

FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: SHA 0100 Y

Product name: DECIDE

Chemical active substance:

Deltamethrin, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT

(authorization)

Applicant: SHARDA Cropchem España S.L.

Submission date: July 2019; July 2021;

MS Finalisation date: 11/2021; 04.2022; 05.2022

Version history

When	What
July 2021	Applicant update
November 2021	ZRMS assessment after an update
January 2022	Applicant update
April 2022	The Final Version of RR
May 2022	The report was amended by: - Efficacy section – complement in accordance with the comments received from the Ministry of Agriculture and Rural Development - Toxicology section – corrections - Ecotoxicology Section on area of risk mitigation measures for aquatic organism

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PART A

RISK MANAGEMENT

1 Details of the application

1.1 Application background

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

This application is for approval of Deltamethrin 5% CS, a Capsule suspension containing 50 g/L of Deltamethrin for use as insecticide on brassicas (cabbage, Brussels sprouts, cauliflower), strawberry, tomato and ornamentals.

1.2 Letters of Access

Not applicable. Letter of access not needed.

1.3 Justification for submission of tests and studies

This dossier relied on new tests and studies, providing data and information specific to the formulation Deltamethrin 5% CS as required by the EU regulations.

1.4 Data protection claims

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

2 Details of the authorization decision

2.1 Product identity

Product code	SHA 0100 Y
Product name in MS	Deltamethrin 5% CS
Authorization number	First authorisation
Function	Insecticide
Applicant	SHARDA Cropchem España S.L.
Active substance(s) (incl. content)	Deltamethrin, 50 g/L
Formulation type	Capsule suspension [Code: CS]
Packaging	COEX HDPE/EVOH; COEX HDPE/PA: 50 mL, 100mL, 500 mL, 1 L, 5 L, 10 L, Professional user

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

2.2 Conclusion

The evaluation of the application for Deltamethrin 5% CS resulted in the decision to grant the authorization.

Section Mammalian toxicology

The evaluation of the application for Deltamethrin 5% CS resulted in the decision to grant the authorization.

Section Phys-chem:

Authorisation can be granted for one year only.

Section Analytical Methods:

No data gaps.

Section Metabolism and residues:

Noticed data gaps are:

Cabbage and brussels sprouts: residue trials.

Section Ecotoxicology:

The evaluation of the application for Deltamethrin 5% CS resulted in the decision to grant the authorization on area of Ecotoxicology.

2.3 Substances of concern for national monitoring

Not relevant.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Eye Dam. 1 Acute Tox. 3 Aquatic Acute 1 Aquatic Chronic 1
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The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold**:

Hazard pictograms:	GHS05, GHS09
Signal word:	Danger
Hazard statement(s):	H318, H331, H410
Precautionary statement(s):	P273, P280, P305+P351+P338, P310, P391, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	Contains 1,2-benzisothiazolin-3-one (2634-33-5) and Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction. [EUH208]
	Repeated exposure may cause skin dryness or cracking. [EUH066]

Special rule for labelling of plant protection product (PPP):	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
EUH 208	Contains 1,2-benzisothiazolin-3-one (2634-33-5) and Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.
EUH 066	Repeated exposure may cause skin dryness or cracking.

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

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe 3	<p>To protect aquatic organism the following risk mitigation measures should be applied:</p> <p>Leafy vegetables (brassicac) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies</p> <p>Ornamentals (apple early BBCH 10) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m with 50% drift reduction nozzles OR respect an unsprayed buffer zone of 20 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 15 m buffer zone with 75% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 90% of nozzle reduction to surface water bodies or 35 meter buffer zone</p> <p>Ornamentals (apple late BBCH 85) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.</p> <p>Ornamentals (onion) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies</p> <p>Strawberry (leafy vegetables 1st crop) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.</p> <p>Tomato (field uses): To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies or 75 drift reduction nozzles.</p>

	<p>To protect non-target arthropods , respect an unsprayed following buffer zones to non-crop land</p> <p>Field crops (brassicas) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land.</p> <p>Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 15m OR 10m with 50% drift reduction nozzles OR 5m and 90% drift reduction nozzles to non-agricultural land.</p> <p>Ornamentals and small fruits – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land</p> <p>SPe8: Dangerous for bees. In order to protect bees and other pollinating insects, do not apply the product to crop plants when in flower or during weed’s flowering. Remove weeds before the period of flowering. Do not use where bees are actively foraging. Remove or cover beehives during application.</p> <p>Protected crops: For the use in permanent greenhouses the exposure of bees in protected crops cannot be excluded, unless pollinators are not used.</p>
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2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

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2.5 Risk management

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
P280	Wear eye protection, face protection, protective clothing, protective gloves
Worker protection:	
-	Wear protective clothing, protective gloves
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe 3	<p>To protect aquatic organism the following risk mitigation measures should be applied:</p> <p>Leafy vegetables (brassicas) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies or 75 % drift reduction nozzles</p> <p>Ornamentals (apple early BBCH 10) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m with 50% drift reduction nozzles OR respect an unsprayed buffer zone of 20 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 15 m buffer zone with 75% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 90% of nozzle reduction to surface water bodies or 35 meter buffer zone</p> <p>Ornamentals (apple late BBCH 85) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of</p>

	<p>nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.</p> <p>Ornamentals (onion) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies</p> <p>Strawberry (leafy vegetables 1st crop) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies</p> <p>Tomato (field uses): To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies or 75 drift reduction nozzles.</p> <p><u>To protect non-target arthropods , respect an unsprayed following buffer zones to non-crop land</u></p> <p>Field crops (brassicas) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land.</p> <p>Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 15m OR 10m with 50% drift reduction nozzles OR 5m and 90% drift reduction nozzles to non-agricultural land.</p> <p>Ornamentals and small fruits – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land</p> <p>SPe8: Dangerous for bees. In order to protect bees and other pollinating insects, do not apply the product to crop plants when in flower or during weed’s flowering. Remove weeds before the period of flowering. Do not use where bees are actively foraging. Remove or cover beehives during application.</p> <p>Protected crops: For the use in permanent greenhouses the exposure of bees in protected crops cannot be excluded, unless pollinators are not used.</p>
Other specific restrictions	
-	

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

Integrated pest management (IPM)/sustainable use:	
-	Dangerous for bees. Do not allow bees and other pollinators into the greenhouse. Integrated pest management (IPM)/ not recommended to use <ul style="list-style-type: none"> • Warning: This product may be harmful to natural enemies.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

