mandipropamid from Syngenta Crop Protection AG was requested in the light of a signed data access agreement.

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	GLOB2106cF
Product name in MS	Revus Pro
Authorization number	/
Function	Fungicide
Applicant	Globachem NV
Active substance(s) (incl. content)	Propamocarb-HCl: 450 g/L Mandipropamid: 75 g/L
Formulation type	Suspension concentrate (SC)
Packaging	0.1, 0.15, 0.25, 0.5, 1, 2, 3, 5, 10, 15, 20 L HDPE, HDPE/PA, HDPE/F, HDPE/EVOH, PET
Coformulants of concern for national authorizations	None
Restrictions related to identity	None
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation resulted in the decision to grant the authorization.

It should be noted that the following data gaps were identified regarding the analytical methods for residue determination:

for propamocarb:

- a primary, confirmatory and ILV methods for the determination of propamocarb in drinking water
- a primary method for the determination of propamocarb in surface water
- a primary method and confirmation for the analysis of propamocarb in body tissues and body fluids

In the opinion of the zRMS, the Applicant should complete them post-registration after the renewal of approval for propamocarb. However, the final decision should be taken by risk managers.

for mandipropamide:

- an ILV method for the determination of mandipropamid in drinking water is missing
- a primary method and confirmation is required for the analysis of mandipropamid in body tissues and body fluids
- the extraction efficiency of method for products of plant origin

In the opinion of the zRMS, the Applicant should complete them post-registration after the renewal of approval for mandipropamid. However, the final decision should be taken by risk managers.

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 Chronic 2
-------------------------------	---------------------------------

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

Hazard pictograms:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H317 - May cause an allergic skin reaction. H411 - Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	P261 - Avoid breathing dust/fume/ gas/mist/vapours/spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P391 - Collect spillage. P501 - Dispose of contents/ container to...
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401] Contains 1,2-benzisothiazol-3(2H)-on.

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

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

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).
------	---

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 toxicological properties of the product (Skin Sens. 1, H317), the operator should wear workwear and protective gloves during mixing, loading and handling the undiluted product.
Worker protection:	
	No PPE required
Integrated pest management (IPM)/sustainable use:	
	/
Environmental protection	
P501	Dispose of contents/container in accordance with local/regional/national regulation.
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
Other specific restrictions	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

Integrated pest management (IPM)/sustainable use:	
	/

2.5.2 Specific restrictions linked to the intended uses

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

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

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code):	Revus Pro/GLOB2106cF	Formulation type:	GAP rev. 1.0, date: 2023-02-28 Suspension concentrate (SC) ^(a,b)
Active substance 1:	Propamocarb-HCl	Conc. of as 1:	450 g/L ^(c)
Active substance 2:	Mandipropamid	Conc. of as 2:	75 g/L ^(c)
Safener:	/	Conc. of safener:	/ ^(c)
Synergist:	/	Conc. of synergist:	/ ^(c)
Applicant:	Globachem NV	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	yes		

Field of use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	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
					Method / Kind	Timing / Growth stage of crop & season	Max. number/year	Min. interval between applications (days)	L product/ha max. rate per appl.	kg as/ha a) max. rate per appl.	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	Seed, ware and starch potato (SOLTU) code: 0211000	F	<i>Phytophthora infestans</i> (PHYTIN)	Normal downward spraying	After emergence to shortly before harvest (BBCH 21- 89)	a) 3 b) 3	7	a) 1.9 b) 5.7	a) Propamocarb-HCl: 0.855 + Mandipropamid: 0.1425 b) Propamocarb-HCl: 2.565 + Mandipropamid: 0.4275	150-300	14	A

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPP0-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPP0-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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	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.	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: 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 uniform white, opaque liquid formulation, with a solvent odour. It is not explosive, has no oxidising properties. The product is not highly flammable. It has a self ignition temperature of above 400°C. In aqueous solution, it has a pH value around 5 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*. Its technical characteristics are acceptable for a *suspension concentrate* formulation.

zRMS

Accelerated storage stability test indicate a shelf life of at least 2 years at ambient temperature when stored in *HDPE*.

A 2 and 3 year storage stability study at ambient temperature is ongoing. A shelf-life for the PPP should be evaluated based on the results of real time data in post-registration at national level.

Implications for labelling: none

Compliance with FAO specifications: The product GLOB2106cF complies with the general FAO specifications.

