

FINAL REGISTRATION REPORT

Part B

Section 1: Identity

Section 2: Physical and chemical properties

Section 4: Further information

Detailed summary of the risk assessment

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

(authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: October 2020

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MS Finalisation date: April 2021, March 2023

Version history

When	What
April 2021	Updated by applicant
April 2021	zRMS finalised the dRR assessment
January 2023	Updated by applicant
March 2023	The final version of RR

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Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- ~~2 years ambient shelf life study (authorisation can be granted for 1 year only)~~
- none

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name: Sharda Cropchem España S.L.
Address: Edificio Atalayas Business Center,
Carril Condomina nº 6, 12th Floor,
30006 Murcia, Spain
Phone: xxx
Fax: xxx

1.2 Producer of the plant protection product and of the active substances (KCP 1.2)

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Propamocarb

Propamocarb hydrochloride min. 920 g/kg (Regulation (EU) No. 540/2011 and SANCO/10057/2006 final 25 April 2007)
min. 970 g/kg Sharda source

1.2.3.2 Cymoxanil

Cymoxanil min. 970 g/kg (SANCO/179/08-final rev. 1 9 July 2010)
min. 990 g/kg Sharda source

Comments of zRMS:	The active ingredient sources used are approved at EU level. See Part C for details.
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1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name: Please refer to Registration Report Part A for the relevant country (or)
 Trade name: PROSIM
 Company code number: SHA 076127 A

1.4 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/L or g/kg)	FAO Limits (min – max)	Technical content* (g/L or g/kg)	Technical content** (%w/w)
Propamocarb hydrochloride	400 g/L	380 – 420 g/L (FAO limits \pm 5%)	412.37 g/L	38.77%
Cymoxanil	50 g/L	45 – 55 g/L (FAO limits \pm 10%)	50.51 g/L	4.75%

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers

** Based on the density of the formulation = 1.0636 g/mL. (Note: only applies if a liquid formulation – delete this comment if not needed)reported.

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-2: Information on Propamocarb

Type	Name/Code Number	
ISO common name	Propamocarb	Propamocarb hydrochloride
CAS No.	24579-73-5	25606-41-1
EC No.	607-406-2	247-125-9
CIPAC No.	399	399.601

Table 1.4-3: Information on Cymoxanil

Type	Name/Code Number
ISO common name	Cymoxanil
CAS No.	57966-95-7
EC No.	261-043-0
CIPAC No.	419

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

CONFIDENTIAL information is provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Suspension concentrate

[Code: SC]

1.6 Function (KCP 1.6)

Propamocarb 40% + Cymoxanil 5% SC is intended to be used as a fungicide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of grey viscous liquid with characteristic intensive acetic acid odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 390 °C. In aqueous solution, it has a pH value around 3.39. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The storage stability for 2 years study is on-going and will be provided as soon as possible. The results of the storage stability after 1-year-2-year study indicate the good stability of the product. Its technical characteristics are acceptable for a *Suspension concentrate* formulation.

The intended concentration of use is 0.625% to 1.25%.

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Neither classification or labelling are relevant for this section.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

No risk and safety phrases are relevant for this section.

Compliance with FAO specifications:

The product SHA 076127 A complies with FAO specifications.

At the time of evaluation no FAO specification was allocated for the formulation containing both a.s. propanoic acid hydrochloride and cymoxanil.

Formulation used for tests

The product used to determinate the physical, chemical and technical properties is the once cited in Part C (SHA 076127 A)