Integrated pest management (IPM)/sustainable use:		Relevant for use no.
-	-	-
Environmental protection:		Relevant for use no.
-	-	-

2.6 Intended uses (only NATIONAL GAP)

PPP (product name/code): Deltamethrin 5% CS Formulation type: CS (Capsule suspension)
 Active substance 1: Deltamethrin Conc. of as 1: 50 g/L
 Active substance 2: - Conc. of as 2: -
 Safener: - Conc. of safener: -
 Synergist: - Conc. of synergist: -
 Applicant: SHARDA Cropchem España S.L. Professional use:
 Zone(s): Southern Non professional use:
 Verified by MS: yes/no

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

Field of use: Insecticide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Aphids	Foliar spray	BBCH 11-43	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200- 600	7	Residues and Efficacy section: only use on cauliflower can be accepted.
2	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Caterpillars	Foliar spray	BBCH 11-43	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200- 600	7	Residues and Efficacy section: only use on cauliflower can be accepted.

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmen- tal stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
3	CEU	Strawberry	F	Aphids	Foliar spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200- 600	3	-
4	CEU	Strawberry	F	Lepidoptera	Foliar spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200- 600	3	Efficacy section: field use against lepidoptera is not accepted.
5	CEU	Tomato	F	Aphids	Foliar spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300- 1000	3	-
6	CEU	Tomato	G	Whitefly	Foliar spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300- 1000	3	-
7	CEU	Ornamentals	F	Aphids	Foliar spray	BBCH 10-89	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300- 1000	-	-

Remarks table heading:

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

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

Remarks columns:

1 Numeration necessary to allow references
 2 Use official codes/nomenclatures of EU Member States
 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
 4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
 5 Scientific names and EPP0-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
 6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
 8 The maximum number of application possible under practical conditions of use must be provided.
 9 Minimum interval (in days) between applications of the same product
 10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPP0-Guideline PP 1/239 Dose expression for plant protection products.
 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
 13 PHI - minimum pre-harvest interval
 14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of liquid creamy hazelnut. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of 97.7 °C. It has a self-ignition temperature of 599.6 °C. In 1% aqueous solution, it has a pH value around 7.06 ± 0.05 at $20 \pm 2^\circ\text{C}$. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The shelf-life of at least 2 years at ambient temperature is on-going, the final report will be provided as soon as available. Its technical characteristics are acceptable for a *capsule suspension* formulation.

The intended concentration of use is 0.015% v/v to 0.075% v/v.

3.2 Efficacy (Part B, Section 3)

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.

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

- **One** application per season (BBCH 11-43) to control Aphids in Brassicas (cabbage, Brussels sprouts and cauliflower), target rate: **0.15** L/ha.
- **One** application per season (BBCH 11-43) to control Caterpillar in Brassicas (cabbage, Brussels sprouts and cauliflower), target rate: 0.15 L/ha.
- **One** application per season (BBCH 11-81) to control Aphids in Strawberry, target rate: **0.15** L/ha.
- **One** application per season (BBCH 11-81) to control Lepidoptera in Strawberry, target rate: 0.15 L/ha.
- **One** application per season (BBCH 11-85) to control Aphids and Whitefly in Tomato, target rate: **0.15** L/ha.
- **One** application per season (BBCH 10-89) to control Aphids in Ornamentals, target rate: **0.15** L/ha.

This document serves the registration of Deltamethrin 5% CS in the Central zone of the EU. The objective of this document is to prove and support the label claims of the fungicidal efficacy Deltamethrin 5% CS in the label claimed crops.

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

The data demonstrate that the pest control and safety to the crop of Deltamethrin 5% CS is comparable to that of the reference products registered in the EU Central zone, and the applicant therefore wishes to cite the original registrant's data on 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.

3.3 Efficacy data

Preliminary tests

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.

Minimum effective dose tests

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).

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 50% 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 50% to 166% 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.

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 once 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.

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 once 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.

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 once 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.

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 three times 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.

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 once 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.

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 **once 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.**

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 **once at 0.15 L/ha**.

Conclusion: **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.

Efficacy tests and conclusions regarding authorization of intended uses

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.

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.

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.

FIELD TRIALS:

Brassicas plants:

• aphids:

- ✓ 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.

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 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.

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.

• 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).

- ✓ 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.

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.**

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.

Strawberry:

- **aphids:**

- ✓ Maritime EPPO zone – lack of trials.
- ✓ 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.**
- ✓ South-East – 2 trials performed in Hungary (1 application per season was studied). **APHIFO was studied in trials as pest.**
- ✓ Mediterranean – 3 trials were carried out in Greece (3 applications per season were studied). **APHIFO was studied in trials as pest.**

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.

- **lepidoptera:**

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

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

Tomatoes:

- **aphids:**

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

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 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.

- **whitefly:**

- ✓ 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.

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.

Ornamental plants: according to EPPO 1/23, the test organisms should be the non-winged stages of aphids, such as *Myzus persicae* (MYZUPE), *Aphis fabae* (APHIFA), *Aulacorthum circumflexum* (MYZUCI), *Macrosiphoniella sanborni* (MACRCH), *Brachycaudus helichrysi* (ANURHE), *Macrosiphum rosae* (MACSRO), *Aphis gossypii* (APHIGO).

- **aphids:**

- ✓ 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. ROSS (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.**

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 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:

Brassicac 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.
- ✓ Mediterranean- 3 trials (3 application per seasons were studied). **HELVSP as a pest was studied in trials.**

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.**

Tomatoes:

- **aphids:**

- ✓ 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.**

✓ Mediterranean – lack of trials.

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.**

• **whiteflies:**

✓ 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.**

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 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.

Ornamental plants:

• **aphids:**

✓ Maritime EPPO zone – lack of trials.

✓ North-East EPPO zone – lack of trials.

✓ South-East – lack of trials.

✓ Mediterranean – **6 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.**

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.

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.

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.

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..

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

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.

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.

Known resistance occurrence according to IRAC website is not known against: *Oulema melanopus*, *Pegomyia hyoscyami*, *Aphis fabae*, *Delia radicum*, *Ceutorhynchus assimilis* and *Dasineura brassicae*. Resistance occurred, for example at *Leptinotarsa decemlineata*, *Meligethes aeneus*, *Psylliodes chrysocephala*.

