

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: SHA 076127 A

Product name(s): 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

Submission date: October 2020

MS Finalisation date: 05/2021; 03/2023 03/2024

Version history

When	What
May 2021	Applicant update document
May 2021	ZRMs evaluated updated by Applicant dRR
March 2023	The Final Registration Report
March 2024	ZRMs corrected fRR (information's about yield and its quality were added).

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). Information's about yield and its quality were added to fRR in line to comments from MRiRW. Those changes are marked by yellow.
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
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 con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. num- ber 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	<i>Phytophthora infestans</i>	Foliar Spray	BBCH 21-95	a) 1 b) 6	7-10	a) 2.5 b) 15	a) 1 propamo- carb + 0.125 cymoxanil b) 6 propamo- carb + 0.75 cymoxanil	200-400	14		To be confirmed by cMS

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** 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

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **Propamocarb 40% + Cymoxanil 5% SC (PROSIM; Product code: SHA 076127 A)** containing the active substance Propamocarb + Cymoxanil, which has been included into Annex I of Council Directive 91/414/EEC and has been applied for renewal of approval under article 14 of regulation (EU) No 1107/2009.

The SANCO report for Propamocarb (SANCO/10057/2006-final) is considered to provide the relevant review information or a reference to where such information can be found.

The SANCO report for Cymoxanil (SANCO/179/08-final rev. 1) is considered to provide the relevant review information or a reference to where such information can be found.

For the implementation of the uniform principles of Annex VI, the conclusions of the review reports on the active substances Propamocarb + Cymoxanil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17th June 2011 and 29th September 2006, respectively, shall be taken into account. Consideration of active substances for Annex I inclusion does not include an evaluation of efficacy. Therefore, there are no concerns to address arising from the inclusion directive of Propamocarb + Cymoxanil relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier Propamocarb 40% + Cymoxanil 5% SC, Central
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Description of the plant protection product

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 in potato– please refer to Appendix 2 to see the GAP covered by this BAD.

To support the registration of Propamocarb 40% + Cymoxanil 5% SC in the GAP claimed crops, trials have been set up in potato field crops. In these trials conducted in Germany, Hungary, United Kingdom, Czech Republic and Poland from 2016 to 2017, the Propamocarb + Cymoxanil formulation prepared by Sharda Cropchem España – Propamocarb 40% + Cymoxanil 5% SC – was compared against a reference Propamocarb + Cymoxanil formulation currently on the market in Germany, Hungary, United Kingdom, Czech Republic and Poland (Proxanil) and in Poland (Axidor), for comparison.

According to the GAP, the proposed application rate of Propamocarb 40% + Cymoxanil 5% SC in potato is 2.5 L per hectare (L/ha), with up to 6 applications per season. This will deliver 1000 g Propamocarb and 125 g Cymoxanil per hectare. In the current document, results obtained in field trials with Propamocarb 40% + Cymoxanil 5% SC applied at 1.5 L/ha to 2.5 L/ha will be presented where these have been tested against similar dose rates of Propamocarb + Cymoxanil reference products currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim of Propamocarb 40% + Cymoxanil 5% SC for the control of *Phytophthora infestans* in potato.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Crop / disease	Application method	Spray volume (L/ha)	Max. individual application rate (kg f.p./ha) [kg a.s./ha]	Max. number of applications	Application timing (e.g. BBCH)
Potato / Phytophthora infestans	Spray	200-400	(2.5) [1.125]	6	BBCH 21-95

Further details are in the table “All intended uses” in Part B - Section 0.

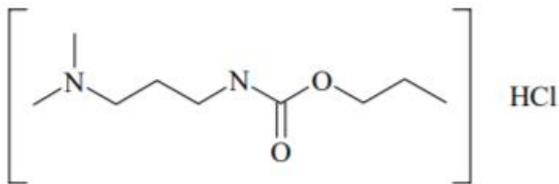
Description of active substance Propamocarb + Cymoxanil

Propamocarb + Cymoxanil is a mixed fungicide. It belongs to the Carbamate and Cyanoacetamideoxime group, respectively.

Today, Propamocarb + Cymoxanil is registered and commercialised in several formulations, as straight product as well as in mixtures, around the world.

Table 3.2-2: Identity of Cymoxanil and Propamocarb

Common name (ISO)	Cymoxanil
Chemical name (IUPAC)	<i>1-[(E/Z)-2-cyano-2-methoxyiminoacetyl]-3-ethylurea</i>
Chemical name (CA)	2-cyano-N-[(ethylamino)carbonyl]-2-(methoxyimino)acetamide
CIPAC No	419
CAS No	57966-95-7
EEC No	261-043-0
FAO SPECIFICATION	Not less than 970 g/kg 419/TC (March 2006)
Minimum purity	≥970 g/kg
Molecular formula	C ₇ H ₁₀ N ₄ O ₃
Molecular mass	198.2 g/mol
Structural formula	

Common name (ISO)	Propamocarb (unless otherwise stated, the following data relate to the variant propamocarb hydrochloride)
Chemical name (IUPAC)	Propyl 3-(dimethylamino)propylcarbamate (propamocarb) Propyl 3-(dimethylamino) propylcarbamate hydrochloride
Chemical name (CA)	Propyl [3-(dimethylamino)propyl]carbamate (propamocarb) carbamic acid, [3-dimethylaminopropyl]-, propyl ester, monochloride
CIPAC No	399 (Propamocarb) 399.601 (Propamocarb HCl)
CAS No	24579-73-5 (Propamocarb) 25606-41-1 (Propamocarb HCl)
EEC No	247-125-9 (Propamocarb HCl)
FAO SPECIFICATION	No FAO specification
Minimum purity	TC: 92% w/w, 920g/kg (Bayer CropScience) 97% w/w, 970 g/kg (Chimac Agriphar) TK: 69% w/w, 749 g/L (Bayer CropScience)
Molecular formula	C ₉ H ₂₁ ClN ₂ O ₂
Molecular mass	224.7
Structural formula	

Mode of action of the active ingredient

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.

FRAC (Fungicide Resistance Action Committee) presents propamocarb as a Carbamate (FRAC code: 28. Group F4) and Cymoxanil as a Cyanoacetamideoxime (FRAC code: 27. Unknown mode of action).

Information on similar formulations and current approvals

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. Data presented in this dossier is generated using this formulation in comparison with reference product containing Propamocarb + Cymoxanil. Propamocarb + Cymoxanil is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-3: Current approvals of Propamocarb + Cymoxanil containing products in the EU Central zone as well as connected EPPO zones where trials were conducted.

Country	Product	Active ingredient	Approval number
Czech Republic	Proxanil	Cymoxanil 50g/L + Propamocarb 334.62 g/L	4922-0
Germany	Proxanil	Cymoxanil 50g/L + Propamocarb 334.62 g/L	006481-00
Hungary	Proxanil	Cymoxanil 50g/L + Propamocarb 334.62 g/L	04.2/2958-1/2012
Poland	Proxanil	Cymoxanil 50g/L + Propamocarb 400 g/L	R-6/2015wu
	Axidor	Cymoxanil 50g/L + Propamocarb 400 g/L	R-5/2015wu
United Kingdom	Proxanil	Cymoxanil 50g/L + Propamocarb 400 g/L	16664

Description of the target pests

Key targets for this product *Phytophthora infestans* in potato, which are present throughout or in parts of the Central zone and in relevant EPPO zones. The key targets for this product is described in detail in the Biological Assessment Dossier.