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	OPPTS 830.6302, OPPTS 830.6303 and OPPTS 830.6304	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	Grey viscous liquid with characteristic, intensive acetic acid odor	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Explosive properties (KCP 2.2.1)	EC method A.14	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	The test item does not have explosive properties.	Y	Pawel Sliwa, 2018, report No. BW-32/18 Michalec-Minch M., 2018, report No. 109/2018	In thermal sensitivity (Koenen) test no explosion occurred. In mechanical sensitivity test (shock) no explosion occurred. Accepted.
Oxidizing properties (KCP 2.2.2)	EC method A.21	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	The test item has not the oxidizing properties.	Y	Przemyslaw Grojs, 2018, report No. BC-87/18 Michalec-Minch M., 2018, report No. 109/2018	Pressure did not reach the critical value of 690 kPa. Accepted.
Flash point (KCP 2.3.1)	EC method A.9	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	The test item didn't show the typical flammability phenomena until 100°C. At 100°C the boiling of the sample was observed.	Y	Michalec-Minch M., 2018, report No. 109/2018	The test was performed with Pensky-Martens apparatus. The formulation is not flammable.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						Accepted.
Flammability (KCP 2.3.2)	-	-	Please refer to KCP 2.3.1 The test item is not flammable.	-	-	
Self-heating (KCP 2.3.3)	EC method A.15	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	Auto-ignition temperature = 390°C	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Acidity or alkalinity and pH (KCP 2.4.1)	CIPAC MT 191	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	4.53% (as H ₂ SO ₄ w/w)	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	3.39	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Viscosity (KCP 2.5.1)	PN-EN ISO 3219:2000 (CIPAC MT 192 / OECD 114)	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	At 20°C: For the shear rate 13.2 – 132 s ⁻¹ 919.47 – 192.40 mPa.s At 40°C For the shear rate 13.2 – 132 s ⁻¹ 718.53-139.10 mPa.s	Y	Michalec-Minch M., 2018, report No. 109/2018	The rotational viscometer was used. The formulation is non-Newtonian liquid. Accepted.
Surface tension (KCP 2.5.2)	EC method A.5	Propamocarb 40% + Cymoxanil 5% SC	1 g/L aqueous solution: 47.72 mN/m 12.5 mL/L aqueous solution: 42.59 mN/m	Y	Michalec-Minch M., 2018, report No. 109/2018	The ring method was used. The test was performed for the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
		(batch SCL-64932)				concentration lower than the minimum recommended conc. (0.625% v/v) and for the maximum recommended conc. (1.25% v/v). The formulation is surface-active. Accepted.
Relative density (KCP 2.6.1)	EC method A.3	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	1.0636 g/cm ³	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Bulk density (KCP 2.6.2)	-	-	Not relevant for SC formulation.			