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:**

- only in the recommended dose,
- alternating with other insecticides containing active substances from other groups with a different mechanism of action.

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.

3.3.2 Adverse effects on treated crops

Phytotoxicity to host crop

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).

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. In the trials where Deltamethrin 5% CS was applied at dose recommended rate, no unacceptable detrimental effects were observed, when assessed in any of the trials.

For crops and recommendations claimed on the label not supported with trials, the applicant wishes to bridge to the trials conducted in brassicas, strawberry, tomato and ornamentals where equivalence between the selectivity of Deltamethrin 5% CS and the reference products currently registered in the EU Southern zone was demonstrated and no negative impact of the application was observed. Sharda therefore wishes to cite the original Registrants 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 Rapporteur extrapolate from those data.

Effects on yield and quality

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

Effect on transformation processes

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 7) 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.

3.3.3 Observations on other undesirable or unintended side-effects

Impact on succeeding crops.

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.

Impact on other plants including adjacent crops

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.

Effects on beneficial and other non-target organisms

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

3.4 Methods of analysis (Part B, Section 5)

Analytical method for deltamethrin in food, feed of plant and animal origin, soil, water and air and in the formulation Deltamethrin 5% CS (SHA 0100 Y) are available.

3.4.1 Analytical method for the formulation

An analytical method for the determination of deltamethrin in the formulation Deltamethrin 5% CS has been developed and sufficiently validated according to the SANCO/3030/99 rev.4 guidance document in terms of linearity, precision, recovery and specificity. Proposed method fulfils also the requirements of SANCO/3030/99 rev.5 guidance. The determination of the active ingredient is performed by HPLC-DAD with determination at 202 nm.

	Deltamethrin
Author(s), year	XXX, V.S., 2018
Principle of method	HPLC-DAD
Linearity (linear between mg/L / % range of the declared content) (correlation coefficient, expressed as r)	Y = 4565623.21x + 1389528.19 (linear between 4.99 to 149.55 µg/mL) r = 1.000
Precision – Repeatability Mean n = 5 (%RSD)	0.40 % RSD
Accuracy n = 6 (% Recovery)	98.92%
Interference/ Specificity	Specific, no interferences
Comment	-

3.4.2 Analytical methods for residues

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

Noticed data gaps are:

- none

Commodity/crop	Supported/ Not supported
Brassicas	Supported
Strawberries	Supported

Commodity/crop	Supported/ Not supported
Tomatoes	Supported
Ornamentals	Not required

3.5 Mammalian toxicology (Part B, Section 6)

Acute toxicity studies for Deltamethrin 5% CS were not evaluated as part of the EU review of Deltamethrin. All relevant data were provided and are considered adequate. The results are summarised in the table below.

H331, H318

3.5.1 Acute toxicity

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	= 5000 mg/kg bw	Yes	None	XXX XXX M., 2018
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	XXX XXX M., 2018
LC ₅₀ inhalation, rat (OECD 403)	> 0.15 mg/L air	Yes	H331/ Acute Tox.3	S. B. XXX XXX, 2018
Skin irritation, RHE (OECD 431 and 439)	Non-irritant.	Yes	None	P. S. XXX, 2017
Eye irritation, model system (OECD xxx)	Damage	Yes	H318/Eye Dam.1	NA
Skin sensitisation, CBA/Ca mice (OECD 429/LLNA)	Non-sensitising	Yes	None	S. B. XXX XXX, 2018
Supplementary studies for combinations of plant protection products	No data – not required			

3.5.2 Operator exposure

Operator exposure to Deltamethrin 5% CS was not evaluated as part of the EU review of Deltamethrin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimations of potential operator exposure have been undertaken for Deltamethrin using the AOEM model.

Conclusion

According to the AOEM model, calculations, it can be concluded that the risk for the operator using DECIDE is acceptable without use of personal protective equipment.

Acceptable

3.5.3 Worker exposure

Worker exposure to Deltamethrin 5% CS was not evaluated as part of the EU review of Deltamethrin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Calculations were made using the standard dermal absorption value and the AOEM model.

Conclusion

It can be concluded there is no unacceptable risk anticipated for the worker re-entering the treated crops even without suitable protective clothing.

Acceptable

3.5.4 Bystander and resident exposure

Bystander and resident exposure to Deltamethrin 5% CS was not evaluated as part of the EU review of Deltamethrin for this submitted rate/crop. Therefore, all relevant data and risk assessments have been provided and are considered to be adequate.

Estimation of potential resident and bystander's exposures have been undertaken for Deltamethrin using EFSA model (EFSA Journal 2014;12(10):3874).

Conclusions: According to the EFSA calculator, there is no undue risk to any bystander after accidental short-term exposure nor to any resident exposure to Deltamethrin 5% CS. Buffer zone 2-3 m

Implication for labelling: None.

Acceptable

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

The preparation Deltamethrin 5% CS is composed of Deltamethrin.

Reference value	Source	Year	Value	Study relied upon	Safety factor
Deltamethrin					
ADI	EU	2002	0.01 mg/kg bw/d	1-year dog 90 days dog	100
ARfD	EU	2002	As the ADI: 0.01 mg/kg bw/d	As the ADI: 1-year dog 90 days dog	As the ADI: 100

3.6.1 Residues

Storage stability

EFSA conclusion (EFSA Journal 2015;13(11):4309): Storage stability of deltamethrin was demonstrated at -20 °C for a period of 24 months in high water content commodities (cabbage, lettuce and tomatoes) and at -12°C for 30 months in high oil content commodities (cotton seed) and for 9 month in dry/high starch commodities (cereals grain) (Sweden, 1998).

The available data were considered sufficient to conclude on the storage stability of deltamethrin in acidic

matrices (EFSA Journal 2015;13(11):4309)

Metabolism in plants and animals

The metabolism of deltamethrin in primary crops following foliar treatment has been investigated in fruits and fruiting vegetables (apples and tomatoes), pulses and oilseeds (cotton seed and leaves) and cereals (corn).

The metabolism of deltamethrin in rotational crops – carrots, lettuce, spinach, radishes, barley - has been evaluated during the peer review.

The metabolism of deltamethrin was studied with laying hens, and lactating cows

Endpoints:

Plant and animal residue definition for monitoring (Regulation n°2018/832): deltamethrin (cis-deltamethrin)

Plant and animal residue definition for risk assessment (RD-RA): Sum of deltamethrin and its alpha-R isomer and trans-isomer (tentative).

