

# **FINAL REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**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**

## **NATIONAL ASSESSMENT**

**Poland**

**Applicant: SHARDA Cropchem España S.L.**

**Submission date: dd/mm/yyyy**

**MS Finalisation date:** 12/2022; 03/2023; 08/2023; 08/2023 02/2024  
03/2024; 03/2024

## Version history

When	What
12/2022	zRMS finalised the dRR assesment
March 2023	Assessment with respect to comments in the Reporting Table
August 2023	Corrected by expert
August 2023	Corrected
February 2024	Correction in Residues and consumer exposure section
March 2024	Efficacy section added information's about yield and its quality to fRR
March 2024	Corrected - bees

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

#### 1.1 Application background

This application is submitted by SHARDA CROPCHEM ESPAÑA S.L.

This application is for approval PROSIM (Propamocarb hydrochloride 40% + Cymoxanil 5% SC), a soluble concentrate containing 400 g/L of Propamocarb hydrochloride and 50 g/L of Cymoxanil as fungicide on potato.

zRMS: Poland

#### 1.2 Letters of Access

Not application. Letter of access not needed.

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

This dossier relies on new tests and studies, providing data and information specific to the formulation Propamocarb hydrochloride 40% + Cymoxanil 5% SC as required by EU regulations.

#### 1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

### 2 Details of the authorization decision

#### 2.1 Product identity

Product code	SHA 076127 A
Product name in MS	PROSIM Propamocarb hydrochloride 40% + Cymoxanil 5% SC
Authorization number	First authorisation
Function	Fungicide
Applicant	SHARDA Cropchem España S.L.
Active substances (incl. content)	Propamocarb hydrochloride, 400 g/L Cymoxanil, 50 g/L
Formulation type	Suspension Concentrate [Code: SC]
Packaging	0.25, 0.5, 1, 5, 10L bottles COEX HDPE/PA; 20 L bottle COEX

	HDPE/Fluorinated; 0.25, 0.5, 1 L bottle HDPE; 5, 10, 20 L jerrycan HDPE
Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

## 2.2 Conclusion

The evaluation of the application for Propamocarb 40% + Cymoxanil 5% SC resulted in the decision to grant the authorization.

### Section Phys-chem:

~~Lack of the 2 years ambient shelf life study (authorisation can be granted for 1 year only).~~

### Efficacy section:

PROSIM can be granted in Poland according to accepted GAP table. In the opinion of ZRMs Applicant submitted sufficient documentation for N-E and Maritime EPPO zone. CMS from S-E should decide if limited number of trials can be accepted.

## 2.3 Substances of concern for national monitoring

Not relevant.

## 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, Repr. 2, Aquatic Chronic 2
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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, GHS08, GH09</b>
Signal word:	<b>Warning</b>
Hazard statement(s):	<b>H317, H361fd, H411</b>
Precautionary statement(s):	P201, P202, <b>P261</b> , P272, <b>P273</b> , <b>P280</b> , P302+P352, P321, P308+P313, <b>P333+P313</b> , P362+P364, <b>P391</b> , <b>P405</b> , <b>P501</b>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

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:	
-	-

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

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## 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:	
P280	Workwear + gloves during mixing/loading
Worker protection:	
P280	Work wear + 2 days re-entry period
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-
Other specific restrictions	
-	-

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)

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

PPP (product name/code): Propamocarb 40% + Cymoxanil 5% SC  
Active substance 1: Propamocarb  
Active substance 2: Cymoxanil  
Safener: -  
Synergist: -  
Applicant: SHARDA Cropchem España S.L.  
Zone(s): Central  
Verified by MS: yes/no

Formulation type: SC (Suspension Concentrate)  
Conc. of as 1: 400 g/L  
Conc. of as 2: 50 g/L  
Conc. of safener: -  
Conc. of synergist: -  
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. <sup>(e)</sup>	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: 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)	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.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha <sup>(f)</sup>
					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		
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 ap- plication				
	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 <sup>3</sup> 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						12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.				
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.						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)

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 grey viscous liquid with characteristic intensive acetic acid odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 390 °C. In aqueous solution, it has a pH value around 3.39. 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 storage stability for 2 years study is on-going and will be provided as soon as possible. The results of the storage stability after ~~1-year~~ 2-year study indicate the good stability of the product. Its technical characteristics are acceptable for a *Suspension concentrate* formulation. The intended concentration of use is 0.625% to 1.25%.

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

Propamocarb 40% + Cymoxanil 5% SC is an Suspension Concentrate (SC) formulation containing 400 grams per liter (g/L) Propamocarb and 50 grams per liter (g/L) Cymoxanil for use against *Phytophthora infestans* in potato.

In compliance with the GAP the following dose rates are applied for registration:

- Up to 6 applications in potato to control *Phytophthora infestans*, target rate: 2.5 L/ha

This document serves the registration of Propamocarb 40% + Cymoxanil 5% SC in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicide efficacy and crop safety of Propamocarb 40% + Cymoxanil 5% SC in potato, as claimed in the GAP table.

Comprehensive field trials were conducted in 2016/17 season in a range of European countries in the Maritime (i.e. United Kingdom, Czech Republic and Germany), North-East (i.e. Poland and Lithuania) and South-East (i.e. Hungary) EPPO zones. The trials followed the corresponding EPPO guidelines.

This document clearly demonstrates – as will be demonstrated in the following sections – that the efficacy and crop safety of Propamocarb 40% + Cymoxanil 5% SC is equivalent to the standard Propamocarb + Cymoxanil containing products to which it was compared. The applicant therefore wishes to cite the data on Propamocarb + Cymoxanil now out of protection in additional support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the zonal and national evaluators extrapolate from those data.

#### 3.3 Efficacy data

##### Preliminary tests

The activity of Propamocarb + Cymoxanil is well known; both actives have been marketed by for the control of fungal pests in potato for a number of years. Based on the knowledge about the active substances (more than 30 years) and the experiences with the actives in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

### Minimum effective dose tests

Propamocarb 40% + Cymoxanil 5% SC was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with Propamocarb 40% + Cymoxanil 5% SC applied at 1.5 L/ha, 2.0 L/ha and 2.5 L/ha was evaluated in 14 potato trials, for the control of *Phytophthora infestans*. The dose rates tested in potato reflects 60%, 80% and 100% of the recommended rate of Propamocarb 40% + Cymoxanil 5% SC, in accordance with the EPPO guideline PP 1/225(2) "Minimum effective dose". The dose rates are selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented from trials conducted in the Maritime EPPO zone (i.e. Czech Republic, United Kingdom and Germany), the North-east EPPO zone (i.e. Poland) and the South-east EPPO zone (i.e. Hungary).

**Conclusion:** In summary, reducing the application rate of Propamocarb 40% + Cymoxanil 5% SC from the proposed dose rate resulted in decreased efficacy against the causal agents of *Phytophthora infestans*.

According to the presented results, the dose rate of 2.5 L/ha per application, for control of *Phytophthora infestans* in potato provided the optimal overall control and should be considered as effective against the diseases, for which activity of Propamocarb 40% + Cymoxanil 5% SC is claimed. As diseases often occur as complexes of several pathogens throughout a season, up to six applications per season of Propamocarb 40% + Cymoxanil 5% SC at the proposed rate should be used to efficiently control all pathogens claimed on the label.

### Efficacy tests and conclusions regarding authorization of intended uses

Details of experiment are presented above by Applicant. All used methodology is in accordance to GEP rules, in exception of conduction studies during one growing season (2016/2017). However, Applicant submitted explanation which was accepted by Evaluator.

