

FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

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

Submission date: July/2019

MS Finalisation date: 08/2021; 04/2022 05/2022

Version history

When	What
July 2021	Applicant update dossier according to dose of 7.5 g as/ha and one application for all uses as per recommendation of evaluators
August 2021	ZRMs evaluated updated version of dr.
April 2022	The final version of RR
May 2022	The report was completed in accordance with the comments received from the Ministry of Agriculture and Rural Development

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	The commenting boxes are filled-in by the zRMS. They are usually placed at the end of each chapter. Commenting boxes should be understandable alone and refer very precisely to the text commented. The main advantage of their use is to distinguish easily between the applicant and the zRMS text. The report was completed in accordance with the comments received from the Ministry of Agriculture and Rural Development (marked by yellow).
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3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product **DELTAMETHRIN 5% CS (DECIDE; product code: SHA 0100 Y)** containing the active substance deltamethrin. Deltamethrin is authorised in the Commission Regulation (EU) No. 823/2012 after assessment under and inclusion into Annex I of Council Directive 91/414/EEC (2003/5/EC).

The SANCO review report for deltamethrin (6504/VI/99-final) is considered to provide the relevant review information or a reference to where such information can be found.

Regulation 823/2012 provides specific provisions under Part B which need to be considered by the applicant in the preparation of its submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on deltamethrin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 18/10/2002 shall be taken into account. Consideration of active substances for Annex 1 inclusion does not include an evaluation of efficacy. Therefore there are no concerns to address arising from the inclusion directive of deltamethrin relating to efficacy.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

The detailed assessment of the individual trial and study data is located in the following report:

Report:	KCP 6.0/001 Biological Assessment Dossier DELTAMETHRIN 5% CS, Central
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Description of the plant protection product

DELTAMETHRIN 5% CS is a Capsule suspension (CS) containing 50 g/L deltamethrin for use in brassicas (cabbage, brussels sprouts, cauliflower), strawberry, tomato and ornamentals.

According to the GAP, the proposed application rate of DELTAMETHRIN 5% CS is 0.15 L per hectare (L/ha), with single application per season, for the control of aphids in brassicas (cabbage, brussels sprouts, cauliflower), strawberry, tomato and ornamentals. This will deliver 7.5 g deltamethrin per hectare. In the treated crops, the test product was tested against registered rates of the reference products employed, currently marketed in the countries where the trials were conducted.

The data presented in this dossier fully support the label claim for deltamethrin for the control of aphids and caterpillar in brassicas, aphids and Lepidoptera in strawberry, aphids and whiteflies in tomato and aphids in ornamentals.

Table 3.2-1: Simplified table of currently registered uses and requested uses for the product code.

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPS
Crop(s)	Target(s)			
Brassicas (cabbage brussels sprouts, cauliflower)	Aphids	CEU	0.15 L/ha	-
Brassicas (cabbage brussels sprouts, cauliflower)	Caterpillar	CEU	0.15 L/ha	-
Strawberry	Aphids	CEU	0.15 L/ha	-
Strawberry	Lepidoptera	CEU	0.15 L/ha	-
Tomato	Aphids	CEU	0.15 L/ha	-
Tomato	Whitefly	CEU	0.15 L/ha	-
Ornamentals	Aphids	CEU	0.15 L/ha	-

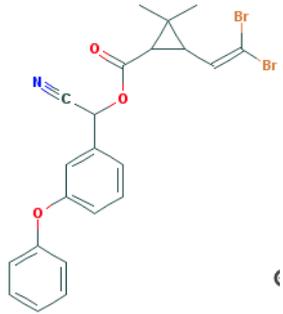
Further details are in the table “All intended uses” in Part B - Section 0.

Description of active substance deltamethrin

Deltamethrin was first introduced in 1974. Today, deltamethrin is registered and commercialised in several formulations around the world.

Table 3.2-2: Identity of deltamethrin

Common name	Deltamethrin
IUPAC name	[cyano-(3-phenoxyphenyl)methyl] 3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropane-1-carboxylate
CA name	1R-[1 α (S*),3 α]-3-(2,2-dibromoethenyl)-2,2-dimethyl- cyclopropanecarboxylic acid, cyano(3-phenoxyphenyl) methyl ester
CIPAC No	333
CAS Registry No.	52820-00-5
EEC No	258-256-6

Minimum purity	980 g/kg
Structural formula¹	
Empirical formula	C ₂₂ H ₁₉ Br ₂ NOS ₃
Molecular mass	505.2 g/mol

Mode of action

Deltamethrin is a thiocarbamate insecticide that targets the meristematic region, or growing points, of plants. The mode of action of deltamethrin acts on the pest by contact or ingestion. Deltamethrin is a synthetic insecticide based structurally on natural pyrethrins, which rapidly paralyze the insect nervous system giving a quick knockdown effect. Death of insects seems to be due to irreversible damage to the nervous system occurring when poisoning lasts more than a few hours. Deltamethrin poisoning occurs through cuticular penetration or oral uptake. The susceptibility of insects is dependent on a variety of factors and can vary, as with many insecticides, according to the environmental conditions.

Information on similar formulations and current approvals

Data presented in this dossier is generated using this formulation in comparison with reference products containing deltamethrin compounds. Deltamethrin is currently registered under a variety of trade names and formulations throughout Europe and a selection of these are described in table below.

Table 3.2-3: Current approvals of deltamethrin products used as reference products in Europe as well as examples of Sharda deltamethrin approvals in the in the EU

Country	Product	Active ingredient	Approval number
Austria	Decis Forte	Deltamethrin 100 g/L EC	3554-0
Czech Republic	Decis Forte	Deltamethrin 100 g/L EC	5450-0
	Decis Mega	Deltamethrin 50 g/L EC	4244-15
	Decis Protech	Deltamethrin 15 g/L EC	4538-4
Croatia	Decis 100 EC	Deltamethrin 100 g/L EC	UP/I-320-20/13-01/383
France	Decis Protech	Deltamethrin 15 g/L EC	2010023
	Decis Expert	Deltamethrin 100 g/L EC	2000324
Germany	Decis Forte	Deltamethrin 100 g/L EC	007418-00
Greece	Poleci 2.5 EC	Deltamethrin 250 g/L EC	14408
	Decis Expert	Deltamethrin 100 g/L EC	14345
	Decis Protech	Deltamethrin 15 g/L EC	14346
Ireland	Decis Protech	Deltamethrin 15 g/L EC	05269
Italy	Decis 15 EW	Deltamethrin 15 g/L EC	010352
Poland	Decis Mega	Deltamethrin 50 g/L EC	R-9/2012
Spain	Decis Evo	Deltamethrin 25 g/L EC	25838
	Super Delta	Deltamethrin 25 g/L EC	25700
	Poleci	Deltamethrin 25 g/L EC	25509
UK	Decis Forte	Deltamethrin 50 g/L EC	16110
	Decis Protech	Deltamethrin 15 g/L EC	16160

¹ Source: Royal Society of Chemistry (RSC). Internet, Friday June 8th, 2018. URL: <http://www.chemspider.com/Chemical-Structure.55867.html>

Bold: Sharda deltamethrin registrations

Description of the target pests

Key targets for this product are aphids, caterpillar, lepidoptera and whiteflies in brassicas, strawberry, tomato and ornamentals.

The key targets for this product are described below:

Table 3.2-4: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
Aphids		
APHIFO	<i>Aphis forbesi</i>	Strawberry aphid
APHIFG	<i>Aphis frangulae</i>	Strawberry aphid
CHTSFR	<i>Chaetosiphon fragaefolii</i>	Strawberry aphid
MYZUPE	<i>Myzus persicae</i>	Green aphid
MACSEU	<i>Macrosiphum euphorbiae</i>	Tomato aphid
APHISP	<i>Aphis sp.</i>	-
Caterpillar		
PIERBR	<i>Pieris brassicae</i>	Cabbage caterpillar
BARABR	<i>Mamestra brassicae</i>	Cabbage armyworm
Lepidoptera		
DROSSU	<i>Drosophila suzukii</i>	Spotted-wing drosophila
HELVSP	<i>Helicoverpa sp.</i>	-
Whitefly		
BEMITA	<i>Bemisia tabaci</i>	Silver-leaf whitefly
TRIAVA	<i>Trialeurodes vaporariorum</i>	Greenhouse whitefly

Table 3.2-5: Major / minor status of intended uses (for all cMS and zRMS).

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Brassicas (cabbage brussels sprouts, cauliflower)	CEU	CEU	Aphids	CEU	CEU
Brassicas (cabbage brussels sprouts, cauliflower)	CEU	CEU	Caterpillar	CEU	CEU
Strawberry	CEU	CEU	Aphids	CEU	CEU
Strawberry	CEU	CEU	Lepidoptera	CEU	CEU
Tomato	CEU	CEU	Aphids	CEU	CEU
Tomato	CEU	CEU	Whitefly	CEU	CEU
Ornamentals	CEU	CEU	Aphids	CEU	CEU

Aphids sp.

Aphids are small sap-sucking insects and members of the superfamily Aphidoidea. Common names include greenfly and blackfly, although individuals within a species can vary widely in colour. The group

includes the fluffy white woolly aphids. A typical life cycle involves flightless females giving living birth to female nymphs without the involvement of males. Maturing rapidly, females breed profusely so that the number of these insects multiplies quickly. Winged females may develop later in the season, allowing the insects to colonise new plants. In temperate regions, a phase of sexual reproduction occurs in the autumn, with the insects often overwintering as eggs.

Aphids are among the most destructive insect pests on cultivated plants in temperate regions. In addition to weakening the plant by sucking sap, they act as vectors for plant viruses and disfigure ornamental plants with deposits of honeydew and the subsequent growth of sooty moulds. Because of their ability to rapidly increase in numbers by asexual reproduction, they are a highly successful group of organisms from an ecological standpoint.

Caterpillar

Caterpillars are the larval stage of various butterflies and moths. There are several species of caterpillar that feed on cabbages, other brassicas and other plants including turnip, swede, horseradish and nasturtiums. Large cabbage white butterfly caterpillars are yellow and black with obvious hairs on their bodies (see picture above). Those of small cabbage white butterfly are pale green and covered in short, velvet-like hairs. Cabbage moth caterpillars are yellowish green or brownish green, with no obvious hairs on their bodies.

Holes are eaten in the outer leaves of all brassicas and damage may also be seen on the inner leaves of cabbages when the heart is cut through. Caterpillars and their excrement are often found on the plants.

Bemisia tabaci

The silverleaf whitefly (*Bemisia tabaci*, also informally referred to as the sweet potato whitefly) is one of several species of whitefly that are currently important agricultural pests. A review in 2011 concluded that the silverleaf whitefly is actually a species complex containing at least 24 morphologically indistinguishable species

The silverleaf whitefly thrives worldwide in tropical, subtropical, and less predominately in temperate habitats. Cold temperatures kill both the adults and the nymphs of the species. The silverleaf whitefly can be confused with other insects such as the common fruitfly, but with close inspection, the whitefly is slightly smaller and has a distinct wing color that helps to differentiate it from other insects.

While the silverleaf whitefly had been known in the United States since 1896, in the mid-1980s a virulent strain appeared in poinsettia crops in Florida. For convenience that strain was referred to as strain B (biotype B), to distinguish it from the milder infestation of the earlier known strain A. Less than a year after its identification, strain B was found to have moved to tomatoes, and other fruit and vegetable crops. Within five years, the silverleaf whitefly had caused over \$100 million in damage to Texas and California agriculture industries.

Lepidoptera

Lepidoptera is an order of insects that includes butterflies and moths (both are called lepidopterans). About 180,000 species of the Lepidoptera are described, in 126 families and 46 superfamilies, 10 per cent of the total described species of living organisms. It is one of the most widespread and widely recognizable insect orders in the world. The Lepidoptera show many variations of the basic body structure that have evolved to gain advantages in lifestyle and distribution.

Butterflies and moths play an important role in the natural ecosystem as pollinators and as food in the food chain; conversely, their larvae are considered very problematic to vegetation in agriculture, as their main source of food is often live plant matter. In many species, the female may produce from 200 to 600 eggs, while in others, the number may approach 30,000 eggs in one day. The caterpillars hatching from these eggs can cause damage to large quantities of crops. Many moth and butterfly species are of economic interest by virtue of their role as pollinators, the silk they produce, or as pest species.

Compliance with the Uniform Principles

Comprehensive field trials were conducted in Italy, Greece and France in 2017. The trials followed the corresponding EPPO guidelines. The GEP-requirement and the Uniform Principles are taken care of.

Information on trials submitted (3.1 Efficacy data)

Trials in this dossier were carried out by contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

On the basis of the EPPO guideline 1/241(1) "Guidance on comparable climates", the trials included in this dossier have been grouped and summarized by EPPO zone. EPPO zone have been defined by taking into account differences between the agro-climatic sub-areas of the EPPO region.

In general the trials were conducted according to the respective EPPO guidelines.

In support of the current application, 6 trials were conducted in the Maritime EPPO zone, 34 trials were conducted in the North-east EPPO zone, 5 trials were conducted in the South-east EPPO zone, 36 efficacy trials were conducted in the Mediterranean EPPO zone and 29 trials were conducted in greenhouse.

Table 3.2-6: Presentation of efficacy trials (efficacy trials, preliminary trials...)