Compatibility of mixtures: not applicable as no tank mixtures are mentioned on the label.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of GLOB2106cF has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

The trials package of GLOB2106cF 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 GLOB2106cF under a wide range of climatic and edaphic conditions.

All of the results are in support of the 1.9 L/ha dose rate for GLOB2106cF for the control of a late blight (*Phytophthora infestans*) on potatoes.

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.

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.

Therefore GLOB2106cF can be considered safe for use on potatoes.

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.

To assess the potential impact on succeeding crops a seedling emergence study and seedling growth test was performed where the product was incorporated into the soil.

For none of the tested species any effect on fresh shoot weight or visual injury was measured, not even at the highest tested dose rate. Therefore it can be stated that GLOB2106cF is safe for succeeding crops, even when the equivalent of 6 applications at a dose rate of 2 L/ha are performed all at once (double the requested seasonal dose rate).

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of Propamocarb-HCl and Mandipropamid in GLOB2106cF 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 LC-QQQ method was submitted to analyse the Propamocarb-HCl content in the formulation. An HPLC-PDA method was submitted to analyse the content of Mandipropamid in the formulation. The methods were successfully validated.

3.3.2 Analytical methods for residues

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

Noticed data gaps are:

for propamocarb:

- a primary, confirmatory and ILV methods for the determination of propamocarb in drinking water
- a primary method for the determination of propamocarb in surface water
- a primary method and confirmation for the analysis of propamocarb in body tissues and body fluids

In the opinion of the zRMS, the Applicant should complete them post-registration after the renewal of approval for propamocarb. However, the final decision should be taken by risk managers.

for mandipropamide:

- an ILV method for the determination of mandipropamid in drinking water is missing
- a primary method and confirmation is required for the analysis of mandipropamid in body tissues and body fluids
- the extraction efficiency of method for products of plant origin

In the opinion of the zRMS, the Applicant should complete them post-registration after the renewal of approval for mandipropamid. However, the final decision should be taken by risk managers.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

No vertebrate studies were performed. The toxicological classification of GLOB2106cF was based on theoretical calculations according to Regulation 1272/2008. GLOB2106cF must be classified for skin sensitisation.

3.4.2 Operator exposure

Operator exposure to GLOB2106cF was not evaluated as part of the EU review of Propamocarb-HCl and Mandipropamid. Therefore all relevant data and risk assessments are provided here and are considered adequate.

Operator exposure was assessed against the AOEL agreed in the EU review of Propamocarb-HCl (0.29 mg a.i./kg bw/d) and Mandipropamid (0.17 mg/kg bw/d). For dermal absorption of Mandipropamid, default values of 10% for the concentrate and 50% for the spray solution were used. For dermal absorption of Propamocarb-HCl, the default value of 10% was used for the concentrate. For the spray solution, a dermal absorption values of 5.1% and 1.2% were used as determined in a dermal absorption study. Operator exposure was modelled using the online AOEM model.

According to the model calculations, it can be concluded that the risk for the operator using GLOB2106cF according to the intended use is acceptable without personal protective equipment.

However, due to the toxicological properties of the product (Skin Sens. 1, H317), the operator should wear workwear and protective gloves during mixing, loading and handling the undiluted product.

3.4.3 Worker exposure

Worker exposure to GLOB2106cF was not evaluated as part of the EU review of Propamocarb-HCl and Mandipropamid. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with GLOB2106cF. 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.

3.4.4 Bystander and resident exposure

Bystander and resident exposure to GLOB2106cF was not evaluated as part of the EU review of Propamocarb-HCl and Mandipropamid. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no undue risk to any bystander after accidental short-term exposure or to any resident after long-term exposure to GLOB2106cF. No mitigation measures are needed.

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

3.5.1 Residues

For the applied use of GLOB2106cF in potatoes, reference is made to existing studies submitted at EU level. The evaluated GAP is covering the one intended for GLOB2106cF.

Compliance with the EU MRLs of Propamocarb-HCl and Mandipropamid is met for the intended uses of GLOB2106cF.

3.5.2 Consumer exposure

Based on PRIMO calculations made to estimate the risk for consumer through diet and other means, it can be concluded that the proposed use of Propamocarb-HCl and Mandipropamid in the product GLOB2106cF does not lead to an unacceptable risk for consumers.