Applicant submitted in total 14 efficacy trials carried out on potato in three EPPO zones: Maritime EPPO zone (6 trials: DE-2, UK-2, CZ-2), North-East EPPO zone (6 trials: PL) and South-East EPPO zone (2 trials: HU). 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.

The following efficacy scale was used:

- L – limiting (0-60% efficacy)
- ME – moderately efficiency (60-80%)
- E – efficiently (>80%)

We are dealing with the active substances used commonly for many years in many countries. We must emphasize that each pest should be representative by sufficient number of field efficacy tests (at least 6 for major pest and at least 3 for minor pest). Applicant submitted for N-E – 10 trials (PL-6, CZ-2, DE-2) and for MAR – 6 trials against late blight of potato which is acceptable and according to rules. cMS from S-E should decide if limited number of trials can be sufficient.

PESSEV and PESINC was acceptable in all submitted trials by Applicant. Results were presented by the Applicant in the tables above and in the BAD in appendixes.

Efficacy of PROSIM:

- MAR – efficacy for leaf was presented on the basis of 1 trial carried out in DE; efficacy for plant was observed in 5 trials (UK-2, CZ-2, DE-1) and on stem in 2 English trials. PROSIM effectively control the late blight of potato on leaf and stem and moderately effectively at all plant. Results were compared to standard reference product.
- N-E – efficacy on the leaf was noted in 2 trials and on the plant – during 4 trials. PROSIM limited the late blight of potato on leaf and moderately effectively at all plant. Results were compared to standard reference product.

- *S-E* – efficacy on the plant was observed during 2 trials. It can be concluded that PROSIM moderately effectively control the late blight of potato.

Interval between application:

- *MAR*: 7-18 days
- *N-E*: 7-11 days
- *MED*: 12-14 days

In the opinion of Evaluator, interval between application amounting to 7-10 days is acceptable for MAR and N-E. cMS from S-E should decide if this interval (7-10) can be accepted, considering that such interval in this zone has not been tested.

Application widow:

- *MAR*: BBCH 21-91
- *N-E*: BBCH 38-85
- *S-E*: BBCH 37 -49

In the opinion of Evaluator, window application amounting to BBCH 21-95 is acceptable for MAR and N-E. cMS from S-E should decide if this window application can be accepted, considering that such application window in this zone has not been tested.

Number of applications:

- *MAR*: 6 appl.
- *N-E*: 4 in 3 trials (357-01-F17-259; 357-02-F17-260; 357-03-F17-261) and 6 in 3 trials
- *S-E*: 6 appl.

In the opinion of Evaluator max. 6 application per season can be accepted in Mar, N-E and S-E. Because of, 7 valid trials for PL with 6 applications (PL-3, DE-2, CZ-2).

Water volume:

- *MAR*: 200-400 L/ha
- *N-E*: 200-400 L/ha
- *S-E*: 500 L/ha

In the opinion of Evaluator, water volume amounting to 200-400 L/ha is acceptable for MAR and N-E. cMS from S-E should decide if this water volume can be accepted, considering that such water volume in this zone has not been tested.

ZRMs agree with Applicant that: *Propamocarb 40% + Cymoxanil 5% SC applied in potato provided a moderate to high level control of Phytophthora infestans with the recommended dose rate of 2.5 L/ha. As diseases often occur as a complex of several diseases with different susceptibility towards Propamocarb + Cymoxanil, up to 6 applications per season of Propamocarb 40% + Cymoxanil 5% SC at the proposed dose rate should be used to efficiently control the diseases claimed on the label.*

Compared to the cymoxanil and propamocarb chloride reference products tested, the efficacy obtained with PROSIM was comparable against *Phytophthora infestans*.

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

Cymoxanil's mode of action is as a local systemic. It penetrates rapidly and when inside the plant, it cannot be washed off by rain. It controls diseases during the incubation period and prevents the appearance of damage on the crop. The fungicide is primarily active on fungi belonging to the *Peronosporales* order: *Phytophthora*, *Plasmopara*, and *Peronospora*.

Propamocarb hydrochloride is a systemic fungicide commonly used for control of *Phytophthora* diseases of nursery crops. The mode of action is different compared to other *Oomycete* fungicides, which provides for efficacy against strains that have developed resistance to other fungicides. Systemic, with protective action absorbed by roots and leaves and translocated. Lipid synthesis inhibitor.

The mechanism of resistance of propamocarb is not known. In studies done in laboratory, the mechanism of resistance observed in the isolates is not known, but it could be related to increased efflux of the fungicides with the aid of ATP-binding cassette (ABC) transporters that leads to a kind of resistance known as multidrug resistance.

Since the mode of action of cymoxanil is not clearly understood, the mechanism of resistance is also unknown. However, the existence of different groups of sensitivity suggests that different genes might be involved in the acquisition of resistance and its maintenance.

### 3.3.2 Adverse effects on treated crops

#### Phytotoxicity to host crop

Data from 14 efficacy trials in potato have been presented for selectivity results conducted in the Maritime EPPO zone (14, i.e Germany, United Kingdom and Czech Republic), the North-East EPPO zone (6, i.e Poland) and the South-East EPPO zone (2, Hungary) have been included in this biological assessment dossier to support the label claims and recommendations on selectivity in the EU Central Registration zone.

Potato is claimed on the label. The claims of crop safety on potato are supported with a total of 14 potato trials conducted in Germany, Czech Republic, United Kingdom, Poland and Hungary from 2016 to 2017. In all trials, Propamocarb 40% + Cymoxanil 5% SC applied at the proposed label recommended rates in potato proved to be crop safe and did not significantly affect the crop adversely when applied at a range of growth stages within and occasionally beyond the label recommended range.

As the data on potato show, the crop safety and efficacy of Propamocarb 40% + Cymoxanil 5% SC is equivalent to that of the Propamocarb + Cymoxanil formulated reference products tested in the trials. As comparability between the formulations has been demonstrated, the applicant therefore wishes to cite the original registrant's data on Propamocarb + Cymoxanil now out of protection in support of those recommendations on the draft label that are not adequately supported by the applicant's data and requests that the Zonal Evaluator extrapolate from those data.

#### Effects on yield and quality

**No studies of yield and quality of the crops had been recorded.**

14 efficacy trials were conducted to obtain selectivity results with the same formulation currently under registration, Propamocarb 40% + Cymoxanil 5% SC, in the Maritime EPPO zone (6; i.e. Germany, Czech Republic and United Kingdom), North-east EPPO zone (6; i.e. Poland) and South-East EPPO zone (2; i.e. Hungary) to evaluate the effect of Propamocarb 40% + Cymoxanil 5% SC on the quality of the harvested crop of potato (SOLTU).

#### Maritime, North-east and South-east zone – Crop yield (t/ha or kg/plot) of potato treated with Propamocarb 40% + Cymoxanil 5% SC, 6 applications, as % of untreated (Untreated = 100%)

Crop, trial type	No. of trials	Untreated	Propamocarb 40% + Cymoxanil 5% SC at:			Ref. prod. at:
		Mean (min-max)	% relative, compared to untreated (min-max, no. of trials)			
		kg/plot	1.5 L/ha	2.0 L/ha	2.5 L/ha	IN
<b>Potato – Efficacy trials, all reference products</b>						
Maritime EPPO zone	6	39.8 (13.5-93.9)	120.1 (88.1-191.5)	152.7 (94.3-309.4)	155.7 (86.1-338.0)	145.7 (76.7-253.5)
North-east	6	36.7 (30.5-43.6)	105.2 (99.3-115.6)	107.9 (101.0-125)	110.5 (101.0-140.1)	109.4 (98.7-142.2)
South-east EPPO zone	2	11.5 (10.0-13.0)	110.7 (107.3-114.1)	117 (115.5-118.5)	120.7 (119.0-122.3)	122 (119.9-124.1)

The data obtained in trials harvested demonstrate that PROSIM (product code: SHA 076127 A) is as safe to the crop as the reference products used in the trials.