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
PHYTIN	<i>Phytophthora infestans</i>	Late blight

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Potato	CEU	-	<i>Phytophthora infestans</i>	CEU	-

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Germany, Czech Republic, United Kingdom, Poland and Hungary in 2016-2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (6.2 Testing effectiveness)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Propamocarb 40% + Cymoxanil 5% SC, 14 efficacy trials with efficacy results were conducted in the Maritime, North-east and South-East EPPO zones:

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	N-E	S-E	MED			
SOLTU	Germany	E + S + Y + Q	2				2016/17	GEP	
	United Kingdom	E + S + Y + Q	2				2016/17	GEP	
	Czech Republic	E + S + Y + Q	2				2016/17	GEP	
	Poland	E + S + Y + Q		6			2016/17	GEP	
	Hungary	E + S + Y + Q			2		2016/17	GEP	
	Total, Potato (eff.)			6	6	2	-		

In the trials used to assess the level of control obtained with Propamocarb 40% + Cymoxanil 5% SC, a different number of assessments were conducted during the course of the trials. In some trials, a single assessment was conducted on the specific plant part and in others, two or more assessments were conducted. Therefore, not to bias the data from any trial with more than one assessment, the summary tables contain the data from one assessment per plant part per trial. An assessment is only considered valid for evaluation if the level of pest severity (PESSEV) is minimum 1% in the untreated check or if pest incidence (PESINC) is minimum 5% in the untreated check. The data selected from each trial is either the final assessment timing on each plant part or the assessment timing most commonly used.

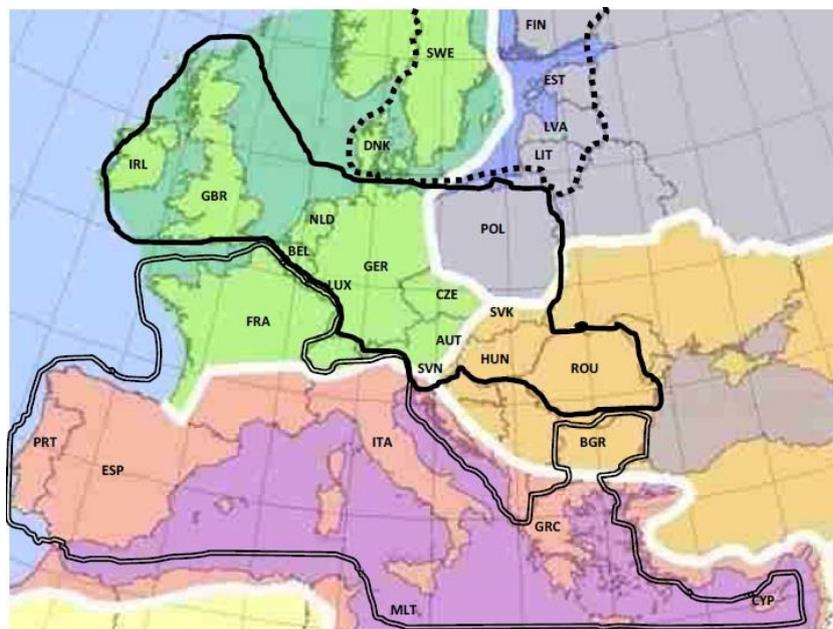
Climatic zones

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country¹.

Germany, United Kingdom and Czech Republic are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; and Hungary is located in the South-east EPPO zone (Figure 3.2-1).

¹ Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



This document is prepared to support the submission of Propamocarb 40% + Cymoxanil 5% SC throughout the Central Registration zone, therefore data from the Maritime EPPO zone, the North-East EPPO zone and the South-east EPPO zone are included.

Agronomic conditions

Cultural conditions and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between the countries in the Southern and Central EU, but common is that pests attack foliar- and ear diseases of cereals attack cereals from the South to the North, from East to West when the weather conditions are favourable for the pests to infest the crops.

The same Propamocarb + Cymoxanil containing fungicides are already registered and used in the countries where the trials were conducted to support the current application for registration. Please refer to Table 3.2-3 for the registration numbers in the different countries. In Southern and Central zone countries, Propamocarb + Cymoxanil -containing fungicides are used as a protective fungicide, which should be applied during the growing season, before or shortly after outbreaks of the diseases claimed on the label are foreseen. Depending on the forecast and the diseases to be controlled, the important period may stretch from April to September.

(i) Pest physiology

The physiology of *Phytophthora infestans*, is similar throughout Southern and Central Europe. Although trials were performed in different countries, sites were selected to exert maximum disease pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted.

(ii) Site selection

Although trials were performed throughout the Southern and Central EU, in each country the sites were carefully selected to ensure that for each fungal disease, the level of control was assessed on a range of populations, when treated at the recommended application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials, which contained high infestation levels. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted.

(iii) *Agronomic practices*

Agronomic practices for cultivating cereals are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are also generally similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, observations on selectivity have not indicated any particular varietal sensitivity. The crop safety of Propamocarb 40% + Cymoxanil 5% SC has been tested on a wide range of varieties in efficacy- and selectivity trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance and yield data generated in one country is therefore relevant in other Member states. To increase the probability of high levels of disease in the trials, the varieties chosen in each country were the ones with the least resistance to the selected disease. Therefore, the results from each country can be considered as the worst case.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for cereal production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

It is not expected that a foliar applied fungicide will be affected in any way by soil type and so this factor can be ignored for the purposes of this document.

On the basis that the above factors do not influence the overall performance of Propamocarb 40% + Cymoxanil 5% SC, it is the applicant's contention that data from Germany, United Kingdom, Czech Republic, Poland and Hungary is equally valid in demonstrating the products performance throughout the Central EU zone.

14 efficacy trials conducted in potato were carried out with Propamocarb 40% + Cymoxanil 5% SC in comparison to a commercially available reference product containing Propamocarb + Cymoxanil (Aridor, Proxanil; 400 g/L Propamocarb + 50 g/L Cymoxanil SC). The trials were all carried out in potato.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Propamocarb + Cymoxanil formulation					
Proxanil	SC	400 g/L Propamocarb + 50 g/L Cymoxanil	2.5	Germany United kingdom Czech Republic Poland Hungary	2 2 2 4 2
Aridor	SC	400 g/L Propamocarb + 50 g/L Cymoxanil	2.5	Poland	2

Comments of zRMS:	<p>Propamocarb + Cymoxanil containing fungicides are already registered and used in the countries where the trials were conducted to support the current application for registration.</p> <p>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 fungi-</p>
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	<p>cide is primarily active on fungi belonging to the <i>Peronosporales</i> order: <i>Phytophthora</i>, <i>Plasmopara</i>, and <i>Peronospora</i>.</p> <p>Propamocarb hydrochloride is a systemic fungicide commonly used for control of <i>Phytophthora</i> diseases of nursery crops. The mode of action is different compared to other <i>Oomycete</i> 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.</p> <p>This document summarises the information related to the efficacy of the plant protection product – PROSIM (product code: SHA 076127 A), according to Article 33 of Regulation 1107/2009. The formulation of this product is a suspension concentrate (SC) and it containing two active substances: cymoxanil (50 g/L) and propamocarb hydrochloride (400 g/L). Both, cymoxanil and propamocarb hydrochloride are on the list of approved active substances.</p> <p>In Poland 2 plant protection products (Axidor and Proxanil) with the same active compounds – cymoxanil and propamocarb hydrochloride are registered and commonly used for protection plants. What, is important those products have the same formulation, content of active substances, recommended dose and window for application as tested product. The only difference is the maximum number of applications per season. The evaluated product is recommended to be applied up to 6 times per season, while products registered on the Polish market up to 4 times.</p> <p>Poland is a ZRMs.</p>
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3.2.1 Preliminary tests (KCP 6.1)

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.