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Brassicas (Field)	Aphids	Spain	2018	MED + E	-	3 (3)	-	-	GEP	
		Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		France	2017	MED + E	1 (1)	-	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Czech Rep.	2017	MED + E	1 (1)	-	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
						2 (2)	9 (9)		6 (6)	
	Caterpillar	Romania	2017	MED + E	-	-	2 (2)	-	GEP	
		Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		France	2017	MED + E	2 (2)	-	-	-	GEP	
		Spain	2018	MED + E	-	3 (3)	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
						2 (2)	6 (6)	2 (2)	-	
Brassicas (Greenhouse)	Aphids	Germany	2017	MED + E	1 (1)	-	-	-	GEP	
							1 (1)	-	-	-
Strawberry (Field)	Aphids	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Aphids	2017	MED + E	-	-	-	6 (6)	GEP	
						-	3 (3)	2 (2)	6 (6)	
	Lepidoptera	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
					-	6 (6)	-	-		
Strawberry (Greenhouse)	Aphids	Italy	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Germany	2017	MED + E	1 (1)	-	-	-	GEP	
					1 (1)	6 (6)				
	Lepidoptera	Italy	2017	MED + E	-	3 (3)	-	-	GEP	
					-	3 (3)	-	-	-	
Tomato (Field)	Aphids	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
					-	6 (6)	-	6 (6)		
	Whitefly	Poland	2017	MED + E	-	-	-	6 (6)	GEP	
					-	-	-	6 (6)		
Tomato (Greenhouse)	Aphids and whitefly	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Romania	2017	MED + E	-	-	4 (4)	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
						3 (·)	5 (5)			
	Whitefly	Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		France	2017	MED + E	1 (1)	-	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
					1 (1)	6 (6)	-	-	-	
Ornamentals (Field)	Aphids	Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Czech Rep.	2017	MED + E	2 (2)	-	-	-	GEP	
		Poland	2017	MED + E	-	-	-	4 (4)		
						2 (2)	6 (6)	1 (1)	4 (4)	
Ornamentals (Greenhouse)	Aphids	Spain	2018	MED + E	-	3 (3)	-	-	GEP	
					-	3 (3)	-	-		
Total, all crops					9 (9)	57 (57)	10 (10)	34 (34)		

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Climatic zones

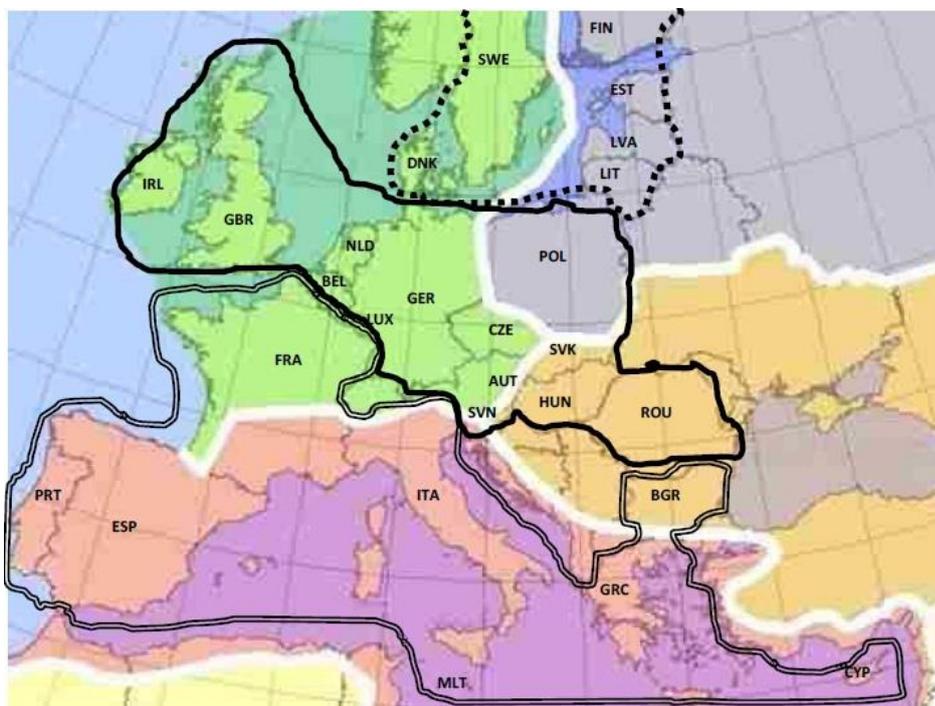
In the current document, data from 110 trials conducted in the Maritime (N-France, Germany and Czech Republic), North-east (Poland), South-east (Romania and Hungary) and the Mediterranean (Spain, Greece

and Italy) EPPO zone has been included to support the registration of Deltamethrin 5% CS in the EU South zone. However, the data from each climatic zone is summarised separately.

Europe is divided into four climatic zones, according to EPPO standard PP 1/241 (1) (Figure 3.2-1). Besides providing guidance in determining comparability of climatic conditions between geographical areas where efficacy evaluation trials are performed, the standard also supports the use of data generated in one country to support registration in another country².

N-France, Germany and Czech Republic are located in the Maritime EPPO zone; Poland is located in the North-east EPPO zone; Hungary and Romania are located in the South-east EPPO zone; and Spain, Greece and Italy are located in the Mediterranean EPPO zone are included.

Figure 3.2-1: Representation of EPPO climatic zones (in colour: EPPO Standard PP1/241, Guidance on comparable climates) superimposed with the 3 European zones (EC Regulation 1107/2009) (Source: EPPO)



Agronomic conditions

Cultural conditions of the different crops and agronomy (e.g. cultivations used, application methods, cultivars, fertilizer regime, relative times of planting and harvest) do not differ significantly between Germany, Czech Republic, Romania, Hungary, Poland, Greece, France, Spain and Italy. In brassicas, strawberry, tomato and ornamentals, the same deltamethrin containing insecticides are already registered and used in the countries where tested for the same uses, i.e. to control aphids, caterpillar, lepidoptera and whiteflies with three applications.

(i) Pest physiology

The physiology of individual pests presented is common throughout Europe. Although trials were performed in different countries and EPPO zones, sites were selected to exert maximum control pressure and to exacerbate treatment differences. No difference in the level of control was apparent between the different countries or regions in which the trials were conducted. The level of control achieved from DELTAMETHRIN 5% CS in the different countries was equivalent throughout the EU.

² Development of Comparable Agro-Climatic Zones for the International Exchange of Data on the Efficacy and Crop Safety of Plant Protection Products, E. Bouma, 2005 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 35, 233-238.

(ii) *Site selection*

Although trials were performed throughout the EU, in each country the sites were carefully selected to ensure that for each pest species the level of control was assessed on a range of populations and application timings. To exert maximum control pressure and to exacerbate treatment differences in each country this included some trials which contained high pests densities. No differences in the level of control were apparent between the different countries or regions in which the trials were conducted. For each pest species equivalent levels of control were recorded in the countries where present in trials.

(iii) *Agronomic practices*

Agronomic practices in brassicas, strawberry, tomato and ornamentals crops are similar throughout the Central zone as well as in the countries in the connected EPPO zones where trials were conducted. The levels of inorganic fertilizers and other crop inputs are similar between the countries.

(iv) *Varieties*

Although crop varieties tend to differ between countries, the crop safety of DELTAMETHRIN 5% CS has been tested on a wide range of varieties in efficacy trials. The results from these trials show that there are no particularly sensitive varieties. Crop tolerance data generated in one country is therefore relevant in another Member state.

(v) *Trial methodology*

Similar trial methodology was used in all countries. All trials were conducted to GEP by officially recognised testing organisations and in accordance with relevant EPPO standards.

(vi) *Locations*

Trials were performed in the major crop growing areas in each respective country. These areas have been found to be particularly suitable for crops production due to their innate similarity in terms of soil type and climate.

(vii) *Soil*

The active ingredient of DELTAMETHRIN 5% CS – deltamethrin – has both soil and foliar activity. Therefore, in each country, trials have been conducted on a range of soil types with no difference seen in the level of control.

In all efficacy trials conducted in brassicas, strawberry, tomato and ornamentals in Greece, Poland, Spain, France, Hungary, Czech Republic, Italy and Romania, the performance of Deltamethrin 5% CS was compared against a commercial standard formulation of deltamethrin currently on the market in Central and Central Europe (Decis protech, Decis Mega, Decis Forte). In Germany, Karate zeon (Lambda cyhalothrin 10 g/L CS) was used as reference product in one efficacy trial carried out in brassicas as well as one efficacy trial conducted in strawberry. In Spain, Abanto (Pyrethrins 4 g/L EC) was used as an additional reference product in three efficacy trials conducted in ornamentals. The trials were carried out on brassicas, strawberry, tomato and ornamentals.

Table 3.2-7: Presentation of reference standards used in trials (efficacy trials, preliminary trials...)

Trade name	Formulation	Active Ingredient	AI content	Use rates	Countries where used and targets
Deltamethrin reference product					
DECIS PROTECH	EW	Deltamethrin	15 g/l	0.50 l/ha 0.60 l/ha 0.62 l/ha 0.80 l/ha 0.83 l/ha	Greece, Spain, France, Czech Republic and Hungary
DECIS PROTECH	EW	Deltamethrin	25 g/l	0.225 l/ha 0.30 l/ha 0.375 l/ha 0.50 l/ha	Italy
DECIS MEGA	EW	Deltamethrin	50 g/l	0.15 l/ha 0.20 l/ha 0.25 l/ha	Hungary, Poland and Romania
DECIS FORTE	EC	Deltamethrin	100 g/l	0.30 l/ha 0.40 l/ha	Czech Republic
National reference product					
KARATE ZEON	CS	Lambda cyhalothrin	10 g/l	0.1 l/ha 0.2 l/ha	Germany
ABANTO	EC	Pyrethrins	4 g/l	1.5 l/ha 2.0 l/ha	Spain

Comments of zRMS:	<p>This document summarises the information related to the efficacy of the plant protection product – Decide (product code: SHA 0100 Y). The formulation of this product is a soluble concentrate (SC) and it is containing active substances: deltamethrin (50 g/l). For now, deltamethrin is on the list of approved active substances.</p> <p>Deltamethrin is an established active substance in more important common crops as foliar spray treatment and it belongs to the old group of insecticides, the pyrethroids. Deltamethrin disrupts the normal functioning of the nervous system in an organism. The mode of action this substance consists in disturbing dynamics functioning of sodium channel in neurons. By disrupting the nervous system of insects, this substance may cause paralysis or death.</p> <p>In Poland 33 insecticides with the same active compound – deltamethrin are registered and commonly used for protection crops against pests. The product – Decide (product code: SHA 0100 Y) by Sharda Cropchem España has not been previously evaluated in any country according to Uniform Principles.</p> <p>Poland is a ZRMs. All necessary information's are presented above by Applicant.</p>
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3.2.1 Preliminary tests (KCP 6.1)

The activity of deltamethrin is well known, as it has been marketed since 1978 to control a wide range of pests including Coleoptera, Lepidoptera, Diptera, Heteroptera, Homoptera and Acarides in many crops as well as in home pest control. Based on the knowledge about the active substance and the experiences with deltamethrin in the GAP claimed uses, 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.

Comments of zRMS:	The active substance Decide (product code: SHA 0100 Y) – deltamethrin (50 g/l) is registered and has been commonly used in crop protection in EU Countries for many years (since 1978). Also, a large-scale efficacy trials are available to evaluate the effectiveness of products containing deltamethrin as active compound. Therefore, there was no need for preliminary range-finding tests in the opinion of Evaluator.
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3.2.2 Minimum effective dose tests (KCP 6.2)

To determine the minimum effective dose rate, data from 34 trials conducted in brassicas, 27 trials conducted in strawberry, 33 trials conducted in tomato and 16 trials conducted in ornamentals field crops are included in this section. In the one hundred and ten trials, Deltamethrin 5% CS was applied at 0.05 to 0.25 L/ha for the control of aphids. The dose rates tested reflects 20% to 166% of the recommended rate of Deltamethrin 5% CS. In the sixteen trials, Deltamethrin 5% CS was applied at 0.05 to 0.25 L/ha for the control of caterpillar in brassicas. In the six trials, Deltamethrin 5% CS was applied at 0.075, 0.10 and 0.15 L/ha for the control of Lepidoptera in strawberry. The dose rates tested reflects 20% to 100% of the recommended rate of Deltamethrin 5% CS, in accordance with the EPPO guideline PP 1/225(2) “Minimum effective dose”. The dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. Efficacy is tested under a range of environmental conditions to fully challenge the product. Data is presented from trials conducted in the Maritime EPPO zone (6; i.e. N-France (3) and Czech Republic (3), the North-east EPPO zone (34; i.e. Poland), the South-east EPPO zone (5; i.e. Hungary (3) and Romania (2)) and greenhouse (29) and the Mediterranean EPPO zone (36, i.e. Spain (18) and Greece (18)). Data from each zone has been summarized separately.

Control of aphids in brassicas

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of aphids in brassica crops (cabbage, Brussels sprouts, cauliflower), the assessment results of 18 efficacy trials performed in the Maritime EPPO zone (2), the North-east (6), the Mediterranean EPPO zone (9) and the greenhouse (1) in 2017 and 2018 season, are reported. Deltamethrin 5% CS was included in these trials at 0.25 L/ha to demonstrate the dose rate as well as at two lower dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). At the Polish trials, Deltamethrin 5% CS was included at 0.10 L/ha to demonstrate the recommended dose rate as well as two lower than recommended doses rates (0.05 L/ha [2.5 g deltamethrin per hectare] and 0.075 L/ha [3.75 g deltamethrin per hectare]). The rates reflect the proposed label rate as well as 50 to 166% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPO standard PP 1/225(2) ‘Minimum effective dose’ and the Central zone efficacy requirements.

A summary of the dose response results obtained in Maritime, North-east, the Mediterranean and greenhouse efficacy trials is provided in Table 3.2-8.

Table 3.2-8: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on aphids in brassicas.

Target: <i>Aphids</i>	No. of trials	Untreated DAMINS (1-4)		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
Mediterranean EPPO zone									
3-4 days after treatments	3	2.09	1.63-2.65	67.6	63.9-73.8	69.3	65.1-72.2	65.1	60.0-71.0
7 days after treatments	3	2.09	1.64-2.65	78.6	67.9-87.5	79.8	67.9-87.0	77.0	68.9-85.7
Target: <i>Aphids</i>	No. of trials	Untreated COUINS		0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range

Target: <i>Aphids</i>	No. of trials	Untreated DAMINS (1-4)		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
3 days after treatments	6	156.1	20.8-348	84.7	81.4-88.9	94.3	93.1-95.3	97.1	93.6-98.7
7 days after treatments	6	165.3	20.8-317	85.8	82.9-88.5	94.1	92.5-95.3	97.5	94.6-99.5
14 days after treatments	6	159.3	27.6-330	75.8	45.8-85.2	91.6	87.5-95.7	96.0	94.2-98.1
Maritime EPPO zone									
2-3 days after treatments	2	316.3	11.1-621	53.0	21.6-84.4	59.3	33.4-85.1	55.2	22.5-87.8
6-7 days after treatments	2	356.3	8.08-704	55.2	21.3-89.0	66.0	38.1-93.9	66.5	34.3-98.7
14 days after treatments	1	775.5	-	89.0	-	93.9	-	98.7	-
Greenhouse									
3 days after treatments	1	78.5	-	90.0	-	91.2	-	80.5	-
7 days after treatments	1	72.8	-	92.9	-	96.9	-	77.0	-
Target: <i>Aphids</i>	No. of trials	Untreated COUNS		0.05 l/ha = 2.5 g ai/ha		0.075 l/ha = 3.75 g ai/ha		0.10 l/ha = 5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
North-east EPPO zone									
2 days after treatments	6	411.5	207-1064	68.1	46.0-96.2	73.3	49.8-100	80.1	58.8-100
7-9 days after treatments	6	437	163-1170	64.4	40.3-100	70.0	45.3-100	77.6	53.8-100
13-14 days after treatments	4	488.9	85.8-1314	48.7	27.5-63.0	56.8	36.3-65.3	65.7	47.8-97.1

Results from the three EPPO zones and greenhouse provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on aphids in 18 brassicas (cabbage, Brussels sprouts, cauliflower) trials treated with two or three applications, it can be concluded that to consistently control frequently occurring aphids in brassicas crops, Deltamethrin 5% CS should be applied single time at 0.15 L/ha.