All applied products increased yield above the level of untreated check. The highest yield was noted after treatment by recommended dose (2,5 L/ha) of PROSIM. Those results were comparable to st. ref. product.

## Effect on the quality of yield of treated plants or plant product

Applicant during trials presented yield results in tonnes per hectare. Those results were presented in the table 3.4-5 *Maritime, North-east and South-east zone – Crop yield (t/ha or kg/plot) of potato treated with Propamocarb 40% + Cymoxanil 5% SC, 6 applications, as % of untreated (Untreated = 100%) by Applicant.*

Below, ZRMs presented results for weight of tubers in each size class after sorting and the percentage of tubers affected by disease after storage. Starch content was not studied, but lack of those results are accepted by ZRMs.

Weight of tubers in each size class after sorting and the percentage of tubers affected by disease after storage:

✓ **N-E EPPO zone: PL (6 trials)**

### Weight of tubers

		Yield <35 mm	Yield 36-50 mm	Yield 36-60 mm	Yield >60 mm	Yield unmarketable
		kg	kg	kg	kg	kg
Control	-	10,66	13,55	82,25	36,87	13,03
Prosim	1,5 L/ha	8,32	12,12	76,10	45,22	14,27
Prosim	2,0 L/ha	6,45	13,27	64,45	47,81	15,32
Prosim	2,5 l/ha	5,59	12,38	69,60	51,13	15,63
Propamocarb 72 SL	1,0 L/ha	10,25	13,51	83,55	41,37	14,00
Propamocarb 72 SL	1,4 L/ha	7,75	12,85	75,20	43,67	14,19
Proxanil	2,0 L/ha	1,02	12,56	n.a.	16,40	0,74
Proxanil	2,5 L/ha	0,99	12,54	n.a.	17,03	0,65
Axidior	2,0 L/ha	18,4	n.a.	63,00	110,95	43,2
Ahidior	2,5 L/ha	14,7	n.a.	59,45	116,75	46,35

### The percentage of tubers affected by disease after storage

		PESSEV at 4 weeks storage	PESSEV at 8 weeks storage	PESSEV UNCK % after 8 weeks storage
Control	-	0,00	0,42	0,00
Prosim	1,5 L/ha	0,00	0,14	88,20
Prosim	2,0 L/ha	0,00	0,06	96,53
Prosim	2,5 l/ha	0,00	0,00	100
Propamocarb 72 SL	1,0 L/ha	0,00	0,00	100
Propamocarb 72 SL	1,4 L/ha	0,00	0,00	100
Proxanil	2,0 L/ha	0,00	0,00	100
Proxanil	2,5 L/ha	0,00	0,00	100
Axidior	2,0 L/ha	0,00	0,00	100
Ahidior	2,5 L/ha	0,00	0,00	100

During harvest all tubers were divided according to tuber size: small tubers – <35mm, medium tubers – 36-50 mm (4 trials) and large tubers – > 60mm. The weight of each size of tuber were measured in kg/plot. Most tubers were in medium size. Treated plots characterized higher number of medium and lower number of small tubers compare to untreated. The harvested tubers were assessed for pest incidence. Tested items showed no influence on yield quantity and quality. No symptoms of *P.infestans* on tubers were observed after storage for recommended dose of PROSIM and st. ref. products used during trials.

✓ **Maritime EPPO zone (6 trials):**

<sup>1)</sup> **Results for DE (2 trials):**

### Weight of tubers

	Yield small tubers	Yield medium tubers	Yield large tubers
	kg	kg	kg

Control	-	2,66	10,51	7,12
Prosim	1,5 L/ha	3,14	15,85	10,58
Prosim	2,0 L/ha	3,76	22,06	11,23
Prosim	2,5 l/ha	2,70	21,21	13,54
Propamocarb 72 SL	1,0 L/ha	3,79	17,53	11,49
Propamocarb 72 SL	1,4 L/ha	3,14	18,26	11,44
Proxanil	2,0 L/ha	3,33	18,20	12,69
Proxanil	2,5 L/ha	2,90	18,36	12,04

**The percentage of tubers affected by disease after storage**

		PESSEV at 4 weeks storage	PESSEV at 8 weeks storage	PESSEV UNCK % after 8 weeks storage
Control	-	0,00	0,00	0,00
Prosim	1,5 L/ha	0,00	0,00	82,5
Prosim	2,0 L/ha	0,00	0,00	100
Prosim	2,5 l/ha	0,00	0,00	100
Propamocarb 72 SL	1,0 L/ha	0,00	0,00	100
Propamocarb 72 SL	1,4 L/ha	0,00	0,00	100
Proxanil	2,0 L/ha	0,00	0,00	100
Proxanil	2,5 L/ha	0,00	0,00	100

During harvest all tubers were devided according tuber size: small tubers, medium tubers and large tubers. The weight of each size of tuber were measured in kg/plot. Most tubers were in medium size. Treated plots characterized higher number of medium and lower number of small tubers compare to untreated. The harvested tubers were assessed for pest incidence. Tested items showed no influence on yield quantity and quality. No symptoms of *P. infestans* on tubers were observed after storage for recommended dose (2,5 L/ha) of PROSIM and st. ref. products used during trials.

**2) Results for CZ (2 trials):**

**Weight of tubers**

		Yield small tubers (<40mm)	Yield medium tubers (40-70mm)	Yield large tubers (>70mm)
		kg	kg	kg
Control	-	6,90	31,87	1,5
Prosim	1,5 L/ha	7,93	38,32	1,3
Prosim	2,0 L/ha	9,47	40,47	0,9
Prosim	2,5 l/ha	10,41	42,64	0,9
Propamocarb 72 SL	1,0 L/ha	7,66	39,89	0,9
Propamocarb 72 SL	1,4 L/ha	7,58	41,36	1,4
Proxanil	2,0 L/ha	9,23	43,71	0,7
Proxanil	2,5 L/ha	8,27	43,26	1,5

**The percentage of tubers affected by disease after storage**

		PESSEV at 4 weeks storage	PESSEV at 8 weeks storage	PESSEV UNCK % after 8 weeks storage
Control	-	13,09	18,85	0,00
Prosim	1,5 L/ha	1,71	0,80	98,5
Prosim	2,0 L/ha	1,34	1,00	100
Prosim	2,5 l/ha	1,93	0,65	100
Propamocarb 72 SL	1,0 L/ha	1,27	1,25	100
Propamocarb 72 SL	1,4 L/ha	0,73	1,15	100
Proxanil	2,0 L/ha	1,80	0,40	100
Proxanil	2,5 L/ha	1,03	0,40	100

During harvest all tubers were devided according tuber size: small tubers (<40 mm), medium tubers (40-70 mm) and large tubers (>70mm). The weight of each size of tuber were measured in kg/plot. Most tubers were in medium size. Treated plots characterized higher number of medium and lower number of large tubers compare to untreated. The harvested tubers were assessed for pest incidence. Tested items showed no influence on yield quantity and quality. No symptoms of *P. infestans* on tubers were observed after storage for recommended dose (2,5 L/ha) of PROSIM and st. ref. products used during trials.



