

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 3600 B

Product name: LABAMBA

Chemical active substance:

Lambda-cyhalothrin, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation)

Applicant: Sharda Cropchem España S.L.

Submission date: March 2022

MS Finalisation date: 07/2022; 11/2022; 04/2023; 09/2023

Version history

When	What
03/2022	Submission date
07/2022	ZRMS Assessment
11/2022	Assessment of the applicant's supplements
04/2023	ZRMs from eff. sec. corrected RR according to comments from MRiRW
09/2023	ZRMs from ecotox section corrected fRR according to comments from MRiRW

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

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.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	Poland LABAMBA	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of Lambda cyhalothrin

Table 0.1-2: Summary of regulatory history of CAS No: 91465-08-6

Status	
Approved in EU	Yes
Original Inclusion Directive or Commission Implementing Regulation	Commission directive 00/80/EC Or Commission Implementing Regulation Reg. 2016/146
RMS	RMS : EL ; Co-RMS : FR The former RMS was SE
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/04/2016
Current expiration of approval	31/03/2023

Status	
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- protection of operators, workers and bystanders;
- metabolites potentially formed in processed commodities;
- risk to aquatic organisms, mammals and non-target arthropods.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for Lambda-cyhalothrin (SANCO/12282/2014 Rev 4 -11 December 2015) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 11 March 2015 (EFSA Journal 2014;12(5):3677).

Table 0.1-3: Information on minimum purity of Lambda-cyhalothrin

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
900 g/kg	Min. 980 g/kg Equivalence report available: Y RMS: UK (HSE ref.: COP2016/01890)

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

Uses to be considered safe on the basis of EU methodology:

Section Efficacy: 1-9

Section Residues: 1 (cabbage), 2 (cabbage), 3-9

Section Ecotox: 1-9

Section Fate: 1-9

Uses to be considered non-safe on the basis of EU methodology:

Section Efficacy: none

Section Residues: 1 (Brussels sprouts, cauliflower), 2 (Brussels sprouts, cauliflower)

Section Ecotox: 1-2 none

Section Fate: none

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

none

Section Ecotox: The risk assessment for brassicas for vole should be considered at MSs level.

The risk mitigation measures for aquatic organism, non-target plants and NTA should be considered at MSs level.

Section Residues: Uses on cereals, cabbage, tomatoes and oilseed rape/ GAPs are covered by established MRLs.

zRMS conclusions:

Phys-chem section:

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

Shelf life – 1 year.

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

Efficacy section:

In generally, the final decision about acceptance uses presented in GAP table is left to each CMS.

Detailed assessment is presented in dRR B3

Metabolism and residues:

Only use on cereals is acceptable.

Data gaps: one residue trial on cauliflower and residue trials on Brussels sprouts are required.

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 2-3 m

Fate section:

No risk for groundwater for proposed GAP

Appendix 1 ALL intended uses

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/no

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. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, 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 (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Brassicac (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
2	CEU	Brassicac (cabbage, Brussels sprouts, cauliflower)	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 sprouts, cauliflower)	B7: not accepted: Brussels sprouts, cauliflower accepted: cabbage B9: 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	
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
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: 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 For PL – only CEUTNA at 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:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey. Use should be crossed out when the notifier no longer supports this use.

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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	