Control of caterpillar in brassicas

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of caterpillar in brassica crops (cabbage, Brussels sprouts, cauliflower), the assessment results of 16 efficacy trials performed in the Maritime EPPO zone (2), the North-east zone (6), the South-east zone (2) and the Mediterranean EPPO zone (6) in 2017 and 2018 season, are reported. Deltamethrin 5% CS was included in these trials at 0.25 L/ha as well as at two lower dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). At the Polish trials, deltamethrin 5% CS was included in these trials at 0.10 L/ha dose rate as well as at two lower dose rates (0.075 L/ha [3.75 g deltamethrin per hectare] and 0.05 L/ha [2.5 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 50 and 166% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

A summary of the dose response results obtained in the Maritime, North-east, South-east and Mediterranean efficacy trials is provided in Table 3.2-9.

Table 3.2-9: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on caterpillar in brassicas.

	Mean % Control at a range of doses of deltamethrin
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Target: <i>Caterpillar</i>	No. of trials	Untreated COUINS		Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
<i>3 days after treatments</i>	3	27.3	25.5-29.9	80.7	79.6-81.3	89.7	87.9-90.7	92.9	91.9-93.9
<i>7 days after treatments</i>	6	12.2	1.02-24.7	81.6	62.6-88.2	88.4	70.2-94.1	93.9	84.0-98.8
<i>14 days after treatments</i>	3	20.2	19.6-21.2	74.6	74.3-74.8	84.8	81.9-86.9	91.7	90.3-92.6
Maritime EPPO zone									
<i>3 days after treatments</i>	2	7.25	5.25-9.25	66.2	37.2-95.2	70.3	54.8-85.7	77.0	58.7-95.2
<i>12 days after treatments</i>	2	3.78	1.55-6.0	82.9	78.1-87.8	66.3	59.5-73.2	87.3	86.7-87.8
South-east EPPO zone									
<i>1-2 days after treatments</i>	2	18.2	13.5-22.9	63.5	56.3-70.6	72.7	68.8-76.5	92.6	89.6-95.6
<i>7 days after treatments</i>	2	24.4	20.9-27.9	74.7	74.5-75.0	81.2	80.0-82.4	88.9	86.8-90.9
<i>14 days after treatments</i>	2	19.8	18.4-21.2	69.1	68.4-69.7	75.6	75.4-75.8	96.5	93.0-100
Target: <i>Caterpillar</i>	No. of trials	Untreated COUINS		0.05 l/ha = 2.5 g ai/ha		0.075 l/ha = 3.75 g ai/ha		0.10 l/ha = 5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
North-east EPPO zone									
<i>2-3 days after treatments</i>	6	44.6	25.8-107	34.0	29.4-51.4	49.6	41.4-64.8	64.5	57.4-81.0
<i>7-9 days after treatments</i>	5	45.9	15.0-102	42.7	26.5-59.5	58.2	42.4-66.5	81.7	79.3-83.7
<i>14 days after treatments</i>	1	18.8	-	46.6	-	49.7	-	79.8	-

Results from the four EPPO zones provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections.

Based on results achieved on caterpillar in 16 brassicas (cabbage, Brussels sprouts, cauliflower) trials treated with two or three applications, it can be concluded that to consistently control frequently occurring aphids in brassicas crops, Deltamethrin 5% CS should be applied single time at 0.15 L/ha.

Control of aphids in strawberry

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of aphids in strawberry crops, the assessment results of 18 efficacy trials performed in the North-east zone (6), the South-east zone (2), the Mediterranean EPPO zone (3) and the greenhouse (7) in 2017 season, are reported. Deltamethrin 5% CS was included in these trials at 0.25 L/ha to demonstrate the dose rate as well as at two lower than dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 60 and 166% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

A summary of the dose response results obtained in South-east, the Mediterranean and greenhouse efficacy trials is provided in Table 3.2-10.

Table 3.2-10: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on aphids in strawberry.

Target: <i>Aphids</i>	No. of trials	Untreated COUINS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
<i>3 days after treatments</i>	3	62.5	59.8-65.8	86.4	76.9-95.9	92.3	89.0-97.6	95.0	89.3-100
<i>7 days after treatments</i>	3	63.9	56.5-70.8	89.6	80.8-98.7	94.9	89.4-100	96.9	91.7-100
South-east EPPO zone									
<i>2-3 days after treatments</i>	2	86.6	38.8-134	75.5	64.8-86.1	86.7	83.9-89.4	85.9	82.5-89.2

Target: <i>Aphids</i>	No. of trials	Untreated COUNS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
6-7 days after treatments	2	74.2	45.9-102	50.5	29.5-71.6	72.3	71.4-73.3	64.7	61.9-67.4
North-east EPPO zone									
2-3 days after treatments	5	104.3	27.0-278	61.2	34.4-80.2	78.0	49.9-93.2	86.3	63.7-97.1
7-10 days after treatments	5	112.6	31.3-311	64.7	24.6-76.6	79.9	41.9-95.0	83.8	48.6-97.9
19 days after treatments	1	27.5	-	79.6	-	91.5	-	97.3	-
Greenhouse									
3 days after treatments	4	18.3	9.4-32.1	81.8	59.8-99.9	85.2	66.1-99.8	91.5	77.1-98.8
7 days after treatments	4	13.7	9.9-24.1	76.7	45.9-99.2	78.8	46.8-100	83.3	57.3-98.3
Target: <i>Aphids</i>	No. of trials	Untreated PESSEV		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Greenhouse									
2-3 days after treatments	3	2.56	2.5-2.6	72.3	71.4-72.8	78.2	77.1-78.8	79.4	78.4-80.0
7-8 days after treatments	3	3.53	3.4-3.6	73.4	72.1-74.3	78.8	77.8-79.5	80.0	79.0-80.6
14 days after treatments	3	4.46	4.3-4.6	70.6	69.7-71.3	74.4	73.3-75.2	75.5	74.4-76.3
Target: <i>Aphids</i>	No. of trials	Untreated PESINC		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
Greenhouse									
2-3 days after treatments	3	45.3	43.8-46.3	71.2	69.2-72.2	77.0	74.9-78.2	78.3	76.1-79.4
7-8 days after treatments	3	49.6	48.0-50.5	71.8	69.9-72.9	77.7	75.6-78.9	78.8	76.9-79.9
14 days after treatments	3	53.3	51.3-54.8	69.2	67.3-70.3	72.8	71.2-73.4	74.0	72.3-75.0

Results from the three EPPO zones and greenhouse provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on caterpillar in 18 strawberry trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in strawberry crops, Deltamethrin 5% CS should be applied one time at 0.15 L/ha.

Control of lepidoptera in strawberry

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of Lepidoptera in strawberry crops, the assessment results of 9 efficacy trials performed in the Mediterranean EPPO zone (6) and the greenhouse (3) in 2017 season, are reported. Deltamethrin 5% CS was included in these trials at 0.15 L/ha to demonstrate the recommended dose rate as well as at two lower than recommended dose rates (0.075 L/ha [3.75 g deltamethrin per hectare] and 0.10 L/ha [5 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 50 and 67% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

A summary of the dose response results obtained in the Mediterranean and greenhouse efficacy trials is provided in Table 3.2-11.

Table 3.2-11: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 50% and 67% dose rates on lepidoptera in strawberry.

Target: <i>lepidoptera</i>	No. of trials	Untreated COUNS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.075 l/ha = 3.75 g ai/ha		0.10 l/ha = 5 g ai/ha		0.15 l/ha = 7.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
3 days after treatments	6	8.32	1.5-17.8	46.7	26.3-83.3	60.5	42.1-83.3	68.9	52.4-100
7 days after treatments	6	8.89	1.0-19.3	43.9	20.0-100	63.9	38.7-100	75.3	52.3-100
Target: <i>lepidoptera</i>	No. of trials	Untreated PESSEV		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.075 l/ha = 3.75 g ai/ha		0.10 l/ha = 5 g ai/ha		0.15 l/ha = 7.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Greenhouse									
2-3 days after treatments	3	80.8	78.5-84.5	72.5	72.0-72.8	78.6	78.2-78.8	79.9	79.5-80.2
7-8 days after treatments	3	91.5	89.3-94.8	72.9	72.4-73.5	78.7	78.3-79.0	80.2	79.7-80.4
14 days after treatments	3	101.3	99.5-104	70.3	69.7-70.9	74.1	73.7-74.7	75.3	74.8-75.9
Target: <i>lepidoptera</i>	No. of trials	Untreated PESINC		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.075 l/ha = 3.75 g ai/ha		0.10 l/ha = 5 g ai/ha		0.15 l/ha = 7.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Greenhouse									
2-3 days after treatments	3	40.0	39.0-41.3	72.6	72.2-73.2	78.6	78.4-79.1	79.8	79.3-80.5
7-8 days after treatments	3	45.4	44.3-46.5	73.4	72.9-74.1	79.0	78.8-79.4	80.1	79.7-80.7
14 days after treatments	3	50.3	49.5-51.0	70.5	70.1-71.0	74.2	73.8-74.8	75.5	75.1-75.9

Results from one EPPO zone and greenhouse provided similar outcomes. The tested product applied at the recommended dose rate (0.15 l/ha) obtained a higher degree of control than was observed in plots treated with the lower than recommended dose rates. Furthermore, the control obtained with the recommended dose rate was with less variability at the assessment timing than was observed with the less than recommended dose rates. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on lepidoptera in 9 strawberry trials treated with three applications, it can be concluded that to consistently control frequently occurring lepidoptera in strawberry crops, Deltamethrin 5% CS should be applied **one time at 0.15 L/ha**.

Control of aphids in tomato

In order to prove and to support the requested dose rate of **0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare]** applied for the control of aphids in tomato crops, the assessment results of 17 efficacy trials performed in the north-east (6), the Mediterranean EPPO zone (6) and the greenhouse (5) in 2017 season, are reported. **Deltamethrin 5% CS** was included in these trials at 0.25 L/ha to demonstrate the dose rate as well as at two lower than dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 60 and 166% of the full recommended rate of **Deltamethrin 5% CS**, in accordance with the EPPO standard PP 1/225(2) ‘Minimum effective dose’ and the Central zone efficacy requirements.

A summary of the dose response results obtained in the North-east, Mediterranean and greenhouse efficacy trials is provided in Table 3.2-12.

Table 3.2-12: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on aphids in tomato.

Target: <i>Aphids</i>	No. of trials	Untreated COUINS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPO zone									
3 days after treatments	3	348.3	329-372	85.5	85.3-85.8	92.6	92.4-93.1	98.8	98.0-99.9
7 days after treatments	3	311.4	285-326	88.2	87.8-88.6	94.9	94.6-95.3	99.7	99.5-100
14 days after treatments	3	278.3	264-302	79.5	78.2-80.8	88.5	87.7-89.6	96.8	95.0-99.7
North-east EPPO zone									
1-3 days after treatments	6	142.9	57.0-305	42.3	35.4-47.2	47.6	38.3-55.9	56.9	45.9-71.8
7 days after treatments	6	160.8	61.5-347	45.4	32.9-60.9	52.4	41.2-70.6	61.9	48.0-76.8
12-14 days after treatments	6	173.9	60.8-384	40.2	28.0-55.8	51.7	35.2-68.9	57.6	40.0-76.1
Greenhouse									
2-3 days after treatments	5	41.6	8.5-56.9	60.4	41.5-92.8	67.5	54.4-94.3	72.8	61.6-93.1
7-8 days after treatments	5	45.3	9.2-57.5	85.8	81.9-90.5	91.2	89.6-93.2	94.5	91.3-96.8
14 days after treatments	5	63.7	8.7-96.0	84.1	77.9-84.9	86.9	80.4-90.4	90.4	81.2-93.5

Results from two EPPO zone and greenhouse provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on aphids in 17 tomato trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in tomato crops, Deltamethrin 5% CS should be applied one time at 0.15 L/ha.

Control of whitefly in tomato

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of whitefly in tomato crops, the assessment results of 16 efficacy trials performed in North-east EPPO zone and greenhouse in 2017 season, are reported. Deltamethrin 5% CS was included in these trials at 0.25 L/ha to demonstrate the dose rate as well as at two lower than dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 60 and 166% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPO standard PP 1/225(2) 'Minimum effective dose' and the Central zone efficacy requirements.

A summary of the dose response results obtained in the North-east and greenhouse efficacy trials is provided in Table 3.2-13.

Table 3.2-13: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on whiteflies in tomato.

Target: <i>Aphids</i>	No. of trials	Untreated COUINS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Greenhouse									
3-4 days after treatments	8	214.7	3.76-369	82.0	26.2-93.7	86.9	49.9-95.4	93.9	42.9-98.6
7-10 days after treatments	7	169.6	2.10-340	65.8	16.4-82.8	72.8	32.1-88.7	82.9	28.1-97.9
14 days after treatments	3	275.9	253-317	76.5	75.8-77.3	81.8	81.3-82.3	91.5	90.9-91.8
21 days after treatments	3	267.8	250-302	68.0	67.1-68.7	77.2	76.2-78.1	87.3	86.3-87.9
North-east EPPo zone									
2-4 days after treatments	6	65.1	32.3-130	45.9	37.1-51.9	52.9	40.6-60.4	57.7	45.6-66.2

Results from one EPPo zone and greenhouse provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on whiteflies in 16 tomato trials treated with the applications, it can be concluded that to consistently control frequently occurring aphids in tomato crops, Deltamethrin 5% CS should be applied one time at 0.15 L/ha.

Control of aphids in ornamentals

In order to prove and to support the requested dose rate of 0.15 L/ha Deltamethrin 5% CS [7.5 g deltamethrin per hectare] applied for the control of aphids in ornamentals crops, the assessment results of 16 efficacy trials performed in the Maritime EPPo zone (2), the North-east (4), the South-east zone (1), the Mediterranean EPPo zone (6) and greenhouse (3) in 2017 and 2018 season, are reported. Deltamethrin 5% CS was included in these trials at 0.25 L/ha to demonstrate the dose rate as well as at two lower than dose rates (0.15 L/ha [7.5 g deltamethrin per hectare] and 0.20 L/ha [10.0 g deltamethrin /ha]). The rates reflect the proposed label rate as well as 60 and 166% of the full recommended rate of Deltamethrin 5% CS, in accordance with the EPPo standard PP 1/225(2) ‘Minimum effective dose’ and the Central zone efficacy requirements.

A summary of the dose response results obtained in the Maritime, North-east, South-east, Mediterranean and greenhouse efficacy trials is provided in Table 3.2-14.

Table 3.2-14: Minimum effective dose – Efficacy of Deltamethrin 5% CS at proposed label rate and at 133% and 166% dose rates on aphids in ornamentals.