### 3) Results for UK (2 trials):

#### Weight of tubers

		Yield Tuber Grade 1	Yield Tuber Grade 2	Yield Tuber Grade 3	Yield Tuber Grade 4	Yield Tuber Grade 5
		kg	kg	kg	kg	kg
Control	-	0,45	3,38	9,57	9,68	8,94
Prosim	1,5 L/ha	0,54	3,43	9,94	10,52	7,84
Prosim	2,0 L/ha	0,52	2,79	9,15	9,70	9,35
Prosim	2,5 l/ha	0,39	2,99	9,16	9,63	7,08
Propamocarb 72 SL	1,0 L/ha	0,48	3,15	8,33	8,48	7,14
Propamocarb 72 SL	1,4 L/ha	0,54	2,72	8,80	9,32	8,98
Proxanil	2,0 L/ha	0,39	3,04	7,89	8,79	7,78
Proxanil	2,5 L/ha	0,40	2,66	8,34	8,37	7,68

#### The percentage of tubers affected by disease after storage

		PESSEV at 4 weeks storage	PESSEV at 8 weeks storage	PESSEV UNCK % after 8 weeks storage
Control	-	7,25	2,38	0,00
Prosim	1,5 L/ha	1,88	1,02	59,40
Prosim	2,0 L/ha	5,13	1,67	54,70
Prosim	2,5 l/ha	3,00	1,42	65,50
Propamocarb 72 SL	1,0 L/ha	4,38	0,63	60,13
Propamocarb 72 SL	1,4 L/ha	2,38	0,85	78,65
Proxanil	2,0 L/ha	1,50	1,25	73,70
Proxanil	2,5 L/ha	2,88	1,84	63,15

During harvest all tubers were divided according tuber size: Grade 1, Grade 2, Grade 3, Grade 4 and Grade 5. The majority of the tubers were in grade 3 and 4. The yield of tubers infected with *Phytophthora infestans* showed a dose response in reduction for the higher rates of the test items as well as the higher rate of the reference product, with the highest rate of PROSIM giving the best results. After the storage of the potatoes a significant decrease in tuber infection was visible for all products. PROSIM as well as the different rates of Propamocarb are showing a dose response and were comparable to each other.

### ✓ S-E EPPO zone: HU (2 trials)

#### Weight of tubers

		Yield <40 mm	Yield 40-50 mm	Yield >50 mm
		kg	kg	kg
Control	-	1,58	16,36	5,06
Prosim	1,5 L/ha	1,79	18,08	5,40
Prosim	2,0 L/ha	1,69	18,83	5,87
Prosim	2,5 l/ha	1,63	19,16	6,48
Propamocarb 72 SL	1,0 L/ha	1,84	18,22	5,92
Propamocarb 72 SL	1,4 L/ha	1,78	18,73	5,79
Proxanil	2,0 L/ha	1,63	18,78	6,32
Proxanil	2,5 L/ha	1,50	19,15	6,95

#### The percentage of tubers affected by disease after storage

		PESSEV at 4 weeks stor- age	PESSEV UNCK % at 4 weeks storage	PESSEV at 9 weeks storage	PESSEV UNCK % after 9 weeks storage
Control	-	2,15	0,00	0,05	0,00
Prosim	1,5 L/ha	0,05	92,3	0,00	92,66
Prosim	2,0 L/ha	0,05	92,15	0,00	93,75
Prosim	2,5 l/ha	0,05	95,95	0,00	97,15
Propamocarb 72 SL	1,0 L/ha	0,10	94,25	0,00	95,70
Propamocarb 72 SL	1,4 L/ha	0,05	96,30	0,00	97,55
Proxanil	2,0 L/ha	0,05	95,85	0,00	97,1
Proxanil	2,5 L/ha	0,05	96,90	0,00	98,00

Yield was not statistically influenced by the fungicide treatments compared to the untreated control, however more large (>5 cm) tubers were found in case of PROSIM at 2,5 l/ha and Proxanil 450 SC at 2,5 l/ha. The weight of medium tubers (4-5 cm) was statistically higher in case of the 2,5 l/ha rate of PROSIM and Proxanil 450 SC. According to the assessment of the weight of infected tubers at harvest highest rate of PROSIM and both rate of the standard Proxanil 450 SC gave an efficacy value of about 95%, which was higher compared to the lower rates of PROSIM. After removing the affected tubers only very few new tuber infection was found during the storage in case of the untreated control. Rate of new tuber infection was lower in case of each fungicide treatment, compared to the untreated control.

**PROSIM (product code: SHA 075127 A) applied at dose recommended did not significantly affect the crop yield Also, no phytotoxic symptoms were present in trials.**

### 3.3.3 Observations on other undesirable or unintended side-effects

#### Impact on treated plants or plant products to be used for propagations

Propamocarb 40% + Cymoxanil 5% SC is composed of Propamocarb + Cymoxanil, which both have been widely used for several years on e.g. potato, without identifying any issues in regard to ability of grains of treated plants to germinate.

Thus, negative effects of the active ingredient on parts of plant used for propagating purposes can be excluded due to the fungicidal nature of the product. Furthermore, phytotoxicity assessments in the performed trials demonstrated the crop safety of the product and the absence of any negative effect on the plants or plant products in the vast majority of the trials.

**The product complies with the Uniform Principles.**

#### Impact on other plants including adjacent crops

##### Propamocarb

According to the data requirements for plant protection products (Commission Regulation (EU) No 284/2013), screening data shall only be required for plant protection products other than those exhibiting herbicidal or plant growth regulator activity.

The studies on non-target plants (seedling emergence and vegetative vigour) that have been conducted with the representative formulation Propamocarb hydrochloride 722 SL to meet US-EPA regulatory requirements are presented in the respective MCP under Annex Point 10.6.2. Further information on the biological activity of Propamocarb hydrochloride is given in the respective MCA-Summary Section 3.

##### *Assessment of relevance to potential impact on non-target species*

Risk assessments for all non-target species are performed in the formulation specific MCP-dossiers.

##### Cymoxanil

Terrestrial non-target plants may be exposed to cymoxanil by spray drift in the vicinity of the treated area. A quantitative risk assessment approach was taken according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002). TERs were determined based on drift deposition at 1 m from the edge of the field considering a multiple application factor (MAF) and the worst case application scenario for the crops lettuce and potatoes.

The resulting TERs exceed the trigger for all intended GAPs and indicate that at a distance of 1 m to the edge of the field no significant damage will occur to non-target terrestrial plants.

This is based on the effects of the “single formulation” Cymoxanil 50WP and also covers the cymoxanil component of the formulation TANOS. For national authorisations of TANOS the RMS recommends a risk assessment based on effects data for the combination product.

Conclusion:

The submitted studies on terrestrial plants and the calculated TER-values indicate that the risk for nontarget plants after the use of cymoxanil according to GAP is low at a distance of 1 m to the treated area.

### Effects on beneficial and other non-target organisms

#### Propamocarb

In view of the results presented above, no further studies are deemed necessary. From the testing presented, there isn't any unacceptable risk to non-target higher plants from the use of the p.p.p. according to the intended GAP.

#### Cymoxanil

No data submitted.

### The product complies with the Uniform Principles.

### Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

## 3.4 Methods of analysis (Part B, Section 5)

Analytical method for Propamocarb hydrochloride and Cymoxanil in food and feed of plant and animal origin, soil, water and air and in the formulation Propamocarb hydrochloride 40% + Cymoxanil 5% SC are available.