Comments of zRMS:	No results of the preliminary range-finding tests were submitted by the Applicant which is acceptable. The active substances of PROSIM – cymoxanil and propamocarb hydrochloride are registered and has been commonly used in agricultural practice for many years. (over 30 years). So, a large-scale efficacy trials are available to evaluate the effectiveness of products containing those active compounds. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator.
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3.2.2 Minimum effective dose tests (KCP 6.2)

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, Unit-

ed Kingdom and Germany), the North-east EPPO zone (i.e. Poland) and the South-east EPPO zone (i.e. Hungary).

Control of *Phytophthora infestans* in Potato (CEU)

To prove and to support the proposed dose rate of 2.5 L/ha Propamocarb 40% + Cymoxanil 5% SC [1000 g propamocarb + 125 g cymoxanil per hectare, per application] for the control of *Phytophthora infestans* (PHYTIN) in potato, the assessment results from 14 efficacy trials performed in the Maritime EPPO zone (6), the North-east EPPO zone (6) and the South-east EPPO zone (2) are reported. The trials were conducted in Czech Republic (2), Germany (2), United Kingdom (2), Hungary (2) and Poland (6). Propamocarb 40% + Cymoxanil 5% SC was included in these trials at 2.5 L/ha to demonstrate the recommended dose rate as well as at two lower dose rates (1.5 L/ha and 2.0 L/ha [600 g propamocarb + 75 g cymoxanil per hectare, per application and 800 g propamocarb + 100 g cymoxanil per hectare, per application]). In the trials, specifically targeted for this pathogen, up to 6 applications were applied at growth stages ranging between BBCH 37 and BBCH 85.

The results obtained with Propamocarb 40% + Cymoxanil 5% SC applied for the control of *Phytophthora infestans* in potato are presented in Table 3.2-8, Table 3.2-9 and

Target: PHYTIN	No. of trials	Untreated Mean % (range)	Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Propamocarb 40% + Cymoxanil 5% SC					
			1.5 L/ha		2.0 L/ha		2.5 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato		PESSEV						
Mean % control, one observation on PLANT per trial, PESSEV at 8-100 DAT	4	21.3 (0.7-55.0)	57.4	43.2-79.2	78.1	54.4-91.7	85.6	60.2-100
Mean % control, one observation on LEAF per trial, PESSEV at 7 DAT	2	36.9 (33.8-40.0)	22.8	21.6-24.0	39.3	37.0-41.5	55.6	53.2-57.9

Table 3.2-10 for results obtained in the Maritime EPPO zone, North-East EPPO zone and the South-east EPPO zone.

The data from the trials proves that the minimum effective dose rate of Propamocarb + Cymoxanil to control *Phytophthora infestans* in potato is 2.5 L/ha, with up to 6 applications per season. Furthermore, the data demonstrated that if the application rate is reduced below this, a decrease in control as well as in persistence is observed.

Table 3.2-8: Maritime zone: Minimum effective dose of Propamocarb 40% + Cymoxanil 5% SC against PHYTIN in potato.

Target: PHYTIN	No. of trials	Untreated Mean % (range)	Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Propamocarb 40% + Cymoxanil 5% SC					
			1.5 L/ha		2.0 L/ha		2.5 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato		PESSEV						
Mean % control, one observation on LEAF per trial, PESSEV at 14 DAT	1	98.8	87.2	-	100	-	100	-
Mean % control, one observation on PLANT per trial, PESSEV at 1-9 DAT	5	51.3 (4.6-97.5)	57.3	8.3-99.0	64.3	39.2-99.5	79.0	49.9-100
Mean % control, one observation on STEM per	1	90.0	100	-	100	-	100	-

trial, PESSEV at 14 DAT								
Potato		PESINC						
Mean % control, one observation on PLANT per trial, PESINC at 61-139 DAT	2	3.6 (2.3- 4.8)	59.4	55.6-63.2	54.7	31.6-77.8	65.5	42.1-88.9

Table 3.2-9: North-east zone: Minimum effective dose of Propamocarb 40% + Cymoxanil 5% SC against PHYTIN in potato.

Target: PHYTIN	No. of trials	Untreated Mean % (range)	Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Propamocarb 40% + Cymoxanil 5% SC					
			1.5 L/ha		2.0 L/ha		2.5 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato		PESSEV						
Mean % control, one observation on PLANT per trial, PESSEV at 8-100 DAT	4	21.3 (0.7- 55.0)	57.4	43.2-79.2	78.1	54.4-91.7	85.6	60.2-100
Mean % control, one observation on LEAF per trial, PESSEV at 7 DAT	2	36.9 (33.8- 40.0)	22.8	21.6-24.0	39.3	37.0-41.5	55.6	53.2-57.9

Table 3.2-10: South-east zone: Minimum effective dose of Propamocarb 40% + Cymoxanil 5% SC against PHYTIN in potato.

Target: PHYTIN	No. of trials	Untreated Mean % (range)	Mean % Control from 4 trials in the Maritime EPPO Zone at a range of doses of Propamocarb 40% + Cymoxanil 5% SC					
			1.5 L/ha		2.0 L/ha		2.5 L/ha	
			Mean	Range	Mean	Range	Mean	Range
Potato		PESSEV						
Mean % control, one observation on PLANT per trial, PESSEV at 7-9 DAT2	2	89.7 (79.4- 100)	38.9	21.8-55.9	43.3	27.8-58.7	64.6	54.0-75.3

Summary and conclusions on the minimum effective dose

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.

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.

Comments of zRMS:	<p>In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least one lower dose(s) (for example 60–80% of the recommended dose) to that which would be recommended. It is utilized to achieve the desired effect. In the appropriate researches of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2).</p> <p><u>Applicant for support the MED (minimum effective dose) was studied following doses:</u></p> <ul style="list-style-type: none"> • potato against <i>Phytophthora infestans</i> – three different doses were studied: 1,5 l/ha (0,6N); 2,0 l/ha (0,8N) and 2,5 l/ha (N) in MAR (6 trials), S-E (2 trials) and N-E trials (6 trials). <p>According to the presented results, the dose rate of 2.5 L/ha per application, for control of <i>Phytophthora infestans</i> 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. 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.</p>
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3.2.3 Efficacy tests (KCP 6.2)

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

Table 3.2-11: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3/4)
	Specific guidelines	EPPO PP 1/2 (4)
Experimental design	Plot design	RCBD (14)
	Plot size	16-30 m ²
	Number of replications	4 (14)
Crop	Trials per crop	Potato (14)
	Varieties per crop	Potato: Allians, Bintje, Maris Bard, Estima, Adela, Red Anna, Melody, Irga , Vineta (3), Sante, Red Scarlet, Desiree.
	Sowing period	Potato: 04 th April to May 19 th
Application	Application period	Potato: June 3 rd to August 25 th
	Crop stage (BBCH)* at application	Potato (14): BBCH 37-91
	Number of appl. Intervals between appl.	4 (3), 6 (11) 7-18
	Spray volumes	200-500 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to ‘untreated’ (‘untreated’ = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour

	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Sandy loam, clayey sand, fine loam, humus earth, silty clay, loamy sand, clay loam, sandy silt loam, candy clay loam.
	Organic matter content	1.4-4.1
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

Use 001: Efficacy against *Phytophthora infestans* in potato

The efficacy trials were conducted to prove the following label claims:

Crop	Potato
Use rate	2.5 L/ha Propamocarb 40% + Cymoxanil 5% SC
Use frequency	Up to 6x
Application timing	BBCH 21-95
Target disease	<i>Phytophthora infestans</i>

The effectiveness of applying Propamocarb 40% + Cymoxanil 5% SC against GAP claimed diseases in potato was evaluated in 14 trials, assessed for pest severity and pest incidence on specific parts. These trials were carried out in 2016/17 in the Maritime EPPO zone (6; i.e. Germany (2), United Kingdom (2) and the Czech Republic (2)), the North-East EPPO zone (6; i.e. Poland), and the South-east EPPO zone (2; i.e. Hungary). The objective was to confirm the performance of Propamocarb 40% + Cymoxanil 5% SC at the proposed dose rate of 2.5 L/ha (i.e. 1000 g Propamocarb and 125 g Cymoxanil per hectare). In the trials specifically targeted for this pathogen, up to 6 applications were applied in the spring (April-May) at growth stages ranging between BBCH 21 and BBCH 95.