No further data are required to support the proposed uses.

Magnitude of residues in plants

Brassicacae (cabbage, brussels sprouts, cauliflowers)

Proposed GAP: BBCH 11-43; 1 application, 0.0075 kg as/ha, PHI: 7 days

Cauliflower belongs to Flowering brassicas group

Cabbage and brussels sprouts belongs to Head brassicas group

No new data are submitted in the framework of this application.

Residue trials on cauliflowers from NEU are available (7 trials below LOQ). Number of trials is sufficient as results are below 0.01 mg/kg.

GAP on which EU a.s. assessment is based: 3 x 7.5g as/ha, interval: 14 days, PHI 7d, outdoor (NEU)

Residues: 2 x <0.005, 5 x <0.01 mg/kg.

The residues arising from the proposed use on cauliflowers will not exceed the MRL established for cauliflower (0.1 mg/kg, Reg. (EU) 2018/832)

Extrapolation to head brassica is not possible (SANCO 7525/VI/95_rev 10.3)

Proposed use on cauliflowers is accepted.

Proposed uses on cabbage and brussels sprouts are not accepted. Residue trials are required.

Strawberry

Proposed GAP: BBCH 11-81 1 application, 0.0075 as/ha, PHI: 3 days

6 NEU residue trials on strawberries are available (DAR addendum of deltamethrin).

GAP on which EU a.s. assessment is based: 2 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 4 x < 0.02, 0.02, 0.03

Eight trials are required for a major crop such as strawberry.

Two new trials were conducted in Hungary in 2020 and two in Poland (2020).

Hungary:

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues; 2 x <0.01 mg/kg

Poland:

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 2 x <0.01 mg/kg

Trials are overdosed but acceptable because all the results are below LOQ.

Number of available trials is sufficient. The residues arising from the proposed use will not exceed the MRL established for strawberry (0.2 mg/kg, Reg. (EU) 2018/832). Use is accepted.

Tomato (field and greenhouse uses)

Proposed GAP: BBCH 11-81 1 application, 0.0075 kg as/ha, PHI: 3 days

Greenhouse uses

No new data are submitted in the framework of this application.

NEU residue trials on indoor tomatoes are available.

GAP on which EU a.s. assessment is based: 4 x 12.5 g a.s./ha, PHI 3d, indoor

Residues: 2 x <0.01, 3x0.01, 0.013, 0.014, 0.03 mg/kg

The residues arising from the proposed use on indoor tomatoes will not exceed the MRL (0.07 mg/kg, Reg. (EU) 2018/832).

Greenhouse use is accepted.

Field use

4 NEU residue trials on tomatoes in the open field are summarized in the DAR addendum of deltamethrin. Residues: <0.01, 2x0.01, 0.03 mg/kg

Three new trials were conducted in Hungary and three in Poland in 2020 under open field condition.

Trials GAP: 3 x 12.5 g a.s./ha, PHI 3d, outdoor

Residues: 6 x <0.01 mg/kg

The residues arising from the proposed use on outdoor tomatoes will not exceed the MRL (0.07 mg/kg, Reg. (EU) 2018/832).

Field use is accepted.

Ornamentals

No data is required.

Magnitude of residues in livestock

The requested uses do not modify the theoretical maximum daily intake for animals, therefore there is no risk for animal MRL to be exceeded.

Processing studies

Data/information on processing studies was reviewed during the approval of active substance and were considered acceptable.

Magnitude of residues in representative succeeding crops

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of Deltamethrin 5% CS. Therefore, other special studies are not needed.

Noticed data gaps are:

Cabbage and brussels sprouts: residue trials

3.6.2 Consumer exposure

TMDI (% ADI) according to EFSA PRIMo rev.3.1	301 % (based on NL toddler) 196% (based on DK child) 154% (based on GEMS/FoodG06) 150% (based on DE child) 131% (based on GEMS/food G08) 121% (based on GEMS/Food G15) 119% (based on GEMS/Food G10) 111% (based on GEMS/Food G11) 111% (based on GEMS/Food G07) 108% (based on NL child) 107% (based on RO general) 104% (based on UK infant) 102% (based on FR child 3-15 year)
IEDI (% ADI) according to EFSA PRIMo rev.3.1	80 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo rev.3.1	Unprocessed commodities: Results for children 57.93% Cauliflowers 44.24% Head cabbages 40.70% Tomatoes

	32.69% Strawberries 0.84% Brussels sprouts Results for adults 42.05% Head cabbages 23.19% Cauliflowers 18.66% Strawberries 11.10% Tomatoes 0.60% Brussels sprouts Processed commodities: Results for children 69.6% Cauliflowers / boiled 13.3% Tomatoes / juice 6.7% Tomatoes / sauce/puree 5.8% Head cabbages / canned 1.0% Brussels sprouts / boiled Results for adults 41.7% Cauliflowers / boiled 9.40% Head cabbages / canned 5.75% Tomatoes / sauce/puree
NTMDI (% ADI)	-
NEDI (% ADI)	-
NESTI (% ARfD)	-

The proposed uses of Deltamethrin in the formulation Deltamethrin 5% Cs do not represent an unacceptable acute and chronic risks for the consumer.

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

Concentration of Deltamethrin in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentration (PEC values) in soil, surface water, sediment and ground water are predicted.

Intended use pattern of Deltamethrin 5% CS

Crop	Application rate (kg a.s./ha)	Application method	Max. number of applications	Min. application interval	Application timing
Brassicas (cabbage, Brussels sprouts, cauliflower)	0.0125 0.0075	Foliar spray	2 1	10	BBCH 11-43
Strawberry	0.0125 0.0075	Foliar spray	3 1	10	BBCH 11-81
Tomato	0.0125 0.0075	Foliar spray	3 1	10	BBCH 11-85
Ornamentals (Apple and Onions)	0.0125 0.0075	Foliar spray	3 1	10	BBCH 10-89

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

PEC_{soil} calculations have been conducted with Deltamethrin and its relevant metabolites Br2CA and D-COOH using the EU agreed endpoints (SANCO 6504/VI/99-final).