Target: <i>Aphids</i>	No. of trials	Untreated COUINS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
		Mean	Range	Mean	Range	Mean	Range	Mean	Range
Mediterranean EPPo zone									
3 days after treatments	6	56.9	10.5-132	78.5	44.3-97.4	86.9	67.1-99.3	89.8	68.3-100
7 days after treatments	6	63.7	13.3-160	77.2	42.8-96.3	86.2	65.7-98.8	89.4	66.6-100
Maritime EPPo zone									
3 days after treatments	2	1889.4	532-3247	62.2	41.5-82.9	68.7	52.8-84.5	84.1	82.2-85.9

Target: <i>Aphids</i>	No. of trials	Untreated COUNS		Mean % Control at a range of doses of deltamethrin Deltamethrin 5% CS					
		Mean	Range	0.15 l/ha = 7.5 g ai/ha		0.20 l/ha = 10.0 g ai/ha		0.25 l/ha = 12.5 g ai/ha	
				Mean	Range	Mean	Range	Mean	Range
10 days after treatments	2	2440.3	681-4200	91.2	83.5-98.9	97.4	95.2-99.5	99.7	99.5-99.9
17 days after treatments	2	3864.7	804-6930	24.3	23.3-25.3	34.5	28.6-40.4	55.6	47.3-63.8
South-east EPPO zone									
2 days after treatments	1	17.5	-	86.9	-	76.1	-	89.9	-
7 days after treatments	1	19.9	-	71.1	-	48.1	-	70.6	-
North-east EPPO zone									
2 days after treatments	2	222.3	219-225	92.6	89.3-95.8	96.0	93.9-98.1	97.9	97.1-98.7
7 days after treatments	4	301.5	215-485	95.6	88.5-98.3	97.4	93.3-99.8	98.4	93.8-100
Greenhouse									
2-3 days after treatments	3	11.2	4.48-20.7	64.9	0-98.3	66.3	0-100	65.8	0-98.9
7 days after treatments	3	8.42	6.4-11.4	97.3	95.2-100	98.0	96.5-99.2	99.2	98.5-100

Results from the four EPPO zones and greenhouse provided similar outcomes. The data showed that the application of 0.15 l/ha was sufficient for a good and persistent control, therefore the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators of other sections. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Based on results achieved on aphids in 16 ornamentals trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in ornamental crops, Deltamethrin 5% CS should be applied one time at 0.15 L/ha.

Summary and conclusions on the minimum effective dose

Deltamethrin 5% CS applied at 0.15 L/ha to control aphids in brassicas (cabbage, Brussels sprouts, cauliflower), to control caterpillar in brassicas (cabbage, Brussels sprouts, cauliflower), to control aphids and whiteflies in strawberry, tomato and ornamentals and to control Lepidoptera in strawberry achieved moderate to excellent control of all target pests. To ensure that a satisfactory level of control is achieved with the proposed dose rate, it is recommended that Deltamethrin 5% CS is applied under optimal conditions, i.e. early growth stage of the pests and optimal weather conditions.

The same pests are controlled by deltamethrin in the different crops. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

As will be demonstrated in the following section, this document clearly demonstrates that the efficacy and crop safety of Deltamethrin 5% CS is equivalent to that of the standard deltamethrin reference products (i.e. Decis protech, Decis Mega, Decis Forte) to which it was compared. The applicant therefore wishes to cite the original registrant's data on deltamethrin 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.

Comments of zRMS:	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. During field tests Applicant used different doses of insecticide – Decide (product code: SHA 0100 Y). So, in the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance with EPPO 1/225 (2). What is more, insecticides containing active ingredients – deltamethrin have been allowed
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to use for many years (since 1978). Also, in the literature of crop protection vast amounts of information can be found on efficacy of the plant protection products containing deltamethrin.

To determine the minimum effective dose rate, data from 34 trials conducted in brassicas, 27 trials conducted in strawberry, 33 trials conducted in tomato and 16 trials conducted in ornamentals field crops are included in this section. In the one hundred and ten trials, Deltamethrin 5% CS was applied at 0.05 to 0.25 L/ha for the control of aphids. The dose rates tested reflects 20% to 100% of the recommended rate of Deltamethrin 5% CS. However, **the dose has been reduced to 0.15 l/ha due to the requirement by the evaluators from other sections. And that's why the current recommended dose is 0,15 l/ha for use only once a season. Therefore, the remaining doses tested by the Applicant are respectively 1,33 N (0,20 l/ha) and 1,66 N (0,25 l/ha).**

Ornamental plants:

- **aphids:** Based on results achieved on aphids in 16 ornamentals trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in ornamental crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

Tomato:

- **whiteflies:** Based on results achieved on whiteflies in 16 tomato trials treated with the applications, it can be concluded that to consistently control frequently occurring aphids in tomato crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

- **aphids:** Based on results achieved on aphids in 17 tomato trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in tomato crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

Strawberry:

- **lepidoptera:** Based on results achieved on lepidoptera in 9 strawberry trials treated with three applications, it can be concluded that to consistently control frequently occurring lepidoptera in strawberry crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

- **caterpillar:** Based on results achieved on caterpillar in 18 strawberry trials treated with three applications, it can be concluded that to consistently control frequently occurring aphids in strawberry crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

Brassicas:

- **caterpillar:** Based on results achieved on caterpillar in 16 brassicas (cabbage, brussels sprouts, cauliflower) trials treated with two or three applications, it can be concluded that to consistently control frequently occurring aphids in brassicas crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

- **aphids:** Based on results achieved on aphids in 18 brassicas (cabbage, brussels sprouts, cauliflower) trials treated with two or three applications, it can be concluded that to consistently control frequently occurring aphids in brassicas crops. According to reduction dose by Ecotoxicology section – Deltamethrin 5% CS can be applied only once a season at 0.15 L/ha.

	ZRMs agree with Applicant: “To ensure that a satisfactory level of control is achieved with the proposed dose rate, it is recommended that Deltamethrin 5% CS is applied under optimal conditions, i.e., early growth stage of the pests and optimal weather conditions”. Deltamethrin 5% CS applied at 0.15 L/ha to control aphids in brassicas (cabbage, Brussels sprouts, cauliflower), to control caterpillar in brassicas (cabbage, Brussels sprouts, cauliflower), to control aphids and whiteflies in strawberry, tomato, and ornamentals and to control Lepidoptera in strawberry achieved moderate to excellent control of all target pests.
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3.2.3 Efficacy tests (KCP 6.2)

Data from 110 efficacy trials conducted in the Maritime EPPO zone (6; i.e. N-France (3) and Czech Republic (3), the North-east EPPO zone (34; i.e. Poland), the South-east EPPO zone (5; i.e. Hungary (3) and Romania (2)), the Mediterranean EPPO zone (36, i.e. Spain (18) and Greece (18)) and greenhouse (29) have been included in this biological assessment dossier to support the label claims and recommendations on efficacy and selectivity in the EU Central Registration zone.

The 110 efficacy trials were conducted in brassicas (34), strawberry (27), tomato (33) and ornamentals (16).

Efficacy evaluation was based on count of insects caused by the insects on the crop. In the field trials, the number of insects was assessed by counting the number of insects on a sample of a defined number of plants per plot. In the trials used to assess the efficacy of Deltamethrin 5% CS, up to four or more assessments were conducted, starting at the date of application. The summary tables in the following sub sections contain the data from the assessment conducted at three or four different timings after application.

Table 3.2-15: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4), PP 1/239(2), PP 1/230(1)
	Specific guidelines	Brassicas: EPPO PP 1/83(2) Strawberry: EPPO PP 1/295(1) Tomato: EPPO PP 1/36(3) Ornamentals: EPPO PP 1/23(2)
Experimental design	Plot design	RCBD (110)
	Plot size	12-34.5 m ²
	Number of replications	4 (110)
Crop	Trials per crop	Brassicas (34), i.e. BRSOL (6) and BRSOB (28) Strawberry (27), i.e. FRASS (15) and FRAAN (12) Tomato (33), i.e. LYPES (33) Ornamentals (16): GEBSS (2), ROSSS (4), NNNZZ (4), ATHMM (1), MDVSA (3), FRERE (2)
	Varieties per crop	<u>Brassicas</u> : Sentender, Skywalker, Medusa, Abruzzi F1, Kernis F1, Hispalis, Cartier, Charif, Casper RZ F1, Brio, Cercy RZ F1, Fargo, Carianee, Melissa, Delta, De buzau, Cabral, Bruce F1, Momentum, Guideline, Foteleza, Adona, Gohan, Charlot. <u>Strawberry</u> : Camarosa, Selva, Sabrina, Candonga, Primoris, Victory, San Andreas, Fortuna, Sengana, Jolly, Antea, Marmolada, Honeoye, Clery, Roxana, Hanoya <u>Tomato</u> : Guarapo, Boludo Rio grande, Meteor, Primadona, Torry, Eliseo, Valenciano, Genio, Cardina, Hector, Operet F1, Karina, Siriana, Prekos, Dyno, Callista, Sunshine, Bobeat, Galilea, Awizo, Fortix. <u>Ornamentals</u> : Fabio, Rosseta, Grand amore, Ranunculus Blanc, Potomac White, Alehli Caneto, Velvet red, Delta, Parade, Burgund, Pigy Pink, Rapid red.

	Sowing period	Brassicas: Sep 30 th to August 20 th Strawberry: August 15 th to Novembre 1 st Tomato: February 20 th to August 7 th Ornamentals: September 1 st to May 9 th
Application	Crop stage (BBCH)* at application	Brassicas: BBCH 13-72 Strawberry: BBCH 57-89 Tomato: BBCH 21-81 Ornamentals: BBCH 30-64
	Timing	Brassicas: March 17 th to September 3 rd Strawberry: December 17 th to June 12 th Tomato: May18 th to November 10 th Ornamentals: January 9 th to May 19 th
	Pest stage at appl. (1)	BBCH 00-71 – for details on the growth stage of the specific pests at application, please refer to summary tables in Appendix 5
	Number of appl. Intervals between appl.	3 (64), 2 (31), 1 (15)
	Spray volumes	200-1000 L/ha
Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on pests counts (COUNT) in a defined area, as compared to the untreated check.
	Assessment dates	Efficacy: 1 to 14 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

Control of aphids in brassica crops

Maritime EPPO Zone

When applied at **0.15 L/ha** in the Maritime zone, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 5 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-16: Maritime zone: Control obtained with **0.15 L/ha Deltamethrin 5% CS against aphids in brassicas crops – application timing: BBCH 11-43.**

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha [7.5 g ai/ha]	1 N [12.45 g ai/ha]				
COUNS								
2-3 days after treatments	2	316.3 (11.1-621)	53.0 (21.6-84.4)	63.4 (38.4-88.3)			2	<
6-7 days after treatments	2	356.3	55.2	58.4		1	1	=

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
		(8.08-704)	0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
14 days after treatments	1	775.5 (-)	89.0 (-)	88.7 (-)		1		1

North-east EPPO Zone

When applied at 0.10 L/ha in the North-east zone, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 16 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-17: North-east zone: Control obtained with 0.10 L/ha Deltamethrin 5% CS against aphids in brassicas crops – application timing: BBCH 12-40.

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 12.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.10 L/ha [5 g ai/ha]	1 N [5.5 g ai/ha]				
COUNS								
2 days after treatments	6	411.5 (206-1064)	80.1 (58.8-100)	78.9 (66.9-100)		2	4	<
7-9 days after treatments	6	437 (163-1170)	77.6 (53.8-100)	75.6 (55.5-100)	1	2	3	<
13-14 days after treatments	4	488.9 (85.8-1314)	65.7 (47.8-97.1)	66.7 (55.2-79.2)	1		3	<

Mediterranean EPPO Zone

When applied at 0.15 L/ha in the Mediterranean zone, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 24 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-18: Mediterranean zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in brassicas crops – application timing: BBCH 11-43.

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
COUNS								
3 days after treatments	6	156.1 (20.8-348)	84.7 (81.4-88.9)	96.8 (94.9-98.3)			6	6
7 days after treatments	6	165.3 (20.8-317)	85.8 (82.9-88.5)	97.5 (95.0-99.6)			6	6
14 days after treatments	6	159.3	75.8	96.3			6	6

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin refer- ence product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
		(27.6-330)	0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
DAMINS (1-4)								
<i>3 days after treatments</i>	3	2.09 (1.63-2.65)	67.6 (63.9-73.8)	67.4 (60.0-73.4)		3		■
<i>7 days after treatments</i>	3	2.09 (1.64-2.65)	78.6 (67.9-87.5)	75.9 (70.7-79.2)	1	2		■

Greenhouse

When applied at 0.15 L/ha in the greenhouse, Deltamethrin 5% CS achieved very good to excellent control of aphids commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 2 assessments carried out, where statistical evaluation of the assessment was reported. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Table 3.2-19: Greenhouse: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in brassicas crops – application timing: BBCH 11-43.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin refer- ence product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
COUNS								
<i>3 days after treatments</i>	1	78.5	90.0	94.1		1		■
<i>7 days after treatments</i>	1	72.8	92.9	94.3		1		■

Conclusion

The individual trial results clearly show that Deltamethrin 5% CS gave high, persistent levels of control of aphids, equivalent to that achieved by the reference product, even slightly better. This was true in most trials, at all of the assessment timings.

Control of caterpillar in brassica crops

Maritime EPP0 Zone

When applied at 0.15 L/ha in the Maritime zone, Deltamethrin 5% CS achieved good to very-good control of caterpillar commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 4 assessments carried out, where statistical evaluation of the assessment was reported.

		0.15 L/ha [7.5 g ai/ha]	1 N [10 g ai/ha]	>	=	<	
COUNS							
<i>1-2 days after treatments</i>	2	18.2 (13.5-22.9)	63.5 (56.3-70.6)	83.3 (81.3-85.3)			2 <
<i>7 days after treatments</i>	2	24.4 (20.9-27.9)	74.7 (74.5-75.0)	95.1 (94.6-95.6)			2 <
<i>14 days after treatments</i>	2	19.8 (18.4-21.2)	69.1 (68.4-69.7)	92.6 (91.2-93.9)			2 <

Mediterranean EPPO Zone

When applied at 0.15 L/ha in the Mediterranean zone, Deltamethrin 5% CS achieved excellent control of caterpillar commonly found in brassicas. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 12 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-23: Mediterranean zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against caterpillar in brassicas crops – application timing: BBCH 11-43.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 9 g ai/ha. = : ± 5% control	>	=	<	Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at					
			Mean (min-max)						
			0.15 L/ha [7.5 g ai/ha]	1 N [9 g ai/ha]					
COUNS									
<i>3 days after treatments</i>	3	27.3 (25.5-29.9)	80.7 (79.6-81.3)	87.3 (85.3-90.1)				3	<
<i>7 days after treatments</i>	6	12.2 (1.02-24.7)	81.6 (62.6-88.2)	88.4 (77.1-93.4)		3		3	=
<i>14 days after treatments</i>	3	20.2 (19.6-21.2)	74.6 (74.3-74.8)	84.4 (82.1-86.4)				3	<

Conclusion

The individual trial results clearly show that Deltamethrin 5% CS gave high, persistent levels of control of caterpillar, equivalent to that achieved by the reference product. This was true in the most trials, at all of the assessment timings.