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

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

The PEC of Propamocarb-HCl, Mandipropamid and its metabolites in soil have been assessed with the FOCUS model and the DT₅₀ values established in the EU review.

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

The PEC of Propamocarb-HCl, Mandipropamid and its metabolites in ground water has been determined with standard FOCUS scenarios to obtain outputs from the FOCUS PEARL 5.5.5 and PELMO 6.6.4 models.

The PEC_{gw} of the active substances and its metabolites did not exceed the threshold of 0.1 µg/L. Therefore, no unacceptable leaching to groundwater is anticipated for the intended use of GLOB2106cF.

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

The PEC values (PEC_{sw} and PEC_{sed}) resulting from the FOCUS STEP 1 to 3 of Propamocarb-HCl, Mandipropamid and its metabolites were calculated for the intended use. These were then used for the ecotoxicological risk assessment.

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

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

Both active substances are regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems due to volatilization with subsequent deposition should not be considered.

3.7 Ecotoxicology (Part B, Section 9)

3.7.1 Effects on terrestrial vertebrates

Birds

Effects on birds for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid. Therefore, all relevant data and risk assessments are provided here and are considered adequate. The risk assessment for effects on birds is carried out according to the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009)¹.

The acute and long-term risks of GLOB2106cF to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with Propamocarb-HCl or Mandipropamid, and maximum residues occurring on food items following applications according to the proposed use pattern. The acute and long-term risk were acceptable at the first-tier assessment.

¹ EFSA (2009). Guidance of EFSA – Risk assessment for Birds and Mammals. EFSA Journal 2009; 7(12):1438.

Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has been assessed for Mandipropamid and its metabolite SYN 539678, as these compounds have a $\log P_{ow} > 3.0$.

Since GLOB2106cF contains 2 active ingredients, a combined risk assessment was also performed.

In conclusion, the TER_A and TER_{LT} values are greater than the Annex VI trigger of 10 and 5 respectively, indicating low acute and long-term risks to birds following application of GLOB2106cF according to the intended uses.

Terrestrial vertebrates (other than birds)

Effects on terrestrial vertebrates other than birds for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

The acute and long-term risks of GLOB2106cF to wild mammals were assessed using the 'Guidance of EFSA – Risk assessment for Birds and Mammals' (EFSA 2009) by calculating the toxicity exposure ratios between toxicity endpoints, estimated from studies with Propamocarb-HCl or Mandipropamid, and maximum residues occurring on food items following applications according to the use pattern. The acute and long-term risk were acceptable at the first-tier assessment.

Risk of secondary poisoning through contaminated drinking water has also been assessed. The risk of secondary poisoning through bioaccumulation has been assessed for Mandipropamid and its metabolite SYN 539678, as these compounds have a $\log P_{ow} > 3.0$.

Since GLOB2106cF contains 2 active ingredients, a combined risk assessment was also performed.

In conclusion, the TER_A and TER_{LT} values are greater than the Annex VI trigger of 10 and 5 respectively, indicating low acute and long-term risks to mammals following application of GLOB2106cF according to the intended uses.

3.7.2 Effects on aquatic species

Effects on aquatic organisms for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid. A new risk assessment was performed for the intended uses using the toxicity data of GLOB2106cF, the active substances as well as the metabolites.

An acceptable risk is concluded for Propamocarb-HCl and the Mandipropamid metabolites SYN 504851, SYN 500003, CGA 380778, SYN 521195 and SYN 539678 at Step 2. The risk for Mandipropamid is acceptable at Step 3.

An acceptable risk for the formulation GLOB2106cF following spray drift is concluded without risk mitigation measures.

3.7.3 Effects on bees

Effects on bees for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid.

The risk of GLOB2106cF to honeybees and bumble bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with the formulated product, and the single application rate of 2051.81 g/ha. All the hazard quotients are considerably less than 50, indicating that GLOB2106cF poses a low acute risk to honeybees and bumble bees.

The chronic risk to honeybees (adult and larvae) was assessed according to the modified EPP0 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028), using toxicity endpoints

estimated from chronic studies with the formulated product. It was demonstrated that GLOB2106cF poses a low chronic risk to honeybees.

No risk mitigation measure is necessary.

3.7.4 Effects on other arthropod species other than bees

Effects on non-target arthropods for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid.