Maximum PEC_{soil} value for Deltamethrin was 0.008, 0.007, 0.005, 0.004 and 0.009 0.039 mg/kg, in

cabbage, strawberry, tomato, apple and onions respectively 0.002, 0.002, 0.002, 0.001 and 0.003-0.040 mg/kg for Br₂CA in cabbage, strawberry, tomato, apple and onions respectively and 0.001, 0.001, <0.001, <0.001 and 0.001-0.004 for D-COOH in cabbage, strawberry, tomato, apple and onions respectively following the highest application rate of 1 x 7.5 ±2.5 g deltamethrin/ha.

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

PEC_{gw} have been realised for Deltamethrin and its relevant metabolites Br₂CA and D-COOH.

PEC_{gw} values were all below 0.001 µg/L for both Deltamethrin, BR₂CA and D-COOH.

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

The PEC_{sw/sed} of Deltamethrin and its relevant metabolites Br₂CA, D-COOH, mPBacid, α-R-deltamethrin and 4'OH-deltamethrin have been assessed with the models FOCUS STEPS 1, 2, 3 and 4 (when necessary). For Tomato and ornamentals greenhouse uses drift calculations GEM v 3.3.2 has have been run for soilless scenarios since Tomato is a permanent crop and usually hydroponic. Please refer to Part B, Section 9, Point 8.9 for more details about the results obtained.

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

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

3.8 Ecotoxicology (Part B, Section 9)

According to the risk assessment for Deltamethrin 5% CS, the following risk mitigation measures for active substance to aquatic organism should be considered:

Leafy vegetables (brassicas) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Ornamentals (apple early BBCH 10) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m OR respect an unsprayed buffer zone of 20 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 15 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (apple late BBCH 85) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (onion) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Strawberry (leafy vegetables 1st crop) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Field crops (brassicas) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land.

Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 15m OR 10m with 50% drift reduction nozzles OR 5m and 90% drift reduction nozzles to non-agricultural land.

Ornamentals and small fruits – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land

Decide:

To protect aquatic organism the following risk mitigation measures for Decide (drift only) should be applied to surface water bodies:

- 5 meter buffer zone for Brassicas (cabbage); Strawberry and tomato; Ornamentals (onions) or 75/90% drift reduction nozzles
- 15 meter buffer zone with 75 %/90% drift reduction nozzles or 30 meter with 50% drift reduction nozzles or 35 meter buffer zone (apple early)
- 10 meter buffer zone with 50%/75% drift reduction nozzles or 15 meter buffer zone (apple late)

To protect aquatic organism the following final risk mitigation measures should be applied:

Leafy vegetables (brassicas) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies

Ornamentals (apple early BBCH 10) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m with 50% drift reduction nozzles OR respect an unsprayed 15 m buffer zone with 75% of nozzle reduction OR 35 meter buffer zone

Ornamentals (apple late BBCH 85) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (onion) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Strawberry (leafy vegetables 1st crop) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Tomato (field uses): To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies or 75 drift reduction nozzles.

Protected crops NTA:

For the use in permanent greenhouses:

- The off-field exposure is not relevant;
- The in-field exposure could be relevant for beneficial insects and non-target arthropods used as natural enemies in integrated pest management systems, a warning should be placed in the label “Warning: This product may be harmful to natural enemies.”

3.8.1 Effects on terrestrial vertebrates

- **Birds**

According to the screening assessment, all TER_a and TER_{it} values for the active substance Deltamethrin

are greater than the Annex VI trigger of 10 and 5, respectively, indicating the DECIDE presents no unacceptable acute and long-term risk to birds according to the intended uses. Moreover, the risk for birds due to uptake of contaminated drinking water was considered as low.

Deltamethrin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm-eating and fish-eating birds according to the intended uses of DECIDE.

- **Mammals**

According to the screening assessment, the TER_a value for the active substance Deltamethrin is greater than the Annex VI trigger of 10, indicating the DECIDE presents no unacceptable acute and long-term risk to birds according to the intended uses. Moreover, the risk for mammals due to uptake of contaminated drinking water was considered as low

Deltamethrin has been shown to have the potential for bioaccumulation, however, there is no risk to earthworm-eating and fish-eating mammals according to the intended uses of DECIDE.

3.8.2 Effects on aquatic species

The PEC/RAC ratios were calculated based on a microcosm study results: the risk for invertebrate, including sediment living organisms characterised by an EAC of 0.0032 g/L and LC50 for acute toxicity for fish of 0.0026 mg a.s./L considering reduced exposure of surface water bodies. After Step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1. An acceptable risk for a.s. was obtained with the following mitigation measures:

Leafy vegetables (brassicas) – Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Ornamentals (apple early BBCH 10) – Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m OR respect an unsprayed buffer zone of 20 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 15 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (apple late BBCH 85) – Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (onion) – Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Strawberry (leafy vegetables 1st crop) – Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

For glasshouse permanent use for tomato for Poland the risk assessment is considered acceptable.

In addition, the risk assessment for field uses covers the risk for glasshouse uses.

No risk mitigation measures to aquatic organism is required for field and glasshouse uses.

The risk assessment for formulation Decide (+ drift only):

Based on data for formulation the risk mitigation measures are proposed to surface water bodies: To protect aquatic organism the following risk mitigation measures should be applied to surface water bodies:

- 5 meter buffer zone for Brassicas (cabbage); Strawberry and tomato; Ornamentals (onions) or 75/90% drift reduction nozzles
- 15 meter with 75 %/90% drift reduction nozzles or 30 meter with 50% drift reduction nozzles

(apple-early)

•—10 meter with 50%/75%—drift-reduction nozzles or 15-meter-buffer zone (apple-late)

The risk-for-formulation-is-covered-by-the-risk-mitigation-for-the-a.s.

In addition the risk mitigation measures were provided for Decide (drift only).

In conclusion:

To protect aquatic organism the following final risk mitigation measures should be applied to the label of ppp:

Leafy vegetables (brassicas) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies

Ornamentals (apple early BBCH 10) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 30 m with 50% drift reduction nozzles OR respect an unsprayed 15 m buffer zone with 75% of nozzle reduction OR 35 meter buffer zone

Ornamentals (apple late BBCH 85) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m OR respect an unsprayed buffer zone of 15 m with 50% of nozzle reduction OR respect an unsprayed buffer zone of 10 m with 75% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 90% of nozzle reduction to surface water bodies.

Ornamentals (onion) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Strawberry (leafy vegetables 1st crop) - Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies.