In the Czech, German, United Kingdom, Polish and Hungarian trials, Propamocarb 40% + Cymoxanil 5% SC was tested alongside an EU approved Propamocarb + Cymoxanil, i.e. Proxanil / Axidor.

***Phytophthora infestans*, Maritime EPPO zone**

In all 6 trials, pest severity of *Phytophthora infestans* on leaves was evaluated at 11 assessment timings which were considered valid for the summary (i.e. PESSEV \geq 1%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-12 therefore only contains one assessment per plant part from the Maritime trials assessed repeatedly.

Table 3.2-12: Maritime zone: Efficacy of 2.5 L/ha Propamocarb 40% + Cymoxanil 5% SC and Propamocarb + Cymoxanil reference product at 2.5 L/ha dose rate applied against *Phytophthora infestans* in potato in the efficacy tests – 1-139 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Prop 40% + Cym 5% SC 1125 g ai/ha is >, < or =, compared to the Reference product at 1125 g ai/ha = : \pm 5% control			Overall
				Prop 40% + Cym 5% SC 2.5 L/ha (1125g ai/ha)	Prop + Cym Ref. Standard 2.5 L/ha (1125g ai/ha)				
				Mean (min-max)		>	=	<	
Pest severity				PESSEV					
Leaf	14 DAT	1	98.8	100	100		1		=
Plant	1-9 DAT	5	51.3 (4.6-97.5)	79.0 (49.9-100)	82.6 (66.8-100)		5		=

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Prop 40% + Cym 5% SC 1125 g ai/ha is >, < or =, compared to the Reference product at 1125 g ai/ha = : ± 5% control			Overall
				Prop 40% + Cym 5% SC 2.5 L/ha (1125g ai/ha)	Prop + Cym Ref. Standard 2.5 L/ha (1125g ai/ha)				
				Mean (min-max)		>	=	<	
Stem	14 DAT	1	90.0	100	100		1		=
Pest incidence PESINC									
Plant	61-139 DAT	2	3.6 (2.3-4.8)	65.5 (42.1-88.9)	63.2 (26.3-100)		2		=

The individual trial results show that Propamocarb 40% + Cymoxanil 5% SC gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the Propamocarb + Cymoxanil reference product. No significant differences were observed between the tested products at any of the 9 assessments.

***Phytophthora infestans*, North-East Eppo zone**

In all 6 trials, pest severity of *Phytophthora infestans* on leaves was evaluated at 6 assessment timings which were considered valid for the summary (i.e. PESSEV ≥ 1%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-13 therefore only contains one assessment per plant part from the North-east trials assessed repeatedly.

Table 3.2-13: North-east zone: Efficacy of 2.5 L/ha Propamocarb 40% + Cymoxanil 5% SC and Propamocarb + Cymoxanil reference product at 2.5 L/ha dose rate applied against *Phytophthora infestans* in potato in the efficacy tests – 7-11 DALT.

Part assessed	Days after Last Treatment. (DALT)	No. of trials	Mean infestation level (%)	Efficacy obtained with		No. of trials where Prop 40% + Cym 5% SC 1125 g ai/ha is >, < or =, compared to the Reference product at 1125 g ai/ha = : ± 5% control			Overall
				Prop 40% + Cym 5% SC 2.5 L/ha (1125g ai/ha)	Prop + Cym Ref. Standard 2.5 L/ha (1125g ai/ha)				
				Mean (min-max)		>	=	<	
Pest severity PESSEV									
Plant	8-11 DAT2	4	21.3 (0.7-55.0)	85.6 (60.2-100)	85.6 (59.3-100)		4		=
Leaf	7-8 DAT2	2	36.9 (33.8-40.0)	55.6 (53.2-57.9)	23.4 (12.5-34.2)	2			>

The individual trial results show that Propamocarb 40% + Cymoxanil 5% SC gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the Propamocarb + Cymoxanil reference product. No significant differences were observed between the tested products at any of the 6 assessments.

***Phytophthora infestans*, South-East Eppo zone**

In all 2 trials, pest severity of *Phytophthora infestans* on leaves was evaluated at 2 assessment timings which were considered valid for the summary (i.e. PESSEV ≥ 1%). In order not to bias the data from any trials with data from more than one assessment on each plant part, repeated assessments were excluded from summary. Table 3.2-14 therefore only contains one assessment per plant part from the South-east trials assessed repeatedly.

Table 3.2-14: South-East zone: Efficacy of 2.5 L/ha Propamocarb 40% + Cymoxanil 5% SC and Propamocarb + Cymoxanil reference product at 2.5 L/ha dose rate applied against *Phytophthora infestans* in potato in the efficacy tests – 7-9 DALT.

Part assessed	Days after	No.	Mean infesta-	Efficacy obtained with	No. of trials where Prop 40% + Cym
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Last Treatment. (DALT)	of trials	tion level (%)	Prop 40% + Cym 5% SC 2.5 L/ha (1125g ai/ha)	Prop + Cym Ref. Standard 2.5 L/ha (1125g ai/ha)	5% SC 1125 g ai/ha is >, < or =, compared to the Reference product at 1125 g ai/ha = : ± 5% control			Overall
			Mean (min-max)		>	=	<	
			2.5 L/ha	2.5 L/ha				
Pest severity		PESSEV						
Plant	7-9 DAT	2	89.7 (79.4-100)	64.6 (54.0-75.3)	64.8 (54.1-75.4)		2	=

The individual trial results show that Propamocarb 40% + Cymoxanil 5% SC gave good to excellent control of *Phytophthora infestans*, equivalent to that achieved by the Propamocarb + Cymoxanil reference product. No significant differences were observed between the tested products at any of the 2 assessments.

Summary and conclusion

Based on the results of 14 field efficacy trials carried out from 2016 to 2017, the following can be concluded for the intended use of Propamocarb 40% + Cymoxanil 5% SC applied at 2.5 L/ha per application in potato:

- 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 Propamocarb + Cymoxanil reference product tested in the potato trials, the efficacy obtained with Propamocarb 40% + Cymoxanil 5% SC is comparable against the key disease tested.
- The trial results are considered valid for all intended Central zone countries.

Propamocarb 40% + Cymoxanil 5% SC is suitable for the control of foliar diseases (*Phytophthora infestans*) in potato.