Control of aphids in strawberry crops

North-east EPPO Zone

When applied at 0.15 L/ha in the North-east zone, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in strawberry. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 11 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-24: North-east: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in strawberry crops – application timing: BBCH 11-81.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.5 g ai/ha]				
COUNS								
2-3 days after treatments	5	104.3 (27.0-278)	61.2 (34.4-80.2)	81.4 (63.6-91.3)		1	4	<
7-10 days after treatments	5	112.6 (31.3-311)	64.7 (24.6-76.6)	82.7 (68.9-92.8)	1	2	2	=
19 days after treatments	1	27.5 (-)	79.6 (-)	99.1 (-)			1	<

South-east EPPO Zone

When applied at 0.15 L/ha in the South-east zone, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in strawberry. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 4 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-25: South-east: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in strawberry crops – application timing: BBCH 11-81.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
COUNS								
2-3 days after treatments	2	86.6 (38.8-134)	75.5 (64.8-86.1)	87.8 (85.9-90.0)		1	1	=
6-7 days after treatments	2	74.2 (45.9-102)	50.5 (29.5-71.6)	72.3 (68.8-75.9)		1	1	=

Mediterranean EPPO Zone

When applied at 0.15 L/ha in the Mediterranean zone, Deltamethrin 5% CS achieved excellent control of aphids commonly found in strawberry. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 6 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-26: Mediterranean zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in strawberry crops – application timing: BBCH 11-81.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.45 g ai/ha]				
COUNS								

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha [7.5 g ai/ha]	1 N [12.45 g ai/ha]				
3 days after treatments	3	62.5 (59.8-65.8)	86.4 (76.9-95.9)	97.1 (95.6-98.8)		1	2	2
7 days after treatments	3	63.9 (56.5-70.8)	89.6 (80.8-98.7)	99.2 (97.6-100)		1	2	2

Greenhouse

When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved good to very good control of aphids commonly found in strawberry. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 22 assessments carried out, where statistical evaluation of the assessment was reported. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Table 3.2-27: Greenhouse: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in strawberry crops – application timing: BBCH 11-81.

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.45 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha [7.5 g ai/ha]	1 N [12.45 g ai/ha]				
COUINS								
2-3 days after treatments	2	86.6 (38.8-134)	81.8 (59.8-99.9)	87.8 (85.9-90.0)		1	1	=
6-7 days after treatments	2	74.2 (45.9-102)	76.7 (45.9-99.2)	72.3 (68.8-75.9)			2	<
PESSEV								
2-3 days after treatments	3	2.56 (2.5-2.6)	72.3 (71.4-72.8)	78.7 (77.1-80.2)		2	1	=
7-8 days after treatments	3	3.53 (3.4-3.6)	73.4 (72.1-74.3)	79.3 (77.8-80.8)		2	1	=
14 days after treatments	3	4.46 (4.3-4.6)	75.5 (74.4-76.3)	74.8 (73.3-76.1)		2	1	=
PESINC								
2-3 days after treatments	3	45.3 (43.8-46.3)	71.2 (69.2-72.2)	78.7 (76.6-79.9)		2	1	=
7-8 days after treatments	3	49.6 (48.0-50.5)	71.8 (69.9-72.9)	78.7 (75.6-80.4)		1	2	<
14 days after treatments	3	53.3 (51.3-54.8)	69.2 (67.3-70.3)	74.3 (72.4-75.6)		1	2	<

Conclusion

Table 3.2-31: Mediterranean zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in tomato crops – application timing: BBCH 11-85.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin refer- ence product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.5 g ai/ha]				
COUNS								
3 days after treatments	3	348.3 (329-372)	85.5 (85.3-85.8)	98.5 (98.0-99.0)			3	▲
7 days after treatments	3	311.4 (285-326)	88.2 (87.8-88.6)	99.5 (99.4-99.7)			3	▲
14 days after treatments	3	278.3 (264-302)	79.5 (78.2-80.8)	96.3 (94.7-98.9)			3	▲
THOHEU								
7 days after treatments	3	30.6 (-)	56.3 (-)	79.6 (-)			3	▲

Greenhouse

When applied at 0.15 L/ha in the greenhouse, Deltamethrin 5% CS achieved good to excellent control of aphids commonly found in tomato. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 15 assessments carried out, where statistical evaluation of the assessment was reported. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Table 3.2-32: Greenhouse: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in tomato crops – application timing: BBCH 11-85.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin refer- ence product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)					
			0.15 L/ha 7.5 g ai/ha	1 N [12.5 g ai/ha]				
COUNS								
3 days after treatments	5	41.6 (8.5-56.9)	60.4 (41.5-92.8)	66.9 (51.1-93.8)		3	2	■
7 days after treatments	5	45.3 (9.2-57.5)	85.8 (81.9-90.5)	91.2 (88.9-93.5)		3	2	■
14 days after treatments	5	63.7 (8.7-96.0)	84.1 (77.9-84.9)	85.5 (80.5-88.0)	1	2	2	■

Conclusion

The individual trial results clearly show that Deltamethrin 5% CS gave high, persistent levels of control of aphids in tomato, equivalent to that achieved by the reference product, even slightly better. This was true in the most trials, at all of the assessment timings.

Control of whitefly in tomato

North-east EPP0 zone

When applied at 0.15 L/ha in the North-east zone, Deltamethrin 5% CS achieved good control of

whiteflies commonly found in tomato. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, some significant differences were observed between the two tested products at the assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-33: North-east EPPO zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against whiteflies in tomato crops – application timing: BBCH 11-85.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with			No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 7.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at		>	=	<	
			Mean (min-max)	1 N	1 N				
			0.15 L/ha [7.5 g ai/ha]	1 N [7.5 g ai/ha]	1 N [12.5 g ai/ha]				
COUNS									
2-4 days after treatments	6	65.1 (32.3-130)	45.9 (37.1-51.9)	62.5 (55.2-72.2)	57.2 (52.7-61.6)			6	<

Greenhouse

When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved moderate to excellent control of whiteflies commonly found in tomato. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 21 assessments carried out, where statistical evaluation of the assessment was reported. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Table 3.2-34: Greenhouse: Control obtained with 0.15 L/ha Deltamethrin 5% CS against whiteflies in tomato crops – application timing: BBCH 11-85.

EPPO Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	>	=	<	
			Mean (min-max)	1 N				
			0.15 L/ha [7.5 g ai/ha]	1 N [12.5 g ai/ha]				
COUNS								
3-4 days after treatments	8	214.7 (3.76-369)	82.0 (26.2-93.7)	83.3 (26.5-96.1)		6	2	=
7-10 days after treatments	7	169.6 (2.10-340)	65.8 (16.4-82.8)	66.0 (16.8-97.8)	1	4	2	=
14 days after treatments	3	275.9 (253-317)	76.5 (75.8-77.3)	91.0 (90.5-91.4)		2	1	=
21 days after treatments	3	267.8 (250-302)	68.0 (67.1-68.7)	87.7 (86.9-88.2)		2	1	=

Conclusion

The individual trial results clearly show that Deltamethrin 5% CS gave high, persistent levels of control of whiteflies in tomato, equivalent to that achieved by the reference product, even slightly better. This was true in the most trials, at all of the assessment timings.

Table 3.2-37: South-east zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in ornamentals crops – application timing: BBCH 11-89.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with			No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	National ref. prod. at	>	=	<	
			Mean (min-max)						
			0.15 L/ha 7.5 g ai/ha	1 N [12-12.5 g ai/ha]	1 N				
COUNS									

Mediterranean EPP0 zone

When applied at 0.15 L/ha in the Mediterranean zone, Deltamethrin 5% CS achieved very good to excellent control of aphids commonly found in ornamentals. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 12 assessments carried out, where statistical evaluation of the assessment was reported.

Table 3.2-38: Mediterranean zone: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in ornamentals crops – application timing: BBCH 11-89.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with			No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	National ref. prod. at	>	=	<	
			Mean (min-max)						
			0.15 L/ha 7.5 g ai/ha	1 N [12.5 g ai/ha]	1 N				
COUNS									

Greenhouse

When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved excellent control of aphids commonly found in ornamentals. In all species evaluated, the effect achieved with Deltamethrin 5% CS was similar to the effect obtained with the deltamethrin reference product applied in the trials. Statistical evaluation supports this statement as, no significant differences were observed between the two tested products at any of the 6 assessments carried out, where statistical evaluation of the assessment was reported. Trials conducted under glasshouse represent a more challenging situation to control these 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.

Table 3.2-39: Greenhouse: Control obtained with 0.15 L/ha Deltamethrin 5% CS against aphids in ornamentals crops – application timing: BBCH 11-89.

EPP0 Code	No. of trials	Mean (min-max)	Efficacy obtained with			No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at	National ref. prod. at	>	=	<	
			Mean (min-max)						
			0.15 L/ha 7.5 g ai/ha	1 N [12-12.5 g ai/ha]	1 N				

Eppo Code	No. of trials	Mean (min-max)	Efficacy obtained with		No. of trials Deltamethrin 5% CS at 7.5 g deltamethrin/ha is >, < or =, compared to the deltamethrin reference product at 12.5 g ai/ha. = : ± 5% control			Overall
			Deltamethrin 5% CS at:	Deltamethrin ref. prod. at				
			Mean (min-max)		>	=	<	
			0.15 L/ha [7.5 g ai/ha]	1 N [12-12.5 g ai/ha]				
COUNS								
2-3 days after treatments	3	11.2 (4.48-20.7)	64.9 (0.0-98.3)	65.9 (0-99.1)		3		=
7 days after treatments	3	8.42 (6.4-11.4)	97.3 (95.2-100)	98.4 (96.3-99.6)		3		=

Conclusion

The individual trial results clearly show that Deltamethrin 5% CS gave high, persistent levels of control of aphids in ornamentals, equivalent to that achieved by the reference product, even slightly better. This was true in the most trials, at all of the assessment timings.

3.2.3.1 Overall conclusion

Based on the results of 110 field efficacy trials carried out in 2017 and 2018 season, the following can be concluded for the intended use control of aphids and caterpillar in brassicas, aphids and lepidoptera in strawberry, aphids and whitefly in tomato and aphids in ornamentals with Deltamethrin 5% CS:

- Deltamethrin 5% CS applied at the proposed dose rate of 0.15 L/ha provides a high level of control of aphids found in brassicas, of caterpillar found in brassicas, of a aphids and whitefly commonly found in strawberry, tomato and ornamentals and of lepidoptera in strawberry. Single application of Deltamethrin 5% CS in all crops should be used to efficiently control all pests claimed on the label.
- Compared to the deltamethrin reference product, the efficacy obtained with Deltamethrin 5% CS is comparable against all pests.
- Compared to the national reference products containing pyrethrins and lambda cyhalothrin, the efficacy obtained with Deltamethrin 5% CS was comparable to inferior against the pests present in the trials.
- The trial results are considered valid for all intended South zone countries.

The dose has been reduced to 0.15 l/ha in all uses due to the requirement of the evaluators in the ecotoxicology section. When treating the similar pests, the same level of control would be expected, in all GAP claimed crops and this has been seen in the trials. Therefore, for any label claims not adequately supported for one crop type, Sharda Cropchem España requests that the Zonal Evaluators reads across to the data on the other crop types and application timings.

This BAD also clearly demonstrates that the efficacy and cropsafety of Deltamethrin 5% CS is equivalent to the efficacy and cropsafety of the standard deltamethrin reference products against which Deltamethrin 5% CS was compared. The applicant therefore wishes to cite the original registrant’s data on deltamethrin 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.

Applicant would like to refer to the EPPO standard PP 1/226(3) where is indicated that full number of trials in different years is required “ particularly for plant protection products or active substances which not have been on the market in the EPPO region in which authorization is sought”. It is important to remark that the EPPO standard is referring to the region where registration is sought and not to a specific country, thus applicant considers that presence of standards has to be evaluated taking into account the registers in the whole Central Zone. The same EPPO PP 1/226(3) indicates that reduced number of trials

can be presented “where there is a large amount of supporting evidence from use of the product, or of similar products with the same active substance on closely related pests or against the same pests on different crops”. Deltamethrin formulations have been registered in Central zone and in countries where trials were conducted for various years like Decis Mega (reg. nr R-9/2012) registered in Poland since 2012, Decis Forte (reg. nr 5450-0) registered in the Czech Republic in 2008, Decis Mega (reg. nr 4244-15) registered in the Czech Republic in 2006, Decis Forte (reg. nr 16110) registered in the United Kingdom in 2013 or Decis Forte (reg. nr 00718-00) registered in Germany since 2014. According to this formulation has been widely proved in Central zone where registration is sought, thus applicant considers that number of trials are enough to register formulation.