Tomato (field uses): To protect aquatic organisms, respect an unsprayed buffer zone of 5 m to surface water bodies or 75 drift reduction nozzles.

3.8.3 Effects on bees

Based on the higher tier studies on bees reported in the monograph and in the list of endpoints, it can be concluded that a safe use of deltamethrin is not demonstrated following applications above 6.25 g a.s/ha. Therefore, risk mitigation measures are necessary.

Field uses:

Spe8: Dangerous for bees. In order to protect bees and other pollinating insects, do not apply the product to crop plants when in flower or during weed's flowering. Remove weeds before the period of flowering. Do not use where bees are actively foraging. Remove or cover beehives during application.

Protected crops:

For the use in permanent greenhouses the exposure of bees in protected crops cannot be excluded, unless pollinators are not used. zRMS proposes the following warning:

Dangerous for bees. Do not allow bees and other pollinators into the greenhouse.

According Reg. 284/2009 the chronic adult and chronic larvae tests were provided by the applicant for the product Decide 5CS.

3.8.4 Effects on other arthropod species other than bees

An acceptable risk for NTA was obtained with the proposed application with the following risk mitigation measures:

Field crops (brassicas) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land.

Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 15m OR 10m with 50% drift reduction nozzles OR 5m and 90% drift reduction nozzles to non-agricultural land.

Ornamentals and small fruits – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 5m OR 1m with 90% drift reduction nozzles to non-agricultural land

Protected crops:

For the use in permanent greenhouses:

- The off-field exposure is not relevant;
- The in-field exposure could be relevant for beneficial insects and non-target arthropods used as natural enemies in integrated pest management systems, a warning should be placed in the label “**Warning: This product may be harmful to natural enemies.**”

3.8.5 Effects on soil organisms

The acute and chronic TER values for earthworms for Deltamethrin were above the relevant Annex VI trigger of 10 and 5, respectively. Therefore, it is concluded that the active substance Deltamethrin do not pose an acute and chronic risk to earthworms.

Risk assessment conducted with relevant PEC_{soil} for the active substance Deltamethrin indicate a low risk to soil microorganisms when applied according to the proposed use rates.

3.8.6 Effects on non-target terrestrial plants

Effects on non-target terrestrial plants of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. Actually, no studies on the toxicity of Deltamethrin to other non-target organisms were submitted in the dossier (DAR, 1998).

According to Regulation (EU) No 284/2013, studies of effects on non-target plants shall be required for herbicide and plant growth regulator plant protection products. As deltamethrin is an insecticide, the studies on non-target terrestrial plants are not required.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

It is not considered likely that the normal field use of deltamethrin will result in contamination of sewage treatment plants. At the use of deltamethrin in greenhouses and other indoor applications, exposure could be anticipated. At present, there is no method available for quantification of the exposure levels. However, in the study presented above no adverse effects were seen at the highest concentration tested (1000 mg as/l). Therefore, the risk for harmful effects on biological methods of sewage treatment is considered to be acceptable (*Addendum to the Monograph Annex B, 2002*).

3.9 Relevance of metabolites (Part B, Section 10)

The metabolites BR₂CA and D-COOH are predicted to occur in groundwater at concentrations below 0.1 µg/L (see dRR Part B8, Chapter 8.8). Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore not required.

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

Not relevant, the active substance Deltamethrin is not Candidate for Substitution.

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

The results of the two years storage stability study should be provided by the Applicant.

Appendix 1 Copy of the product authorization

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

Appendix 2 Copy of the product label

Pozostałości:

Brak zgody na zastosowanie w ochronie: kapusta głowiasta, kapusta brukselska

Ekotoksykologia:

Użycie środka w szklarniach z użyciem stawonogów pożytecznych nie jest rekomendowane.

Toksykologia:

Dodać **Usunąć** frazę H331

Załącznik do zezwolenia MRiRW nr R- / z dnia r.

Posiadacz zezwolenia:

Sharda Poland Sp. z o.o., ul. Bonifraterska 17, 00-203 Warszawa, tel.: 22 886 93 28 lub 17 240 13 07, e-mail: eu.sales@shardaintl.com

DECIDE

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnej:

deltametryna (związek z grupy pyretroidów) – **50 g/l (4,89 % w/w)**.

Zezwolenie MRiRW nr R- z dnia r.



Niebezpieczeństwo

H318 - Powoduje poważne uszkodzenie oczu

H331- Działa toksycznie w następstwie wdychania

H410 - Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.

H331- Działa toksycznie w następstwie wdychania.

EUH208 - Zawiera 1,2-benzotiazol-3(2H)-on (2634-33-5), masa poreakcyjna 5-chloro-2-metylo-2H-izotiazol-3-onu i 2-metylo-2H-izotiazol-3-onu (3:1)(55965-84-9). Może powodować wystąpienie reakcji alergicznej.

EUH066 - Powtarzające się narażenie może powodować wysuszenie lub pęknięcie skóry.

EUH401 - W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.

~~P273 – Unikać uwolnienia do środowiska.~~

P280 - Stosować ochronę oczu, ochronę twarzy, odzież ochronną, rękawice ochronne.
P305+P351+P338 - W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać.
P310 - Natychmiast skontaktować się z lekarzem, z OŚRODKIEM ZATRUĆ.
P391 - Zebrać wyciek.
P501 - Zawartość i pojemnik usuwać do specjalny punkt zbioru niebezpiecznych lub specjalnych odpadów, zgodnie z przepisami miejscowymi, regionalnymi, krajowymi i/lub międzynarodowymi.

OPIS DZIAŁANIA

Środek owadobójczy w formie zawiesiny kapsuł w cieczy przeznaczony do rozcieńczania wodą przed zastosowaniem, o działaniu kontaktowym i żołądkowym, przeznaczony do zwalczania niektórych szkodników w uprawie roślin warzywnych, sadowniczych i ozdobnych. Na roślinie działa powierzchniowo.

Środek przeznaczony do stosowania przy użyciu opryskiwaczy polowych, sadowniczych oraz ręcznych.

