

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 3600 B

Product name(s): LABAMBA

Chemical active substance:

Lambda cyhalothrin, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem Limited

Submission date: February 2020, March 2022, December 2023

MS Finalisation date: 01.2021, 05.2022; 11.2022; 03.2024

Version history

When	What
02.2020	Submission date
01.2021	RMS Assessment
March 2022	Updated by applicant
05.2022	RMS Final Assessment
11.2022	Final Registration Report
12.2023	Updated by the Applicant (shelf life study)
03.2024	zRMS evaluation (shelf life study)

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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 gap:

Ambient temperature shelf life, (KCP 2.7.5) Study “on going”

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 3, 12th Floor,
30006 Murcia, Spain

xxxxx

Name: Sharda Cropchem Ltd.
Address: 2nd floor, Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India

XXXXXXXXXX

xxxxx

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

1.2.1 Producer(s) of the preparation

Name: Sharda Cropchem Ltd.
Address: 2nd floor, Prime Business Park
Dashrathlal Joshi Road
Vile Parle (West)
Mumbai – 400 056
India

Xxxxx

xxxxx

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

Name: xxx.
Address: xxx
xxx
xxx

XXXX

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

1.2.3.1 Lambda-cyhalothrin (SANCO/12282/2014 Rev 4)

Lambda-cyhalothrin min. 980 g/kg Sharda source

(min. 900 g/kg Commission Implementing Regulation (EU) 2016/146,
min 810 g/kg FAO Specification 463/TC (August 2015))

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: LABAMBA
Company code number: SHA 3600 B

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)
Lambda-cyhalothrin	100.0 g/L	90-110 g/L (± 10% of the declared content)	102.0 g/L	10.0 %

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

** Based on the density of the formulation = 1.0203 (Note: only applies if a liquid formulation – delete this comment if not needed)

Table 1.4-2: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Not relevant.	Not relevant.

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

Table 1.4-3: Information on Lambda-cyhalothrin

Type	LABAMBA/SHA 3600 B
ISO common name	Lambda-cyhalothrin
CAS No.	91465-08-6
EC No.	415-130-7
CIPAC No.	463

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: Capsule suspension

[Code: CS]

1.6 Function (KCP 1.6)

The product LABAMBA (Lambda-cyhalothrin 10 CS) is an insecticide.

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 beige liquid, with a moderate aromatic odour. The product is not explosive, has no oxidizing properties. In aqueous solution, it has a pH value around 6.42 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after heat/thaw test (18 hour freeze ($-10 \pm 2^\circ\text{C}$)/6 hour melt ($20 \pm 2^\circ\text{C}$) cycles for a total of 4 cycles and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The product is not flammable and has a flash point of 96 °C. It has a self-ignition temperature of 599.7 °C.

The shelf life of at least 2 years at ambient temperature, study is on going.

The final report will be provided as soon as available.

The stability data is available and indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/COEX.

The intended concentration of use is 0.0075% to 0.0375%.

Applicant proposes that dose rates of use of product have changed for min. 0.0075% and max 0.0375% v/v. Physico-chemical parameters tests have been performed for the lowest concentration of use of 0.0063% v/v and highest concentration of use 0.2% v/v therefore both minimum and maximum concentrations of use are covered and from the scientific point of view there is no need to produce any additional data. Moreover according to SANCO/10473/2003-rev. 5 the physico-chemical studies package is complete and sufficient for evaluation.

RMS Comments:

According to SANCO/10473/2003-rev. 5 the physico-chemical studies package is complete and sufficient for evaluation but for different concentration. But because recommended concentration is very small and similar to the first recommendation, presented studies are accepted

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 3600 B complies with FAO specifications.

Formulation used for tests

The product used to determine the physical, chemical and technical properties is the one cited in Part C (LABAMBA / SHA 3600 B).

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 OPPTS 830.6304	Lambda Cyhalothrin 10% CS	Test item color: Beige (5Y 9/1 in Munsell notation) Test item odour: moderate aromatic Physical state: liquid	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted
Explosive properties (KCP 2.2.1)	EEC A.14	Lambda Cyhalothrin 10% CS	The formulations has no explosive properties.	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13947	Accepted
Oxidizing properties (KCP 2.2.2)	EEC A.21	Lambda Cyhalothrin 10% CS	The formulation should not exhibit an oxidizing properties.	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13948	Accepted
Flash point (KCP 2.3.1)	EEC A.9 CIPAC MT 12	Lambda Cyhalothrin 10% CS	Not flammable with the mean flash point of formulation is above $96.0 \pm 0.2^{\circ}\text{C}$.	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13949	Accepted
Flammability (KCP 2.3.2)	-	-	Not relevant.	-	-	Statement accepted
Self-heating (KCP 2.3.3)	EEC A.15	Lambda Cyhalothrin 10% CS	The sample has an auto-ignition temperature of $599.7 \pm 0.5^{\circ}\text{C}$ at the ambient pressure of 684.6 mmHg.	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13954	Accepted
Acidity or alkalinity and pH (KCP 2.4.1)	-	-	Not required since the pH of test item is between 4 and 10.	-	-	Statement accepted
pH of a 1% aqueous dilution, emulsion or dispersion	CIPAC MT 75.3	Lambda Cyhalothrin 10% CS	Neat iteam pH = 5.54 ± 0.01 1% aqueous suspension pH = 6.42 ± 0.03	Y	Eurofins Advinus Limited, 2019 D. Prakash	Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
(KCP 2.4.2)					Report G13955	
Viscosity (KCP 2.5.1)	CIPAC MT 192	Lambda Cyhalothrin 10% CS	<u>At 20°C temperature:</u> at 20 rpm: 683.8 ± 0.0 mPa·s, at 30 rpm: 502.56 ± 2.31 mPa·s, at 40 rpm: 407.91 ± 3.0 mPa·s, at 30 rpm: 497.22 ± 2.31 mPa·s. at 20 rpm: 669.86 ± 3.46 mPa·s. <u>At 40°C temperature:</u> at 20 rpm: 591.87 ± 3.46 mPa·s, at 30 rpm: 443.91 ± 0.0 mPa·s, at 40 rpm: 362.92 ± 1.73 mPa·s, at 30 rpm: 439.91 ± 4.00 mPa·s. at 20 rpm: 579.88 ± 6.92 mPa·s.	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13950	Accepted RMS Comments; Taking into account the dynamic viscosity and the density, the kinematic viscosity results are from 670.1 to 355.7 mm ² / s.
Surface tension (KCP 2.5.2)	OECD 115 EEC A.5	Lambda Cyhalothrin 10% CS	<u>At 20°C:</u> test article 39 mN/m 0.2% v/v: 52 mN/m	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13951	Accepted RMS Comments: < 60 mN/m Surface active substance
Relative density (KCP 2.6.1)	OPPTS 930.7300 CIPAC MT 3 EEC A.3	Lambda Cyhalothrin 10% CS	Density at 20°C: 1.0203 ± 0.0021 g/mL Relative density at 20°C: 1.0203 ± 0.0021 g/mL	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13952	Accepted
Bulk density (KCP 2.6.2)	-	-	Not required for liquid formulation.	-	-	Statement accepted
Storage Stability after 14 days at 54° C (KCP 2.7.1)	OPPTS 630.6313 CIPAC MT 46.3.1	Lambda Cyhalothrin 10% CS	Active ingredient content Before storage: 9.45 ± 0.0 % (w/w) After storage: 9.48 ± 0.01 % (w/w) Color, odor, and physical appearance Before storage: Color: beige (5Y 9/1 in Munsell notation)	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted RMS Comments: The product is stable in the accelerated storage stability study. All obtained results are

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Odor: moderate aromatic Physical state: liquid</p> <p>After storage: Color: beige (5Y 9/1 in Munsell notation) Odor: moderate aromatic Physical state: liquid</p> <p>pH Before storage: 1% w/v pH = 6.42 ± 0.03 Neat item pH = 5.54 ± 0.01 After storage: 1% w/v pH = 6.52 ± 0.05 Neat item pH = 5.57 ± 0.03</p> <p>Pourability Before storage: Residue = $1.94 \pm 0.64\%$ Rinsed residue: $0.37 \pm 0.05\%$ After storage: Residue = $1.56 \pm 0.01\%$ Rinsed residue: $0.35 \pm 0.01\%$</p> <p>Spontaneity of dispersion Before storage: $99.96 \pm 0.07\%$ After storage: $98.82 \pm 0.03\%$</p> <p>Suspensibility Before storage: 0.0063% v/v: $96.82 \pm 0.54\%$ 0.2 % v/v: $95.48 \pm 0.13\%$ After storage: 0.0063% v/v: $83.25 \pm 0.0\%$ 0.2 % v/v: $87.76 \pm 0.0\%$</p>			<p>within the limits. The test carried out in HDPE-PA/COEX bottles and no significant change was found after storage.</p> <p>Based on accelerated storage stability study extrapolation for shelf life in Poland is 1 year.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			Wet Sieve test: Before storage: $0.022 \pm 0.003\%$ retained in sieve mesh size of $75\mu\text{m}$ After storage: $0.023 \pm 0.001\%$ retained in sieve mesh size of $75\mu\text{m}$ Corrosion characteristics There was no significant change in the weights of HDPE/COEX containers on day '0' and after 14 days of storage at $54 \pm 2^\circ\text{C}$			
Stability after storage for other periods and/or temperatures (KCP 2.7.2)	-	-	Not relevant.	-	-	Statement Accepted
Minimum content after heat stability testing (KCP 2.7.3)	-	-	Not relevant.	-	-	Statement Accepted
Effect of low temperatures on stability (KCP 2.7.4)	FAO: 7.33.5.1	Lambda Cyhalothrin 10% CS	The test item stored at 18 hour freeze ($-10 \pm 2^\circ\text{C}$)/6 hour melt ($20 \pm 2^\circ\text{C}$) cycles for a total of 4 cycles. Color, odor, and physical appearance Before storage: Color: beige (5Y 9/1 in Munsell notation) Odor: moderate aromatic Physical state: liquid After storage: Color: beige (5Y 9/1 in Munsell notation) Odor: moderate aromatic Physical state: liquid pH Before storage:	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted Comments: The product is stable in the test item stored at 18 hour freeze ($-10 \pm 2^\circ\text{C}$)/6 hour melt ($20 \pm 2^\circ\text{C}$) cycles for a total of 4 cycles. All obtained results are within the limits.

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>1% w/v pH = 6.42 ± 0.03 Neat item pH = 5.54 ± 0.01 After storage: 1% w/v pH = 6.41 ± 0.03 Neat item pH = 5.55 ± 0.01</p> <p>Pourability Before storage: Residue = $1.94 \pm 0.64\%$ Rinsed residue: $0.37 \pm 0.05\%$ After storage: Residue = $1.57 \pm 0.01\%$ Rinsed residue: $0.35 \pm 0.01\%$</p> <p>Spontaneity of dispersion Before storage: $99.96 \pm 0.07\%$ After storage: $98.80 \pm 0.01\%$</p> <p>Suspensibility Before storage: 0.0063% v/v: $96.82 \pm 0.54\%$ 0.2 % v/v: $95.48 \pm 0.13\%$ After storage: 0.0063% v/v: $83.25 \pm 0.0\%$ 0.2 % v/v: $87.84 \pm 0.13\%$</p> <p>Wet Sieve test: Before storage: $0.022 \pm 0.003\%$ retained in sieve mesh size of 75µm After storage: $0.022 \pm 0.001\%$ retained in sieve mesh size of 75µm</p>			
Ambient temperature shelf life (KCP 2.7.5)	OPPTS 830.6302 OPPTS 830.6303 OPPTS 830.6304 CIPAC MT 75.3	Lambda Cyhalothrin 10% CS	<p>Study on going.</p> <p>The test item stored in HDPE-COEX ambient temperatur (20 - 30°C) for a period of 2 years (24</p>	Y	Eurofins Advinus Limited, D. Bangera, 2022 Report No.: G13956	<p>Statement Accepted</p> <p>Temp. recorded: 25.7 – 26.8°C.</p>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
	CIPAC MT 47.3 CIPAC MT 148 CIPAC MT 184 CIPAC MT 160 CIPAC MT 185 OPPTS 830.6320 Analytical method HPLC (SANCO/3030/99 rev.4)	Batch: SCL-89123	months). Color, odor, and physical appearance <u>T0:</u> Color: beige Odor: moderate aromatic <u>After 12 months:</u> Color: beige Odor: moderate aromatic Physical state: liquid <u>After 24 months:</u> Color: beige Odor: moderate aromatic Physical state: liquid pH <u>T0:</u> 1% w/v pH = 6.42 ± 0.03 Neat item pH = 5.54 ± 0.01 <u>After 12 months:</u> 1% w/v pH = 5.71 ± 0.02 Neat item pH = 5.19 ± 0.01 <u>After 24 months:</u> 1% w/v pH = 5.17 ± 0.02 5.74 ± 0.01 Neat item pH = 5.74 ± 0.01 5.17 ± 0.02 Pourability <u>T0:</u> Residue = $1.94 \pm 0.64\%$ Rinsed residue: $0.37 \pm 0.05\%$ <u>After 12 months:</u> Residue = $1.51 \pm 0.04\%$ Rinsed residue: $0.32 \pm 0.02\%$ <u>After 24 months:</u> Residue = $1.53 \pm 0.02\%$		Eurofins Advinus Limited, 2019 D. Prakash Report G13955 (T0 results)	A.s. content increased T12: by app. 1.09% T24: by app. 2.7% All results are within the limits specified in SANCO/10473/2003-rev. 5 guidelines. Suspensibility test covers recommended conc. of use. Packaging (commercial COEX PE/PA) remained intact. Initial results (T0) were cited from the report G13955, in both studies the same batch was used. Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>Rinsed residue: $0.33 \pm 0.01\%$</p> <p>Spontaneity of dispersion (for 5% v/v)</p> <p>T0: $99.96 \pm 0.07\%$</p> <p>After 12 months: $97.56 \pm 0.16\%$</p> <p>After 24 months: $99.32 \pm 1.01\%$</p> <p>Suspensibility</p> <p>T0:</p> <p>0.0063% v/v: $96.82 \pm 0.54\%$</p> <p>0.2 % v/v: $95.48 \pm 0.13\%$</p> <p>After 12 months:</p> <p>0.0063% v/v: $96.20 \pm 0.0\%$</p> <p>0.2 % v/v: $99.70 \pm 0.13\%$</p> <p>After 24 months:</p> <p>0.0063% v/v: $97.13 \pm 0.0\%$</p> <p>0.2 % v/v: $99.80 \pm 0.58\%$</p> <p>Wet Sieve test (for 10% w/v)</p> <p>T0:</p> <p>$0.022 \pm 0.003\%$ retained in sieve mesh size of $75\mu\text{m}$</p> <p>After 12 months:</p> <p>$0.023 \pm 0.001\%$ retained in sieve mesh size of $75\mu\text{m}$</p> <p>After 24 months:</p> <p>$0.023 \pm 0.001\%$ retained in sieve mesh size of $75\mu\text{m}$</p> <p>Active ingredient content</p> <p>T0:</p> <p>$96.45 \pm 0.46\%$ g/L ($9.45 \pm 0.0\%$ w/w)</p> <p>After 12 months:</p> <p>$97.5 \pm 0.97\%$ g/L ($9.56 \pm 0.10\%$ w/w)</p> <p>After 24 months:</p> <p>$99.04 \pm 0.06\%$ g/L ($9.71 \pm 0.01\%$ w/w)</p> <p>Presistent foaming</p>			

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			<p>T0:</p> <ul style="list-style-type: none"> - Low dose (0.063 mL/L): 1 min: 4.0 mL 12 min: 2.0 mL - High dose (2mL/L): 1 min: 30 mL 12 min: 22 mL <p>After 12 months:</p> <ul style="list-style-type: none"> - Low dose (0.063 mL/L): 1 min: 4.0 mL 12 min: 2.0 mL - High dose (2mL/L): 1 min: 28 mL 12 min: 20 mL <p>After 24 months:</p> <ul style="list-style-type: none"> - Low dose (0.063 mL/L): 1 min: 2.0 mL 12 min: 2.0 mL - High dose (2mL/L): 1 min: 24 mL 12 min: 20 mL <p>Storage stability and corrosivity Non-corrosive to HDPE-COEX container, no perforation, no leakage, no discoloration and darkening.</p> <p>Weight loss: 0.00 g (container No. 1 for 1 year) 0.00 g (container No. 2 for 1 year) +0.03 g (container No. 3 for 2 year) - 0.05 g (container No. 4 for 2 year)</p>			
Shelf life in months (if less than 2 years) (KCP 2.7.6)	-	-	Not relevant.	-	-	Statement Accepted

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments																				
Wettability (KCP 2.8.1)	-	-	Not required for liquid formulation.	-	-	Statement Accepted																				
Persistence of foaming (KCP 2.8.2)	CIPAC MT 47.3	Lambda Cyhalothrin 10% CS	Low dose (0.063 mL/L) 1 min.: 4 mL 12 min.: 2 mL High dose (2mL/L) 1min.: 30 mL 12 min.: 22 mL	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted																				
Suspensibility (KCP 2.8.3.1)	CIPAC MT 184	Lambda Cyhalothrin 10% CS	0.0063% v/v: 96.82 ± 0.54% 0.2 % v/v: 95.48 ± 0.13%	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted																				
Spontaneity of dispersion (KCP 2.8.3.2)	CIPAC MT 160	Lambda Cyhalothrin 10% CS	99.96 ± 0.07%	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted																				
Dispersion stability (KCP 2.8.3.3)	-	-	Not required.	-	-	Statement Accepted																				
Degree of dissolution and dilution stability (KCP 2.8.4)	-	-	Not required.	-	-	Statement Accepted																				
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	CIPAC MT 187	Lambda Cyhalothrin 10% CS (Batch No. SCL-58261)	<table><tr><th>%</th><th>µm</th></tr><tr><td>10.00</td><td>0.723</td></tr><tr><td>20.00</td><td>1.740</td></tr><tr><td>30.00</td><td>2.567</td></tr><tr><td>40.00</td><td>3.229</td></tr><tr><td>50.00</td><td>3.876</td></tr><tr><td>60.00</td><td>4.561</td></tr><tr><td>70.00</td><td>5.413</td></tr><tr><td>80.00</td><td>6.582</td></tr><tr><td>90.00</td><td>8.691</td></tr></table>	%	µm	10.00	0.723	20.00	1.740	30.00	2.567	40.00	3.229	50.00	3.876	60.00	4.561	70.00	5.413	80.00	6.582	90.00	8.691	Y	A. Wiczorek, 2020 ICB Pharma Report No. ICB/20/2020	Accepted
%	µm																									
10.00	0.723																									
20.00	1.740																									
30.00	2.567																									
40.00	3.229																									
50.00	3.876																									
60.00	4.561																									
70.00	5.413																									
80.00	6.582																									
90.00	8.691																									

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			99.99 38.515			
Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)	-	-	Study on-going.	-	-	Statement Accepted
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Lambda Cyhalothrin 10% CS	0.022 ± 0.003% retained in sieve mesh size of 75µm	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	Accepted
Dust content (KCP 2.8.5.2.1)	-	-	Not required for liquid formulation.	-	-	Statement Accepted
Particle size of dust (KCP 2.8.5.2.2)	-	-	Not required for liquid formulation.	-	-	Statement Accepted
Attrition (KCP 2.8.5.3)	-	-	Not required for liquid formulation.	-	-	Statement Accepted
Hardness and integrity (KCP 2.8.5.4)	-	-	Not required for liquid formulation.	-	-	Statement Accepted
Emulsifiability (KCP 2.8.6.1)	-	-	Not relevant – not an emulsifiable preparation.	-	-	Statement Accepted
Emulsion stability (KCP 2.8.6.2)	-	-	Not relevant – not an emulsifiable preparation.	-	-	Statement Accepted
Re-emulsifiability (KCP 2.8.6.3)	-	-	Not relevant – not an emulsifiable preparation.	-	-	Statement Accepted
Flowability (KCP 2.8.7.1)	-	-	Not relevant – not a granular preparation.	-	-	Statement Accepted
Pourability (KCP 2.8.7.2)	CIPAC MT 148	Lambda Cyhalothrin 10% CS	Residue = 1.94 ± 0.64% Rinsed residue: 0.37 ± 0.05%	Y	Eurofins Advinus Limited, 2019 D. Prakash Report G13955	

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Dustability following accelerated storage (KCP 2.8.7.3)	-	-	Not relevant, only required for dustable powder.	-	-	Statement Accepted
Physical compatibility of tank mixes (KCP 2.9.1)	-	-	Not relevant.	-	-	Statement Accepted
Chemical compatibility of tank mixes (KCP 2.9.2)	-	-	Not relevant.	-	-	Statement Accepted
Adhesion to seeds (KCP 2.10.1)	-	-	Not relevant, not used for seed treatment.	-	-	Statement Accepted
Distribution to seed (KCP 2.10.2)	-	-	Not relevant, not used for seed treatment.	-	-	Statement Accepted
Other/special studies (KCP 2.11)	-	-	Not relevant.	-	-	Statement Accepted

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)

Table 4.1-1: Packaging information for 0.250 liter bottle

Type	Description
Material:	COEX (PE/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 (PE/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 (PE/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
UN/ADR	compliant

Table 4.1-4: Packaging information for 5 liter bottle

Type	Description
Material:	COEX (PE/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 (PE/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:	COEX (PE/PA)
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

RMS Comments:

Recommended packagings have been accepted.

4.2 Procedures for cleaning application equipment (KCP 4.4.2)

Tank cleaning

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom and nozzles three times with clean water until the foam and all traces of product have been removed.

Effectiveness of the cleaning procedures

Experience in use of plant protection products based on lambda-cyhalothrin has not indicated any particular problems. Low levels of residues of LABAMBA (Lambda-cyhalothrin 100 g/L, CS) 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: 0.15 kg product/ha, (15g lambda-cyhalothrin/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 LABAMBA 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, lambda cyhalothrin 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]	active substance [kg as/L]
Tank filling:	2000		
Residues after spraying:	20	7.5×10^{-5}	7.5×10^{-6}
1 st step: 1/10 dilution of residual spray volume:	200		
Residues after spraying:	20	7.5×10^{-6}	7.5×10^{-7}
2 nd step: 20% of tank volume added:	400		
Residues after spraying:	20	3.75×10^{-7}	3.75×10^{-8}
3 rd step: 20% of tank volume added:	400		
Residues after spraying:	20	1.875×10^{-8}	1.875×10^{-9}
Addition of fresh spray solution:	2000		
Residues in the tank filling:		1.875×10^{-10}	1.875×10^{-11}

PPP = LABAMBA as = lambda-cyhalothrin

Residues remaining in the last cleaning solution were calculated to be 0.001875 mg/L of lambda-cyhalothrin resulting in residue concentration of 0.01875 µg/L lambda-cyhalothrin after refilling the tank with 2000 L of water for another spray work. Assuming a range of spray volumes of 200 – 1000 L/ha applied to succeeding crops, residues of 3.75 – 18.75 µg lambda-cyhalothrin will be applied per ha.

A low risk was identified for non-target terrestrial plants according to EFSA Journal 2014;12(5):3677 and the effects on non-target plants was not required. Thus, any detrimental effect on plants from tank residues can be excluded.

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
KCP 2.1 KCP 2.4.2 KCP 2.7.1 KCP 2.7.4 KCP 2.8.2 KCP 2.8.3.1 KCP 2.8.3.2 KCP 2.8.5.1.2 KCP 2.8.7.2	D. Prakash	2019	Accelerated storage stability test by heating at elevated temperature Lambda cyhalothrin 10% CS, Report G13955, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.2.1	D. Prakash	2019	Determination of explosive properties of lambda-cyhalothrin 10% CS. Report G13947, 2019 GLP, Unpublished	N	Sharda Cropchem Limited
KCP 2.2.2	D. Prakash	2019	Oxidizing properties of lambda cyhalothrin 10% CS. Report G13948, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP2.3.1	D. Prakash	2019	Determination of flash point of lambda cyhalothrin 10% CS. Report G13949, 2019 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
KCP 2.3.3	D. Prakash	2019	Determination of auto ignition temperature of lambda cyhalothrin 10% CS. Report G13954, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.1	D. Prakash	2019	Determination of viscosity of lambda cyhalothrin 10% CS. Report G13950, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.5.2	D. Prakash	2019	Surface tension of aqueous solution of lambda ccyhalothrin 10% CS. Report G13951, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.6.1	D. Prakash	2019	Determination of densitty and relative density of lambda cyhalothrin 10% CS. Report G13952, 2019 GLP Unpublished	N	Sharda Cropchem Limited
KCP 2.7.5	D. Banger	2022	Two years storage stability of Lambda Cyhalothrin 10% CS 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
-	-	-	-	-	-

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 Lambda-cyhalothrin