Comments of zRMS:	<p>Details of experiment are presented above by Applicant. All used methodology is in accordance with GEP rules, with one exception. Trials were conducted during only one growing season, which is not in line to EPPO standards. Applicant has provided the necessary explanations about conducting research only during one growing season. Deltamethrin is a substance available on the market since the 1970s, which is why the effectiveness of insecticides based on it is well known. In the opinion of Evaluator, only one growing season should be acceptable.</p> <p>Applicant submitted in total 110 efficacy trials, carried out in the Maritime EPPO zone – 6 trials (FR-3, CZ-3); North-East EPPO zone – 34 trials (PL); South-East EPPO zone – 5 trials (HU-3, RO-2) and Mediterranean EPPO zone – 36 trials (SP-18, GR-18), of which, 29 studies were performed in greenhouse.</p> <p>Applicant presented 34 efficacy trials carried out on brassicas, 27 on strawberries, 33 on tomatoes and 16 trials performed on ornamental plants. Number of trials is in line to EPPO standards, in the exception of brassicas plants. Enough trials should be done on representative plant – BRSOL. However, Applicant carried out trials on BRSOL and BRJOB. We could not assess these crops together. Also, in our opinion extrapolation is not possible without enough trials for representative crop. cMS should decide if limited number of trials for brassicas can be acceptable.</p> <p style="text-align: center;">FIELD TRIALS:</p> <p>Brassicas plants:</p> <ul style="list-style-type: none"> • aphids: <ul style="list-style-type: none"> ✓ Maritime EPPO zone – 2 trials were conducted in France (2 applications per season were studied) on head cabbage and 2 trials on cauliflower in the Czech Republic (1 application per season was studied). BRVCBR as a pest was studied in trials. ✓ North-East EPPO zone – 4 6 trials were carried out on cauliflower in Poland (2 4 applications per season – 2 trials; 3 applications per season – 2 trials). BRVCBR as a pest was studied in 5 trials and APHIFA in 1 trial. Lack of trials for cabbage and brussels sprouts. ✓ South-East – lack of trials ✓ Mediterranean – 9 trials were carried out on cauliflower in Spain (6) and Greece (3). 3 applications per seasons were studied. BRVCBR as a pest was studied in 3 trials and APHISP in 3 trial and BRVCSP in 3 trials. Lack of trials for cabbage and brussels sprouts. <p>Deltamethrin 5% CS applied at the proposed dose rate of 0,15 L/ha provides a from moderately to high level of control of aphids found in brassicas. In the opinion of Evaluator in Poland (N-E) registration the plant protection product - Decide for application on head cabbage and brussels sprouts cannot be accepted. Appropriate number of trials (at least 1-2) carried out on head cabbage and brussels sprouts in Poland or neighboring country is required. Only application against aphids on cauliflower can be register in Poland (N-E EPPO</p>
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	<p>zone). Product was characterized by moderately efficiency in N-E EPPO zone against BRVCBR and APHIFA. For, cauliflower in MED EPPO zone three applications per season were studied, whilst in GAP table Applicant recommended one application per seasons. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. cMS from Maritime should decide if submitted documentation can be accepted. For cauliflower in Maritime EPPO zone one application per season during 2 trials were studied. Registration in S-E without any trials should be not possible. Final decision is left to cMS.</p> <p>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. In Poland, few plant products with deltamethrin are registered for use in brassicas against aphids at this dose: 0,15 l/ha.</p> <ul style="list-style-type: none">• caterpillar: according to EPPO standard 1/83 Test organisms should be: Mamestra brassicae (BARABR), Pieris rapae (PIERRA), Pieris napi (PIERNA), Pieris brassicae (PIERBR), Plutella xylostella (PLUTMA). <ul style="list-style-type: none">✓ Maritime EPPO zone – 2 trials were conducted in France (1 application per season was studied) on head cabbage. BARABR (1 trial) and PIERBR (1 trial) were studied in trials as pests. Lack of trials for cauliflower and brussels sprouts.✓ North-East EPPO zone – 6 trials were carried out on cauliflower in Poland (2 applications per season were studied). PIERRA (4 trials) and PIERBR (2 trials) were studied in trials as pests. Lack of trials for head cabbage and brussels sprouts.✓ South-East – 2 trials carried out in Romania (1 application per season was studied) on head cabbage. PIERBR were studied in trials as pests. Lack of trials for cauliflower and brussels sprouts.✓ Mediterranean- 6 trials performed on cauliflower (SP-3, GR-3). During trials 3 application per seasons were studied. PIERBR were studied in trials as pests. Lack of trials for head cabbage and brussels sprouts. <p>Deltamethrin 5% CS applied at the proposed dose rate of 0,15 L/ha provides a from moderately to high level of control of caterpillars found in brassicas. In the opinion of Evaluator in Poland (N-E) registration the plant protection product - Decide for application on head cabbage and brussels sprouts cannot be accepted. At least 1-2 trials carried out on head cabbage and brussels sprouts in Poland or neighboring country is required. Only application against caterpillars on cauliflower can be register in Poland (N-E). Product was characterized by good efficiency in N-E EPPO zone against PIERRA and PIERBR. cMs from S-E and Maritime should decide if only 2 trials carried out on head cabbage and lack of trials for brussels sprouts and cauliflower are acceptable. In MED EPPO zone only three applications per season were studied during trials, whilst in GAP table Applicant recommended one application per seasons. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. cMS from MED should decide if this situation for cauliflower and lack of trials for head cabbage and brussels sprouts can be acceptable.</p> <p>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. In Poland, lack of registered the plant products with deltamethrin for use in brassicas against caterpillars.</p> <p>Strawberry:</p> <ul style="list-style-type: none">• aphids:
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	<p>✓ Maritime EPPO zone – lack of trials.</p> <p>✓ North-East EPPO zone – 6 trials carried out in Poland (2 applications per season – 5 trials; 1 application per season – 1 trial). APHIFO (4 trials), ANTHRU (1 trial) and APHISP (1 trial) were studied in trials as pests.</p> <p>✓ South-East – 2 trials performed in Hungary (1 application per season was studied). APHIFO was studied in trials as pest.</p> <p>✓ Mediterranean – 3 trials were carried out in Greece (3 applications per season were studied). APHIFO was studied in trials as pest.</p> <p>Deltamethrin 5% CS applied at 0.15 L/ha provides a from moderately to high level of control of aphids commonly found in strawberry. On the basis on presented documentation, registration in MED, N-E and S-E should be possible. In N-E, product was characterized by moderately efficiency against APHIFO, ANTHRU and APHISP. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. cMS from Maritime should decide if extrapolation from other climatic zone is possible, because registration with lack of trials seems to be not acceptable. 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. In Poland one plant protection product is registered for use at dose 0,15 l/ha against aphids on strawberry.</p> <ul style="list-style-type: none"> • <i>lepidoptera:</i> <p>✓ Maritime EPPO zone – lack of trials.</p> <p>✓ North-East EPPO zone – lack of trials.</p> <p>✓ South-East – lack of trials.</p> <p>✓ Mediterranean- 6 trials (SP-3, GR-3). During trials 3 application per seasons were studied. DROSSU (3 trials) and SPODLI (3 trials) were studied as pests in trials.</p> <p>Deltamethrin 5% CS applied at 0.15 L/ha provides an excellent control of lepidoptera in strawberry. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. Applicant submitted sufficient documentation for registration Decide against lepidoptera on strawberries in MED EPPO zone. Due to lack of trials registration Decide against lepidoptera in Poland (N-E) is not possible. cMs from Maritime and South-East EPPO zone should decide if extrapolation results from MED EPPO zone is possible. 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</p> <p>Tomatoes:</p> <ul style="list-style-type: none"> • aphids: <p>✓ Maritime EPPO zone – lack of trials.</p> <p>✓ North-East EPPO zone – 3 6 trials carried out in Poland (3 applications per season were studied). APHIFA (1 trial) and APHISP (5 trials) were studied in trials as pests.</p> <p>✓ South-East – lack of trials.</p> <p>✓ Mediterranean – 6 trials were carried out in GR (3) and SP (3). 3 applications per season were studied during trials. MYZUPE (3 trials) and MACSEU (3 trials) were studied in trials as pests.</p> <p>Deltamethrin 5% CS applied at 0.15 L/ha provides from low to a high level of control of a aphid commonly found in tomatoes. On the basis on presented documentation, registration in MED and N-E (PL) should be possible. In N-E EPPO zone product was characterized by low efficiency, so in the label should be an entry about limiting of aphids (APHIFA and APHISP). MS from S-E and Maritime EPPO zone should decide if extrapolation from other climatic zone is</p>
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<p>possible, because registration with lack of trials seems to be not acceptable.</p> <p>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. In Poland one plant protection product is registered for use at dose 0,15 l/ha against aphids on strawberry.</p> <ul style="list-style-type: none">• whitefly: <ul style="list-style-type: none">✓ Maritime EPPO zone – lack of trials.✓ North-East EPPO zone – 6 trials carried out in PL. During trials 2 applications per season were studied. TRIAVA (3 trials), ALEUPR (1 trial) and ALEYOC (2 trials) were studied in trials as pests.✓ South-East – lack of trials.✓ Mediterranean- lack of trials. <p>When applied at 0.15 L/ha in the North-east zone, Deltamethrin 5% CS achieved good control of whiteflies commonly found in tomato. Applicant submitted sufficient documentation for registration Decide against whiteflies on tomatoes in North-East EPPO zone (PL). An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. Product was characterized by moderately level of efficiency in N-E. In Polish label, TRIAVA, ALEUPR and ALEYOC can be included. Due to lack of trials registration Decide against whiteflies in S-E, Maritime and MED EPPO zone is not possible. cMS from Maritime, MED and South-East EPPO zone should decide if extrapolation results from N-E EPPO zone is possible. 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. In Poland only one plant protection product is registered against whitefly for use on tomato in non-professional use. Lack of products with deltamethrin for professional use.</p> <p>Ornamental plants: according to EPPO 1/23, the test organisms should be the non-winged stages of aphids, such as <i>Myzus persicae</i> (MYZUPE), <i>Aphis fabae</i> (APHIFA), <i>Aulacorthum circumflexum</i> (MYZUCI), <i>Macrosiphoniella sanborni</i> (MACRCH), <i>Brachycaudus helichrysi</i> (ANURHE), <i>Macrosiphum rosae</i> (MACSRO), <i>Aphis gossypii</i> (APHIGO).</p> <ul style="list-style-type: none">• aphids: <ul style="list-style-type: none">✓ Maritime EPPO zone – 2 trials carried out in Czech Republic (1 application per season was studied during trials). NNNZZ was studied during trials. DACTJA as a pest was studied in trials. cMS should decide if trials can be acceptable, because not recommended pest was studied during trials.✓ North-East EPPO zone – 4 trials carried out in Poland (3 applications per season were studied during 2 trials; 1 application per season studied in 2 trials). Evaluation was performed after each application. ROSSS (2 trials) and FRERE (2 trials) were studied during trials. MACSRO as a pest was studied in trials.✓ South-East – 2 trials performed in Hungary (1 application per season was studied). ROSS was studied during trials. MACSRO as a pest was studied in trials.✓ Mediterranean – 6 trials were carried out in Spain. 3 applications per season were studied during 3 trials and 2 application per season were studied during 3 trials. Evaluation was performed after each application. ROSS (1 trial), GEBSS (2 trials), MDVSA (3 trials) were studied during trials. APHISP as a pest was studied in trials. <p>Deltamethrin 5% CS applied at 0.15 L/ha provides a high level of control of aphids commonly found in ornamentals. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per</p>
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season is acceptable. On the basis on presented documentation, registration should be possible in North-east EPPO zone (PL), S-E and MED. In Polish label, ROSS and FRERE can be included. As a pest – MACSRO should be put in Polish label. 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. In Poland only two plant protection products are registered against aphids for use on ornamentals in non-professional use. Lack of products with deltamethrin for professional use.

GREENHOUSE TRIALS:

Brassicas plants:

- **aphids:**

- ✓ Maritime EPPO zone – 1 trial carried out in Germany (3 applications per season was studied during trials). APHDSP was studied as a pest in trial.
- ✓ North-East EPPO zone – lack of trials.
- ✓ South-East – lack of trials
- ✓ Mediterranean – lack of trials.

When applied at 0.15 L/ha in the greenhouse, Deltamethrin 5% CS achieved very good to excellent control of aphids commonly found in brassicas. Trial conducted under glasshouse represent a more challenging situation to control these 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. Detailed assessment about brassicas in the field are presented above by Evaluator. 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. This one test should only be regarded as signaling.

Strawberry:

- **aphids:**

- ✓ Maritime EPPO zone – 1 trial carried out in Germany (2 application per season were studied). APHIFG was studied as a pest in trial.
- ✓ North-East EPPO zone – lack of trials.
- ✓ South-East – lack of trials.
- ✓ Mediterranean – 6 trials (3 applications per season were studied during 3 trials; 2 application per season were studied in 3 trials). CHTSFR (3 trials) and APHISP (3 trials) was studied as a pests in trials.

When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved good to very good control of aphids commonly found in strawberry. For greenhouse use all climatic zones can be assessed together. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. In the opinion of Evaluator, on the basis on 3 valid efficacy trials from MED EPPO zone, tested plant protection product can be register in N-E, S-E, Maritime, and MED for greenhouse on strawberry against aphids. However, final decision is left for cMS. 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. However, this use was not proposed by Applicant in GAP table and label project. Only, field use on strawberry against aphids was included by Applicant. So, this use is presented by Evaluator only as informative.

- *lepidoptera:*

- ✓ Maritime EPPO zone – lack of trials.
- ✓ North-East EPPO zone – lack of trials.
- ✓ South-East – lack of trials.

	<p>✓ Mediterranean- 3 trials (3 application per seasons were studied). HELVSP as a pest was studied in trials.</p> <p>When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved good to very good control of lepidoptera commonly found in strawberry. For greenhouse use all climatic zones can be assessed together. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. In the opinion of Evaluator, on the basis on 3 valid efficacy trials from MED EPPO zone, tested plant protection product can be register in N-E, S-E, Maritime, and MED for greenhouse on strawberry against lepidoptera. However, final decision is left for cMS. 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. However, this use was not proposed by Applicant in GAP table and label project. Only, field use on brassicas against lepidoptera was included by Applicant. So, this use is presented by Evaluator only as informative.</p> <p>Tomatoes:</p> <ul style="list-style-type: none">• aphids: <p>✓ Maritime EPPO zone – lack of trials. ✓ North-East EPPO zone – lack of trials. ✓ South-East – 5 trials (RO-4; HU-1). During 4 trials 3 application per season were studied. In one trial one application per season was studied. MYZUPE (1 trial) and APHIFO (4 trials) were studied in trials as a pests.</p> <p>✓ Mediterranean – lack of trials.</p> <p>When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved good to very good control of aphids commonly found in tomatoes. For greenhouse use all climatic zones can be assessed together. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. In the opinion of Evaluator, on the basis on 4 valid efficacy trials from S-E EPPO zone, tested plant protection product can be register in N-E, S-E, Maritime, and MED for greenhouse on tomatoes against aphids. However, final decision is left to cMS. 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. However, this use was not proposed by Applicant in GAP table and label project. Only, field use on tomatoes against aphids was included by Applicant. So, this use is presented by Evaluator only as informative.</p> <ul style="list-style-type: none">• whiteflies: <p>✓ Maritime EPPO zone – lack of trials. ✓ North-East EPPO zone – lack of trials. ✓ South-East – lack of trials. ✓ Mediterranean- 6 10 trials (3 application per seasons were studied during 3 6 trials; 2 applications per season were studied in 3 4 trials). BEMITA (6 trials) and TRIAVA (4 trials) were studied in trials as a pests.</p> <p>When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved good to very good control of whiteflies commonly found in tomatoes. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. For greenhouse use all climatic zones can be assessed together. In the opinion of Evaluator, on the basis on 3 valid efficacy trials from MED EPPO zone, tested plant protection product can be register in N-E, S-E, Maritime, and MED for greenhouse on tomatoes against whiteflies. In Polish label, BEMITA and TRIAVA can be included (moderately efficiency of DECIDE). However, final decision is left for cMS. The dose has</p>
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	<p>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.</p> <p>Ornamental plants:</p> <ul style="list-style-type: none">• aphids: <ul style="list-style-type: none">✓ Maritime EPPO zone – lack of trials.✓ North-East EPPO zone – lack of trials.✓ South-East – lack of trials.✓ Mediterranean – 3 trials (3 application per season were studied during trials). APHISP as a pest was studied in trials. NNNZZ (2 trials) and ATHMM (1 trial) was studied. <p>When applied at 0.15 L/ha in greenhouse, Deltamethrin 5% CS achieved excellent control of aphids commonly found in ornamentals. 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. An efficacy evaluation was performed after each application, so in our opinion, recommending application only once per season is acceptable. For greenhouse use all climatic zones can be assessed together. In the opinion of Evaluator, on the basis on 6 valid efficacy trials from MED EPPO zone, tested plant protection product can be register in N-E, S-E, Maritime, and MED for greenhouse on ornamental plants against aphids. However, final decision is left to cMS. However, this use was not proposed by Applicant in GAP table and label project. Only, field use on ornamentals was included by Applicant. So, this use is presented by Evaluator only as informative.</p> <p>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. For example, in Poland trials from field and greenhouses carried out on ornamentals should allowed to register ROSS, FRERE and ATHMM in label.</p> <p>Deltamethrin 5% CS applied at the proposed dose rate of 0.15 L/ha provides a from moderately to high level of control of aphids found in brassicas, of caterpillar found in brassicas, of a aphids and whitefly commonly found in strawberry, tomato, and ornamentals and of lepidoptera in strawberry. Single application of Deltamethrin 5% CS in all crops should be used to efficiently control all pests claimed on the label.</p> <p>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.</p>
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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Summary and Conclusions

The following dossier section follows EPPO standard PP 1/213(3) *Resistance risk analysis* in particular point 6. *Registration requirements* of the standard.