This document clearly demonstrates that the efficacy and crop safety of Propamocarb 40% + Cymoxanil 5% SC is equivalent to the standard Propamocarb + Cymoxanil containing products to which the test product was compared. The applicant therefore wishes to cite the data on Propamocarb + Cymoxanil containing products 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.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought”. It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials can be presented “where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops”. Propamocarb + cymoxanil formulations have been registered in Central Zone and in countries where trials were conducted for various years like Proxanil (reg nr R-6/2015) registered in Poland in 2015, Axidor (reg nr R-5/2015) registered in Poland in 2015, Proxanil (reg nr 4922-0) registered in the Czech Republic in 2015, Proxanil (reg nr 006481-00) registered in Germany in 2010, Proxanil (reg nr 16664) registered in the United Kingdom in 2014 or Proxanil (reg nr 04.2/2958-1/2012 registered in Hungary in 2012. According to this, formulation has been widely proved in Central Zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	<p>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.</p> <p>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.</p> <p><u>The following efficacy scale was used:</u></p> <ul style="list-style-type: none">- L – limiting (0-60% efficacy)- ME – moderately efficiency (60-80%)- E – efficiently (>80%) <p>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.</p> <p><u>Efficacy of PROSIM:</u></p> <ul style="list-style-type: none">- <i>MAR</i> – 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.- <i>N-E</i> – 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.- <i>S-E</i> – efficacy on the plant was observed during 2 trials. It can be concluded that PROSIM moderately effectively control the late blight of potato. <p><u>Interval between application:</u></p> <ul style="list-style-type: none">- <i>MAR</i>: 7-18 days- <i>N-E</i>: 7-11 days- <i>MED</i>: 12-14 days <p>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.</p> <p><u>Application widow:</u></p> <ul style="list-style-type: none">- <i>MAR</i>: BBCH 21-91- <i>N-E</i>: BBCH 38-85- <i>S-E</i>: BBCH 37 -49 <p>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.</p>
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<p><u>Number of applications:</u></p> <ul style="list-style-type: none">- 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. <p>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).</p> <p><u>Water volume:</u></p> <ul style="list-style-type: none">- MAR: 200-400 L/ha- N-E: 200-400 L/ha- S-E: 500 L/ha <p>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.</p> <p>ZRMs agree with Applicant that: <i>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.</i></p> <p>Compared to the cymoxanil and propamocarb chloride reference products tested, the efficacy obtained with PROSIM was comparable against <i>Phytophthora infestans</i>.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The following dossier section follows EPPO standard PP 1/213(4) *Resistance risk analysis* in particular point 6. *Registration requirements* and Appendix I of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual can multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the epidemic (or disease severity) and use pattern of the fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term resistance be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and
- (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

3.3.1 Mode of action

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.

3.3.2 Mechanism of resistance

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.

3.3.3 Evidence of resistance

No evidence of resistance of Propamocarb in potato against *Phytophthora infestans* has been recorded. Only one case of resistance has been registered related to Propamocarb. *Pythium spp.* developed resistance against Propamocarb in geranium seedlings.

No evidence of resistance of Cymoxanil in potato against *Phytophthora infestans* has been recorded. Only one case of resistance has been registered related to Cymoxanil. *Plasmopara viticola* developed resistance against Cymoxanil in grapevine.

3.3.4 Cross-resistance

No evidence of cross-resistance has been recorded in crops treated with Propamocarb or Cymoxanil.

3.3.5 Sensitivity data

Diseases vary in their sensitivity towards fungicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. These fungicides have been tested and used worldwide for up to 30 years (or more), it is therefore difficult to find unexposed fungal populations. No true base line sensitivity data can therefore be established. FRAC has been monitoring the development in sensitivity in the most important diseases for a number of years, and Sharda will work closely together with FRAC to assist with this work.

3.3.6 Use pattern

Propamocarb 40% + Cymoxanil 5% SC is composed of Propamocarb + Cymoxanil which is a systemic fungicide with protective, curative and eradicator action. In the EU Central zone, the formulation is proposed for control of *Phytophthora infestans* in potato. The fungicide is proposed applied up to 6 times during the season at the recommended dose rate (2.5 L/ha).

The application may be employed when the climatic conditions are favourable for infestation or when warnings have been released in the different regions. For all the crops and the pests to be controlled, this will deliver 1000 g Propamocarb and 125 g Cymoxanil per hectare, per application.

Propamocarb + Cymoxanil has been used as straight product as well as in mixtures for many years.

3.3.7 Resistance risk assessment of unrestricted use pattern

The active substances

FRAC regards the resistance risk of the carbamates and the cyanoacetamideoxime as low to medium risk.

The disease

The target organism for the use of Propamocarb 40% + Cymoxanil 5% SC have developed resistance to a range of fungicide groups: PA fungicides (A1, 4) and CAA fungicides (H5, 40).

The intended disease target for Propamocarb 40% + Cymoxanil 5% SC vary in terms of their intrinsic resistance risk. The resistance risk of target pathogens of Propamocarb 40% + Cymoxanil 5% SC is available at www.frac.info.

Agronomic practice

In terms of agronomic practice, the selection pressure on the intended disease target for Propamocarb 40% + Cymoxanil 5% SC may be low to medium in potato crops.

The plant protection product

For optimum disease control, Propamocarb 40% + Cymoxanil 5% SC is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major target pathogen.

3.3.8 Test methods

There are several monitoring methods approved by FRAC (available on www.frac.info).

3.3.9 Acceptability of the resistance risk

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.), the unrestricted use pattern for Propamocarb 40% + Cymoxanil 5% SC would be season long usage with an unrestricted number of applications.

Overall it is clear that the unrestricted use of Propamocarb 40% + Cymoxanil 5% SC presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.10 Resistance management strategy

As the unmodified use pattern is considered unacceptable, a number of modifiers are proposed which are entirely in accordance with the general recommendations made by FRAC.

- Use in alternation with fungicides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.
- Application should be as a protective application.
- Use other measures such as resistant varieties, good agronomic practice

3.3.11 Implementation of the Management Strategy

Information on the management of resistance and the specific Resistance Management Strategy for Pro-pamocarb 40% + Cymoxanil 5% SC is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts for general information or to address a particular issue in a specific geographical area where it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- FRAC publications including the web site www.frac.info
- Training for distributors/wholesalers/merchants and farmer groups
- Links from company web sites to FRAC and local Fungicide Resistance working groups for information and advice

3.3.12 Monitoring, reporting and reaction to the change in performance

Monitoring of field performance

Where field performance is significantly less than expected (relative to field trial results presented in section 0) and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by FRAC.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance can be confirmed as the cause for loss of field performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical field resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to use only fungicides from alternative mode of action groups for the remainder of the growing season
- Reduction in number of applications
- Recommendation to use only in a programme e.g. before or after an application of a fungicide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>The agronomic risk for the PROSIM which include propamocarb hydrochloride and cymoxanil is estimated as low to medium.</p> <p>The resistance management is coordinated by FRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided.</p> <p>Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, Use pattern, Proposed Risk Modifiers) has to be finalised on national level.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

Data from 14 efficacy trials in potato have been presented for selectivity results conducted in the ~~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.

The 14 efficacy trials were conducted in potato (14).

Information on trials submitted (6.4 Adverse effects on treated crops)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The GEP-requirement and the Uniform Principles are therefore taken care of.

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zones. EPPO zones have been defined by taking into account differences between the agro-climatic subareas of the EPPO region.

In general, the trials were conducted according to the respective EPPO guidelines.