Extended laboratory studies were conducted on *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Chrysoperla carnea* and *Coccinella septempunctata*. The in-field and off-field hazard quotients for all species are below the trigger values recommended by ESCORT 2.

The risk to non-target arthropods following application of GLOB2106cF is considered acceptable. No risk mitigation measure is necessary.

3.7.5 Effects on soil organisms

Effects on earthworms and other soil macro-organisms for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid.

Earthworms

The long-term risk of GLOB2106cF to earthworms was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulation and the maximum PEC_{soil}.

The TER_t due to exposure to Propamocarb-HCl, Mandipropamid and its metabolite CGA 380778 and GLOB2106cF are above the trigger of 5.

No risk mitigation measure is necessary.

Effects on other soil non-target macro-organisms

The long term risk of GLOB2106cF to *Hypoaspis aculeifer* and *Folsomia candida* was assessed from a chronic toxicity exposure ratio (TER) between a chronic toxicity endpoint from a reproduction study on the formulation and the maximum PEC_{soil}.

The chronic TER value for *Hypoaspis aculeifer* and *Folsomia candida* is greater than the Annex IV trigger of 5, indicating an acceptable risk to other soil non-target macro-organisms following application of GLOB2106cF for the intended uses.

Effects on soil non-target micro-organisms

Effects on soil microbial activity of GLOB2106cF were not evaluated as part of the EU review for Propamocarb-HCl or Mandipropamid. Therefore, all relevant data and assessments were provided. They show that GLOB2106cF application according to the intended use has no significant effect on soil micro-organisms.

3.7.6 Effects on non-target terrestrial plants

Effects on non-target plants for GLOB2106cF were not evaluated as part of the EU review of Propamocarb-HCl or Mandipropamid.

The potential effect of GLOB2106vF on vegetative vigour and seedling emergence has been tested through studies performed with the formulation on non-target terrestrial plants.
No mitigation measures are needed to protect non-target plants after application of GLOB2106cF.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorization

Missing storage stability study at ambient temperature. A 2 and 3 year storage stability study at ambient temperature is ongoing. A shelf-life for the PPP may be evaluated in post-registration at national level.

Appendix 1 Copy of the product authorization

Appendix 2 Copy of the product label

Uwagi do etykiety:

Fizykochemia – nie przedłożono do oceny badania dwuletniego przechowywania środka w temperaturze otoczenia.

Toksykologia – dodano zwrot P261, zmieniono treść etykiety w zakresie „Środki ostrożności dla osób stosujących środek” oraz „Pierwsza pomoc”.

Pozostałości – brak uwag do etykiety.

Los i zachowanie w środowisku – usunięto zwrot P273.

Ekotoksykologia – dodano informację o ochronie roślin oraz stawonogów.

Skuteczność działania – dodano informację o średnim poziomie zwalczania.

Posiadacz zezwolenia:

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

REVUS PRO

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

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

mandipropamid (związek z grupy karboksamidów) – 75 g/l

Zawiera : 1,2-benzisothiazol-3(2H)-on]

Zezwolenie MRiRW nr R –



Niebezpieczeństwo

H317 - Może powodować reakcję alergiczną skóry

H411 - Działa toksycznie na organizmy wodne, powodując długotrwałe skutki

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

P261 - Unikać wdychania pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.

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

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

P391 - Zebrać wyciek.

P501 - Zawartość/pojemnik usuwać do ...

OPIS DZIAŁANIA

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

Środek zawiera propamokarb (wg.FRAC grupa 28) oraz mandipropamid, (wg FRAC grupa 40) Środek przeznaczony do stosowania przy użyciu samobieźnych lub ciągnikowych opryskiwaczy polowych.

STOSOWANIE ŚRODKA

Ziemniak

Zaraza ziemniaka - średni poziom zwalczania

Maksymalna/zalecana dawka dla jednorazowego zastosowania: 1,9 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 - 89).

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 przemiennie 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

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 miesadłem) i uzupełnić wodą do potrzebnej ilości.

Po wlaniu środka do zbiornika opryskiwacza nie wyposażonego w miesadło 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 roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

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 – 14 dni

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 lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.~~

Okres ważności - 2 lata

Data produkcji -

Zawartość netto -

Nr partii –

Appendix 3 Letter of Access

This information will be sent to the zRMS by Syngenta Crop Protection AG directly.

Appendix 4 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.