Introduction

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. 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 a 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 Registration of Deltamethrin 5% CS is endorsed.

3.3.2 Mode of action

Deltamethrin is a broad-spectrum insecticide that belongs to the chemical class of pyrethroids. Pyrethroids are synthetic chemicals modeled after the pyrethrin components of pyrethrum. Deltamethrin is effective against insects via direct contact or ingestion. Pyrethroids, in general, interfere with normal production and conduction of nerve signals in the nervous system. Pyrethroids act on nerve membranes by delaying the closing of the activation gate for the sodium ion channel. Researchers distinguish between two classes of pyrethroids based on electrophysiological studies with nerves and symptoms of toxicity. Type II pyrethroids, including deltamethrin, have an α -cyano group that induces “long-lasting” inhibition of the sodium channel activation gate. This results in prolonged permeability of the nerve to sodium and produces a series of repetitive nerve signals in sensory organs, sensory nerves and muscles.

3.3.3 Mechanism- and evidence of resistance

To date, a number of reports have been published where insect resistance towards of deltamethrin has been observed, also in grain storage pests (e.g. Singh and Prakash, 2013³).

Methods of resistance include thickening of the cuticle of the insect to limit permeation of the insecticide, metabolic resistance via overexpression of metabolising P450 mono-oxygenases and glutathione-S-transferases, and the knockdown resistance (kdr) sodium channel mutations which render the action of insecticides ineffectual, even when co-administered with PBO (IRAC, 2014).

As several cases of resistance in grain storage pests towards deltamethrin have been reported, it is advised that caution should be taken when using DELTAMETHRIN 5% CS at the recommend dose rates in stored cereal grains.

3.3.3.1 Cross-resistance

In many cases, not only does resistance render the selecting compound ineffective, it also confers cross-resistance to other chemically related compounds. This is because compounds within a specific chemical group usually share a common target site within the pest and thus share a common MoA. It is common for resistance to develop that is based on a genetic modification of the target site. When this happens, the interaction of the selecting compound with its target site is impaired and the compound loses its pesticidal efficacy. Because all compounds within the chemical group share a common MoA, there is a high risk that existing or developing target-site resistance will confer cross-resistance to all compounds in the same group.

3.3.3.2 Sensitivity data

Insects vary in their sensitivity towards insecticides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. Group 3 insecticides (hereunder deltamethrin as well as especially DDT) have been tested and used worldwide for more than 40 years and it is therefore difficult to find unexposed insect populations. No true base line sensitivity data can therefore be established.

3.3.4 Use pattern

Deltamethrin 5% CS is based on the activity of deltamethrin. In the EU Central zone, the formulation is proposed for use against aphids and caterpillar in brassicas (cabbage, Brussels sprouts, cauliflower) (BBCH 11-43), against aphids and lepidoptera in strawberry (BBCH 11-81), against aphids and whitefly in tomato (BBCH 11-85) and against aphids in ornamentals (BBCH 10.89). The recommended dose rate is 0.15 L/ha (7.5 g ai/ha) to control aphids in brassicas, Caterpillar in brassicas, in strawberry, tomato and ornamentals and lepidoptera in. The maximum number of applications is one application per growing season.

3.3.5 Resistance Risk assessment of unrestricted use pattern

Agronomic practice

Not applicable

The plant protection product

For optimum insect control, deltamethrin is applied at the rates recommended on the proposed label. These have been shown to be the minimum effective dose for the major pest targets.

Unrestricted Use pattern

In the absence of any potential resistance risk and in the absence of any other restrictions on the GAP (residues, toxicology etc.) the unrestricted use pattern for deltamethrin would be season long usage with an unrestricted number of applications.

Resistance risk assessment of unrestricted use pattern

Overall it is clear that the unrestricted use of deltamethrin presents an unacceptable resistance risk and therefore modifiers as part of a Management Strategy are proposed.

3.3.6 Acceptability of the resistance risk

Without any precautions, the resistance risk is unacceptable. However; taking the right precautions and following Good Agricultural Practise, the risk is acceptable. Should resistant populations arise, control

could be achieved through use of alternative products.

3.3.7 Management Strategy

Good Agricultural Practices and Good Plant Protection Practices (EPPO Standard 2/1 (2)) should be the followed in the pests management strategy.

Deltamethrin 5% CS should be used in alternation with insecticides comprising different modes of action to avoid the build-up of resistant biotypes and cross resistance. Do not make more than three applications.

As the unmodified use pattern is considered unacceptable a number of modifiers are proposed which are entirely in accordance with the general recommendations.

- Use in alternation with insecticides with a different mode of action
- Use as recommended on the label. Do not use reduced doses.

3.3.8 Implementation of the management strategy

Information on the management of resistance and the specific Resistance Management Strategy for deltamethrin is disseminated by a number of routes including, but not exclusively:

- Product label has a clear statement regarding resistance risk and the management strategy
- Pack inserts- for general information or to address a particular issue in a specific geographical area were it to occur.
- Leaflets available at, and distributed by distributors/wholesalers/merchants
- Information released by national and local advisory services re. monitoring
- Training for distributors/wholesalers/merchants and farmer groups

Links from company web sites to local Resistance working groups for information and advic.

3.3.9 Monitoring, reporting and reaction to changes in performance

Monitoring of performance

Where performance is significantly less than expected (relative to study results presented in section 6.1.3) and where no other explanation can be found for the reduced performance e.g. application errors, then samples may be taken for sensitivity testing. Where testing is carried out it will be conducted at laboratories experienced in carrying out such testing and using methods recommended by the authorities.

Analysis of performance-related complaints

Where no other reason for a failure in performance can be identified, samples may be taken for testing as described above

Where resistance is confirmed as the cause for loss of performance this will be reported to the authorities on an annual basis or as required.

Containment plan

The above recommendations will be adjusted as needed depending on the success of the proposed strategy. In the event that practical resistance should occur on any significant scale, Sharda's plan for containing the further development or spread of resistance includes a number of possible actions on a temporary or permanent basis, including but not exclusively:

- Recommendations to repeat the treatment with insecticides from alternative mode of action groups
- Recommendation to use only in a programme e.g. before or after an application of an insecticide from a different mode of action group.

Normally any action taken would be in consultation with the relevant authorities.

Comments of zRMS:	<p>Deltamethrin is an established active substance in more important common crops as foliar spray treatment and it belongs to the old group of insecticides, the pyrethroids. Deltamethrin disrupts the normal functioning of the nervous system in an organism.</p> <p>The mode of action this substance consists in disturbing dynamics functioning of sodium channel in neurons.</p> <p>Known resistance occurrence according to IRAC website in not known against: <i>Oulema melanopus</i>, <i>Pegomya hyoscyami</i>, <i>Aphis fabae</i>, <i>Delia radicum</i>, <i>Ceutorhynchus assimilis</i> and <i>Dasineura brassicae</i>. Resistance occurred, for example at <i>Leptinotarsa decemlineata</i>, <i>Meligethes aeneus</i>, <i>Psylliodes chrysocephala</i>.</p> <p>Evaluator accepted the strategy management about possible development of resistance or cross-resistance proposed by Applicant: use alternately insecticides with different modes of action, use as recommended on the label; do not use reduced doses. So, as part of a strategy to prevent resistance, among other things, it is recommended that the product be applied:</p> <ul style="list-style-type: none"> - only in the recommended dose, - alternating with other insecticides containing active substances from other groups with a different mechanism of action. <p>Since the agronomic factors influencing the risk of resistance development tend to vary between the member states, the individual and detailed assessment of the resistance risk (Evaluation of the Agronomic risk of resistance, Management of resistance, use pattern, Proposed Risk Modifiers) has to be finalised on national level.</p>
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3.4 Adverse effects on treated crops (KCP 6.4)

As Deltamethrin 5% CS is an insecticide, no specific studies are required as long as in the efficacy trials no negative effects are observed. The crop safety of applying Deltamethrin 5% CS at the recommended rates in brassicas, strawberry, tomato and ornamentals was evaluated in 110 efficacy trials.

Details on Materials and Methods in the efficacy trials evaluated for selectivity is presented;

Table 3.4-1: Presentation of efficacy trials

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
Brassicas (Field)	Aphids	Spain	2018	MED + E	-	3 (3)	-	-	GEP	
		Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		France	2017	MED + E	1 (1)	-	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Czech Rep.	2017	MED + E	1 (1)	-	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
					2 (2)	9 (9)		6 (6)		
	Caterpillar	Romania	2017	MED + E	-	-	2 (2)	-	GEP	
Greece		2017	MED + E	-	3 (3)	-	-	GEP		

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
		France	2017	MED + E	2 (2)	-	-	-	GEP	
		Spain	2018	MED + E	-	3 (3)	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
					2 (2)	6 (6)	2 (2)	-		
Brassicas (Greenhouse)	Aphids	Germany	2017	MED + E	1 (1)	-	-	-	GEP	
					1 (1)	-	-	-		
Strawberry (Field)	Aphids	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Aphids	2017	MED + E	-	-	-	6 (6)	GEP	
						-	3 (3)	2 (2)	6 (6)	
	Lepidoptera	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
						-	6 (6)	-	-	
Strawberry (Greenhouse)	Aphids	Italy	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Germany	2017	MED + E	1 (1)	-	-	-	GEP	
					1 (1)	6 (6)				
	Lepidoptera	Italy	2017	MED + E	-	3 (3)	-	-	GEP	
						-	3 (3)	-	-	
Tomato (Field)	Aphids	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Poland	2017	MED + E	-	-	-	6 (6)	GEP	
					-	6 (6)	-	6 (6)		
	Whitefly	Poland	2017	MED + E	-	-	-	6 (6)	GEP	
						-	-	-	6 (6)	
Tomato (Greenhouse)	Aphids and whitefly	Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Romania	2017	MED + E	-	-	4 (4)	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
						3 (·)	5 (5)			
	Whitefly	Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		France	2017	MED + E	1 (1)	-	-	-	GEP	
		Spain	2017	MED + E	-	3 (3)	-	-	GEP	
						1 (1)	6 (6)	-	-	
Ornamentals (Field)	Aphids	Spain	2017	MED + E	-	3 (3)	-	-	GEP	
		Greece	2017	MED + E	-	3 (3)	-	-	GEP	
		Hungary	2017	MED + E	-	-	1 (1)	-	GEP	
		Czech Rep.	2017	MED + E	2 (2)	-	-	-	GEP	

Use(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					EPPO zone					
					MAR	MED	S-E	N-E		
		Poland	2017	MED + E	-	-	-	4 (4)		
					2 (2)	6 (6)	1 (1)	4 (4)		
Ornamentals (Greenhouse)	Aphids	Spain	2018	MED + E	-	3 (3)	-	-	GEP	
					-	3 (3)	-	-		
Total, all crops					9 (9)	57 (57)	10 (10)	34 (34)		

Table 3.4-2: Details on efficacy trial methodology

Guidelines	General guidelines	EPPO PP 1/152 (4), PP 1/181 (4), PP 1/135(4), PP 1/239(2), PP 1/230(1)
	Specific guidelines	Brassicas: EPPO PP 1/83(2) Strawberry: EPPO PP 1/295(1) Tomato: EPPO PP 1/36(3) Ornamentals: EPPO PP 1/23(2)
Experimental design	Plot design	RCBD (76)
	Plot size	12-34.5 m ²
	Number of replications	4 (76)
Crop	Trials per crop	Brassicas (22), i.e. BRSOL (6) and BRSOB (16) Strawberry (21), i.e. FRASS (15) and FRAAN (6) Tomato (21), i.e. LYPES (21) Ornamentals (12): GEBSS (2), ROSSS (2), NNNZZ (4), ATHMM (1), MDVSA (3)
	Varieties per crop	<u>Brassicas</u> : Sentender, Skywalker, Medusa, Abruzzi F1, Kernis F1, Hispalis, Cartier, Charif, Casper RZ F1, Brio, Cergy RZ F1, Fargo, Carianee, Melissa, Delta, De buzau <u>Strawberry</u> : Camarosa, Selva, Sabrina, Candonga, Primoris, Victory, San Andreas, Fortuna, Sengana, Jolly, Antea <u>Tomato</u> : Guarapo, Boludo Rio grande, Meteor, Primadona, Torry, Eliseo, Valenciano, Genio, Cardina, Hector, Operet F1, Karina, Siriana, Prekos <u>Ornamentals</u> : Fabio, Rosseta, Grand amore, Ranunculus Blanc, Potomac White, Alehli Caneto, Velvet red, Delta, Parade
	Sowing period	<u>Brassicas</u> : Sep 30 th to August 20 th <u>Strawberry</u> : August 15 th to Novembre 1 st <u>Tomato</u> : February 20 th to August 7 th <u>Ornamentals</u> : September 1 st to May 9 th
Application	Crop stage (BBCH)* at application	Brassicas: BBCH 13-72 Strawberry: BBCH 57-89 Tomato: BBCH 21-81 Ornamentals: BBCH 30-64
	Timing	Brassicas: March 17 th to September 3 rd Strawberry: December 17 th to June 12 th Tomato: May18 th to November 10 th Ornamentals: January 9 th to May 19 th
	Pest stage at appl. (1)	BBCH 00-71 – for details on the growth stage of the specific pests at application, please refer to summary tables in Appendix 5

	Number of appl. Intervals between appl.	3 (53), 2 (11), 1 (12)
	Spray volumes	200-1000 L/ha
Assessment	Assessment types	- Visual estimation of biomass reduction per plot compared to 'untreated' ('untreated' = 0 % control); total control = 100 % control) or calculated, based on pests counts (COUNT) in a defined area, as compared to the untreated check.
	Assessment dates	Efficacy: 1 to 14 DAT
Other relevant information	Soil type	Light to heavy soils
	Natural / artificial inoculation...	Natural
	Field / Greenhouse...	Field

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

One hundred and ten efficacy trials were conducted in 2017 and 2018 in Spain (3), Greece (21), Italy (6), Germany (2), Czech Republic (3), N-France (2), Poland (34), Hungary (4) and Romania (6). These were conducted on brassicas (22), strawberry (21), tomato (21) and ornamentals (12).