In support of the current application for registration of Propamocarb 40% + Cymoxanil 5% SC, 14 efficacy trials with selectivity results were conducted in the Maritime, North-east and South-East EPPO zones:

Table 3.4-1: Presentation of selectivity trials

Crop*	Country	Type of trial**	Number of trials				Years	GEP, non-GEP, official***	Comments (any other relevant information)
			EPPO zone						
			MAR	N-E	S-E	MED			
SOLTU	Germany	E + S + Y + Q	2				2016/17	GEP	
	United Kingdom	E + S + Y + Q	2				2016/17	GEP	
	Czech Republic	E + S + Y + Q	2				2016/17	GEP	
	Poland	E + S + Y + Q		6			2016/17	GEP	
	Hungary	E + S + Y + Q			2		2016/17	GEP	
	Total, Potato (eff.)			6	6	2	-		

Table 3.4-2: Details on selectivity trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(3/4)
	Specific guidelines	EPPO PP 1/2 (4)
Experimental design	Plot design	RCBD (14)
	Plot size	16-30 m ²
	Number of replications	4 (14)
Crop	Trials per crop	Potato (14)
	Varieties per crop	Potato: Allians, Bintje, Maris Bard, Estima, Adela, Red Anna, Melody, Irga , Vineta (3), Sante, Red Scarlet, Desiree.
	Sowing period	Potato: 04 th April to May 19 th
Application	Application period	Potato: June 3 rd to August 25 th
	Crop stage (BBCH)* at application	Potato (14): BBCH 37-91
	Number of appl. Intervals between appl.	4 (3), 6(11) 7-18
	Spray volumes	200-500 L/ha
Assessment	Assessment types	<ul style="list-style-type: none"> - Visual estimation of crop injury and crop stand reduction (thinning) compared to 'untreated' ('untreated' = 0% crop injury; 100% crop injury = total crop destruction). Where appropriate, this overall score was substituted or supplemented by assessments of individual symptoms. - crop vigour
	Assessment dates	As a rule 3 crop injury ratings
Other relevant information	Soil type	Sandy loam, clayey sand, fine loam, humus earth, silty clay, loamy sand, clay loam, sandy silt loam, candy clay loam.
	Organic matter content	1.4-4.1
	Natural / artificial inoculation...	Preferably disease-free conditions
	Field / Greenhouse...	Field

Reference products

In the efficacy trials with selectivity results, the performance of Propamocarb 40% + Cymoxanil 5% SC was measured against a commercially available reference products containing Propamocarb + Cymoxanil (Aridor, Proxanil; 400 g/L Propamocarb + 50 g/L Cymoxanil SC). The trials were carried out on potato.

Table 3.4-3: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

Trade name	Formulation	Composition	Rates	Country	N° of Trials
Propamocarb + Cymoxanil formulation					
Proxanil	SC	400 g/L Propamocarb + 50 g/L Cymoxanil	2.5	Germany	2
				United kingdom	2
				Czech Republic	2
				Poland	4
				Hungary	2
Aridor	SC	400 g/L Propamocarb + 50 g/L Cymoxanil	2.5	Poland	2

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

As Propamocarb 40% + Cymoxanil 5% SC is a fungicide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Propamocarb 40% + Cymoxanil 5% SC at a recommended dose rate in potato was evaluated in 14 efficacy trials (6 MAR, 6 N-E and 2 S-E). In the efficacy trials, Propamocarb 40% + Cymoxanil 5% SC was applied at 1.5 L/ha to 2.5 L/ha.

The trials were conducted in the Maritime zone (6; i.e. Germany (2), Czech Republic (2) and United Kingdom (2)), the North-east zone (6, i.e. Poland (6)) and the South-east zone (2; i.e. Hungary) EPPO zones from 2016 to 2017 to evaluate the crop safety of Propamocarb 40% + Cymoxanil 5% SC in potato.

3.4.1.1 Potato (SOLTU)

Crop phytotoxicity was evaluated in efficacy trials where Propamocarb 40% + Cymoxanil 5% SC was applied at up to 6 applications when the crop was at growth stages ranging from BBCH 21 to BBCH 95, at the rate of 1.5 to 2.5 L/ha in potato. The 2.5 L/ha dose rate corresponds to 100% of the max. proposed dose rate in Central EU countries. Crop phytotoxicity was assessed in all trials at various intervals from first application and up to termination of the trial.

Phytotoxicity in Potato trials, Maritime EPPO zone

A total of 6 efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Propamocarb 40% + Cymoxanil 5% SC when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the 6 efficacy trials treated with Propamocarb 40% + Cymoxanil 5% SC in the Maritime EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in Potato trials, North-east EPPO zone

Six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Propamocarb 40% + Cymoxanil 5% SC when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regards to phytotoxicity and vigour were observed in any of the 6 efficacy trials treated with Propamocarb 40% + Cymoxanil 5% SC in the North-east EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

Phytotoxicity in Potato trials, South-East EPPO zone

A total of two efficacy trials were conducted in the South-East EPPO zone to assess the crop safety of Propamocarb 40% + Cymoxanil 5% SC when applied as recommended in potato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity and vigour were observed in any of the two efficacy trials treated with Propamocarb 40% + Cymoxanil 5% SC in the South-East EPPO zone.

Furthermore, harvest results from trials demonstrated that the applied treatments did not have any detrimental effects on yield or quality of yield either.

3.4.1.2 Overall conclusion

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.

Table 3.4-4: Phytotoxicity of product

Number of trials with...		Efficacy trials (14 trials)	
		Test product	Standard
		2.5 L/ha	1N
Maximum of phytotoxicity recorded during the trials	0% to 5%	14	14
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	14	14
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Comments of zRMS:	<p>The phytotoxicity trials about tested plant protection product have been carried out in accordance with EPPO Guidelines. The conduct of the field work is principally compliant with “Good Agricultural Practice” and in accordance with EPPO Guidelines PP 1/135.</p> <p>The trials were performed with the use of different agricultural practice. The trials were performed with the use of cultivars, differing in growth strength as well as soil and water requirements. The appropriate experimental design was applied. In all trials studied product was compared to the standard reference products. Statistical analysis of the data was performed. Also, quality of yield was evaluated in some trials.</p> <p>14 phytotoxicity studies were performed on potato:</p> <ul style="list-style-type: none"> - MAR: 6 trials (DE-2, UK-2, CZ-2) - N-E: 6 trials (PL) - S-E: 2 trials (HU) <p>No adverse effects regarding to phytotoxicity were observed in any of the 14 efficacy trials (MAR-6; N-E-6; S-E-2). Trials were carried out on potatoes varieties: Allians, Bintje, Maris Bard, Estima, Adela, Red Anna, Melody, Irga, Vineta (3), Sante, Red Scarlet, Desiree. Only dose N was studied. According to EPPPO standards, dose 2N is not required for fungicides. All results were compared to standard reference products.</p> <p>In conclusion, the test product PROSIM is regarded safe for the target crop when</p>
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	used according to the label recommendations.
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

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). The results obtained in the 14 trials are presented in the section below.

3.4.2.1 Materials and methods

Plot yields, as weight plant material, were measured at harvest and converted to t/ha. The data of the treated plots are presented as relative values in relation to the fresh weight for the untreated plots. For further information on materials and methods please refer to CP 3.4 for harvested selectivity trials and CP 3.4 for harvested efficacy trials.

3.4.2.2 Summary and evaluation of the field trials conducted in potato, treated with 6 applications

A summary of the mean yield assessments, expressed as %-relative of the untreated, are presented in Table 3.4-5 for trials conducted in potato.

Potato

A total of 14 efficacy trials in potato were harvested. The trials were conducted in Germany (2), United Kingdom (2), Czech Republic (2), Poland (6) and Hungary (2) in 2016/17. In the efficacy trials, Propamocarb 40% + Cymoxanil 5% SC was applied at 1.5, 2.0 and 2.5 L/ha. The trials were sprayed at crop growth stages ranging between BBCH 21 and BBCH 95. In Table 3.4-5, the results obtained in the efficacy trials when treated with 1.5, 2.0 and 2.5 L/ha are presented.

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%)

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	1N
Potato – Efficacy trials, all reference products						
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)

Neither Propamocarb 40% + Cymoxanil 5% SC nor the reference standard significantly affected the yield when applied at the proposed dose rate (1.5 L/ha) in either of the 14 trials. Rather, overall Propamocarb 40% + Cymoxanil 5% SC provided an increase in the yield mass of the treated crop which is most likely as a consequence of the disease control in the efficacy trials as presented in Section 6.2.2. The results obtained in the trials supports the label claim that Propamocarb 40% + Cymoxanil 5% SC is safe to be applied at the recommended dose rate to potato at the recommended number of applications.