Annex point	Method used / deviations	Test material	Findings			GLP Y/N	Reference	Acceptability / comments
Storage Stability after 14 days at 54° C (KCP 2.7.1)	CIPAC MT 46.3	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)		0 days	54°C, 14 days	Y	Michalec-Minch M., 2018, report No. 109/2018	During the storage, the temperature ranged from 54.4 to 54.8°. The tested material was stored in the HDPE bottle. See KCP 2.8.3.1 for comment on the suspensibility results and KCP 2.8.3.2 for spontaneity of dispersion results. Accepted.
			Propamocarb hydrochloride	38.8% w/w 412.63 g/L	39.2% w/w 415.73 g/L			
			Cymoxanil	4.92% w/w 52.28 g/L	4.71% w/w 49.93 g/L			
			Appearance	Grey viscous liquid with characteristic, intensive acetic acid odor	Grey viscous liquid with characteristic intensive acetic acid odor			
			pH value	3.39	3.43			
			Acidity	4.53% (as H ₂ SO ₄)	4.49% (as H ₂ SO ₄)			
			Suspensibility (2 mL/L)	93%	93%			
			Suspensibility (12.5 mL/L)	99%	99%			
			Spontanetity of dispersion	99%	100%			
			Wet sieve test	0.006%	0.008%			
			Pourability	4.70% of residue 0.25% of rinsed residue	4.83% of residue 0.23% of rinsed residue			
			Stability of packaging	No effect of formulation on the package	No changes in appearance Loss of weight 0.05% w/w			
Stability after storage for other periods and/or temperatures	-	-	Not relevant.			-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																														
(KCP 2.7.2)																																				
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Please refer to KCP 2.7.1	-	-																															
Effect of low temperatures on stability (KCP 2.7.4)	CIPAC MT 39.3	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	No changes in sample appearance; No visual separation of solid or liquid material <table border="1"> <thead> <tr> <th></th> <th>0 days</th> <th>7 d at 0°C</th> </tr> </thead> <tbody> <tr> <td>Suspensibility (2 mL/L)</td> <td>93%</td> <td>93%</td> </tr> <tr> <td>Suspensibility (12.5 mL/L)</td> <td>99%</td> <td>99%</td> </tr> <tr> <td>Wet sieve test</td> <td>0.006%</td> <td>0.006%</td> </tr> </tbody> </table>		0 days	7 d at 0°C	Suspensibility (2 mL/L)	93%	93%	Suspensibility (12.5 mL/L)	99%	99%	Wet sieve test	0.006%	0.006%	Y	Michalec-Minch M., 2018, report No. 109/2018	See KCP 2.8.3.1 for comment on the suspensibility results. Accepted.																		
	0 days	7 d at 0°C																																		
Suspensibility (2 mL/L)	93%	93%																																		
Suspensibility (12.5 mL/L)	99%	99%																																		
Wet sieve test	0.006%	0.006%																																		
Ambient temperature shelf life (KCP 2.7.5)	HPLC-UV validated method OPPTS 830.6303 OPPTS 830.6303 OPTTS 830.6304 CIPAC MT 75.3 CIPAC MT 191 EEC A.3 CIPAC MT 184 CIPAC MT 160 CIPAC MT 185 CIPAC MT 148 Technical Monograph CropLife	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	<table border="1"> <thead> <tr> <th>Test</th> <th>0 day</th> <th>6 months</th> <th>12 months</th> <th>24 months</th> </tr> </thead> <tbody> <tr> <td>a.s. content</td> <td>Propamocarb hydrochloride 38.80 w/w 412.63 g/L Cymoxanil 4.92% w/w 52.28 g/L</td> <td>Propamocarb hydrochloride 39.03% w/w 418.31 g/L Cymoxanil 4.94% w/w 52.94 g/L</td> <td>Propamocarb hydrochloride 39.15% w/w 429.26 g/L Cymoxanil 4.95% w/w 53.03 g/L</td> <td>Propamocarb hydrochloride 39.88% w/w 427.15 g/L Cymoxanil 5.09% w/w 54.50 g/L</td> </tr> <tr> <td>Appearance</td> <td>Grey viscoud liquid with characteristic intensive acetic acid odor</td> <td>Grey viscoud liquid with characteristic intensive acetic acid odor</td> <td>Grey viscoud liquid with characteristic intensive acetic acid odor</td> <td>Grey viscous liquid with characteristic intensive acetic acid odor</td> </tr> <tr> <td>pH 1% aqueous solution</td> <td>3.39</td> <td>3.39</td> <td>3.41</td> <td>3.41</td> </tr> <tr> <td>Acidity</td> <td>4.53% (as H₂SO₄)</td> <td>4.49% (as H₂SO₄)</td> <td>4.50% (as H₂SO₄)</td> <td>4.46% (as H₂SO₄)</td> </tr> <tr> <td>Relative</td> <td>1.0636 g/ml</td> <td>1.0717 g/ml</td> <td>1.0710 g/ml</td> <td>1.0710</td> </tr> </tbody> </table>	Test	0 day	6 months	12 months	24 months	a.s. content	Propamocarb hydrochloride 38.80 w/w 412.63 g/L Cymoxanil 4.92% w/w 52.28 g/L	Propamocarb hydrochloride 39.03% w/w 418.31 g/L Cymoxanil 4.94% w/w 52.94 g/L	Propamocarb hydrochloride 39.15% w/w 429.26 g/L Cymoxanil 4.95% w/w 53.03 g/L	Propamocarb hydrochloride 39.88% w/w 427.15 g/L Cymoxanil 5.09% w/w 54.50 g/L	Appearance	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscous liquid with characteristic intensive acetic acid odor	pH 1% aqueous solution	3.39	3.39	3.41	3.41	Acidity	4.53% (as H ₂ SO ₄)	4.49% (as H ₂ SO ₄)	4.50% (as H ₂ SO ₄)	4.46% (as H ₂ SO ₄)	Relative	1.0636 g/ml	1.0717 g/ml	1.0710 g/ml	1.0710	Y	Partial study report No. 1 (2019) and No. 2 (2020) M. Kurka, 2020, report No. 110/2018	The tested material was stored in the 1 litre HDPE-COEX bottles (commercial packaging). During the storage, the temperature ranged from 19.1 17.5 to 20.5 20.8°C. The change in a.s. contents were 4 3.5% (propamocarb hydrochloride) and 1.4 4.2% (cymoxanil). During storage, no significant changes in formulation
Test	0 day	6 months	12 months	24 months																																
a.s. content	Propamocarb hydrochloride 38.80 w/w 412.63 g/L Cymoxanil 4.92% w/w 52.28 g/L	Propamocarb hydrochloride 39.03% w/w 418.31 g/L Cymoxanil 4.94% w/w 52.94 g/L	Propamocarb hydrochloride 39.15% w/w 429.26 g/L Cymoxanil 4.95% w/w 53.03 g/L	Propamocarb hydrochloride 39.88% w/w 427.15 g/L Cymoxanil 5.09% w/w 54.50 g/L																																
Appearance	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscoud liquid with characteristic intensive acetic acid odor	Grey viscous liquid with characteristic intensive acetic acid odor																																
pH 1% aqueous solution	3.39	3.39	3.41	3.41																																
Acidity	4.53% (as H ₂ SO ₄)	4.49% (as H ₂ SO ₄)	4.50% (as H ₂ SO ₄)	4.46% (as H ₂ SO ₄)																																
Relative	1.0636 g/ml	1.0717 g/ml	1.0710 g/ml	1.0710																																