STOSOWANIE ŚRODKA

ROŚLINY WARZYWNE UPRAWIANE W GRUNCIE

Kapusta głowiasta, kalafior

Mszycyca kapuściana i mszyca burakowa (średni poziom skuteczności)

Maksymalna dawka dla jednorazowego zastosowania: ~~0,25~~ 0,15 l/ha

Zalecana dawka dla jednorazowego zastosowania: 0,15 ~~0,10~~ ~~0,25~~ l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy osiągnięcia przez główki 30% typowej wielkości (BBCH 11 - 43).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~2~~ 1

~~Odstęp między zabiegami: co najmniej 10 dni~~

Zalecana ilość wody: 200 - 600 l/ha

Gąsienice gatunków, np. Bielinek rzepnik, Bielinek kapustnik (dobry poziom skuteczności)

Maksymalna dawka dla jednorazowego zastosowania: 0.15 l/ha

Zalecana dawka dla jednorazowego zastosowania: ~~0,10~~ 0.15 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy osiągnięcia przez główki 30% typowej wielkości (BBCH 11 - 43).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~2~~ 1

~~Odstęp między zabiegami: co najmniej 10 dni~~

Zalecana ilość wody: 200 - 600 l/ha

Kapusta brukselska

~~mszyca~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0.25 l/ha~~

~~Zalecana dawka dla jednorazowego zastosowania: 0.10 0.25 l/ha~~

~~Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy 30% rozgałęzień mocno zamkniętych (BBCH 11 - 43).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2~~

~~Odstęp między zabiegami: co najmniej 10 dni
Zalecana ilość wody: 200 – 600 l/ha~~

~~gąsionice~~

~~Maksymalna dawka dla jednorazowego zastosowania: 0,15 l/ha
Zalecana dawka dla jednorazowego zastosowania: 0,10-0,15 l/ha
Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy 30% rozgałęzień mocno zamkniętych (BBCH 11 – 43).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp między zabiegami: co najmniej 10 dni
Zalecana ilość wody: 200 – 600 l/ha~~

Pomidor

Mszycy **burakowa i inne gatunki mszyc (ograniczenie występowania)**

Maksymalna /zalecana dawka dla jednorazowego zastosowania: ~~0,25~~ 0,15 l/ha
Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy kiedy 50% owoców uzyska typową barwę (BBCH 11 - 85).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~3~~ 1
~~Odstęp między zabiegami: co najmniej 10 dni
Zalecana ilość wody: 300 - 1000 l/ha~~

ROŚLINY WARZYWNE UPRAWIANE POD OSŁONAMI

Pomidor

mączlik szklarniowy, **mączlik ostroskrzydły (średni poziom skuteczności)**

Maksymalna /zalecana dawka dla jednorazowego zastosowania: ~~0,25~~ 0,15 l/ha
Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do fazy kiedy 50% owoców uzyska typową barwę (BBCH 11- 85).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~3~~ 1
~~Odstęp między zabiegami: co najmniej 10 dni
Zalecana ilość wody: 300 - 1000 l/ha~~

ROŚLINY SADOWNICZE

Truskawka

Mszycy **truskawkowa, mszyca kruszynowo-ziemniaczana i inne gatunki mszyc (średni poziom skuteczności)**

Maksymalna /zalecana dawka dla jednorazowego zastosowania: ~~0,25~~ 0,15 l/ha
Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do początkowej fazy dojrzewania (BBCH 11 - 81).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~3~~ 1
~~Odstęp między zabiegami: co najmniej 10 dni
Zalecana ilość wody: 200 - 600 l/ha~~

~~gąsionice motyli~~

~~Maksymalna /zalecana dawka dla jednorazowego zastosowania: 0,15 l/ha~~

~~Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach, od fazy rozwiniętego pierwszego liścia właściwego do początkowej fazy dojrzewania (BBCH 11 – 81).~~

~~Maksymalna liczba zabiegów w sezonie wegetacyjnym: 3~~

~~Odstęp między zabiegami: co najmniej 10 dni~~

~~Zalecana ilość wody: 200 – 600 l/ha~~

ROŚLINY OZDOBNE (np. róża, frezja, wyżlin większy)

Mszycyca **różano-szczeciowa** (dobry poziom skuteczności)

Maksymalna /zalecana dawka dla jednorazowego zastosowania: ~~0,25~~ 0,15 l/ha

Termin stosowania: Rośliny opryskiwać z chwilą ukazania się pierwszych symptomów żerowania lub pojawieniem się szkodnika na roślinach (BBCH 10 - 89).

Maksymalna liczba zabiegów w sezonie wegetacyjnym: ~~3~~ 1

~~Odstęp między zabiegami: co najmniej 10 dni~~

Zalecana ilość wody: 300 - 1000 l/ha

ŚRODKI OSTROŻNOŚCI I ZALECENIA STOSOWANIA ZWIĄZANE Z DOBRĄ PRAKTYKĄ ROLNICZĄ:

1. Środek działa najskuteczniej w temperaturze poniżej 20 °C. W temperaturze wyższej zabiegi wykonywać pod koniec dnia.
2. Zabieg wykonać dokładnie, aby wszystkie części roślin były pokryte cieczą użytkową.
3. Silny opad deszczu wcześniej niż 6 godzin po zabiegu może obniżyć skuteczność działania środka.
4. W celu ochrony pszczoł i innych owadów zapylających środka nie należy stosować:
 - kiedy na uprawie chronionej występują kwitnące chwasty,
 - w miejscach, gdzie pszczoły mają pożytek.
5. Środek zawiera substancję czynną deltametryna, związek z grupy pyretroidów (wg IRAC grupa 3A – substancje działające na układ nerwowy owada – modulatory kanałów sodowych). W ramach strategii przeciwdziałania odporności m. in. zaleca się stosowanie środka:
 - wyłącznie w zalecanej dawce,
 - przemiennie z innymi środkami owadobójczymi, zawierającymi substancje czynne z innych grup, o odmiennym mechanizmie działania.

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed przystąpieniem do sporządzenia cieczy użytkowej dokładnie ustalić potrzebną jej ilość. Odmierzoną ilość środka wlać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem). Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika wody z cieczą użytkową. Następnie zbiornik opryskiwacza uzupełnić wodą do potrzebnej ilości. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne ciecz w zbiorniku mechanicznie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Z resztkami cieczy użytkowej po zabiegu należy postępować w sposób ograniczający ryzyko skażenia wód powierzchniowych i podziemnych w rozumieniu przepisów Prawa wodnego oraz skażenia gruntu, tj.:

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

Po pracy aparaturę dokładnie wymyć. Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.

W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować stosownie do instrukcji dołączonej do środka myjącego.