### 3.4.1 Analytical method for the formulation

	Propamocarb hydrochloride	Cymoxanil
<b>Author(s), year</b>	Marta Michalec-Minch, 2018, report No. 109/2018	
<b>Principle of method</b>	HPLC-UV method validation	
<b>Linearity</b> (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Calibration equation: $y = 0.0677 x - 2.3987$ Correlation coeff. (R) = 1.000 Linear from 261 to 392 mg/L	Calibration equation: $Y = 0.9528 x - 3.3828$ Correlation coeff. (R) = <del>1.000</del> 0.9997 Linear from 28.40 to 42.50 mg/L
<b>Precision – Repeatability Mean n = 7 (%RSD)</b>	Reproductibility RSD = 0.24% Repeatability RSD = 0.47% The RSDr (Horwitz) = 1.54 Horrat value: 0.3	Reproductibility: RSD = 0.36% Repeatability: RSD = 1.50% The RSDr (Horwitz) = 2.10 Horrat value: 0.7
<b>Accuracy n = 7 (% Recovery)</b>	Low (conc. 80%) = 100.4% Medium (conc. 100%) = 101.0% High (conc. 120%) = 99.3%	Low (conc. 80%) = 100.6% Medium (conc. 100%) = 99.8% High (conc. 120%) = 102.0%
<b>Interference/ Specificity</b>	0.14% (test item) 0.11% (standard)	0.11% (test item) 0.08% (standard)
<b>Comment</b>	None	

The proposed analytical method was successfully validated and is suitable for the simultaneous determination of propamocarb hydrochloride and cymoxanil contents in the product Propamocarb hydrochloride 40% + Cymoxanil 5% SC.

### 3.4.2 Analytical methods for residues

Sufficiently sensitive and selective analytical methods are available for all analytes included in the residue definitions.

Noticed data gaps are:

Propamocarb

According to the Regulation No. 283/2013 an analytical method for the determination of residues in body fluids and tissues for enforcement/monitoring purposes is required (post registration requirement).

Cymoxanil

The Applicant is required to complete the methods, in Table 5.3.2 for group of high starch content matrices (potato), with the limit of quantification of 0.01 mg/kg (before registration).

A new method provided by the Applicant was evaluated. However, according to current requirements, ILV for this method must also be provided. This requirement can be considered as a post-registration requirement.

According to the Regulation No. 283/2013 an analytical method for the determination of residues in body fluids and tissues for enforcement/monitoring purposes is required (post registration requirement).

Commodity/crop	Supported/ Not supported
High starch content (Potato)	Supported/

## 3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity for SHA 076127 A / PROSIM were not evaluated as part of the EU review of Propamocarb and Cymoxanil. All relevant data were provided and are considered adequate. All toxicological studies have been performed.

**Classification:** Skin Sens. 1 – H317  
Repr. 2 – H361fd

### 3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD <sub>50</sub> oral, rat	> 2000 mg/kg bw	Yes	None	Calculated
LD <sub>50</sub> dermal, rat	>2000 mg/kg bw	Yes	None	Calculated
LC <sub>50</sub> inhalation, rat	>5 mg/L	Yes	None	Calculated
Skin irritation, rabbit	Non-irritant	Yes	None	Calculated

Eye irritation, rabbit	Non-irritant	Yes	None	Calculated
Skin sensitisation, guinea pig	Sensitising	Yes	<b>H317</b>	Calculated
Supplementary studies for combinations of plant protection products	No data – not required			

### 3.5.2 Operator exposure

Operator exposure to SHA 076127 A / PROSIM was not evaluated as part of the EU review of Propamocarb and Cymoxanil for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential operator exposure have been undertaken for Propamocarb and cymoxanil using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

**Conclusions:** According to the EFSA AOEM Model, it can be concluded that the risk for operator is acceptable with work wear and gloves during mixing/loading and application

**Implication for labelling:** P280: Wear protective work wear and gloves.

### 3.5.3 Worker exposure

Worker exposure to SHA 076127 A / PROSIM was not evaluated as part of the EU review of Propamocarb and Cymoxanil for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential worker exposure have been undertaken for Propamocarb and Cymoxanil using EFSA AOEM Model and default dermal absorption values (10% concentrate and 50% dilution).

**Conclusion:** According to EFSA AOEM Model, it can be concluded that the risk for worker is acceptable with the use of work wear and 2 days re-entry period after treatment.

**Implication for labelling:** P280: Wear protective work wear and gloves.

### 3.5.4 Bystander and resident exposure

Bystander and resident exposure to SHA 076127 A / PROSIM was not evaluated as part of the EU review of Propamocarb and Cymoxanil for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate. Estimation of potential residents and bystander's exposures have been undertaken for Propamocarb and cymoxanil using EFSA AOEM Model and default dermal absorption values (10% concentration and 50% dilution).

**Conclusion:** According to the EFSA AOEM Model, it can be concluded that the risk for residents and bystanders is acceptable.

**Implication for labelling:** Vehicle-mounted-drift reduction with 5m **10 m**-buffer zone.

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

The preparation Propamocarb 40% + Cymoxanil 5% SC is composed of Propamocarb and Cymoxanil.

Reference value	Source	Year	Value	Study relied upon	Safety factor
<b>Propamocarb</b>					
ADI	EFSA	2006	0.29 mg /kg bw/day	52-week dietary study in rats	100
ARfD	EFSA	2006	1 mg /kg bw/day	28-day rat study (gavage)	100
<b>Cymoxanil</b>					
ADI	EFSA	2008	0.013 mg/kg bw/day	Dog, 1-year study	100
ARfD	EFSA	2008	0.08 mg/kg bw/day	Rabbit, teratogenicity study	100

Unprotected data were sufficient to support all the uses of Propamocarb 40% + Cymoxanil 5% SC.

### 3.6.1 Residues

#### Storage stability

##### Propamocarb

The stability of residues for propamocarb was already addressed during the EU Review process.

Under frozen storage condition, propamocarb residues were demonstrated to be stable in high water content matrices for at least one year.

Potatoes belong to the high starch content matrices. The Applicant did not provide residue stability data for this matrix group (data gap).

Data out of protection documenting stability residues for propamocarb in potato are available. Residues of propamocarb are stable in potatoes samples up to 26 months (EU unprotected data). **The Applicant is requested to complete the point 7.2.1 with data on the stability of residues in potatoes.**

##### Cymoxanil

The stability of residues for Cymoxanil was already addressed during the EU Review process.

Lettuce High water content 12 months (-20°C) EFSA, 2008

Potato High starch content 12.5 months (-20°C) EFSA, 2008

#### Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the actives. The data evaluated is regarded as sufficient to support the proposed use on potato.

The residue definitions agreed for monitoring and risk assessment:

##### Propamocarb

Plant residue definition for monitoring	Sum of propamocarb and its satls, expressed as propamocarb Regulation (EU) No. 2020/856
Plant residue definition for risk assessment	Sum of propamocarb and its satls, expressed as propamocarb (EFSA, 2013, 2017)
Animal residue definition for monitoring	Pig, milk and ruminant tissues: N-oxide propamocarb only Poultry tissues and eggs: N-desmethyl propamocarb Regulation EU No. 2020/856

Animal residue definition for risk assessment	Milk, pig and ruminant tissues: sum of propamocarb, N-oxide propamocarb, oxazolidine-2-one propamocarb and 2-hydroxypropamocarb expressed as propamocarb  Poultry tissues: sum of propamocarb and N-desmethyl propamocarb, expressed as propamocarb EFSA Journal 2013;11(4):3214
Conversion factor	1.3 for all poultry tissues and eggs 4.25 for milk 2.2 for ruminant kidney 1.7 for ruminant liver and muscle (EFSA 2013)

### Cymoxanil

Plant residue definition for monitoring	Cymoxanil (Regulation (EU) No. 2018/832, Reg. (EU) 2022/1363 - not yet applicable)
Plant residue definition for risk assessment	Cymoxanil (EFSA, 2015)
Animal residue definition for monitoring	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355
Animal residue definition for risk assessment	Residue definition in animal commodities is not needed but could be set as cymoxanil (for ruminant and pigs) if needed in the future EFSA Journal 2015;13(12):4355

No further data are required.