Annex point	Method used / deviations	Test material	Findings					GLP Y/N	Reference	Acceptability / comments
			density						properties were observed. See KCP 2.8.3.1 comment regarding suspensibility and KCP 2.8.3.2 comment regarding spontaneity of dispersion results. Accepted.	
			Suspensibility	0.2% v/v 93% 1.25% v/v 99%	0.2% v/v 93% 1.25% v/v 98%	0.2% v/v 94.5% 1.25% v/v 99.7%	0.2% v/v 94% 1.25% v/v 100%			
			Spontaneity of dispersion	99%	90%	100%	99%			
			Wet sieve test	0.006%	0.013%	0.009%	0.016%			
			Pourability	4.70% of residue 0.25% of rinsed residue	4.67% of residue 0.25% of rinsed residue	4.91% of residue 0.25% of rinsed residue	4.88% of residue 0.23% of rinsed residue			
			Stability of packaging	-	No changes in appearance of packaging was observed	No changes in appearance of packaging was observed	No changes in appearance of packaging was observed			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.					-	-	
Wettability (KCP 2.8.1)	-	-	Not relevant for SC formulation.					-	-	
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	At 2 mL/L aqueous solution: Maximum 6 mL after 1 minute and 0 mL after 12 min. At 12.5 mL/L aqueous solution: Maximum 0 mL after 1 minute					Y	Michalec-Minch M., 2018, report No. 109/2018	Standard water D was used. The test was performed for the conc. 0.2% v/v which is lower than the minimum recommended conc. (0.625% v/v) and for the

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						maximum recommended conc. (1.25% v/v). Accepted.
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	At 2 mL/L aqueous solution: 93% At 12.5 mL/L aqueous solution: 99%	Y	Michalec-Minch M., 2018, report No. 109/2018	Standard water D was used. The test was performed for the conc. 0.2% v/v which is lower than the minimum recommended conc. (0.625% v/v) and for the maximum recommended conc. (1.25% v/v). In the case of two active substances in the preparation, chemical assay is the only acceptable method for a.s. content determination but in the study the gravimetric method was used. However, as the results are well within the acceptable limits and the result of the spontaneity of dispersion test

