

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

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

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: March 2023

MS Finalisation date: 06/03/2024

Version history

When	What
March 2023	Initial dossier 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

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Evaluator comments:

The text highlighted in grey was provided by the evaluator. The text highlighted in yellow was added by zRMS after the commenting process.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is made for a new product containing 450 g/L Propamocarb-HCl and 75 g/L Mandipropamid formulated as a suspension concentrate (SC).

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

The Annex II data for Propamocarb-HCL and Mandipropamid are out of data protection. In case Globachem NV uses new Annex II data on Mandipropamid (from the SSSD), a Letter of Access is supplied by Syngenta. The Annex III data used for GLOB2106cF are owned by Globachem NV.

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

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Central zone	Poland Revus Pro	BE Belgium; CZ Czech Republic; DE Germany; NL the Netherlands

0.1.3 Regulatory history of the active(s)

0.1.3.1 Propamocarb-HCl

Table 0.1-2: Summary of regulatory history of CAS No: 25606-41-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 91/414/EEC Commission Implementing Regulation (EU) No 540/2011 Commission Implementing Regulation (EU) No 2020/869 Commission Implementing Regulation (EU) No 2021/745 Commission Implementing Regulation (EU) No 2022/708 Commission Implementing Regulation (EU) No 2023/918
RMS	IE

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/10/2007
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/03/2008
Date of final Commission (re-registration) deadline (Step 2)	30/09/2011
Current expiration of approval	31/07/2023 15/06/2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

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

The SANCO report for Propamocarb (SANCO/10057/2006 final – 25 April 2007) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 5 July 2006.

Table 0.1-3: Information on minimum purity of Propamocarb-HCl

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
920 g/kg	950 g/kg Equivalence report available: Y RMS: DE

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Active Substance	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Purity of a.s.	92%	95%

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

0.1.3.2 Mandipropamid

Table 0.1-4: Summary of regulatory history of CAS No: 374726-62-2

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 188/2013 Commission Implementing Regulation (EU) No 2018/155
RMS	AT
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.08.2013
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31.01.2014
Date of final Commission (re-registration) deadline (Step 2)	31.01.2015
Current expiration of approval	31.07.2023 31/12/2025
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

Conditions of use shall include risk mitigation measures, where appropriate.

The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 July 2015.

The SANCO report for Mandipropamid (SANCO/ 12991/2012 rev 4 – 1 February 2013) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 5 November 2012.

Table 0.1-5: Information on minimum purity of Mandipropamid

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalence report *, **
930 g/kg	This information will be sent to the zRMS by Syngenta.

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information

Missing storage stability study at ambient temperature. 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.

Section 3. Efficacy

The Plant Protection Product GLOB2106cF/Revus Pro is intended to control a late blight/*Phytophthora infestans* in potatoes. 16 Preliminary trials and 36 efficacy experiments conducted in 2021 and 2022, in 4 EPPO zones confirmed a proper effectiveness of this fungicide.

The obtained effectiveness qualifies the Glob 2106cF fungicide as moderate control to control of *P. infestans* in Poland. Glob 2106cF shows selectivity towards potatoes crop. No adverse plant symptoms or negative effect of fungicide on potatoes yield were observed. The data obtained in the experiments confirm these features. The policy on counteracting the development of resistance has been properly presented in the dRR.

The results obtained in the experiments justify the needed for registration of studied agent for *P. infestans* control in Poland. The data provided in dRR confirm the above application and authorize the registration of GLOB2106cF/Revus Pro in Poland. The application is submitted for registration of Plant Protection Product GLOB2106cF/Revus Pro in Poland according to art. 33 of Regulation 1107/2009. The zRMS is Poland.

Section 5. Analytical Methods

Accepted.

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.

Section 6. Mammalian Toxicology

Classification: Skin Sens. 1, H317 - *May cause an allergic skin reaction.*

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

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

Section 7. Metabolism and Residues

The Applicant did not provide any new studies. The assessment is based on data evaluated at EU level.

Comparison of intended and critical EU GAPs

Propamocarb

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2013;11(4):3214)	Potatoes	4	Foliar treatment-spraying	BBCH 20-95	840	7
Critical NEU and SEU GAP (SAN-CO/10057/2006 final, 25 April 2007)	Potatoes	6	Foliar spray	As 1 st symptoms occur	1083	14
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	855	14

Mandipropamid

Type of GAP	Crop	Max number of applications	Method of application	Growth stage at last application	Max appl. rate per treatment (g a.s./ha)	PHI (days)
critical NEU GAP (EFSA Journal 2018;16(5):5284)	Potatoes	6	Foliar treatment-spraying	BBCH 31-90	150	3
Intended GAP	Potatoes	3	Normal downward spraying	BBCH 21-89	142.5	14

EU GAPs cover intended GAP.

The proposed uses of Propamocarb-HCl in the formulation GLOB2106cF do not represent unacceptable acute and chronic risks for the consumer.

The proposed uses of mandipropamid in the formulation GLOB2106cF do not represent unacceptable chronic risks for the consumer. No acute risk evaluation was performed as the setting of an ARfD was considered not necessary for mandipropamid.

From a scientific point of view, it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.” Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

Section 8. Environmental Fate

In accordance with proposed pattern use in potatoes, an exposure assessment for the formulation of GLOB2106cF was submitted.

No mitigation measures were proposed.

Section 9. Ecotoxicology

Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed use of GLOB2106cF as a fungicide on potatoes poses acceptable risk to non-target organisms, if applied according to the recommended use pattern.

No mitigation measure is required.

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

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

-

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

-

All uses are covered by established MRLs.

Appendix 1 ALL intended uses

GAP rev. 1.0, date: 2023-03-21

PPP (product name/code): Revus Pro/GLOB2106cF
 Active substance 1: Propamocarb-HCl
 Active substance 2: Mandipropamid
 Safener: /
 Synergist: /
 Applicant: Globachem NV
 Zone(s): Central ^(d)
 Verified by MS: yes/~~no~~

Formulation type: SC ^(a, b)
 Conc. of as 1: 450 g/L ^(c)
 Conc. of as 2: 75 g/L ^(c)
 Conc. of safener: / ^(c)
 Conc. of synergist: / ^(c)
 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. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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	PL, BE, CZ, DE, NL	Seed, ware and starch potato (SOLTU) code: 0211000	F	<i>Phytophthora infestans</i> (PHYTIN)	Normal downward spraying	After emergence to shortly before harvest (BBCH21- 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 EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	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	