### **Magnitude of residues in plants**

Proposed GAP: BBCH 21-95; 1-6 applications (interval: 7-14 days); application rate per treatment 1.0 kg as/ha propamocarb + 0.125 kg as/ha cymoxanil; PHI: 14 days

#### Potatoes

#### Propamocarb

New acceptable studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

New trials GAP: 6 x 1 kg as/ha, BBCH 93, PHI 14-15d, outdoor

Residues (tuber): 0.06, 3x<0.01, 2x 0.01 mg/kg

Additionally Applicant refers to unprotected EU data

DAR, Ireland, 2005	N-EU	GAP on which MRL/EU a.s. assessment is based: 6-7 x 1-2 kg as/ha, BBCH 48-49 (tuber formation, equivalent BBCH 96.5) , PHI 14-21d, outdoor  Tuber: 8 x <0.1 mg/kg
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Proposed use is in line with EU representative GAP (SANCO/10057/2006 final); 25 April 2007.

The number of trials is sufficient as to support the use of propamocarb on potatoes according to the proposed GAP in Central Zone.

It can be concluded that the residues arising from the proposed use will not exceed the MRLs for potatoes set at 0.3 mg/kg (Regulation (EU) No. 2020/856).

#### Cymoxanil

New acceptable studies on the magnitude of residue have been submitted by the applicant in the frame-

work of this application.

Trials GAP: 6 x 0.125 kg as/ha, BBCH 93, PHI 14-15d, outdoor

Residues: 6x<0.01 mg/kg

The number of trials is sufficient as to support the use of cymoxanil on potatoes according to the proposed GAP in Central Zone.

It can be concluded that the residues arising from the proposed use will not exceed the MRLs for potatoes set at 0.01 mg/kg (Regulation (EU) No. 2018/832)

### **Magnitude of residues in livestock**

#### Propamocarb

A dietary burden calculation, including the requested use on potato, has already been made by EFSA in the framework of the Art. 12 evaluation of propamocarb-HCl (EFSA Journal 2013;11(4):3214).

zRMS has been performed a new calculation of the dietary burden using the calculator OECD (2017).

The input values for potatoes were changed to 0.1 mg/kg (STMR/HR) according to the data in Table 7.2-9.

Regarding available feeding data, there is no risk for animal MRL to be exceeded.

No new data were submitted and required in the framework of this application.

#### Cymoxanil

According to EFSA, the previous assessment of residues in livestock (EFSA, 2015) is still valid (EFSA Journal 2019;17(10):5823).

No additional data is required.

### **Industrial Processing and/or Household Preparation**

No supplementary studies on the effects of industrial processing and/or household preparations on residue levels have been conducted or are required.

### **Succeeding crops**

Additional rotational crop residue trials are not required. No waiting periods between application and planting of succeeding crops are necessary.

### **Consumer risk assessment**

The proposed uses of propamocarb and cymoxanil in the formulation PROSIM (SHA 076127 A) do not represent unacceptable acute and chronic risks for the consumer.

Acceptable calculations were made using EFSA PRIMo rev.3.1.

### **Other / special studies**

Potatoes have not melliferous capacity. Studies are not required.

Noticed data gaps are: none

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

## **3.6.2 Consumer exposure**

Acceptable calculations were made using EFSA PRIMo rev.3.1.



### 3.6.2.1 Propamocarb

TMDI (% ADI) according to EFSA PRIMo rev.3.1	24 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IENTI (% ARfD) according to EFSA PRIMo* rev.3.1	<p><b>Raw commodities</b> Based on children: Potatoes: 5%</p> <p>Based on adults: Potatoes: 1%</p> <p><b>Processed commodities</b> Based on children: Potatoes/fried: 3% Potatoes/dried (flakes): 2%</p> <p>Based on adults: Potatoes/chips: 0.3% Potatoes/dried (flakes): 0.2%</p>
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

The proposed uses of Propamocarb in the formulation Propamocarb 40% + Cymoxanil 5% SC do not represent unacceptable acute and chronic risks for the consumer.

### 3.6.2.2 Cymoxanil

TMDI (% ADI) according to EFSA PRIMo rev.3.1	23 % (based on GEMS/Food G06)
IEDI (% ADI) according to EFSA PRIMo	-
IENTI (% ARfD) according to EFSA PRIMo* rev.3.1	<p><b>Raw commodities</b> Based on children: Potatoes: 2%</p> <p>Based on adults: Potatoes: 0.4%</p> <p><b>Processed commodities</b> Based on children: Potatoes/fried: 1% Potatoes/dried (flakes): 0.7%</p> <p>Based on adults: Potatoes/chips: 0.1% Potatoes/dried (flakes)</p>
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

The proposed uses of Cymoxanil in the formulation Propamocarb 40% + Cymoxanil 5% SC do not represent unacceptable acute and chronic risks for the consumer.

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

Concentration of Propamocarb and cymoxanil in various environmental compartments are predicted according to the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment and ground water are provided.

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

PEC<sub>soil</sub> calculations have been conducted with Propamocarb using the EU agreed endpoints (EFSA Scientific Report (2006) 78, 1-80) and with Cymoxanil and its relevant metabolites IN-U3204, IN-W3595 and IN-JW915 using the EU agreed endpoints (EFSA Scientific Report (2008) 167, 1-116).

Maximum, accumulation PEC<sub>soil</sub> value for Propamocarb was 3.094 mg/kg following the highest application rate of 1000 g Propamocarb/ha.

Maximum PEC<sub>soil</sub> values for Cymoxanil was 0.135 mg/kg, for IN-U3204 was 0.017 mg/kg, for IN-W3595 was 0.005 mg/kg and for IN-JX915 was 0.007 mg/kg following the highest application rate of 125 g Cymoxanil/ha.

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

PEC<sub>gw</sub> have been calculated for Propamocarb, Cymoxanil and its relevant metabolites IN-U3402, IN-W3595, IN-JX915 and IN-KQ960.

All PEC<sub>gw</sub> values for Propamocarb, Cymoxanil, IN-U3204, IN-W3595 and IN-JX915 are below 0.001 µg/L

The maximum PEC<sub>gw</sub> value for IN-KQ960 was 0.175 µg/L of the Jokioinen PELMO scenario.

The refinement is proposed and after that the PEC<sub>gw</sub> for cymoxanil and its metabolites were below of 0.1 µg/L in all scenarios. Therefore, the relevance assessment according to SANCO/221/2000 –rev.10 is not necessary.

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

The PEC<sub>sw/sed</sub> of Propamocarb and Cymoxanil and its relevant metabolites IN-U3204, IN-W3595, IN-JX915, IN-KQ960, IN-T4226, IN-R3273, IN-KP533 and Fraction M5 have been assessed with the model FOCUS STEP 1-2, and the DT<sub>50</sub> water/sediment values established in the EU review.

The results for PEC<sub>sw/sed</sub> were used for the eco-toxicological risk assessment. Please refer to Part B, Section 8, Point 8.9 for more details about the results obtained.

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

The vapour pressure at 20 °C of the active substance Propamocarb is  $> 10^{-4}$  Pa. Hence the active substance Propamocarb is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Propamocarb due to volatilization with subsequent deposition should be considered.

The vapour pressure at 20 °C of the active substance Cymoxanil is  $>10^{-4}$  Pa. Hence the active substance cymoxanil is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Cymoxanil due to volatilization with subsequent deposition should be considered.