3.4.2.3 Conclusion

Propamocarb 40% + Cymoxanil 5% SC applied at the proposed dose rate, at a range of growth stages within or occasionally beyond the label recommended range, potato did not affect crop yield significantly in any of the 14 trials harvested. In all efficacy trials as, Propamocarb 40% + Cymoxanil 5% SC applied at recommended dose rates did not significantly affect the crop yield.

Furthermore, the data obtained in trials harvested demonstrate that Propamocarb 40% + Cymoxanil 5% SC is as safe to the crop as the reference products (Propamocarb + Cymoxanil) used in the trials.

For recommendations on the label not sufficiently supported with trials harvested, the applicant wishes to bridge to the trials conducted in potato where harvest data demonstrated the safe use following application of Propamocarb 40% + Cymoxanil 5% SC as recommended. Furthermore, the data presented in this BAD also clearly demonstrates that the efficacy and crop safety of Propamocarb 40% + Cymoxanil 5% SC is equivalent to the standard Propamocarb + Cymoxanil products to which it was compared. The applicant therefore wishes to cite the original registrant's data on Propamocarb 4+ 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.

Comments of zRMS:	<p>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.</p> <p>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.</p>
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Effect on the quality of yield of treated plants or plant product

Quantitative and qualitative recording of yields in line to EPPO PP 1/002 (5) *Phytophthora infestans* on potato: Under normal conditions, before harvesting, the plots should be treated with a desiccant in order to avoid tuber contamination during digging, but omitting this treatment will allow evaluation of the treatment to prevent severe tuber infection.

For each plot, record:

- (a) potato yield in tonnes per hectare. Yield data should be collected from at least 2 rows in the middle of the plot;
- (b) weight of tubers in each size class after sorting (according to national or international standards); (b) weight of tubers in each size class after sorting international standards);
- (c) the percentage of tubers affected by disease after at least 2 to 8 weeks of storage under standard conditions;
- (d) starch content if required.

Comments of zRMS:	<p>Applicant during trials presented yield results in tonnes per hectare. Those results were presented in the table 3.4-5 <i>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%)</i> by Applicant.</p> <p>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.</p> <p><u>Weight of tubers in each size class after sorting and the percentage of tubers affected by disease after storage:</u></p> <p>✓ N-E EPPO zone: PL (6 trials)</p>
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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
Axidor	2,0 L/ha	18,4	n.a.	63,00	110,95	43,2
Ahidor	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		
Axidor	2,0 L/ha	0,00	0,00	100		
Ahidor	2,5 L/ha	0,00	0,00	100		
<p>During harvest all tubers were divided according tuber size: small tubers – <35mm, medium tubers – 36-50 mm (4 trials) and 36-60 mm (2 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 <i>P.infestans</i> on tubers were observed after storage for recommended dose of PROSIM and st. ref. products used during trials.</p>						
<p>✓ Maritime EPPO zone (6 trials):</p>						
<p>¹⁾ Results for DE (2 trials):</p>						
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 divided 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 divided 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	Yield	Yield	Yield	Yield
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		Tuber Grade 1	Tuber Grade 2	Tuber Grade 3	Tuber Grade 4	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		
<p>During harvest all tubers were devided 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 <i>Phytophthora infestans</i> 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 Propamacarb are showing a dose response and were comparable to each other.</p>						
<p>✓ S-E EPPO zone: HU (2 trials)</p>						
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 storage	PESSEV UNCK % at 4 weeks storage	PESSEV at 9 weeks stor- age	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.
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3.4.2.4 Relationship between phytotoxicity and yield

No adverse effects were observed in any of the 14 potato trials conducted. In the trials harvested, no significant reductions in crop yield were recorded in any of the plots treated with Propamocarb 40% + Cymoxanil 5% SC at dose rates representative of the recommended dose rate.

Comments of zRMS:	ZRMs agree with Applicant. 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.
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3.4.3 Effects on transformation processes (KCP 6.4.4)

It has already been shown in effects on the quality of plants section that the application of Propamocarb 40% + Cymoxanil 5% SC at the proposed label rate and rates above this rate has no negative effect on the quality parameters assessed in efficacy trials harvested.

Other processes depend on biological activity and are referred to as ‘transformation’. These include e.g. brewing and baking and are potentially sensitive to plant protection products. Fungicides are usually only considered with regards to their potential effect on transformation processes if applied close to harvest (EPPO standard PP 1/243(1) *Effects of plant protection products on transformation processes*). It is also the case that if residues cannot be detected at harvest (dRR Part B Section 6) then it is reasonable to assume that the likelihood of an effect on transformation processes is greatly reduced.

Finally, it should be noted that currently, Propamocarb + Cymoxanil containing products do not have any label restrictions concerning their use on crops destined for processing. In addition, both actives are part of many products which have been used for a long time as fungicide in e.g. potato. Since the market introduction, no effects on transformation processes have been recorded for any of these products.

Comments of zRMS:	In conclusion, no negative influence of the product PROSIM on the yield and the quality of plants and plant products and the transformation processes is to be expected when applied at the intended dose rate and used according to the label recommendations.
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3.4.4 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

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.

Comments of zRMS:	Submission of data is not considered to be required due to the fungicidal nature of the product (EPPO guideline PP 1/135(3)). Data on plant parts used for propagating purposes are not considered to be required in terms of fungicides being applied to crops that are propagated by cuttings, runners and bulbs or corms. In conclusion, no negative influence of the product PROSIM on propagating purposes is to be expected when applied at the intended dose rate and used according to the label recommendations.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

The impact on succeeding crops is determined in accordance with guidance provided by EPPO standard PP 1/207(2) ‘Effect on succeeding crops’.

Propamocarb

New residue studies have been performed on potatoes. Some of them have already been evaluated within the EFSA “Reasoned opinion” referenced in the EFSA Journal 2013;11 (4): 3214. The representative use supported on potatoes is presented in table below:

Table 3.5-1 Use pattern (GAP) for the spray application of propamocarb containing formulations on potatoes in Europe (Northern and Southern regions)

Crop	Member state or country	F / G or I	Formulation Conc. of as	Pests or group of pests controlled	Growth stage	Number / Type/ (interval)	Water (L/ha)	Application ¹ (kg as/ha)	PHI
Potato	Europe North / South	F	SC 1) 625 g/L propamocarb HCl 2) 62.5 g/L Fluopicolide	<i>Phytophthora infestans</i> (PHYTIN)	BBCH 21-95	4 spray 7days	200-1000	1) 1.0 2) 0.1	7

A total of 20 supplementary trials were performed with SC687.5 product on potatoes since Annex I inclusion to support this use pattern. Within these 20 trials (12 Northern + 8 Southern EU trials), 4 Northern + 4 Southern European trials were done on early potatoes at the cGAP.

Despite the fact that some of them have already been reviewed by EFSA (EFSA Journal 2013;11 (4): 3214), all of them have been summarized together for sake of clarity.