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
						gave comparable result it is acceptable. Accepted.
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	99%	Y	Michalec-Minch M., 2018, report No. 109/2018	Standard water C was used instead of standard water D. The test conc. was 5% v/v. In the case of two active substances in the preparation, chemical assay is the only acceptable method for a.s. content determination but in the study the gravimetric method was used. However, as the result is well within the acceptable limit and the results of the suspensibility test gave comparable results it is acceptable. Accepted.
Dispersion stability (KCP 2.8.3.3)	-	-	Not relevant for a SC formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not relevant for a SC formulation.	-	-	
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Not relevant for a SC formulation.	-	-	
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	0.006 %	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Dust content (KCP 2.8.5.2.1)	-	-	Not relevant for SC formulation.	-	-	
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not relevant for SC formulation.	-	-	
Attrition (KCP 2.8.5.3)	-	-	Not relevant for SC formulation.	-	-	
Hardness and integrity (KCP 2.8.5.4)	-	-	Not relevant for SC formulation.	-	-	
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant for SC formulation.	-	-	
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant for SC formulation.	-	-	
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant for SC formulation.	-	-	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Flowability (KCP 2.8.7.1)	-	-	Not relevant for SC formulation.	-	-	
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Propamocarb 40% + Cymoxanil 5% SC (batch SCL-64932)	4.70% of residue 0.25% of rinsed residue	Y	Michalec-Minch M., 2018, report No. 109/2018	Accepted.
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant for SC formulation.	-	-	
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant.	-	-	
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant.	-	-	
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant, not used for seed treatment.	-	-	
Distribution to seed (KCP 2.10.2)	-	-	Not relevant, not used for seed treatment.	-	-	
Other/special studies (KCP 2.11)	-	-	Not relevant.	-	-	

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

Comment of zRMS:	In the accelerated stability study the formulation has been stored in the HDPE bottles and in the shelf-life study in the commercial packaging made from HDPE-COEX bottles and both packaging remained stable. Since the formulation is SC formulation, it is possible, according to the guideline of Ministry of Agriculture and Rural Development (Wytyczna w sprawie zasad zatwierdzania opakowań w środkach ochrony roślin), to extrapolate the results to other plastic packaging, therefore, the proposed commercial packs are considered acceptable.
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Table 4.1-1: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX HDPE/PA
Shape/size:	Round bottle / approx. 61 mm diameter x 138.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-2: Packaging information for 0.500 liter bottle

Type	Description
Material:	COEX HDPE/PA
Shape/size:	Round bottle / approx. 69 mm diameter x 199.8 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-3: Packaging information for 1 liter bottle

Type	Description
Material:	COEX HDPE/PA
Shape/size:	Round bottle / approx. 88.5 mm diameter x 239.5 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded

Type	Description
UN/ADR	compliant

Table 4.1-4: Packaging information for 5 liter bottle

Type	Description
Material:	COEX HDPE/PA
Shape/size:	jerrycan / approx. 136 mm x 192 mm x 285 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-5: Packaging information for 10 liter bottle

Type	Description
Material:	COEX HDPE/PA
Shape/size:	jerrycan / approx. 174 mm x 226 mm x 368 mm
Opening:	54.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-6: Packaging information for 20 liter bottle

Type	Description
Material:	Fluorinated COEX HDPE/Fluorinated
Shape/size:	jerrycan / approx. 245 mm x 294 mm x 400 mm
Opening:	55.8 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-7: Packaging information for 250 mL bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 62.5 mm diameter x 128.0 mm
Opening:	41.7 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal

Type	Description
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-8: Packaging information for 500 mL bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 69.5 mm x 188.5 mm
Opening:	54.4 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-9: Packaging information for 1 liter bottle

Type	Description
Material:	HDPE
Shape/size:	Round bottle / approx. 88.5 mm diameter x 240 mm
Opening:	42 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-10: Packaging information for 5 liter jerrycan

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 285 mm x 136 mm x 191 mm
Opening:	54.4 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-11: Packaging information for 10 liter jerrycan

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 313 mm x 192 mm x 232 mm
Opening:	47 mm inner diameter

Type	Description
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

Table 4.1-12: Packaging information for 20 liter jerrycan

Type	Description
Material:	HDPE
Shape/size:	jerrycan / approx. 387.5 mm x 240 mm x 285 mm
Opening:	47 mm inner diameter
Closure:	HDPE screw cap
Seal:	Induction heat seal
Manner of construction	extruded
UN/ADR	compliant

4.2 Effectiveness of cleaning procedures

Comment of zRMS:	The effectiveness of cleaning procedure is acceptable.
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Experience in use of plant protection products based on Propamocarb and Cymoxanil has not indicated any particular problems. Low levels of residues of PROSIM (Propamocarb 400 g/L + Cymoxanil 50 g/L, SC) in the equipment are not expected to present any particular risk to crops to be treated from a tank that has previously been used for the product.