### 3.8 Ecotoxicology (Part B, Section 9)

#### 3.8.1 Effects on terrestrial vertebrates

##### • Birds:

According to the first-tier assessment for potatoes, all the  $TER_a$  and  $TER_{lt}$  values for Propamocarb and Cymoxanil are greater than the Annex VI trigger of 10 and 5, respectively, indicating that PROSIM presents no unacceptable acute and long-term risk to birds according to the intended uses on potatoes. The combined risk is considered acceptable for Poland.

##### • Mammals:

Regarding Propamocarb hydrochloride, according to the first-tier assessment for potato, the  $TER_a$  and  $TER_{lt}$  are greater than the Annex VI trigger of 5 and 10, respectively, indicating that the PROSIM presents an acceptable acute and long-term risk to mammals for these uses except to vole for long-term risk assessment. After PD, FIR/bw,  $DT_{50}$ , MAF and ftwa refinement, no unacceptable risk was obtained.

Regarding Cymoxanil, according to the first-tier assessment for potato, the  $TER_a$  and  $TER_{lt}$  are greater than the Annex VI trigger of 5 and 10, respectively, indicating that the PROSIM presents an acceptable acute and long-term risk to mammals for these uses except to vole and lagomorph for long-term risk assessment. After PD, FIR/bw,  $DT_{50}$ , MAF and ftwa refinement, no unacceptable risk was obtained. The combined risk is considered acceptable for Poland.

#### Effects on aquatic species

##### • Propamocarb

For the intended uses on potato, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish prolonged as characterised by an NOEC for *Lepomis macrochirus* of 6300 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-2 scenarios. Therefore, no further assessment is necessary.

##### • Cymoxanil

For the intended uses potato, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish prolonged as characterised by an NOEC for *Oncorhynchus mykiss* of 44 µg/L in connection with an assessment factor of 10) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

**Metabolites of Cymoxanil:** for the intended use on potato, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

**PROSIM:** for the intended use on potato, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms. Therefore, no further assessment is necessary.

#### 3.8.2 Effects on bees

First-tier assessments indicate that no unacceptable risk for bees exposed to PROSIM is expected accord-

ing to the proposed intended uses on potato. According to EU reg. 284/2009 the chronic study for adult bees and larvae for product Prosim should be submitted by the applicant when EFSA Bee GD will be applied at EU level.

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

The PER<sub>in-field</sub> is below the rate with <50% of effects on mortality and reproduction for extended studies for the product PROSIM in potato for the representative species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. Therefore, in-field recovery is expected.

The PER<sub>off-field</sub> corrected is below rate with 50% effects for the product PROSIM for the representative species *Typhlodromus pyri* and *Aphidius*, indicating no risk to non-target arthropods in vegetated off-field areas following application according to the proposed use patterns.

### **3.8.4 Effects on soil organisms**

#### **• Non-target soil meso- and macrofauna:**

The chronic TER for Propamocarb hydrochloride, Cymoxanil and PROSIM are above the Annex VI trigger of 5. Therefore, it is concluded that actives and PROSIM formulation do not poses long-term risk to earthworms.

#### **• Soil microorganisms:**

Risk assessments conducted with relevant PEC<sub>soil</sub> for Propamocarb and Cymoxanil in PROSIM formulation indicate a low risk to soil microorganisms when applied according to the proposed use rates.

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

Risk assessment conducted with relevant toxicity data on non-target terrestrial plants for PROSIM shows that Annex VI trigger of 5 is not exceeded, indicating that PROSIM poses a low risk to non-target plants when applied according to the proposed use rates.

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

Not relevant.

### **3.9 Relevance of metabolites (Part B, Section 10)**

Propamocarb doesn't produce metabolites in soil and the Cymoxanil metabolites IN-U3204, IN-W3595, IN-JX915 and IN-KQ960 are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR section 8, Chapter 8.8.2.2). Assessment of the relevance of these metabolites according to the step-wise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

## **4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)**

Not relevant. PROSIM (Propamocarb 40% + Cymoxanil 5% SC) contains none active substance which is approved as candidate for substitution.

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

Insert any data that the notifier needs to submit following authorization. As a rule, this is restricted to storage stability and monitoring data.

Insert the data that is still required for the evaluation of the product in the case where the product authorization is not granted.

## **Appendix 1    Copy of the product authorization**

MS assessor to insert details of the product authorization for MS country.

## Appendix 2 Copy of the product label

Metabolizm i pozostałości: brak uwag

Toksykologia: dodać buforową streforową 5m 40 m oraz korekta zapisu w części Warunki bezpiecznego.

### Sekcja skuteczność:

Do etykiety dodano zapis dotyczący strategii przeciwdziałania odporności oraz następujące zapisy w części dotyczącej ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ:

*PROSIM zastosowany w ziemniaku zapewniał umiarkowany do wysokiego poziom zwalczania zarazy ziemniaczanej przy zalecanej dawce 2,5 L/ha. Ze względu na to, że choroby często występują jako zespół kilku chorób o różnej podatności na PROSIM, aby skutecznie zwalczać choroby deklarowane w etykiecie należy zastosować do 6 zastosowań w sezonie PROSIM w proponowanej dawce.*

*Bez jakiegokolwiek działania herbicydowego PROSIM stanowi dopuszczalne ryzyko dla roślin uprawianych następnie oraz dla przyległych upraw w następstwie proponowanych zastosowań.*

Pozostałe zapisy w etykiecie zaakceptowano.

Załącznik do zezwolenia MRiRW nr R - ...../..... z dnia .....2020

### Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalayas Business Center Carril Condomina n°3, 12<sup>th</sup> Floor, 30006 Murcia, Hiszpania xxx

### Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Cropchem Ltd. Prime Business Park, Dashrathlal Joshi Road Vile Parle (West), Mumbai – 400 056, Indie, tel.: + xxx

### Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

(...)

## PROSIM

### Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

**Chlorowodorek propamokarbu** (substancja z grupy pochodnych kwasu karbaminowego) - **400 g/l** (37,6%)

Cymoksanil (substancja z grupy iminoacetylomoczników) – **50 g/l** (4,7%)

Zezwolenie MRiRW nr R- /2020 z dnia . .2020 r.



**UWAGA**

H317 H361fd H411	Może powodować reakcję alergiczną skóry. Podejrzewa się, że działa szkodliwie na płodność. Podejrzewa się, że działa szkodliwie na dziecko w łonie matki. Działa toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P261 P273 P280  P333+P313  P391 P405 P501	Unikać wdychania dymu/gazu/mgły/par/rozpylonej cieczy. Nie wypuszczać do środowiska. (Unikać uwalniania do środowiska.) Stosować rękawice ochronne/odzież ochronną/ochronę oczu/ochronę twarzy/ W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza. Zebrać wyciek. Przechowywać pod zamknięciem. Zawartość / pojemnik usuwać zgodnie z przepisami miejscowymi / regionalnymi / narodowymi / międzynarodowymi

## OPIS DZIAŁANIA

PROSIM jest środkiem grzybobójczym w postaci stężonej zawiesiny do rozcieńczania wodą o działaniu wgłębnym i układowym. PROSIM stosuje się zapobiegawczo oraz interwencyjnie w ochronie ziemniaka przed zarazą ziemniaka.

## STOSOWANIE ŚRODKA

### Ziemniak

*Zaraza ziemniaka*

**Maksymalna dawka dla jednorazowego zastosowania:** 2,5 l/ha

**Zalecana dawka dla jednorazowego zastosowania:** 2,5 l/ha

Liczba zabiegów: 6

Termin stosowania środka: stosować od początku fazy drugiego liścia do fazy gdy 50% liści brązowieje (BBCH 21-95)

Zalecana ilość wody: **200-400 l/ha.**

Odstęp między zabiegami: 7-10 dni

Zalecane opryskiwanie: **średniokropliste**

**Maksymalna liczba zabiegów w sezonie wegetacyjnym:** 6

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe.

