

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 0100 Y

Product name: DECIDE

Chemical active substance:

Deltamethrin, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

Submission date: July 2019

MS Finalisation date: October 2021, April 2022

Version history

When	What
June 2021	Applicant update
October 2021	RMS finalised dRR assessment
April 2022	ZRMS assessment after commenting

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted by SHARDA CROP-CHEM ESPAÑA S.L. for approval of DECIDE, a capsule suspension formulation containing 50 g/L of Deltamethrin for use as insecticide on brassicas (cabbage, Brussels sprouts, cauliflowers), strawberries, tomatoes and ornamentals 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	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Deltamethrin

Table 0.1-2: Summary of regulatory history of CAS No: 52918-63-5

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2018/1262 Commission Implementing Regulation (EU) No 540/2011 Extension of the approval period (Reg. (EU) 2017/201511)
RMS	Original RMS: Sweden RMS: UK Co-RMS: AT

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.11.2003
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.04.2004
Date of final Commission (re-registration) deadline (Step 2)	31.10.2007
Current expiration of approval	31.10.2021 31.10.2022
Low risk substance or Candidate for Substitution?	N/A

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:

- The operator safety and must ensure that the conditions of authorisation include appropriate protective measures
- Should observe the acute dietary exposure situation of consumers in view of future revisions of maximum residue levels
- The protection of aquatic organisms, bees and non-target arthropods and must ensure that the conditions of authorisation include risk mitigation measures, where appropriate

The SANCO report for Deltamethrin (SANCO/6504/VI/99 – final – 17 October 2002) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Table 0.1-3: Information on minimum purity of Deltamethrin

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 *, **
≥ 980 g/kg	Minimum purity of the technical active substance of 98% w/w Equivalence report available: Y RMS: UK

* 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 endpoints used in the evaluation are in line with the EU/DAR agreed 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:

Efficacy section: 1-7
Residues section: 1 and 2 (only cauliflower); 3-7
Fate section: 1-7

Ecotoxicology Section: 1-7

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

Efficacy section: none
Residues section: 1 and 2 (cabbage, brussels sprouts)
Fate section: none
Ecotoxicology Section: 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:

Ecotox section: The risk mitigation for aquatic organism , bees, NTA should be decided at MSs level.

Residues section:

All uses/ GAPs are covered by established MRLs except for use in cabbage, brussels sprouts.

Conclusions:

Section Phys-chem:

Lack of results of ambient temperature shelf life (the study is on-going). Based on the results of accelerated storage test (14 days at 54°C) the 1 year registration of the product may be granted.
Final 2-year registration will be possible after providing the results of ambient temperature shelf life.

Section Analytical methods:

No data gaps.

Efficacy section:

The dose has been reduced to 0.15 l/ha due to the requirement by the evaluators from ecotoxicology section. And that's why the current recommended dose is 0,15 l/ha for use only once a season. Trials conducted under glasshouse represent a more challenging situation to control studied insects since the controlled conditions inside glasshouses have better humidity and temperature for the development of insects. Thus, it is considered that glasshouse trials are valid to demonstrate efficacy in the field.

Minor crops which did not pass the assessment under Article 33 due to insufficient research (ex. brussels sprouts, tomatoes, strawberries, cauliflower, and ornamental plants) can be register under Article 51 without efficacy trials. Final decision is left to each CMS. Under Article 51 in Poland could be register brussels sprouts, cabbage and lepidoptera in field strawberries.

Toxicology Section:

Classification is :H318, H331. No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.
Acceptable

Metabolism and Residues:

Noticed data gaps are:

- Cabbage and brussels sprouts: residue trials

Fate section: No risk for groundwater is expected following Decide according GAP

Ecotox Section: An acceptable risk to non-target organism is concluded from exposure of Decide.

Appendix 1 ALL intended uses

GAP rev. 0, date: 2017-September-18th

PPP (product name/code): Deltamethrin 5% CS
Active substance 1: deltamethrin
Active substance 2:
Safener: -
Synergist: -
Applicant: SHARDA Cropchem España
Zone(s): central,
Verified by MS: yes/no

Formulation type: CS (Capsule Suspension)
Conc. of as 1: 50 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: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/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	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Aphids	Foliar Spray	BBCH 11-43	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	7	Residues section
2	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Caterpillars	Foliar Spray	BBCH 11-43	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	7	Residues section
3	CEU	Strawberry	F	Aphids	Foliar Spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	3	
4	CEU	Strawberry	F	Lepidoptera	Foliar Spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	3	
5	CEU	Tomato	F	Aphids	Foliar Spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	3	
6	CEU	Tomato	G	Whitefly	Foliar Spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	3	
7	CEU	Ornamentals	F	Aphids	Foliar Spray	BBCH 10-89	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	-	
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													

Appendix 2

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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/m ³ 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