The number and distribution of residue trials are described in table below:

Table 3.5-2 Number and distribution of residue trials conducted per geographical region on potatoes

Formulation Name	Climatic zone, Countries	Formula-tion type	Year / No. of trials	Reference Study number / Doc No.
Europe North				
Fluopicolide + propamocarb hydrochloride SC 687.5	Germany, United Kingdom and Northern France	SC	2002 / 4	02R286 / M-232144-01-1
	United Kingdom, Germany and the Netherlands	SC	2003 / 4	RA-2604/03 / M-236086-01-1
	Northern France, Germany, Belgium and the Netherlands	SC	2010 / 4	10-2121 / M-398344-01-1
Europe South				
Fluopicolide + propamocarb hydrochloride SC 687.5	Southern France, Italy and Spain	SC	2002 / 4	02R287 / M-232146-01-1
	Spain, Italy, Southern France and Portugal	SC	2010 / 4	10-2122 / M-398345-01-1

Conclusion:

Twenty residue trials (twelve in Northern Europe and eight in Southern Europe) were conducted in/on potato with Infinito (687.5 SC product) under field conditions between 2002 and 2010 to evaluate the residues of propamocarb in potato tubers after application of propamocarb hydrochloride according to the critical GAP: four spray applications at 1.6 L product/ha. Residues of propamocarb in/on potato tubers were found between < LOQ (0.01 mg/kg) and 0.03 mg/kg at the recommended PHI of 14 days.

Cymoxanil

Criteria for potato trials in northern Europe:

Before and at the flowering stage potato plants were treated with DPX-KP481-25 (WG formulation containing 25.0 % cymoxanil + 25.0 % famoxadone as active ingredients) at a nominal rate of 200 g cymoxanil and 200 g famoxadone per hectare, 11 to 12 number of applications per season, total up to 2.400 kg as/ha nominally, an application interval of 5-13 days and a PHI of 14 days. Mature potato tuber were harvested.

Criteria for potato trials in southern Europe:

Potato plants about the flowering stage were treated up to 8 times with DPX-KX007-9 (WG formulation: 30.0 % cymoxanil + 22.5 % famoxadone) at a nominal rate of 240 g cymoxanil and 180 g formoxadone per hectare, total up to 1.920 kg as/ha nominally, a 6 - 11 days interval between the applications. The mature potato tubers were harvested 14 days after last treatment.

Critical GAP for potato (DuPont):

The critical GAP on use of cymoxanil supported by DuPont is identical for N-EU and S-EU:

Spray application, growth stage: BBCH 21-95, up to 8 foliar treatments with a rate of 0.175 kg as/ha each, maximal up to 1.400 kg as/ha, a 7-10 days spray interval and a PHI of 14 days.

Findings

There are no residues of cymoxanil determined at or above the LOQ (= 0.05 mg/kg) in/on potato tuber samples from representative northern and southern European test site locations (each 6 trials, 1 growing season for all trials: April - Sept. 1996 in N-EU and April - Oct. 1996 in S-EU) and harvested 14 days after last treatment under critical GAP conditions (DuPont, N-EU identical with SEU). All 12 outdoor trials on potato in northern and southern regions of Europe submitted by DuPont are covered nearly by the critical GAP (DuPont). The following table B.7.6.2-1 gives an overview of the residue data for cymoxanil in/on potato tuber from 12 supervised field residue trials (each 6 harvest studies from northern and southern EU were performed at 1 growing season) reported by DuPont.

Table 3.5-3 Overview of residue data for cymoxanil on/in potato (DuPont)

Crop, trial site country, year	Application					Residues		Reference
	Formulation, content of as [% (w/w)]	Rate [kg as/ha]	Number of applications	Interval between applications [days]	Total amount of cymoxanil per season [kg as/ha]	DAT [days]	Cymoxanil [mg/kg]	
Northern Europe								
Potato Raineourt N-France, 1996	DPX-KP481-25 WG 25 % cymoxanil + 25% famoxadone	0.176-0.211	11	6-8	2.175	14	<0.05	Dubey L, Jernberg K.M, 1997b, field and analytical phase, report no.: AMR 3788-96
Potato Middlefart Denmark, 1996		0.200 ^{a)}	12	6-8	2.400 ^{a)}	14	<0.05	
Potato Bemmel Netherlands, 1996		0.183-0.209	12	7-8	2.387	14	<0.05	
Potato Gnaschwitz Germany, 1996		0.200 ^{a)}	12	5-13 ^{a)}	2.400 ^{a)}	14	<0.05	
Potato Saint-Amand Belgium, 1996		0.203-0.235	12	6-10	2.617	14	<0.05	
Potato Melbourne (Derbyshire) United Kingdom, 1996		0.204-0.225	12	6-8	2.570	14	<0.05	
Southern Europe								
Potato Calepio di Settala Italy, 1996	DPX-KX007-9 WG 30 % cymoxanil + 22.5% famoxadone	0.234-0.251	8	6-8	1.962	14	<0.05	Dubey L, Jernberg K.M, 1997a, field and analytical phase, report no.: AMR 3767-96
Potato Reyrieux S-France, 1996		0.267-0.294	6	6-8	1.655	14	<0.05	
Potato Kalikratia Greece, 1996		0.235-0.265	8	7	1.997	14	<0.05	
Potato Sernhac S-France, 1996		0.243-0.265	7	7	1.809	14	<0.05	
Potato Utrera Spain, 1996		0.221-0.259	8	6-8	1.987	14	<0.05	
Potato Ermegeira Portugal, 1996		0.244-0.258	8	7-11 ^{b)}	2.010	14	<0.05	

Conclusion

A limited number of 12 supervised outdoor residue trials on potato (6 trials each carried out in representative northern and southern Europe locations) for only one growing season (1996) were submitted by DuPont. All trials were accepted for the evaluation process. A residue of cymoxanil in/on mature potato tuber samples from all 12 residue trials was not determined at or above the LOQ (= 0.05 mg/kg).

Comments of zRMS:	Without any herbicide effect PROSIM poses an acceptable risk to succeeding crops following the proposed uses.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

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.

Summary of preliminary data: Biological activity & dose range finding

Propamocarb is a systemic fungicide with specific activity against a wide range of Oomycete species (including *Pythium spp.*, *Peronospora spp.*, *Pseudoperonospora spp.*, *Phytophthora infestans* and *Bremia spp.*), and is rapidly absorbed by leaf, stem and root tissues. Propamocarb does not cause significant phytotoxicity.

Data and information available from fungicide efficacy screening, submitted during the EU Review for Annex I inclusion of Propamocarb, are included in the DAR and are not repeated in this Supplementary dossier provided by Bayer CropScience and Arysta LifeScience.

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.

Table 3.5-4: Risk assessment for non-target plants

Test substance	Application rate (MAF)	ER ₅₀ (g/ha)	Bufferzone (m)	% spray drift	Exposure ¹ (g/ha)	TER	Trigger
lettuce							
Cymoxanil 50WP	4 x 240 g a.s./ha (2.7)	> 240 g a.s./ha	1	1.85 %	12	> 20	5
potatoes							
Cymoxanil 50WP	8 x 175 g a.s./ha (3.5)	> 240 g a.s./ha	1	1.52 %	9.3	> 26	5

¹ based on Ganzelmeier drift data.

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.

Comments of zRMS:	Without any herbicide effect PROSIM poses an acceptable risk to adjacent crops following the proposed uses.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

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.

Comments of zRMS:	No claims of selectivity or the compatibility with the integrated pest management are made and use in integrated pest management systems is not sought.
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3.5.4 Tank cleaning

Relevant information on tank cleaning is included in dRR Part B124. Please refer to this section for complete evaluation

Comments of zRMS:	Relevant information on tank cleaning are included in dRR Part B124
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3.6 Other/special studies

No other studies were conducted.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified, and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type
			2016-2017
			Efficacy
Potato			
Biochem Agrar	MAR	DE	2
SGS Group	MAR	UK	2
Zkusebni stanice Kujavy s.r.o.	MAR	CZ	1
Zkusebni stanice Rymarov s.r.o.	MAR	CZ	1
Fertico	N-E	PL	4
Anadiag	N-E	PL	2
Plant-Art Research	S-E	HU	2
Total, winter wheat			14

Appendix 1 Lists of data considered in support of the evaluation

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	Owner
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	SHA