FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 076127 A

Product name: PROSIM

Chemical active substances:

Propamocarb hydrochloride, 400 g/L

Cymoxanil, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: October 2020

MS Finalisation date: 12/2022; 03/2023

Version history

When	What
12/2022	zRMS finalised the dRR assessment
March 2023	Final registration report

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted by SHARDA CROPCHEM ESPAÑA S.L. for approval of PROSIM (Propamocarb 40% + Cymoxanil 5% SC), a suspension concentrate containing 400 g/L of Propamocarb hydrochloride and 50 g/L of Cymoxanil for use as fungicide on potato in Central Europe.

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.

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)**
Northern zone	-	-
Central zone	Poland PROSIM	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the actives

0.1.3.1 Propamocarb hydrochloride

Table 0.1-2: Summary of regulatory history of CAS No: 24579-73-5 (propamocarb) and 25606-41-1 (propamocarb hydrochlyride).

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 2007/25/EC Commission Implementing Regulation (EU) 2020/869 extending the approval period
RMS	Original RMS: Ireland RMS: Portugal Co-RMS: Belgium
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.10.2007

Status	
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	~~31.07.2021~~ 31.07.2023
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 authorisation should include protective measures, where appropriate;
- the transfer of soil residues for rotating or succeeding crops;
- the protection of surface and groundwater in vulnerable zones;
The protection of birds, mammals and aquatics organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

The SANCO report for Propamocarb hydrochloride (SANCO/10057/2006 – 25/04/2007) 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 12 May 2006 (EFSA Scientific Report (2006) 78, 1-80).

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

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	minimum purity of active substance: 970 g/kg Equivalence report available: ~~No, evaluation ongoing~~ Yes RMS: Germany

* 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.

0.1.3.2 Cymoxanil

Summary of regulatory history of CAS No: 57966-95-7

Status	
Approved in EU	Y
Original Inclusion Directive Commission Implementing Regulation	Commission Directive 2008/125/EC Commission Implementing Regulation (EU) No 540/2011
RMS	RMS: Lithuania Co-RMS: Finland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.09.2009
Date of first Commission (re-registration) deadline (Step 1) or date of	28.02.2010

Status	
deadline for renewal of authorization (renewal)	
Date of final Commission (re-registration) deadline (Step 2)	28.02.2014
Current expiration of approval	~~31.07.2021~~ 31.07.2023
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 operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment;
- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the protection of aquatic organisms and must ensure that the conditions of authorisation include risk mitigation measures such as buffer zones, where appropriate.

The SANCO report for Cymoxanil (SANCO/179/08 – 09/07/2010) 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 17 September 2008 (EFSA Scientific Report (2008) 167, 1-116).

Table 0.1-4: Information on minimum purity of Cymoxanil

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 *, **
970 g/kg	minimum purity of active substance: 990 g/kg Equivalence report available: Y RMS: UK

* 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.

Comments of zRMS:	All the active ingredient sources used are approved at EU level. See Part C for details.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

Efficacy section: 1

Residues section: 1

Environmental fate and behavior section: 1

Ecotoxicology section: 1

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

Efficacy section: none

Residues section: none

Environmental fate and behavior section: none

Ecotoxicology section: none

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:
Residues section: none

Residues section: Use/ GAP is covered by established MRLs

Physical and chemical properties:

~~Authorisation can be granted for 1 year only.~~

~~Lack of results of ambient temperature shelf life (the study is on-going). Based on the results of accelerated storage test (14 days at 54ºC), the 1 year registration of the product may be granted. Final 2 year registration will be possible after providing the results of ambient temperature shelf life.~~

No data gaps.

Efficacy:

The number of trials is sufficient and fulfil EPPO requirements for a major crop for MAR and N-E. However, cMS form S-E should decide if only 2 studies can be acceptable considering the importance of this crop.

Metabolism and residues:

Noticed data gaps are: none

~~Section 7: The Applicant is requested to complete the point 7.2.1 with data on the stability of residues in potatoes..~~

Toxicology:

Classification of Propamocarb 40% + Cymoxanil 5% SC is Skin Sens. 1/ H317, Repr. 2/ H361fd. No unacceptable risk for operators, workers, residents and bystanders was iden-tified when the product is used as intended . Bufor zone 5 m.

The operator must wear protective clothing, protective gloves and face/eye protection when mixing, loading and handling concentrated product. During application operator must wear work wear and gloves.

Fate:

No risk for groundwater is expected for proposed GAP.

zRMS to insert overall summary of the assessment focusing on the main conclusions only, including a grouping of safe uses, non-safe uses and uses for which the safety could only be established following additional risk mitigation at a national (non-core) level or the safety is to be confirmed by cMS.

Appendix 1 ALL intended uses

GAP rev. 0, date: 2016-November-30th

PPP (product name/code):	Propamocarb 40% + Cymoxanil 5% SC	Formulation type:	SC (Suspension Concentrate)
Active substance 1:	propamocarb	Conc. of as 1:	400 g/L
Active substance 2:	cymoxanil	Conc. of as 2:	50 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	SHARDA Cropchem España	Professional use:	☒
Zone(s):	central,	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Fungicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**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)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	**Potato**	F	*Phytophthora infestans*	Foliar Spray	BBCH 21-95	a) 1 b) 6	7-10	a) 2.5 b) 15	a) 1 propamocarb + 0.125 cymoxanil b) 6 propamocarb + 0.75 cymoxanil	200-400	14	

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