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

PROSIM zastosowany w ziemniaku zapewniał umiarkowany do wysokiego poziom zwalczania zarazy ziemniaczanej przy zalecanej dawce 2,5 L/ha. Ze względu na to, że choroby często występują jako zespół kilku chorób o różnej podatności na PROSIM, aby skutecznie zwalczać choroby deklarowane w etykiecie należy zastosować do 6 zastosowań w sezonie PROSIM w proponowanej dawce.

Środka nie stosować:

- na rośliny osłabione i uszkodzone przez przymrozki, suszę, szkodniki lub choroby
- na plantacjach nasiennych.

Podczas stosowania środka nie dopuścić do:

- znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych
- nakładania się cieczy użytkowej na stykach pasów zabiegowych i uwrociach.



Bez jakiegokolwiek działania herbicydowego PROSIM stanowi dopuszczalne ryzyko dla roślin uprawianych następczo oraz dla przyległych upraw w następstwie proponowanych zastosowań.

#### **Strategia zarządzania odpornością:**

- Stosować przemiennie z fungicydami o innym sposobie działania.
- Stosować zgodnie z zaleceniami zawartymi w etykiecie. Nie stosować dawek zredukowanych.
- Aplikacja powinna być jako aplikacja ochronna.
- Stosować inne środki takie jak: odmiany odporne, dobra praktyka agronomiczna

### **SPORZĄDZANIE CIECZY UŻYTKOWEJ**

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej ilość.

Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego do połowy wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wleciu środka do zbiornika opryskiwacza nie wyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać. W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

### **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 należy postąpić tak, jak z resztkami cieczy użytkowej.

### **WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA**

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

#### **Środki ostrożności dla osób stosujących środek: (pracowników oraz osób postronnych)**

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

Stosować rękawice ochronne oraz odzież ochronną, zabezpieczającą przed oddziaływaniem środków ochrony roślin oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy roboczej oraz w trakcie wykonywania zabiegu.

Strefa buforowa 5 m 10 m

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

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

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

Nie dotyczy

**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 0°C - 30°C, z dala od źródeł ciepła.

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.

Okres ważności - ~~2 lata~~ 1 rok 2 lata

Data produkcji - .....

Zawartość netto - .....

Nr partii - .....

### **Appendix 3 Letter of Access**

Not relevant, no letter of access needed.

## Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.2.2	Przemyslaw Grojs	2018	Propamocarb 40% + Cymoxanil 5% SC Determination of oxidizing properties Institute of Industrial organic chemistry report No. BC-87/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.2.1	Pawel Sliwa	2018	Propamocarb 40% + Cymoxanil 5% SC Determination of explosive properties Institute of Industrial organic chemistry report No. BW-32/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.1, KCP 2.2.1, KCP 2.2.2, KCP 2.3.1, KCP 2.3.3, KCP 2.4.1, KCP 2.4.2, KCP 2.5.1, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1, KCP 2.7.4, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.2, KCP 2.8.7.2	Marta Michalec-Minch	2018	Propamocarb 40% + Cymoxanil 5% SC Analysis of active substance content and physicochemical properties of initial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis report No. 109/2018 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 2.7.2	Malgorzata Kurka	2018	Partial Report No. 1 and No. 2 Propamocarb 40% + cymoxanil 5% SC Evaluation of stability of the product after storage in accordance with the Technical Monograph No. 17 Institute of Heavy Organic Synthesis report No. 110/2018 GLP	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Unpublished				
KCP 5.1.1	Marta Michalec-Minch	2018	Propamocarb 40% + Cymoxanil 5% SC Analysis of active substance content and physicochemical properties of initial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis report No. 109/2018 GLP Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
CP 6.0-001	Anonymous	2020	Biological Assessment Dossier: Propamocarb 40% + Cymoxanil 5% SC (1125 g/L Propamocarb + Cymoxanil SC) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.2.1-01	XXXXXX	2019	Propamocarb 40% + Cymoxanil 5% SC: Rainbow trout, acute toxicity test XXXXXX XXXXXX GLP/Unpublished	Y	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.2.1-02	Tina Turek	2019	Propamocarb 40% + Cymoxanil 5% SC: <i>Daphnia magna</i> , acute immobilisation test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. W/86/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.2.1-03	Tina Turek	2019	Propamocarb 40% + Cymoxanil 5% SC: <i>Raphidocelis subcapitata</i> SAG 61.81 (formerly <i>Pseudokirchneriella subcapitata</i> ) growth inhibition test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. W/87/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.2.1-04	Tina Turek	2019	Propamocarb 40% + Cymoxanil 5% SC: <i>Lemna gibba</i> CPCC 310, growth inhibition test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. W/88/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.1.1.1	Pawel Parma	2018	Propamocarb 40% + Cymoxanil 5% SC: Honeybees ( <i>Apis</i>	N	Y	Data/study report never submitted	SHARDA

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			<i>mellifera</i> L.), acute oral toxicity test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. B/27/17 GLP/Unpublished			before	Cropchem Limited
KCP 10.3.1.1.2	Pawel Parma	2018	Propamocarb 40% + Cymoxanil 5% SC: Honeybees ( <i>Apis mellifera</i> L.), acute contact toxicity test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. B/28/17 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.2.2-01	Pawel Parma	2018	An extended laboratory test for evaluating the effects of Propamocarb 40% + Cymoxanil 5% SC on the predatory mite, <i>Typhlodromus pyri</i> (Sch.) Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. B/30/17 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.3.2.2-02	Pawel Parma	2018	An extended laboratory test for evaluating the effects of Propamocarb 40% + Cymoxanil 5% SC on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De Stefani – Perez) Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. B/29/17 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.4.1.1	Anna Wróbel	2020	Propamocarb 40% + Cymoxanil 5% SC: Earthworm Reproduction Test ( <i>Eisenia andrei</i> ) Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/128/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.4.2.1-01	Anna Wróbel	2019	Propamocarb 40% + Cymoxanil 5% SC: Collembolan ( <i>Folsomia candida</i> ) Reproduction test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/130/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.4.2.1-02	V. Angayarkanni	2020	Effect of Propamocarb 40% + Cymoxanil 5% SC on the reproductive output of the predatory soil mite <i>Hypoaspis</i> ( <i>Geolaelaps</i> ) <i>aculeifer</i> Canestrini (Acari: Laelapidae) in	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			artificial soil Bioscience Research Foundation Report No. G/130/18 GLP/Unpublished				
KCP 10.5-01	Anna Wróbel	2020	Propamocarb 40% + Cymoxanil 5% SC: Soil microorganisms Nitrogen transformation test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/127/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.5-02	Anna Wróbel	2020	Propamocarb 40% + Cymoxanil 5% SC: Soil microorganisms Carbon transformation test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/126/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.6.2-01	Anna Wróbel	2020	Propamocarb 40% + Cymoxanil 5% SC: Terrestrial Plant Test : Seedling emergence and Seedling Growth Test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/132/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited
KCP 10.6.2-02	Anna Wróbel	2020	Propamocarb 40% + Cymoxanil 5% SC: Terrestrial Plant Test : Vegetative Vigour Test Institute of Industrial Organic Chemistry, Branch Pszczyna Report No. G/129/18 GLP/Unpublished	N	Y	Data/study report never submitted before	SHARDA Cropchem Limited

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

The following tables are to be completed by MS

**List of data submitted by the applicant and not relied on**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner

**List of data relied on and not submitted by the applicant but necessary for evaluation**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner