

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 3600 B

Product name: LABAMBA

**Chemical active substance:
Lambda-cyhalothrin, 100 g/L**

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: Sharda Cropchem España S.L.

Submission date: March 2022; May 2022; December 2023

MS Finalisation date: 07/2022; 11/2022; 04/2023; 03/2024

Version history

When	What
May 2022	Applicant update
July 2022	zRMS assessment
November 2022	Assessment of the applicant's supplements
April 2023	Corrections of efficacy section according to MRiRW comments
December 2023	Updated by the Applicant (shelf life study)
March 2024	zRMS evaluation (shelf life study)

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

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

This application is for approval of LABAMBA, a capsule suspension formulation containing 100 g/L of Lambda-cyhalothrin for use as an insecticide on brassicas (cabbage, Brussels sprouts, cauliflower), tomato, winter cereals (wheat, barley, rye, oats, triticale) and winter oilseed rape in Central Europe.

zRMS: Poland

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relies on new tests and studies, providing data and information specific to the formulation LABAMBA (Lambda-cyhalothrin 10 CS) as required by the EU regulations.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 3600 B
Product name in MS	LABAMBA
Authorization number	Fisrt authorization
Function	Insecticide
Applicant	Sharda Cropchem España S.L.
Active substance(s) (incl. content)	Lambda-cyhalothrin, 100 g/L
Formulation type	CS
Packaging	0.25 L, 0.5 L, 1 L, 5 L, 10 L, 20 L COEX (HDPE/PA)

Coformulants of concern for national authorizations	-
Restrictions related to identity	-
Mandatory tank mixtures	-
Recommended tank mixtures	-

2.2 Conclusion

The evaluation of the application for LABAMBA resulted in the decision to grant the authorization.

Phys-chem section:

The evaluation of the application for Labamba resulted in the decision to grant the authorization

Shelf life – ~~1 year~~. 2 years

Recommended packaging: HDPE – PA/COEX (Point 4, Part B1-2,4) have been accepted.

Efficacy section: In Poland we can accept cauliflower and head cabbage (as minor crop -3 trials are accepted) against aphids and cauliflower against caterpillars; tomato against whiteflies (greenhouse use) and aphids (field use); winter wheat from winter cereals against aphids and winter oilseed rape against pollen beetle and **cabbage** stem weevil. In Poland without any trials (at least 1-2 are required) – brussels sprout against aphids and caterpillars and head cabbage against caterpillars can be registered only on the basis on Article 51. Use against aphids and coleseed sawfly is not accepted.

Metabolism and residues section:

~~Only use on cereals is acceptable.~~

Uses not accepted: Brussels sprouts, cauliflower

Toxicology section:

Classification: Acute Tox.4/H302; Skin Sens.1/H317. Use LABAMBA is safe for operator, worker, resident/bystander in accordance with the intended use and conditions of safe use with the indicated buffer zones for resident/bystander (adult& children). Buffer zone 2-3m.

Ecotoxicology Section:

~~Use in Brassicas is considered not acceptable.~~

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4; Skin Sens. 1; Aquatic Acute 1;
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	Aquatic Chronic 1;
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	GHS07, GHS09
Signal word:	Warning
Hazard statement(s):	H302, H317, H400, H410
Precautionary statement(s):	P261, P280, P333+P313, P362+P364, P361, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
-	-
-	-

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	<p>Brassicas , tomato (field use), winter cereals, winter oilseed rape:</p> <p>Spe3: To protect aquatic organisms respect the following an unsprayed buffer zone of 5 m to surface water bodies</p> <p>Brassicas: <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.</i></p> <p>Tomato: <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.</i></p> <p>Winter cereals <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction</i></p> <p>Winter oilseed rape <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction</i></p> <p>AND Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles OR</p>

	Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 10m with 75% drift reducing nozzles OR Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 20m with 50% drift reducing nozzles OR Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 40m
SPe8:	Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present.

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

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
P280	Work wear (arms, body and legs covered) + gloves M/L .
Worker protection:	
P280	None: for Cereals Gloves: for Brassicas, Tomato
Integrated pest management (IPM)/sustainable use:	
	e.g. The risk of resistance has to be indicated on the package and in the instructions of use. Particularly measures for an appropriate risk management have to be declared.
Environmental protection	
SPe3	Brassicas, tomato (field use), winter cereals, winter oilseed rape: <u>Brassicas:</u> <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.</i> <u>Tomato:</u> <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.</i> <u>Winter cereals</u> <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction</i> <u>Winter oilseed rape</u> <i>Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction</i>

	AND Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles OR Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 10m with 75% drift reducing nozzles OR Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 20m with 50% drift reducing nozzles OR Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 40m
SPe8:	Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present.
Other specific restrictions	
-	-

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use:	
-	-

2.5.2 Specific restrictions linked to the intended uses

Not relevant.

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): LABAMBA/Lambda cyhalothrin 10% CS
Active substance 1: Lambda cyhalothrin
Active substance 2:
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): Central,
Verified by MS: **yes**

GAP rev. 0, date: December 2021
Formulation type: CS (Capsule Suspension)
Conc. of as 1: 100 g/L
Conc. of as 2:
Conc. of safener: -
Conc. of synergist: -
Professional use:
Non professional use:

Field of use: Insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ⁽⁶⁾	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safen- er/synergist per ha ⁽⁶⁾
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Aphids	Foliar Spray	BBCH 41-43	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	3 (cabbage), 7 (Brussels sprouts, cauliflower)	B7: not accepted: Brussels sprouts, cauliflower accepted: cabbage B9 not accepted B3: Brussels sprouts, not accepted
2	CEU	Brassicas (cabbage, Brussels sprouts,	F	Caterpillars	Foliar Spray	BBCH 41-43	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	3 (cabbage), 7 (Brussels	B7: not accepted: Brussels sprouts,

		cauliflower)										sprouts; cauliflower)	cauliflower accepted: cabbage B9: not accepted B3: cabbage, Brus- sels sprouts, not accepted
3	CEU	Tomato	F	Aphids	Foliar Spray	BBCH 51-85	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	300- 1000	3	B7: not accepted
4	CEU	Tomato	G	Whitefly	Foliar Spray	BBCH 51-85	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	300- 1000	3	B7: not accepted
5	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Aphids	Foliar Spray	BBCH 41-75	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 400	28	Efficacy section no accepted this use on barley, rye, oat and triticale.
6	CEU	Winter Oilseed rape	F	Aphids	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	35	B7: not accepted B3: not accepted
7	CEU	Winter Oilseed rape	F	Coleseed sawfly	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	35	B7 B3: not accepted: not accepted
8	CEU	Winter Oilseed rape	F	Pollen beetle	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	35	B7: not accepted
9	CEU	Winter Oilseed rape	F	Stem weevil	Foliar Spray	BBCH 50-59 20-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200- 600	35	B7: not accepted In PL only CEUT- NA and BBCH 20- 32 is accepted.
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
3													
4													
Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

Remarks table heading:	<ul style="list-style-type: none"> (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008 (c) g/kg or g/l 	<ul style="list-style-type: none"> (d) Select relevant (e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1 (f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	<ul style="list-style-type: none"> 1 Numeration necessary to allow references 2 Use official codes/nomenclatures of EU Member States 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application 5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated. 	<ul style="list-style-type: none"> 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application 8 The maximum number of application possible under practical conditions of use must be provided. 9 Minimum interval (in days) between applications of the same product 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". 13 PHI - minimum pre-harvest interval 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of 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 ± 2°C)/6 hour melt (20 ± 2°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%.

3.2 Efficacy (Part B, Section 3)

Lambda 10% CS is a Capsule Suspension (CS) containing 100 g/kg lambda-cyhalothrin for use in brassicas, tomato, winter cereals and oilseed rape.

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

- Single application per season at BBCH 11-43 to control aphids and caterpillars in brassicas (cabbage, brussels sprouts, cauliflower), target rate: 0.075 L/ha.
- Single application per season at BBCH 11-85 to control aphids and whiteflies in tomato, target rate: 0.075 L/ha.
- Single application per season at BBCH 13-77 to control aphids in winter cereals (wheat, barley, rye, oats, triticale), target rate: 0.075 L/ha
- Single application per season at BBCH 13-59 to control aphids, colesseed sawfly, pollen beetle and stem weevil in oilseed rape, target rate: 0.075 L/ha.

This document serves the registration of Lambda 10% CS in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicidal efficacy Lambda 10% CS in the label claimed crops.

Comprehensive field trials were conducted in Spain, Italy, Greece, Poland, France, Germany, Czech Republic, Romania and Hungary in 2017 and 2018. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

The data demonstrate that the pest control and safety to the crop of Lambda 10% CS is comparable to that of the reference products registered in the EU Central zone, and the applicant therefore wishes to cite the original registrant's data on lambda 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.

3.3 Efficacy data

Preliminary tests

The activity of lambda-cyhalothrin is well known, as it has been marketed since 1985 to control a wide range of pests including Aphididae, Coleoptera and Lepidoptera in many crops. Furthermore, the Lambda 10% CS formulation from Sharda is already authorized for similar uses in a range of Central European countries (e.g. Germany, France, Czech Republic) in the label claimed crops. Based on the knowledge about the active substance (+30 years) and the experiences with Lambda 10% CS in the GAP claimed crops at the proposed dose rates, the necessary application rates to obtain sufficient control of the pest organism are already known. Therefore, preliminary tests in glasshouses and field trials to assess the biological activity of the active substance or dose range for the plant protection product were not deemed necessary.

Minimum effective dose tests

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).

Applicant presented following trials to support the MED (minimum effective dose):

✓ **carried out on Brassicacas against:**

- *aphids*: MAR (7 trials) and MED (9 trials) – three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N); N-E (6 trials) – two different doses were studied: 0,05 l/ha (0,67N) and 0,075 l/ha (N).
- *catepillars*: MAR (4 trials), S-E (2 trials) and MED (9 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N); N-E (6 trials) - two different doses were studied: 0,05 l/ha (0,67N) and 0,075 l/ha (N).

✓ **carried on tomato against:**

- *aphids*: N-E (6 trials) - two different doses were studied: 0,05 l/ha (0,67N) and 0,075 l/ha (N); MED (6 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).
- *whiteflies*: greenhouse use (all EPPO zones) – 21 trials - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).

✓ **performed on cereals against:**

- *aphids*: N-E (6 trials) – three different doses were used: 0,075 l/ha (0,5N), 0,10 l/ha (0,67N) and 0,15 l/ha (N).

✓ **carried on winter oilseed rape against:**

- *aphids*: MAR (5 trials) and MED (4 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).
- *coleseed sawfly*: S-E (1 trial) and MED (4 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).
- *pollen beetle*: MAR (10 trials), N-E (6 trials), S-E (3 trials) and MED (7 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).
- *stem weevil* – MAR (9 trials), N-E (6 trials), S-E (3 trial) and MED (7 trials) - three different doses were studied: 0,0375 l/ha (0,5N); 0,05 l/ha (0,67N) and 0,075 l/ha (N).

Lambda 10% applied at 0.075 L/ha to control aphids, caterpillars, whiteflies, coleseed sawfly, pollen bee-

tle and stem weevil in brassicas, tomato and winter oilseed rape and at 0.15 L/ha to control aphids in winter cereals achieved moderate to excellent control.

To ensure that a satisfactory level of control is achieved with the proposed dose rate, it is recommended that Lambda 10% is applied under optimal conditions, i.e., early growth stage of the pests and optimal weather conditions.

Concerned Member States should consider the current authorization of a reference product (a.s. lambda-cyhalotrin) in their own Member State when they are setting a minimum effective dose.

Efficacy tests and conclusions regarding authorization of intended uses

All details about efficacy methodology used during efficacy trials are presented above by Applicant. The trials were performed in Poland (North-East EPPO zone), Maritime EPPO zone (Czech Republic, North France, Germany), S-E EPPO zone (Romania, Hungary) and Mediterranean EPPO zone (Italy, Spain, Portugal, South France).

The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards (some exceptions will be described later). Studies were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized.

The number of efficacy of the product presented in this dossier in accordance with the basic number of trials defined in EPPO PP/226 should be represented by 6–15 trials. The Applicant submitted reports showing the results in research into product efficacy carried out between one growing season, which is not in line to EPPO PP 1/181(4). However, the Applicant provided an adequate explanation for conducting the study in only one growing season, which was accepted by Evaluator (ZRMS-PL). Two growing seasons (2017 and 2018) were studied only in MED EPPO zone on brassicas.

We are dealing with the active substances used commonly for many years in many countries. So, in the list of minor pests controlled should be include only those species that occurred (with appropriate intensity) a minimum in three trials, and in the case of major pests – at least in six trials.

To demonstrate the effectiveness of the tested plant protection product at the recommended dose rate against studied pest application in studied crops is compared to the reference product included in the trials.

Brassica crops:

•**against aphids** - Applicant submitted in total 22 field trials carried out in MAR: 7 trials (CZ-2, FR-4, DE-1), MED – 9 trials (ES-6, GR-3) and N-E: 6 trials (PL). Lack of trials for S-E. In the opinion of Evaluator enough number of trials were presented for MAR, N-E and MED. cMS from S-E should decide if trials from other EPPO zone can be acceptable.

According to EPPO 1/24 following pest species should be studied during efficacy trials: *Aphis fabae* (APHIFA), *Myzus persicae* (MYZUPE), *Macrosiphum euphorbiae* (MACSEU), *Aulacorthum solani* (AULASO), *Brevicoryne brassicae* (BRVCBR), *Aphis gossypii* (APHIGO), *Nasonovia ribisnigri* (NASORN), *Acyrtosiphon pisum* (ACYRON). During studies Applicant examined the relevant pests, in exception in one trial from MAR – APHDSP was studied and six trials from MED – in which APHISP (3 trials) and BRVCSP (3 trials) were studied. In Polish label APHIFA (1 trial PL), BRVCBR (5 trial PL, 2 trials CZ) and APHDSP (1 trial DE) can be included.

In the MAR two crops were studied: cauliflower - in three French trials and head cabbage in 4 trials (DE-1, CZ-2, FR-1). In N-E and MED trials only cauliflower was studied. cMS should decide which crops can be accepted on the basis on presented documentation and possibility of extrapolation results. In Poland we can accept cauliflower and head cabbage (as minor crop -3 trials are accepted). In Poland without any trials (at least 1-2 are required) – brussels sprout can be registered only on the basis on Article 51.

-MAR - the best efficacy was observed at 6-10 days and 13-15 days after treatment. Results were slightly better than st. ref product. Labamba was moderately efficient 2-3 days and 20-23 days after treatment.

Results – better than st. ref.

-N-E – Labamba was efficient 2-3 days after treatment and moderately efficient 7-9 days and 10-14 days after treatment. Results comparable to st. ref.

-MED – Labamba was efficient at all terms of assessment. Results comparable to st. ref.

Lambda 10% CS applied at the proposed dose rate of 0.075 L/ha provides a high level of control of a aphids found in brassicas.

•**against caterpillars** – Applicant submitted in total 21 field trials carried out in MAR: 4 trials (FR), MED: 9 trials (ES-6, GR-3), S-E: 2 trials (RO) and N-E: 6 trials (PL). cMS from S-E should decide if only 2 trials can be acceptable, for rest EPPO zones Applicant submitted enough number of trials.

According to EPPO 1/83 following pest species should be studied during efficacy trials: *Mamestra brassicae* (BARABR), *Pieris rapae* (PIERRA), *Pieris napi* (PIERNA), *Pieris brassicae* (PIERBR), *Plutella xylostella* (PLUTMA). During studies Applicant examined the relevant pests, in exception in one trial from MAR – ILLEPIO was studied and three trials from MED – in which ISPODG (3 trials) were studied.

In the MAR two crops were studied: head cabbage - in two French trials and sprouting broccoli in 1 trial (FR). In N-E and MED trials only cauliflower was studied. In S-E only head cabbage was studied. cMS should decide which crops can be accepted on the basis on presented documentation and possibility of extrapolation results. In Poland we can accept only cauliflower. In Poland without any trials (at least 1-2 are required) – brussels sprout and head cabbage can be registered only on the basis on Article 51. In Polish label PIERRA can be included (6 trials PL).

Labamba was characterized by effectively control of caterpillars on brassica crops in MAR, S-E and MED EPPO zone and moderately efficient at N-E EPPO zone. Results were comparable or even slightly higher than st. ref. used.

Lambda 10% CS applied at the proposed dose rate of 0.075 L/ha provides a high level of control of a aphids found in brassicas.

Tomato:

•**against aphids** – Applicant submitted enough number of trials for MED: 6 trials (ES-3, GR-3) and N-E: 6 trials (PL). Lack of trials for MAR and S-E. cMS from MAR and S-E should decide if trials from other EPPO zone can be acceptable.

According to EPPO 1/230 following pest species should be studied during efficacy trials: *Myzus persicae* (MYZUPE); *Macrosiphum euphorbiae* (MACSEU); *Aulacorthum solani* (AULASO); *Aphis nasturtii* (APHINA); *Aphis frangulae* (APHIFG). As there is no EPPO standard for aphids on tomato, the standard for potato, as a crop belonging to the same family, was used. During studies Applicant examined the relevant pests, in exception in five trials from N-E – APHISP was studied. Tests were carried out on aphids (*Aphis* sp.), but the species was not specified during efficacy trials. In our opinion, as there is no specific EPPO standard for tomato, and aphids were tested as the label says - all tests should be considered as acceptable, in the opinion of Evaluator.

cMS should decide about the possibility of acceptance the tomato on the basis on presented documentation. In Poland we can accept this use (tomato is a minor crop, so presented trials are sufficient for registration).

- N-E – 7-8 days after treatment – moderately effective against aphids on tomato and 1-3 days after treatment – limited control. Efficacy slightly lower than st. ref. product. In Polish label APHISP (5 trials) and APHIFA (1 trial) can be included.

- MED – at all terms of assessment – effective control couins of aphids and moderately effective – damins of aphids on tomato.

Lambda 10% CS applied at the proposed dose rate of 0.075 L/ha provides a high level of control of a aphids commonly found in tomato.

•**against whiteflies** – all trials (in number of 21) were carried out in glasshouse, so results can be assessed together from all EPPO zones. Glass-house trials were carried out in MAR (5 trials: FR-2 and DE-3), MED (10 trials: ES-7 and GR-3) and N-E (6 trials: PL).

According to EPPO 1/36 - Test organism: *Trialeurodes vaporariorum* (TRIAVA) Ornamental plants: *Ageratum* spp. (AGESS), *Coleus* spp. (ICXUG), *Euphorbia pulcherrima* (EPHPU), *Fuchsia* spp. (FUCHY), *Heliotropium* spp. (IHEOG), *Pelargonium grandiflorum* (PELGR). Vegetables: cucumber *Cucumis sativus* (CUMSA), tomato *Lycopersicon esculentum* (LYPES) and sweet pepper *Capsicum annuum* (CPSAN). In 10 trials relevant pest was studied – TRIAVA. In our opinion, submitted documentation is sufficient for MED, MAR, N-E and S-E (all trials were carried out in glasshouse). During 11 trials not relevant pest were studied: ALEUPR (PL-2), ALEYOC (PL-2), BEMITA (ES-7).

cMS should decide about the possibility of acceptance the tomato on the basis on presented documentation. In Poland we can accept this use (tomato is a minor crop, so presented trials are sufficient for registration).

Labamba effectively control couins and moderately effective – damins in most terms of assessment. However, Labamba 1-3 days after the treatment only limited whiteflies on tomato. Results were comparable or slightly lower than st. ref. product. **Lambda 10% CS applied at the proposed dose rate of 0.075 L/ha provides a high level of control of whiteflies commonly found in tomato.**

Winter cereals:

•**against aphids** – Applicant submitted enough number of trials only for N-E (6 trials: PL). Lack of trials for MAR, MED and S-E. cMS from MAR, MED and S-E should decide if trials from other EPPO zone can be acceptable.

According to EPPO 1/20 - test organism: non-winged stages of species e.g. *Rhopalosiphum padi* (RHOP-PA) or *Sitobion avenae* (MACSAV). Use barley *Hordeum vulgare* (HORVX) and oats *Avena sativa* (AVESA) for test preparations to control e.g. *Rhopalosiphum padi*, and wheat *Triticum aestivum* (TRZAX) to test preparations to control e.g. *Sitobion avenae*. In all trials relevant pest and crop was studied (MASCAV).

On the basis on submitted documentation it is possible to register use on winter cereals (winter wheat) against aphids in Poland. Winter barley, winter rye, winter oats and winter triticale should be excluded from label and GAP due to lack of trials. In our opinion for winter barley, winter rye, winter oats and winter triticale, the Applicant should submit at least 1-2 efficacy trials.

Labamba effectively control aphids on winter wheat in trials carried out in N-E EPPO zone. Results were comparable to st. ref. product. Lambda 10% CS applied at the proposed dose rate of 0.15 L/ha provides a high level of control of aphids commonly found in winter wheat. **Single application of Lambda 10% CS should be used to efficiently control all pests claimed on the label.** In Polish label MASCAV (6 trials PL) can be included.

Winter oilseed rape:

•**against aphids** – Applicant submitted in total 9 trials carried out in MAR: 5 trials (CZ-3, FR-2) and MED: 4 trials (IT). Lack of trials from N-E and S-E. cMS from MAR should decide if 5 trials are acceptable, and cMS from MED if 4 trials can be sufficient. In the opinion of Evaluator, on the basis on the lack of trials – registration against aphids in S-E and N-E is not possible.

In MAR relevant pest were studied during trials: BRVCBR. In MED trials – during two trials – not relevant pest was studied: *Sitobion avenae* (MASCAV).

cMS should decide about the possibility of acceptance the aphids in winter oilseed rape on the basis on presented documentation. In Poland we cannot accept this use due not enough number of trials (at least 6 trials carried out in PL or neighboring country should be submitted by Applicant).

- MAR – 2-4 days and 6-7 days after treatment – effectively control, 9-14 days after treatment – moderately efficient control. Results higher than st. ref. product.

- MED – at all assessments effectively control aphids. Results comparable or slightly higher than st. ref. product.

Lambda 10% SC applied at the proposed dose rate of 0.075 L/ha provides a high level of control aphids commonly found in winter oilseed rape.

•**against coleseed stawly** – Applicant submitted in total 5 trials carried out in MED: 4 trials (IT) and S-E: 1 trial (HU). cMS from MED should decide if 4 trials can be accepted. In the opinion of Evaluator only 1

trial or lack of trials is not accepted, so registration against colesseed stawly in MAR, N-E and S-E should not be possible.

ATALCO was studied as pest in all trials. cMS should decide about the possibility of acceptance the colesseed stawly in winter oilseed rape on the basis on presented documentation. In Poland we cannot accept this use due not enough number of trials (at least 6 trials carried out in PL or neighboring country should be submitted by Applicant).

- S-E – effective control at all assessments. Slightly lower efficiency than st. ref. product.
- MED – effective control at all assessments. Results slightly lower than st. ref. product.

Lambda 10% SC applied at the proposed dose rate of 0.075 L/ha provides a high level of control colesseed stawly commonly found in winter oilseed rape

•pollen beetle – Applicant submitted in total 23 trials carried out in MAR: 10 trials (CZ-2, FR-6, DE-2), MED: 4 trials (IT), S-E: 3 trials (HU) and N-E: 6 trials (PL). cMS from MED and S-E should decide if limited number of trials can be accepted. For MAR and N-E Applicant submitted enough number of trials.

According to EPPO 1/178 - Test organism: Rape strawberry – *Meligethes aeneus* (MELIAE). For testing, any of the following varieties of *Brassica napus napus* (BRSNN) or *B. rapa oleifera* (BRSRO). During studies Applicant examined the relevant pests (MELIAE), in exception in one trial from S-E – MELISP (1 trial) was studied. cMS should decide about the possibility of acceptance the pollen beetle in winter oilseed rape on the basis on presented documentation. In Poland we can accept this use.

- MAR – limited pollen beetle at winter oilseed crops in all terms of assessment. Results comparable to st. ref. product.
- N-E – effective control at all assessments. Results comparable or slightly lower than st. ref. product.
- MED – effective control at all assessments. Results slightly lower than st. ref. product.
- S-E – 1-2 days after treatment – limited and 4-6 days after treatment – moderately effective control pollen beetle at winter oilseed rape crops. Results slightly higher than st. ref. product.

Lambda 10% SC applied at the proposed dose rate of 0.075 L/ha provides a high level of control pollen beetle commonly found in winter oilseed rape.

•stem weevil – Applicant submitted in total 23 trials carried out in MAR: 9 trials (CZ-3, FR-4, DE-2), MED: 7 trials (IT-5, FR-2), S-E: 1 trial (HU) and N-E: 6 trials (PL). In the opinion of Evaluator, only 1 trial submitted for S-E should not be accepted by cMS. Applicant submitted sufficient number of trials for MAR, MED and N-E.

According to EPPO 1/219 - Test organisms: *Ceutorhynchus napi* (CEUTNA) (corn weevil) and *Ceutorhynchus pallidactylus* (CEUTQU) (stem weevil). Crops: *Brassica napus napus* (BRSNN) (oilseed rape). During studies Applicant examined the relevant pests, in ~~exception in two MAR trials – CEUTSP (CZ-2) was studied and~~ one MED trials – CEUTPL (IT) was studied.

cMS should decide about the possibility of acceptance the stem weevil **and its accepted species included in national labels** in winter oilseed rape on the basis on presented documentation. In Poland we can accept this use **for CEUTNA only.**

- MAR – limited stem weevil at all assessments on winter oilseed rape crops. Results slightly higher than st. re. product. **During trials following pests were studied, CEUTNA (FR-4, DE-2, CZ-1), CEUTQU (CZ-3). During one trial from CZ – simultaneously both CEUTQU and CEUTNA was studied. Crop stage at application was between 30 and 50 BBCH.**
- N-E – effective control at all assessments. Results slightly higher than st. ref. product. **During trials CEUTNA (5 trials) and CEUTQU (1 trial) was studied. Taking into account the number of studies, only CEUTNA can be registered in the Polish label, as the total of 8 trials (PL-5, CZ-1, DE-2) was submitted. For CEUTQU, insufficient number of tests has been presented - only 4 (PL-1, CZ-3) and a minimum is needed – 6 trials. Crop stage at application was between 29-32 BBCH. In Poland, the date of the first observation of this pest usually falls on the phase: 20-29 BBCH. For PL accepted application widow should be 20-32 BBCH, in accordance with the methodology of integrated production of winter rapeseed**

and conservation programs and submitted documentation. First, according to the signalling. After the harmfulness threshold is exceeded, for example, after the pests are caught in yellow dishes.

- S-E – moderately effective control at all assessments. Results slightly lower than st. ref. product. Simultaneously both pests: CEUTNA and CEUTQU was studied in one trial from HU. Crop stage at application was between 28 and 31 BBCH.

- MED – moderately effective at all assessments. Results slightly higher than st. ref. product. During trials following pests were studied: CEUTPL (IT-1 trial), CEUTNA (4-IT, FR-2 trials). Crop stage at application was between 35 and 61 BBCH.

Application window recommended in GAP (BBCH 20-59) by ZRMs was proved by trials in which studied application window was 28-60 BBCH.

Lambda 10% SC applied at the proposed dose rate of 0.075 L/ha provides a high level of control stem weevil commonly found in winter oilseed rape.

The applicant wishes to cite the original registrant's data on lambda-cyhalotrin 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 Rapporteur extrapolate from those data. However, in the opinion of Evaluator it is not possible according to Polish regulations.

Concerned Member States will need to consider the relevance of the submitted formulation comparability data in relation to the current authorized uses for the reference product (a.s. lambda-cyhalotrin) in their own Member State.

It is recommended to authorize the product LABAMBA (SHA 3600 B) in the extent of the authorization of the reference product (a.s. lambda-cyhalotrin) at the equivalent dose rate.

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

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds, fungi and molluscs. 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 insect-resistant population develops because the sensitive population is suppressed and the rare insecticide-resistant individual is allowed to 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 control. As a general principle, resistance develops at different rates depending on the pathogen type, nature of the infestation and use pattern of the insecticide.

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 insect control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, insecticide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential and/or possible resistance cases, the term resistance will be limited to situations where the conditions in both (a) and (b) below are met:

- (a) the development of resistance leads to failure of control under practical field conditions following application of an insecticide 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 insecticide sensitivity.

The phenomenon of pest resistance cannot be completely eliminated, but its negative effects can be controlled and minimised by reducing the selection pressure of plant protection products.

The resistance management for lambda-cyhalotrin is coordinated by IRAC recommendations. Applying the anti-resistance use recommendations, development of resistance can be considerably decreased or avoided. The restriction should be put on the label.

General principles against insect resistance:

- monitor the level of susceptibility of insects to plant protection products,
- apply at the recommended rates according to the label. Too low doses (sub-lethal) quickly select a population with an intermediate degree of resistance, while too high doses result in the development of a very strong degree of resistance.
- in the event of treatment failure, contact an agricultural advisor and state the reasons. Repeat the treatment with a product from a different chemical group with a different mechanism of action. If resistance in the local population is the reason for treatment failure, discontinue the use of the active substance concerned and, if possible other products with a similar mechanism of action with a similar mechanism of action.
- wherever possible, use a rotation not only of active substances active sub-stances, but above all chemical groups with different mechanisms of action.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

The crop safety of Lambda 10% CS was assessed in 119 efficacy trials (34 MAR, 42 N-E, 4 S-E, 31 MED and 8 greenhouse) where Lambda 10% CS was applied at 0.0375 L/ha to 0.15 L/ha.

The trials were conducted in Maritime EPPO zone (34 i.e. Czech Republic (10) and N-France (13)), the North-east EPPO zone (42, i.e. Poland), the South-east (4, i.e. Hungary (4)), the Mediterranean EPPO zone (31, i.e. Spain (12), Italy (12) and Greece (7)) and greenhouse (8) in 2017 and 2018 seasons, to evaluate the crop safeties of Lambda 10% CS in brassicas, tomato, winter cereals and oilseed rape.

Lambda 10% CS applied at the recommended dose rate was perfectly crop safe and did not cause phytotoxicity in any of the trials conducted on cabbage, cauliflower, tomato, winter wheat and winter oilseed rape.

As the data on cabbage, cauliflower, tomato, winter wheat and winter oilseed rape show, the crop safety and efficacy of Lambda 10% CS is equivalent to that of the lambda reference product. For recommendations claimed on the draft Lambda 10% CS label not adequately supported by the applicant's trials data, Sharda wishes to cite the original registrant's data on lambda now out of protection and requests that the evaluators extrapolate from those data.

Effects on yield and quality

Trials with quality results are not required for Lambda 10% CS. According EPPO PP 1/135 (4) Phytotoxicity assessments, Table 1 selectivity trials are not required for Insecticides. Observations for phytotoxic effects should be made in the direct efficacy (effectiveness) trials. No phytotoxicity was observed in any efficacy trial, thus no selectivity trials are required. Additionally, Table 1 indicate that yield in selectivity trials is not required for Insecticides. Data is only required for active substances on major uses where no information on effects on yield is available. Lambda cyhalothrin is a well known active substance and has been registered in Europe for more than 30 years so active substance effects are well known. As per all previous references, results for yield are not required.

Effect on transformation processes

There are no indications that the use of lambda-cyhalothrin will have influence on possible transformation processes. It is therefore expected that Lambda 10% CS, when applied in accordance with good agricultural practices will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 4 Annex Point CP 8.3) clearly demonstrate that, at the proposed application rates, no lambda-cyhalothrin nor its metabolites above the LOQ (= limit of quantification) are found in any of the tested crops. In case of undetectable residues, no special studies are required according to the EPPO guideline PP 1/243(1).

Finally, it should be noted that lambda-cyhalothrin has been used for a long time as an insecticide in the GAP claimed crops. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do lambda-cyhalothrin containing products have any label restrictions concerning their use on crops destined for processing.

According to the Technical circular 471 (December, 2015) from the British Beer & Pub association, lambda-cyhalothrin is included in the UK recommended malting and brewing list.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

Effects on succeeding crops are not to be expected, since the active lambda-cyhalothrin is degraded within the timeframe of a normal cropping season. Furthermore, lambda-cyhalothrin is not phytotoxic.

No label restrictions on succeeding crops following application of Lambda 10% CS are proposed, in accordance with current labelling of existing lambda-cyhalothrin containing products.

Impact on other plants including adjacent crops

According to EPPO PP 1/256, no data are normally required for insecticide such as Lambda 10% CS. Furthermore, lambda has been used for several years on e.g. brassicas, tomato and winter cereals, without identifying any issues.

Effects on beneficial and other non-target organisms

There were no adverse effects on beneficial and other non-target organisms observed in any of the efficacy trials conducted.

3.4 Methods of analysis (Part B, Section 5)

Analytical method for lambda-cyhalothrin in food, feed of plant origin and animal origin, soil, water and air and in the formulation LABAMBA are available.

3.4.1 Analytical method for the formulation

Methods suitable for the determination of active substances lambda-cyhalothrin in plant protection product Lambda cyhalothrin 10% CS/SHA 3600 B has been provided.

According to the SANCO/3030/99 rev.4 (the test was started in April 2019) guidance document, the analytical method for the determination of lambda-cyhalothrin in the test item Lambda cyhalothrin 10% CS

is validated and the method is acceptable.

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

none

Commodity/crop	Supported/ Not supported
High water content commodities / Brassicas (Cabbage, Brussels sprouts, cauliflower), Tomato	Supported
Dry commodities / Winter cereals (wheat, barley, rye, oats, triticale)	Supported
High oil content commodities / Winter Oilseed rape	Supported

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for LABAMBA (Lambda-cyhalothrin 10% CS) were not evaluated as part of the EU review of Lambda-cyhalothrin. Therefore, all relevant data were provided and are considered adequate.

The toxicological classification of LABAMBA(Lambda-cyhalothrin 10% CS) was calculated.

Classification: H302 (harmful if inhaled)
 H317 (May cause an allergic skin reaction)

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (calculation)	994 mg/kg bw	Yes	Acute Tox., 4, H302	Calculated
LD ₅₀ dermal, rat (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LC ₅₀ inhalation, rat (OECD 403)	>2.42 mg/L air	Yes	None	xxx., 2019
Skin irritation, rabbits (calculation)	Non-irritant	Yes	None	Calculated
Eye irritation, rabbits (calculation)	Non-irritant	Yes	None	Calculated
Skin sensitisation, guinea pigs (calculation)	Sensitising	Yes	Skin Sens. 1, H317	Calculated
Supplementary studies for	not required		-	-

combinations of plant protection products				
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3.5.2 Operator exposure

Operator exposure to LABAMBA (Lambda-cyhalothrin 10% CS) was not evaluated as part of the EU review of lambda cyhalothrin. Therefore, all relevant data and risk assessments are provided here and are considered adequate.

According to the AOEM model, calculations, it can be concluded that the risk for the operator using LABAMBA is acceptable for Brassicas, Tomato, Oilseed rape, Cereals with the use of gloves and work wear during mixing/loading using tractor mounted boom spray application outdoors

Implication for labelling: P280: Wear protective gloves/protective clothing.

3.5.3 Worker exposure

Worker exposure to LABAMBA (Lambda-cyhalothrin 10% CS) was not evaluated as part of the EU review of lambda cyhalothrin. Therefore, all relevant data and risk assessments have been provided and are considered adequate.

It is concluded that there is no unacceptable risk anticipated for the worker wearing with Work wear (arms, body and legs covered) + gloves for maintenance activities when for re-entering stone lambda cyhalothrin 10% CS

Implication for labelling: P280: Wear protective gloves/clothing

3.5.4 Bystander and resident exposure

Bystander and resident exposures to LABAMBA (Lambda-cyhalothrin 10% CS) was not evaluated as part of the EU review of lambda cyhalothrin. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Calculations were made using the AOEM model.

It can be concluded that there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to LABAMBA (Lambda-cyhalothrin 10% CS). **Bufor zone 2-3m.**

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

The preparation LABAMBA is composed of lambda-cyhalothrin.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Lambda cyhalothrin					
ADI	<i>EFSA Journal</i> 2014;12(5):3677	2014	0.0025 mg/kg bw/d	Multigeneration study in rat	200
ARfD	<i>EFSA Journal</i> 2014;12(5):3677	2014	0.005 mg/kg bw/d	1-year study in dogs	100

3.6.1 Residues

Stability of Residues

No new data submitted in the framework of this application.

Residues of Lambda cyhalothrin in high water, high starch, high oil content products are stable for 26 months. The animal product residues are stable for 3 months.

Metabolism in plant and animal

The metabolism in plant and animal was assessed for annex 1 inclusion (approval) of the active substance. The data evaluated is sufficient to support the proposed uses.

Sharda has submitted a letter of access to Green M, 2012 study (Lambda-cyhalothrin – The metabolism of [14C]- Lambda-cyhalothrin in Lactating Goat, Syngenta, File No PP321 11503)

The residue definitions agreed for monitoring and risk assessment

Plant and animal residue definition for monitoring (Regulation (EU) 2021/590)

Lambda cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)

Plant and animal residue definition for risk assessment (EFSA 2014, 2015, 2020):

Lambda-cyhalothrin (includes gamma-cyhalothrin) (sum of R,S and S,R isomers)

The data evaluated are sufficient to support the proposed uses.

No further data are required.

Magnitude of residues in plants

Flowering brassica (cauliflower)

Head brassica (brussels sprouts, cabbage)

Proposed uses:

1 application, BBCH 11-43, 0.0075 kg as/ha, PHI: 3 (cabbage), 7 (Brussels sprouts, cauliflower) days

Cauliflower and cabbage are a major crops in northern Europe. A minimum of eight trials of each is required.

No new residue trials were performed. Applicant refers to data of active substance.

One trial on cauliflower and four trials on cabbage are available.

There are insufficient trials to support the proposed uses. Additionally trials on cauliflower and cabbage are required.

Additional data provided by the applicant (September 2022).

- Cauliflower

One decline and one magnitude of residues trials were carried out on the open field in Poland in 2021.

Trials GAP: 2 x 7.5 g as/ha, BBCH 45, PHI 7d, outdoor

Residues: 2x < 0.01 mg/kg

Overall supporting data for cGAP (cauliflower):

Two trials carried out on the open field in Poland more critical trials than proposed uses (2 applications versus to 1 applications). The study can be accepted as the worst case because the residues are below LOQ.

Additionally, the applicant refers to one overdosed trial on cauliflower (DAR 1996, 4 x 10-15 g as/ha). Cauliflower was not assessed during the revision of the active substance assessment. Too little information is available to conclude on the acceptability of this study.

Use is not accepted. Data gap: one trial on cauliflower.

- Head brassica (brussels sprouts, cabbage)

8 new trials on head cabbage were provided by the applicant (Poland, Hungary, Germany).

Trials GAP: 2 x 7.5 g as/ha, BBCH 45, PHI 3d, outdoor

Trials are more critical than proposed uses (2 applications *versus* to 1 applications). The trials can be accepted as the worst case because the residues are below LOQ.

The trials from study KCP 8.3.19 (Poland) are not independent – the same localisation and dates like in the study KCP 8.3.15. These trials (KCP 8.3.19) are not considered in the assessment.

Trial CPRHU21-205-065IR/Hungary/N-EU/2021 and trial CPRHU21-210-065IR/Hungary/N-EU/2021, Kőszeg, Zip code: 97-30 are not independent. Trial CPRHU21-205-065IR/Hungary/N-EU/2021 is not considered in the assessment (KCP 8.3.21).

Acceptable residues: 5 x <0.01 mg/kg

Sufficient number of trials are available to support the proposed use on cabbage (residues <LOQ).

According to SANTE/2019/12752 extrapolation from cabbage to brussels sprouts is not possible. Use on brussels sprouts is not acceptable.

Tomato (indoor, outdoor)

Proposed uses:

1 application, BBCH 51-81, 0.0075 kg as/ha, PHI: 3

Tomato is a major crop in northern Europe. A minimum of eight trials for indoor uses and 8 for outdoor uses is required.

6 overdosed indoor trials are available. Uses are not accepted.

Additional data provided by the applicant (September 2022).

New trials were provided by the applicant.

Trials GAP: 2 x 20 g as/ha, BBCH 85, PHI 3d, outdoor.

KCP 8.3.29 - Trial 21SGS46-01/Poland/N-EU/2021, Kaczkowo ((Kujawsko-Pomorskie), Zip code:88-400 is not consider in the assessment as not independent to trial 21SGS50-01/Poland/N-EU/2021,

Study KCP 8.3.31 is not considered in the assessment as not independent to study KCP 8.3.27.

Acceptable residues:

KCP 8.3.25: <0.01, 0.02 mg/kg – open field

KCP 8.3.27: 2x<0.01 mg/kg - open field

KCP 8.3.29: <0.01 mg/kg - open field

KCP 8.3.31: - open field

KCP 8.3.33: 0.02, 0.03 mg/kg – protected

KCP 8.3.35: 2x<0.01 mg/kg - protected

Summary (outdoor): 4x<0.01, 0.02 mg/kg

Summary (protected): 2x<0.01, 0.02, 0.03 mg/kg

Additionally residues in tomatoes were assessed in the RAR.

Trials GAP (RAR, field N-EU): 2 applications at 12.5 g as/ha, BBCH 10-89, PHI: 3 days

Trials GAP (RAR, G): 2 applications at 25 g as/ha, BBCH 10-89, PHI: 3 days

These trials were performed at a more critical application rate than those intended in this dossier.

Residues (RAR, field N-EU): $8 \times < 0.01$ mg/kg

Residues (RAR, G): $4 \times < 0.01$, 2×0.01 , 4×0.02 , 2×0.03 , 0.04 mg/kg

Sufficient number of trials are available to support the proposed use on outdoor tomato. Use is acceptable.

Sufficient number of trials are available to support the proposed use on indoor tomato. Use is acceptable.

Winter cereals (wheat, barley, rye, oats, triticale)

Proposed use:

1 application, BBCH 41-75, 0.0075 kg as/ha, PHI: 28 days

Applicant refers to unprotected data from DAR and new studies.

Wheat

EFSA, 2014; Sweden 2013: N-EU GAP on which MRL/EU a.s. assessment is based: 2×7.5 ; 2×15 g as/ha, outdoor

Residues: $4 \times < 0.01$ mg/kg

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based: 3×10 g as/ha, , outdoor

Residues: $3 \times < 0.01$ mg/kg

New trials: N-EU Trials GAP: 2×7.5 g as/ha, BBCH: 82-87, PHI 28-29d, outdoor

Residues: $2 \times < 0.01$ mg/kg

Barley

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based: 3×10 g as/ha,

Residues: $4 \times < 0.01$, 3×0.02 mg/kg

New trials: N-EU Trials GAP: 2×7.5 g as/ha, BBCH: 73, PHI 28d

Residues: $1 \times < 0.01$ mg/kg.

Oats

DAR 1996: N-EU GAP on which MRL/EU a.s. assessment is based: 3×10 g as/ha,

Residues: $4 \times < 0.01$ mg/kg

Presented trials are not in line with proposed used (they are overdosed). The available trials were performed with 2 applications at 7.5, 10 and 15 g a.s./ha instead of 1 applications at 7.5 g a.s./ha. Nevertheless, the studies are acceptable to cover the proposed use due to residues below LOQ except for 3 tests with the results of 0.02 mg/kg. Application times in all studies are consistent with proposed GAP.

According to the available data, the intended uses on cereals are considered acceptable. The new studies are accepted.

Winter Oilseed rape

Oilseed rape

Proposed uses:

1 application, BBCH 50-59, 0.0075 kg as/ha, PHI: 35 days

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

The object of this study was to determine the magnitude and decline of residues of lambda-

CYHALOTHRIN in Oilseed rape resulting from three foliar applications at the maximum anticipated labelled rate of lambda-CYHALOTHRIN 2.5% WG (0.0075 kg as/ha).

Residues: $2 \times < 0.01$ mg/kg

The GAP of trials is more critical than proposed uses (3 applications *versus* to 1 applications; growth stage at last treatment are later than proposed). The study can be accepted as the worst case because the residues are below LOQ.

Additionally one residue trial on oilseed rape from Northern Europe is available (2 x 5 g as/ha). This trial can only support GAP with application rate of 0.005 kg as/ha.

Conclusion

A number of trials on oilseed rape can be considered as insufficient (only two accepted trials).

Additional one trial is required as residues were <LOQ in the two accepted trials with non-systemic profile of the active substance.

Use is not accepted.

Additional data provided by the applicant (September 2022).

One decline trial was carried out on the open field in Czech Republic in 2021.

Residues: < 0.01 mg/kg

and

One trial was carried out on the open field in Poland in 2021.

Residues: < 0.01 mg/kg

The GAP of trials (GAP: 3 x 7.5 g as/ha, PHI 35d) is more critical than proposed uses (3 applications *versus* to 1 applications; growth stage at last treatment are later than proposed). The studies can be accepted as the worst case because the residues are below LOQ.

A number of available trials on oilseed rape can be considered as sufficient. Use is accepted.

Magnitude of residues in livestock

There is no risk for animal MRL to be exceeded

Magnitude of residues in processed commodities

Additional data is not required.

Magnitude of residues in representative succeeding crops

EFSA Journal 2019;17(1):5546: *This conclusion was confirmed by rotational crop field trials conducted at a total dose rate of 500 g/ha which resulted in residues of lambda-cyhalothrin and compound Ia below the LOQ in the edible parts at 30 and 60 day plant-back intervals (EFSA, 2014b)*

No residues of lambda-cyhalothrin are expected in rotational crops, provided that the active substance is applied according to the accepted uses. No risk mitigation measures are required.

Noticed data gaps are:

- one residue trial on cauliflower and residue trials on Brussels sprouts are required.

3.6.2 Consumer exposure

The accepted uses of lambda-cyhalothrin in the formulation SHA 3600 B do not represent unacceptable acute and chronic risks for the consumer.

TMDI (% ADI) according to EFSA PRIMo	277 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	82% % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	<p>Unprocessed commodities:</p> <p>-results for children Cauliflowers: 81% Head cabbages: 80% Tomatoes: 56% Strawberries: 20% Barley: 10% Brussels sprouts: 3% Wheat: 3% Oat: 2% Rye: 1% Rapeseeds/canola seeds: 0.3%</p> <p>-results for adults Head cabbages: 76% Cauliflowers: 32% Tomatoes: 16% Strawberries: 11% Barley: 9% Brussels sprouts: 2% Wheat: 2% Oat: 1% Rye: 1% Rapeseeds/canola seeds: 0.1%</p> <p>Processed commodities:</p> <p>-results for children Cauliflowers/boiled: 97% Tomatoes/juice: 8% Oat/boiled: 7% Barley/cooked: 7% Oat/milling(flakes): 5% Brussels sprouts/boiled: 4% Tomatoes/sauce/puree: 4% Head cabbages/canned: 3% Barley/milling (flour): 3% Wheat/milling (flour): 2% Wheat/milling (wholemeal)-baking: 1% Rye/boiled: 0.7% Rye/milling (wholemeal)-baking: 0.7% Rapeseeds/oils: 0.1%</p> <p>-results for adults Cauliflowers/boiled: 58% Barley/beer: 13% Head cabbages/canned: 6% Tomatoes/sauce/puree: 3% Oat/boiled: 3% Barley/cooked: 7% Wheat/bread/pizza: 0.9% Wheat/pasta: 0.8% Wheat/bread: 0.7%</p>
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

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

Concentrations of LABAMBA in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, sur-face water, sediment, groundwater and air are provided.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC_{soil} calculations have been conducted with lambda-cyhalothrin and its relevant metabolites using the endpoints in the EFSA conclusions of lambda-cyhalothrin (EFSA Journal 2014;12(5):3677).

Maximum PEC_{soil} for lambda-cyhalothrin was **0.003mg/kg** following single application on brassicas (as worst case). PEC_{soil} calculated for brassicas covered other uses presented in GAP.

PEC_{soil} values for the metabolites were determined as if it was parent compound with an application rate corrected taking into account the molecular weights (MW) and the maximum occurrence of the metabolite in soil.

Maximum PEC_s for the metabolites are following:

- for metabolite Ia: <0.001 mg/kg
- for metabolite V (PBA): <0.003 mg/kg
- for metabolite XV: <0.001 mg/kg

Maximum PEC_s for the product LABAMBA was 0.031 mg/kg following 1 applications at 0.075 L/ha (equivalent to 76.52 g/ha) on brassicas.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

The PEC_{GW} of LABAMBA in groundwater has been assessed with the models FOCUS PELMO v6.6.4 and FOCUS Pearl v5.5.5, the interception values and the DT₅₀ and the soil sorption values established in the EU review.

PEC_{GW} for the active ingredient lambda-cyhalothrin and its metabolites Ia, V (PBA) and XV were calculated.

The PEC_{GW} for lambda-cyhalothrin and its metabolites were lower than 0.1µg/L for all scenarios and crops.

The calculations performed for using in field cover all proposed uses in permanent greenhouse (according to EU Regulation 1107/2009).

The use of LABAMDA doesn't pose any risk for ground water and no relevant assessment for metabolites according to SANCO/221/2000 –rev.11 is necessary

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The PEC_{sw/sed} of Lambda-cyhalothrin 10 % CS has been assessed with the models FOCUS step 1/2, FOCUS SWASH, FOCUS PRZM, FOCUS MACRO, FOCUS TOXSWA and SWAN. the DT₅₀ and the soil sorption values established in the EU review.

PEC_{SW/SED} calculations have been done for lambda-cyhalothrin and its metabolites Ia, V (PBA) and XV at Step 1&2 for all crops.

Furthermore, PEC_{SW/SED} calculations have been performed at step 3 for lambda-cyhalothrin and it's metabolite XV for all crops.

Further PEC_{SW/SED} calculations considering risk mitigation measures has been conducted for lambda-cyhalothrin in all crops.

Please refer to dRR Part B, Section 8, Chapter 8.9 for more details about the results obtained.

The scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for leafy vegetables 1st.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

The vapour pressure at 20 °C of the active substance Lambda cyhalothrin is < 10⁻⁵ Pa. Hence the active substance Lambda cyhalothrin is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Lambda cyhalothrin due to volatilization with subsequent deposition should not be considered.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

No unacceptable risks for birds were identified for an application of LABAMBA in respect of the GAP. No acute risk for mammals is expected after the application of SHA 3600 B/LABAMBA. However, after Tier I assessment, long-term risk for mammals was observed for vole and lagomorph in brassicas and oilseed rape, for vole in winter cereals and for rat and vole in tomato.

Based on higher-tier assessment the long-term risk assessment for vole for brassicas **was considered acceptable.** ~~needs further refinement.~~

3.8.2 Effects on aquatic species

After Step1/2 calculations a risk for all aquatic organisms except algae was determined for lambda cyhalothrin and for metabolite XV in all crops (except sediment organisms).

After Step 3 calculations, metabolite XV was shown to present no unacceptable risk to aquatic and sediment dwelling organisms, whereas lambda-cyhalothrin still presented a risk for aquatic organisms.

After application of mitigation and step 4 calculations it has been shown to present no unacceptable acute and chronic risk to sediment dwelling organisms and for aquatic organisms.

The risk for aquatic organism is acceptable when the following risk mitigation measures are considered for: Brassicas, tomato field, winter cereals, winter oilseed rape:

Spe3- to protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Brassicas:

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.

Tomato:

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.

Winter cereals

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction

Winter oilseed rape

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction

3.8.3 Effects on bees

Hazard quotients showed that no acute oral risk to bees is expected, whereas acute contact risk to bees is expected after the application of Lambda cyhalothrin 10CS.

Peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin in EFSA Journal 2014;12(5):367717 in 5/9 FOCUS scenarios for the use on honey bees, oral and contact hazard quotients (HQ_{oral} and $HQ_{contact}$) were calculated using the available toxicity data with the active substance and three of the four representative formulations ('Lambda-Cyhalothrin 100 CS', 'Karate 10CS' and 'Lambda 50 EC').

The calculated $HQ_{contact}$ values indicated a high risk from the active substance for all representative field

uses, whilst the HQ_{oral} values for the active substance were all less than the trigger value indicating a low risk.

Honey bee semi-field (tunnel study) and field studies were available with two of the four representative formulations ('Karate 10CS' (or similar formulation) and 'Lambda-Cyhalothrin 100 CS') on flowering Phacelia tanacetifolia or oilseed rape. Adult honey bee mortality was observed in the tunnel study performed with 'Lambda-Cyhalothrin 100 CS' but the magnitude and the duration of this effect was considered not relevant. The study included detailed bee brood assessments and no clear adverse effect was observed. Some effects on mortality were also observed in the field studies performed with the representative formulation 'Karate 10CS' (and similar formulation). On the basis of these studies, overall, a low risk to honey bees was concluded for the representative uses in spring and winter cereals (Northern and Southern Europe), potatoes and seed potatoes (Northern and Southern Europe) and field tomatoes (Northern and Southern Europe).

It should be noted that, due to the variation in toxicity observed in the available acute studies, the experts at the Pesticides Peer Review Experts' Meeting 107 did not consider appropriate to read-across the available higher tier data between the different formulations. Therefore, whilst a low risk to bees was concluded for the representative field uses of lambda-cyhalothrin, further consideration of the risk posed by the plant protection products is required. In addition, it was not considered appropriate to extrapolate the studies performed on flowering Phacelia tanacetifolia and oilseed rape to crops other than field crops.

A low risk to honey bees was concluded for the representative uses in glasshouse tomatoes. No assessment of the risk to pollinators which may be used in glasshouses was available.

For formulation SHA 3600 B/LABAMBA, HQ values were below 50, indicating acceptable risk for bees.

The acute risk for bees for the a.s. – lambda cyhalothrin is unacceptable but several semi-field studies are available and they are considered sufficient to conclude an acceptable risk for bees with the following mitigations measure:

SPe8: Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present.

3.8.4 Effects on other arthropod species other than bees

The results of the risk assessment showed unacceptable in-field risk after the application of SHA 3600 B/LABAMBA according to the GAP. The off-field risk is acceptable when the following risk mitigation measures are considered for:

- Brassicas, tomato (field), winter cereals and winter oilseed rape:

Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles or an unsprayed buffer zone of 10m with 75% drift reducing nozzles or an unsprayed buffer zone of 20m with 50% drift reducing nozzles or an unsprayed buffer zone of 40m.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworm and soil macro and microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna).

To achieve a concise risk assessment, the risk envelope approach is applied. The assessment for the use group Brassicas also covers the risk for the soil microorganisms from all other intended uses in groups (see **Błąd! Nie można odnaleźć źródła odwołania.**). The risk is considered acceptable for all soil organism.

3.8.6 Effects on non-target terrestrial plants

No risk for non-target terrestrial plants is expected after the application of LABAMBA as the trigger value was above 5.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not required.

3.9 Relevance of metabolites (Part B, Section 10)

The PEC_{gw} of all metabolites were lower than 0.1 µg/L, please for details see dRR Part B8 chapter 8.8.

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

LABAMBA contains lambda-cyhalothrin (100 g/L) which is approved as a candidate for substitution because low ADI / ARfD / AOEL, two PBT criteria.

As conclusion of this comparative assessment, the plant protection product LABAMBA is not suitable for substitution.

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

Section Ecotoxicology: Further refinement is required for vole for use in Brassicas.

Copy of the product authorization

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

Appendix 1 Copy of the product label

Fizykochemia: okres ważności – 2 lata

Metabolizm i pozostałości: Akceptowalne zastosowanie środka: tylko w ochronie zbóż.

Brak zgody na zastosowanie w ochronie kalafiora i brukselki. Brak restrykcji dla upraw następczych nawet w przypadku wcześniejszej likwidacji plantacji.

Skuteczność: z uwagi na ocenę innych sekcji, w etykiecie produktu pozostawiono tylko zastosowanie na pszenicy ozimej przeciwko mszycy zbożowej, a zastosowanie na kalafiorze i kapuście głowiastej, pomidorze, rzepaku ozimym – zostało wykreślone.

Brak zgody na zastosowanie przeciw mszycom i gnatarzowi rzepakowemu na rzepaku; mszycom na brukselce; gąsienicom na kapuście i brukselce; mszycom na jęczmieniu ozimym, życie ozimym, owsie ozimym, pszenżycie ozimym. Zgoda na zastosowanie na rzepaku ozimym przeciw słodyszkowi rzepakowemu oraz chowaczowi czterozębemu brukwiaczkowi (w fazie BBCH 20-32), pszenicy ozimej przeciw mszycy zbożowej, pomidorze w warunkach szklarniowych przeciwko mączlikom i w warunkach polowych przeciwko mszycy (w tym mszycy burakowej); mszycom (np. burakowej, kapuścianej) na kapuście i kalafiorze oraz gąsienicom na kalafiorze. Brukselka (mszyce i gąsienice) oraz kapusta (gąsienice) może być tylko zaakceptowana jako uprawa małoobszarowa w trybie Artykułu 51.

Ekotoksykologia: Wszystkie proponowane w GAP zastosowanie zostały zaakceptowane.

Załącznik do zezwolenia MRiRW nr R -/..... z dnia2022

Posiadacz zezwolenia:

Sharda Cropchem España S.L., Edificio Atalaya Business Center, Carril Condomina nº6, Planta 12, 30006, Murcia, Hiszpania, tel.: +34 868 12 75 89

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: +48 17 240 13 07, e-mail: eu.sales@shardaintl.com.

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin:

.....

LABAMBA

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

Lambda-cyhalotryna (substancja z grupy pyretroidów) - **100 g/l** (9.80 %)

Grupa IRAC 3A

Zezwolenie MRiRW nr R- /2020 z dnia . .2022 r.

	
UWAGA	
H302 H317 H410	Działa szkodliwie po połknięciu. Może powodować reakcję alergiczną skóry. Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska należy postępować zgodnie z instrukcją użycia.
P261 P273 P280	Unikać wdychania mgły, rozpylonej cieczy, par. Unikać uwolnienia do środowiska. Stosować ochronę oczu, ochronę twarzy, odzież ochronną, rękawice ochronne.
P333+P313	W przypadku wystąpienia podrażnienia skóry lub wysypki: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
P362+P364	Zanieczyszczoną odzież z zdjąć i wyprać przed ponownym użyciem.
P391	Zebrać wyciek.
P501	Zawartość/pojemnik usuwać do specjalny punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi

OPIS DZIAŁANIA

INSEKTYCYD w formie zawiesiny kapsuł w cieczy do rozcieńczania wodą (CS), o działaniu kontaktowym i żołądkowym, przeznaczony do zwalczania szkodników gryzących i ssących w roślinach kapustnych (kapusta głowiasta, brukselka, kalafior), zbożach ozimych (pszenica ozima, jęczmień ozimy, żyto ozime, pszenżyto ozime, owies ozimy), uprawach truskawek, pomidorów i rzepaku ozimego. Na roślinach działa powierzchniowo.

Zgodnie z klasyfikacją IRAC substancja czynna lambda-cyhalotryna zaliczana jest do grupy 3A.

STOSOWANIE ŚRODKA

Środek przeznaczony do stosowania przy użyciu samobieżnych lub ciągnikowych opryskiwaczy polowych.

Rośliny kapustne (kapusta głowiasta, brukselka, kalafior)

Mszyce (np. burakowa, kapuściana) – średni stopień zwalczania, gąsienice

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0,075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Zabieg wykonać po wystąpieniu szkodników lub po zauważeniu pierwszych objawów żerowania (BBCH 41-43)

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pomidory (zastosowanie polowe)

Mszyce (w tym mszyca burakowa – średni poziom zwalczania)

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0,075 l/ha

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0,075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Środek stosować w okresie pojawienia się szkodnika, od początku rozwoju kwiatostanu do fazy, w której 50% owoców uzyska typową barwę (BBCH 51-85)

Zalecana ilość wody: 300-1000 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pomidory (zastosowanie szklarniowe)

mączlik (średni stopień zwalczania)

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0,075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Środek stosować w okresie pojawienia się szkodnika, od początku rozwoju kwiatostanu do fazy, w której 50% owoców uzyska typową barwę (BBCH 51-85)

Zalecana ilość wody: 300-1000 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Pszenvica ozima, jęczmień ozimy, żyto ozime, owies ozimy, pszenżyto ozime

~~Mszycy~~ *mszyca zbożowa* (dobry poziom zwalczania)

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0,075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Środek zastosować po wystąpieniu szkodnika, Od fazy początku grubienia (nabrzmiwania) pochwy liściowej liścia flagowego - wczesna faza rozwoju kłosa do fazy pełnej dojrzałości młecznej ziarniaków (BBCH 41 – 75)

Zalecana ilość wody: 200-400 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Rzepak ozimy

~~Mszycy~~ ~~chowacz czterozębny~~ (dobry poziom zwalczania); *gnatarz rzepakowiec*, *Ślodyszek rzepakowy* (dobry poziom zwalczania)

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0.075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Środek zastosować w momencie nalotu szkodnika na plantację, zgodnie z sygnalizacją, od fazy początku rozwoju pąków kwiatowych (pąkowania) do fazy żółtego pąka (BBCH 50-59)

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

chowacz brukwiaczek (dobry poziom zwalczania)

Zalecana/maksymalna dawka dla jednorazowego zastosowania: 0.075 l/ha

Liczba zabiegów: 1

Termin stosowania środka: Środek zastosować w momencie nalotu szkodnika na plantację, zgodnie z sygnalizacją, od zakończenia wzrostu roślin i tworzenia nowych liści (BBCH 20) do początku wydłużania pędu głównego (BBCH 32)

Zalecana ilość wody: 200-600 l/ha.

Zalecane opryskiwanie: średniokropliste

Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1

Zabieg wykonać opryskiwaczem wyposażonym w rozpylacze antyznoszeniowe. Belka połowa opryskiwacza winna być nisko zawieszona.

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):

Kapusta głowiasta – 3 dni

Pomidory – 3 dni

Brukselka, kalafior – 7 dni

Zboża ozime – 28 dni

Rzepak ozimy – 35 dni

1. W ramach strategii antyodpornościowej rekomenduje się stosowanie środków zawierających lambda-cyhalotrynę:
 - tylko w dawkach /stężeniach zalecanych, zgodnie z etykietą,
 - przemiennie ze środkami owadobójczymi, zawierającymi substancje czynne należące do innych grup chemicznych, o odmiennym mechanizmie działania,
 - w momencie przekroczenia przez szkodnika progu ekonomicznej szkodliwości.
2. Zaprzestać stosowania środków zawierających lambda-cyhalotrynę w przypadku potwierdzenia odporności w populacji zwalczanego gatunku szkodnika.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Ciecz użytkową przygotować bezpośrednio przed zastosowaniem.

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

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

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej oraz wodę użytą do mycia aparatury należy:

- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

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

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

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

Zachować strefę buforową 2-3m

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

Unikać niezgodnego z przeznaczeniem uwalniania do środowiska.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej od zbiorników i cieków wodnych o szerokości 5-20 metrów wraz z użyciem końcówek rozpylaczy redukujących znoszenie o 90% lub zastosowanie strefy ochronnej o szerokości 50 metrów w tym zadarnionej o szerokości 20 metrów wraz z użyciem końcówek rozpylaczy redukujących znoszenie o 75%, w uprawie kapusty głowiastej, brukselki, kalafiora

W celu ochrony organizmów wodnych konieczne jest wyznaczenie zadarnionej strefy ochronnej od zbiorników i cieków wodnych o szerokości 20 metrów wraz z użyciem końcówek rozpylaczy redukujących znoszenie o 90%, w uprawie pomidora, zbóż ozimych i rzepaku ozimego.

W celu ochrony stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 40 m od terenów nieużytkowanych rolniczo LUB wyznaczenie strefy ochronnej o szerokości 20 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% LUB wyznaczenie strefy ochronnej o szerokości 10 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 75% LUB wyznaczenie strefy ochronnej o szerokości 5 m od terenów nieużytkowanych rolniczo z równoczesnym zastosowaniem technik redukujących znoszenie cieczy użytkowej podczas zabiegu o 90%.

SPe8 Niebezpieczny dla pszczół:

W celu ochrony pszczół i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia. Nie używać w miejscach gdzie pszczoły mają pożytek. Nie stosować kiedy występują kwitnące chwasty.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi

Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0°C-30°C.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.
Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.
Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.

W przypadku połknięcia: w przypadku złego samopoczucia skontaktować się z ośrodkiem zatruc/lekarzem. Wypłukać usta.

Okres ważności – – 2 lata. ~~1 rok~~

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 2 Letter of Access

Not relevant.

Appendix 3 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1 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	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.2.1	D. Prakash	2019	Determination of explosive properties of lambda-cyhalothrin 10% CS. Report G13947, India, 2019 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.2.2	D. Prakash	2019	Oxidizing properties of lambda cyhalothrin 10% CS. Report G13948, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KC 2.3.1	D. Prakash	2019	Determination of flash point of lambda cyhalothrin 10% CS. Report G13949, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.3.3	D. Prakash	2019	Determination of auto ignition temperature of lambda cyhalothrin 10% CS. Report G13954, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.5.1	D. Prakash	2019	Determination of viscosity of lambda cyhalothrin 10% CS. Report G13950, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.5.2	D. Prakash	2019	Surface tension of aqueous solution of lambda ccyhalothrin 10% CS. Report G13951, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.6.1	D. Prakash	2019	Determination of density and relative density of lambda cyhalothrin 10% CS. Report G13952, India, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 2.7.5	D. Bangera	2022	Two years storage stability of Lambda Cyhalothrin 10% CS, Report No.: G13956, India, 2022 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 5.1.1	D. Prakash	2019	Accelerated storage stability test by heating at elevated temperature Lambda cyhalothrin 10% CS, Report G13955, 2019 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 5.2	M. Pivato	2016	Validation of the analytical procedure for the determination of lambda cyhalothrin in surface water by liquid chromatography. Report No. 16.554813.0002 GLP Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 7.1.3	xxx	2019	“Acute inhalation toxicity study of lambda cyhalothrin 10% CS in rats” xxx, n° G13185 GLP, Unpublished	Y	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.1	K. Rump	2016	Determination of residues at harvest and decline of lambda-cyhalothrin in Oilseed rape, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions Central Europe – Season 2016. Germany, Report FRS 068/16 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.2	P. Sikorski	2016	Determination of lambda-cyhalothrin residues in oilseed rape samples after application of “Lambda-cyhalothrin 2.5% WG” in two trials (1 DCS and 1 HS), Report ZBBZ-2016/19DPL/2DE GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.3	K. Rump	2016	Determination of residues at harvest and decline of lambda-cyhalothrin in wheat, following broadcast applications of lambda-cyhalothrin 2.5% WG, under open field conditions Central Europe – Season 2016, Germany Report FRS 070/16 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.4	P. Sikorski	2016	Determination of lambda-cyhalothrin residues in winter wheat samples after application of “Lambda-cyhalothrin 2.5% WG”. Report ZBBZ-2016/19DPL/4DE	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.5	T. Roehl	2017	Residue study (Harvest) in barley following two applications with Lambda 2.5 WG in Germany 2017. Germany Report CT17-1-42 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 8.3.6	M. Rubino	2018	Determination of p lambda cyhalothrin (CAS: 91465-08-6) in cereals by LC-MS according to SOPa-190-LABCHI-rev. 2., Report FR 18.618095.0001, Italy 2018 GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP	Deppika Rani S.	2018	“Lambda-cyhalotrin 10% CS: Acute Oral Toxicity Test in	N	Y	Data/study report never submit-	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.3.1.1.1			Honey Bees” Study No.: G13384 Eurofins Advinus Limited GLP, Unpublished			ted before to Poland	Cropchem Limited.
KCP 10.3.1.1.2	Deppika Rani S.	2018	“Lambda-cyhalotrin 10% CS: Acute Contact Toxicity Test in Honey Bees” Study No.: G13385 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.3.1.5	Portail B.	2018	“Lambda cyhalothrin 2.5 WG: A semi-field study to evaluate side effects on honey-bees (<i>Apis mellifera</i> L.) in <i>Phacelia tanacetifolia</i> in Germany 2017” Study No.: S17-02719, 2018 Eurofins Agrosience Services Ecotox GmbH GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.3.2-01	Bala P.	2020	“An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the predatory mite, <i>Typhlodromus pyri</i> (Scheuten)” Study No.: 6026/2019. Bioscience Research Foundation GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.3.2-02	Mohanruj M.	2020	“An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on on larvae of the green lacewing <i>Chrysoperla carnea</i> (L.)” Study No.: 6194/2019 Bioscience Research Foundation GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.3.2-03	Sonali G.	2019	An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the parasitic wasp, <i>Aphidius rhopalosiphi</i> (De StefaniPerez) Study No.: 6024/2019 Bioscience Research Foundation GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP	Angayarkanni V.	2019	An extended laboratory test for evaluating the effects of	N	Y	Data/study report never submit-	Sharda

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
10.3.2-04			Lambda Cyhalothrin 10% CS on the rove beetle, Aleochara bilineala (Gyllenhal) Study No.: 6195/2019 Bioscience Research Foundation GLP, Unpublished			ted before to Poland	Cropchem Limited.
KCP 10.3.2.4	Varela S.	2021	Lambda cyhalothrin 10% CS: Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions Study No.: S20-07842 Eurofins Trialcamp S.L.U. GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.3.2.4	Serrano C.	2007	“Side effects of Lambda cyhalothrin 2.5% WG on predatory mites (Acari: Phytoseiidae) in peach trees under field conditions” Study No.: TRC07-21BA- TrialCamp GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.5.1	Anand H. S	2019	“Soil Microorganisms: Nitrogen Transformation Test od Lambda-cyhalotrin 10% CS” Study No.: G13389 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.
KCP 10.5.2	Anand H. S	2019	“Soil Microorganisms: Carbon Transformation Test od Lambda-cyhalotrin 10% CS” Study No.: G13388 Eurofins Advinus Limited GLP, Unpublished	N	Y	Data/study report never submitted before to Poland	Sharda Cropchem Limited.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Y/N	Data/study report never submitted before to <insert MS> If previously submitted in this MS: Data protection started with: <insert authorization number of first authorization>	Owner