The efficacy of cleaning of the application equipment with regard to impacts on “other” crops can be estimated on the basis of the PSD Efficacy Guideline 302 (December 2001). As worst case, the following prerequisites were considered:

Application rate:	2.5 L product/ha, (1 kg propamocarb + 0.125 kg cymoxanil/ha)
Tank volume:	2000 L
Volume remaining in spray lines and pump after spraying:	20 L
Spray volume:	200 L/ha (lowest spray volume corresponding to the maximum concentration of PROSIM in diluted spray)

Based on these prerequisites and in consideration of 3 rinses with each 500 – 1000 L of water based on good agricultural cleaning procedures, propamocarb and cymoxanil residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volume [L]	Concentration of residues		
		product [L PPP/L water]	Propamocarb [kg as/L]	Cymoxanil [kg as/L]

Tank filling: Residues after spraying:	2000 20	0.0125	5×10^{-3}	6.25×10^{-4}
1 st step: 1/10 dilution of residual spray volume: Residues after spraying:	200 20	1.25×10^{-3}	5×10^{-4}	6.25×10^{-5}
2 nd step: 20% of tank volume added: Residues after spraying:	400 20	6.25×10^{-5}	2.5×10^{-5}	3.125×10^{-6}
3 rd step: 20% of tank volume added: Residues after spraying:	400 20	3.125×10^{-6}	1.25×10^{-6}	1.563×10^{-7}
Addition of fresh spray solution: Residues in the tank filling:	2000 20	3.125×10^{-8}	1.25×10^{-8}	1.563×10^{-9}

PPP = PROSIM

Residues remaining in the last cleaning solution were calculated to be 1.25 mg/L of Propamocarb resulting in residue concentration of 12.5 µg/L Propamocarb after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 400 L/ha applied to succeeding crops, residues of 2.5 – 5 mg of Propamocarb will be applied per ha. These residue levels should not present any effect on non-target plants and may be considered as acceptable.

Residues remaining in the last cleaning solution were calculated to be 0.1563 mg/L of Cymoxanil resulting in residue concentration of 1.563 µg/L Cymoxanil after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 400 L/ha applied to succeeding crops, residues of 0.31 – 0.63 mg of Cymoxanil will be applied per ha. These residue levels should not present any effect on non-target plants and may be considered as acceptable.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 2.2.2	Przemyslaw Grojs	2018	Propamocarb 40% + Cymoxanil 5% SC Determination of oxidizing properties Institute of Industrial organic chemistry report No. BC-87/18 GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.2.1	Pawel Sliwa	2018	Propamocarb 40% + Cymoxanil 5% SC Determination of explosive properties Institute of Industrial organic chemistry report No. BW-32/18 GLP Unpublished	N	SHARDA Cropchem Limited
KCP 2.1, KCP 2.2.1, KCP 2.2.2, KCP 2.3.1, KCP 2.3.3, KCP 2.4.1, KCP 2.4.2, KCP 2.5.1, KCP 2.5.2, KCP 2.6.1, KCP 2.7.1, KCP 2.7.4, KCP 2.8.2, KCP	Marta Michalec- Minch	2018	Propamocarb 40% + Cymoxanil 5% SC Analysis of active substance content and physicochemical properties of intial preparation and preparation after accelerated storage procedure Institute of Heavy Organic Synthesis report No. 109/2018 GLP Unpublished	N	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.2, KCP 2.8.7.2					
KCP 2.7.2	Malgorzata Kurka	2018 2020	Partial Report No. 1 and No. 2 Propamocarb 40% + cymoxanil 5% SC Evaluation of stability of the product after storage in accordance with the Technical Monograph No. 17 Institute of Heavy Organic Synthesis report No. 110/2018 GLP Unpublished	N	SHARDA Cropchem Limited

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

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

A 2.1 Propamocarb

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

A 2.2 Cymoxanil

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