The performance of Deltamethrin 5% CS was measured against a commercial standard formulation of deltamethrin. The standard used in the trials was (Decis protech, Decis Mega, Decis Forte). In Germany, Karate zeon (Lambda cyhalothrin 10 g/L CS) was used as reference product in one efficacy trial carried out in brassicas as well as one efficacy trial conducted in strawberry. In Spain, Abanto (Pyrethrins 4 g/L EC) was used as an additional reference product in three efficacy trials conducted in ornamentals.

3.4.1.1 Brassicas

Crop phytotoxicity was evaluated in efficacy trials where Deltamethrin 5% CS was applied at growth stages ranging from BBCH 11 to BBCH 43, at the rate of 0.15 to 0.25 L/ha in brassicas. 0.25 L/ha corresponds to 166% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals.

Phytotoxicity in brassicas trials, Maritime EPPO zone

Five efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in brassicas. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the five efficacy trials conducted in the Maritime EPPO zone.

Phytotoxicity in brassicas trials, North-east EPPO zone

Twelve efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in brassicas. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the twelve efficacy trials conducted in the North-east EPPO zone.

Phytotoxicity in brassicas trials, Mediterranean EPPO zone

Fifteen efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in brassicas. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the fifteen efficacy trials conducted in the Mediterranean EPPO zone.

3.4.1.2 Strawberry

Crop phytotoxicity was evaluated in efficacy trials where Deltamethrin 5% CS was applied at growth stages ranging from BBCH 11 to BBCH 81, at the rate of 0.075 to 0.25 L/ha in strawberry. 0.25 L/ha corresponds to 166% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals.

Phytotoxicity in strawberry trials, Mediterranean EPPO zone

Eighteen efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the eighteen efficacy trials conducted in the Mediterranean EPPO zone.

Phytotoxicity in strawberry trials, Maritime EPPO zone

One efficacy trial was conducted in the Maritime EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the efficacy trial conducted in the Maritime EPPO zone.

Phytotoxicity in strawberry trials, North-east EPPO zone

Six efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the two efficacy trials conducted in the North-east EPPO zone.

Phytotoxicity in strawberry trials, South-east EPPO zone

Two efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in strawberry. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the two efficacy trials conducted in the South-east EPPO zone.

3.4.1.3 Tomato

Crop phytotoxicity was evaluated in efficacy trials where Deltamethrin 5% CS was applied at growth stages ranging from BBCH 11 to BBCH 85, at the rate of 0.15 to 0.25 L/ha in tomato. 0.25 L/ha corresponds to 166% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals.

Phytotoxicity in tomato trials, Mediterranean EPPO zone

Fifteen efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in tomato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the fifteen efficacy trials conducted in the Mediterranean EPPO zone.

Phytotoxicity in tomato trials, Maritime EPPO zone

One efficacy trial was conducted in the Maritime EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in tomato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the efficacy trial conducted in the Maritime EPPO zone.

Phytotoxicity in tomato trials, North-east EPPO zone

Twelve efficacy trials were conducted in the North-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in tomato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the Twelve efficacy trials conducted in the North-east EPPO zone

Phytotoxicity in tomato trials, South-east EPPO zone

Five efficacy trials were conducted in the South-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in tomato. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the five efficacy trials conducted in the South-east EPPO zone.

3.4.1.4 Ornamentals

Crop phytotoxicity was evaluated in efficacy trials where Deltamethrin 5% CS was applied at growth stages ranging from BBCH 10 to BBCH 89, at the rate of 0.15 to 0.25 L/ha in ornamentals. 0.25 L/ha corresponds to 166% of the proposed dose rate. Crop phytotoxicity was assessed in all trials at various intervals.

Phytotoxicity in ornamentals trials, Mediterranean EPPO zone

Nine efficacy trials were conducted in the Mediterranean EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in ornamentals. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the nine efficacy trials conducted in the Mediterranean EPPO zone.

Phytotoxicity in ornamentals trials, Maritime EPPO zone

Two efficacy trials were conducted in the Maritime EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in ornamentals. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the two efficacy trials conducted in the Maritime EPPO zone.

Phytotoxicity in ornamentals trials, North-east EPPO zone

Four efficacy trial was conducted in the North-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in ornamentals. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in any of the four efficacy trials conducted in the North-east EPPO zone.

Phytotoxicity in ornamentals trials, South-east EPPO zone

One efficacy trial was conducted in the South-east EPPO zone to assess the crop safety of Deltamethrin 5% CS when applied as recommended in ornamentals. The trials were conducted on commercially available varieties.

No adverse effects in regard to phytotoxicity were observed in the efficacy trial conducted in the South-east EPPO zone.

3.4.1.5 Overall conclusion

Deltamethrin 5% CS applied at the recommended dose rate was perfectly crop safe and did not cause phytotoxicity in any of the trials conducted on brassicas, strawberry, tomato and ornamentals.

As the data on brassicas, strawberry, tomato and ornamentals show, the crop safety and efficacy of Deltamethrin 5% CS is equivalent to that of the Deltamethrin reference product. For recommendations claimed on the draft Deltamethrin 5% CS label not adequately supported by the applicant's trials data, Sharda wishes to cite the original registrant's data on deltamethrin now out of protection and requests that the evaluators extrapolate from those data.

Table 3.4-3: Phytotoxicity of test- and reference product

Number of trials with...		Efficacy trials (76 trials)							
		Test product				Standard 1			
		1N	1N	1N	1N	1N	1N	1N	1N
		Brassicas	Strawberry	Tomato	Ornamentals	Brassicas	Strawberry	Tomato	Ornamentals
Maximum of phytotoxicity recorded during the trials	0% to 5%	34	27	33	16	34	27	33	16
	>5% to 10%	0	0	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	34	27	33	16	34	27	33	16
	>5% to 10%	0	0	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0	0

Comments of zRMS:	Both EU Directive 91/414 (EU, 1991) and EPPO PP 1/226 (3) – Number of efficacy trials requires testing phytotoxicity at normal (N) and double (2N) recommended dose. However, EPPO 1/135 (3) – Phytotoxicity assessment states: ‘EPPO Standards on fungicides, insecticides and plant growth regulators, on the other hand, include only a relatively simple special section on phytotoxicity assessment, because, for these types of plant protection products, phytotoxic effects will be less frequent’. Selectivity trials were not required, which is in accordance with EPPO 1/135 (3).
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	<p>Phytotoxicity was assessed during 110 efficacy trials. Detailed information's are presented by Applicant. No phytotoxicity symptoms caused by a tested product at the proposed dose rate.</p> <p>The applicant was notified that according to PP 1/226 at least 6 trials from each climatic zone are required. CMS should decide if submitted documentation is acceptable for registration Decide.</p> <p>Based on similar selectivity of tested product and reference, the applicant wishes to cite the original registrant's data on deltamethrin now out of protection in support of those recommendations on the draft label that are not adequately supported. Such extrapolations should be considered by individual member states on a national level based on current registration, data protection and experience with similar deltamethrin products.</p> <p>For Poland (N-E EPPo zone) submitted documentation is sufficient for cauliflower, strawberry, tomatoes and ornamental plants (studied species were presented in chapter 3.2.3. Efficacy tests in commenting box). Not enough trials were presented for head cabbage and brussels sprouts.</p> <p>Deltamethrin 5% CS applied at the recommended dose rate was perfectly crop safe and did not cause phytotoxicity in any of the trials conducted on brassicas, strawberry, tomato and ornamentals.</p>
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3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Trials with yield results are not required for Deltamethrin 5% CS.

Active substance comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe. There is absence of any evidence concerning the influence of insecticide Deltamethrin 5% CS on the quality of yield.

According to the above statement no additional research are required in this range.

Comments of zRMS:	ZRMs agree with Applicant.
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3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Trials with quality results are not required for Deltamethrin 5% CS.

Active substance comprising in this product has been applied for many years, not only in Poland but also in the other countries of Europe. There is absence of any evidence concerning the influence of insecticide Deltamethrin 5% CS on the quality of yield.

According to the above statement no additional research are required in this range.

Comments of zRMS:	ZRMs agree with Applicant.
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3.4.4 Effects on transformation processes (KCP 6.4.4)

There are no indications that the use of deltamethrin will have influence on possible transformation processes. It is therefore expected that Deltamethrin 5% CS, when applied as recommended in the GAP claimed uses will not cause any unacceptable adverse effects on transformation processes.

Furthermore, the residue data (see Part B Section 6) clearly demonstrate that, at the proposed application rates, no deltamethrin 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 deltamethrin has been used for a long time as a insecticide. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor do deltamethrin containing products have any label restrictions concerning their use on crops destined for processing.

Comments of zRMS:	ZRMs agree with Applicant. Since the market introduction no effects on transformation processes have been recorded for any of these products, nor no deltamethrin containing products have any label restrictions concerning their use on crops destined for processing.
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3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Deltamethrin 5% CS is composed of deltamethrin, which has been widely used for several years on the GAP claimed crops, without identifying any issues in regards to ability of grains of treated plants to germinate.

According to the Guideline EPPO 1/135(4), it is only necessary to study the insecticide in seeds and tubers only where the plant protection product has systemic activity, is applied close to harvest and some phytotoxic effects are seen in some crops, therefore in our case it is not required.

Comments of zRMS:	Information provided by the Applicant was limited due to fact that plant protection product – Deltamethrin 5% CS is not intended to protect seeds, grains, cutting, tubers or rhizomes. Also, no phytotoxicity symptoms occurring during the field trials suggested that product application in accordance with label recommendation has no negative impact on parts of plant used for propagating purposes.
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3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Deltamethrin is registered as an insecticide for protection of grain and pulses in a number of products already on the market. Long-standing practical experiences, since the active substance was first introduced into the market, has shown that within the scope of normal crop rotation no restrictions on succeeding crops do exist. In addition, the active substance is also used as foliar insecticide. There have been no cases of negative impacts on succeeding crops even with foliar applications.

Deltamethrin lack any herbicidal activity. This and the fact that the overall concentration in the soil following planting grains treated with Deltamethrin 5% CS at storage is very low, are two more reasons to underline that Deltamethrin 5% CS does not have any impact on succeeding crops.

Conclusion

Based on experiences with the solo active ingredient, the risk that the product Deltamethrin 5% CS has negative impact on succeeding crops, if applied at the proposed GAP for protection against insect feeding, is regarded to be negligible. Thus the recommendation of no restrictions on following crops after sowing seeds treated with Deltamethrin 5% CS is justified.

Comments of zRMS:	Applicant did not provide any new data and did not submit the results of the trials on possible impact on succeeding crops. However, a review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggest that product application in accordance with label recommendation shall not adversely impact on succeeding crops. What is important, active substance comprising in this product have been applied for many years not only in Poland but also in other countries of Europe. Based on the absence of any adverse effects in typical cropping situations, it was concluded that the insecticide Deltamethrin 5% poses no risk to succeeding crops.
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3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

During the conduct of efficacy trials, no observations about negative effects on other plants or neighbouring crops were reported. Furthermore, it was demonstrated that Deltamethrin 5% CS is not phytotoxic to the crops claimed in the GAP.

According to EPPO PP 1/256, no data are normally required for insecticide such as Deltamethrin 5% CS. Furthermore, deltamethrin has been used for several years on e.g. ornamentals, tomato, brassicas crops, without identifying any issues.

Comments of zRMS:	The Applicant did not submit the results of the trials on possible impact on adjacent crops. The information collected in previous section and a review of available literature as well as the lack of phytotoxicity symptoms recorded during the field trials suggests that product application in accordance with label recommendation has no negative impact on adjacent crops.
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3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

From the experimentation carried out with Deltamethrin 5% CS in 2017 and 2018, no problems regarding adverse effects on beneficial organisms were reported.

Special tests to investigate this purpose are not required.

For more information, see the results of the standard ecotoxicological tests being presented in dRR Part B section 6.

Compatibility with current management practices including IPM

This is not an EC data requirement/ not required by Directive 91/414/EEC.

Comments of zRMS:	Adverse effects on beneficial organisms (other than bees) are presented in section
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	6 Ecotoxicology.
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3.6 Other/special studies

No other studies were conducted

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials mentioned in this document were conducted. All facilities are certified and the trials were conducted according to GEP guidelines.

Table 3.7-1: List of test facilities

Testing facility	Zone	Country	Year and trial type	
			Efficacy trials	
			2017	2018
Brassicas				
Daye desarrollo agrícola	MED	ES		3
Agriscience	MED	GR	6	
Sicop	MED	ES	3	3
Eurofins agrosience services	MAR	FR	3	
Hetterich FieldWork GbR	MAR	DE	1	
ZKUSEBNI STANICE Trutnov	MAR	CZ	1	
Research Institute for Vegetables	S-E	RO	2	
Fertico Sp. Z o.o.	N-E	PL	12	
Total, Brassicas			28	6
Strawberry				
Agrolab RDS	MED	GR	6	
Biofarm S.r.l.	MED	IT	6	
Sicop	MED	ES	6	
Hetterich FieldWork GbR	MAR	DE	1	
Syntech Research	S-E	HU	1	
Plant-Art Research Kft.	S-E	HU	1	
Fertico Sp. Z o.o.	N-E	PL	6	
Total, Strawberry			27	
Tomato				
Daye desarrollo agrícola	MED	ES	3	
Agriscience	MED	GR	6	
Sicop	MED	ES	6	
Eurofins agrosience services	MAR	FR	1	
Research Development institute for plant protection	S-E	RO	4	
Syntech Research	S-E	HU	1	
Fertico Sp. Z o.o.	N-E	PL	12	
Total, Tomato			33	
Ornamentals				
Daye desarrollo agrícola	MED	ES		3
Agrolab RDS	MED	GR	3	
Sicop	MED	ES	3	
ZKUSEBNI STANICE Trutnov	MAR	CZ	2	
Syntech Research	S-E	HU	1	
SGS	N-E	PL	4	
Total, Ornamentals			13	3
Total, All crops			101	9

This table has been coded. For a complete view with the GEP certificates please refer to KCP 6.0-001 Biological Assessment Dossier Deltamethrin 5% CS.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
CP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Deltamethrin 5% CS (50 g/kg deltamethrin) – EU Central zone Sharda Cropchem España -, - Unpublished	N	SHA