WARUNKI BEZPIECZNEGO STOSOWANIA ŚRODKA

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

Środki ostrożności dla osób stosujących środek:

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

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

Strefa buforowa 2-3 m

Środki ostrożności związane z ochroną środowiska naturalnego:

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem.

Nie myć aparatury w pobliżu wód powierzchniowych.

Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

~~Kapusta głowiasta, brukselska, Kalafior, truskawka, pomidor, czosnek ozdobny~~

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych w uprawie kapusty głowiastej, brukselski, kalafiora, truskawki, pomidora, czosnku ozdobnym

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 30 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% od zbiorników i cieków wodnych LUB 20 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 50% LUB 15 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75%. lub 10 m z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 90% lub zastosowanie 35 metrowej strefy ochronnej w uprawie roślin ozdobnych: róży, frezji, wyżlin większego (zabieg od fazy BBCH 10)

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 20 m od zbiorników i cieków wodnych lub zastosowanie strefy ochronnej o szerokości 15 metrów wraz z użyciem rozpylaczy redukujących znoszenie o 50 % z LUB 10 m strefy ochronnej z równoczesnym zastosowaniem rozpylaczy redukujących znoszenie cieczy użytkowej podczas zabiegu o 75 % lub zastosowanie strefy ochronnej o szerokości 5 metrów wraz z użyciem rozpylaczy redukujących znoszenie o 90 % w uprawie roślin ozdobnych: róży, frezji, wyżlin większego (późny zabieg – po fazie BBCH 85)

W celu ochrony organizmów wodnych konieczne jest wyznaczenie strefy ochronnej o szerokości 5 m od zbiorników i cieków wodnych w uprawie polowej pomidora lub zastosowanie rozpylaczy redukujących znoszenie o 75 % od zbiorników i cieków wodnych.

W celu ochrony stawonogów niebędących celem zwalczania konieczne jest wyznaczenie strefy ochronnej od terenów nieużytkowanych rolniczo o szerokości:

- 5 metrów lub zastosowanie strefy ochronnej o szerokości 1 metra wraz z użyciem rozpylaczy redukujących znoszenie o 90 % w uprawie kapusty głowiastej, brukselski, kalafiora,

-15 metrów lub zastosowanie strefy ochronnej o szerokości 10 metrów wraz z użyciem rozpylaczy redukujących znoszenie o 50 % lub strefy ochronnej o szerokości 5 metrów wraz z użyciem rozpylaczy redukujących znoszenie o 90 % w uprawie pomidora
- strefy ochronnej o szerokości 5 metrów lub strefy ochronnej 1 metra wraz z użyciem rozpylaczy redukujących znoszenie o 90 % w uprawie czosnku ozdobnego, róży, frezji, wyżlin większego

SP8 Niebezpieczny dla pszczoł.

W celu ochrony pszczoł i innych owadów zapylających nie stosować na rośliny uprawne w czasie kwitnienia/Nie używać w miejscach, gdzie pszczoły mają pożytek/Usuwać lub przykrywać ule podczas. Nie stosować kiedy występują kwitnące chwasty. Usuwać chwasty przed kwitnieniem. Nie stosować w szklarniach w czasie, kiedy są wprowadzane owady zapylające.

OKRES OD ZASTOSOWANIA ŚRODKA DO DNIA, W KTÓRYM NA OBSZAR, NA KTÓRYM ZASTOSOWANO ŚRODEK MOGĄ WEJŚĆ LUDZIE ORAZ ZOSTAĆ WPROWADZONE ZWIERZĘTA:

Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA DO DNIA ZBIORU ROŚLINY UPRAWNEJ (okres karencji):

Kapusta głowiasta, kapusta brukselska, kalafior – 7 dni

Truskawka, pomidor – 3 dni

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY DO DNIA, W KTÓRYM MOŻNA SIAĆ LUB SADZIĆ ROŚLINY UPRAWIANE NASTĘPCZO:

Nie dotyczy.

OKRES OD OSTATNIEGO ZASTOSOWANIA ŚRODKA NA ROŚLINY PRZEZNACZONE NA PASZĘ DO DNIA, W KTÓRYM ZWIERZĘTA MOGĄ BYĆ KARMIONE TYMI ROŚLINAMI (okres karencji dla pasz):

Nie dotyczy.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN

I OPAKOWANIA

Chronić przed dziećmi

Środek ochrony roślin przechowywać:

- w miejscach lub obiektach, w których zastosowano odpowiednie rozwiązania zabezpieczające przed skażeniem środowiska oraz dostępem osób trzecich,
- w oryginalnych opakowaniach, w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą,
- w temperaturze 0°C-30°C, z dala od źródeł ciepła.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów.

Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych.

Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin lub można je potraktować jako odpady komunalne. W razie wątpliwości dotyczących postępowania z opakowaniami poradzić się sprzedawcy środków ochrony roślin.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.

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

Okres ważności – 2 lata 1 rok.

Data produkcji -

Zawartość netto -

Nr partii -

Appendix 3 Letter of Access

No letter of Access to protected data are required.

Appendix 4 Lists of data considered for national authorization

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.1, KCP 2.4.1, KCP 2.7.1, KCP 2.7.4, KCP 2.8.2, KCP 2.8.3.1, KCP 2.8.3.2, KCP 2.8.5.1.2 and KCP 2.8.7.2	XXX V. S. M.	2018	Accelerated storage stability test by heating at elevated temperature of Deltamethrin 5% CS Eurofins, Study No. G13965 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.2.1	XXX V. S. M.	2018	Determination of explosive properties of deltamethrin 5% CS Eurofins report No. G13957 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.2.2	XXX V. S. M.	2018	Oxidizing properties of Deltamethrin 5% CS Eurofins report No G13958 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.3.1 and KCP 2.3.2	XXX V. S. M.	2018	Determination of flash point of Deltamethrin 5% CS Eurofins, report No. G13959 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.3.3	XXX V. S. M.	2018	Determination of auto ignition temperature of Deltamethrin 5% CS Eurofins, report No. G 13964 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 2.5.1	XXX V. S. M.	2018	Determination of viscosity of Deltamethrin 5% CS Eurofins, report No. G13960 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.5.2	XXX V. S. M.	2018	Surface tension of aqueous solution of Deltamethrin 5% CS Eurofins, report No. G13961 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.6.1	XXX V. S. M.	2018	Determination of relative density of Deltamethrin 5% CS Eurofins, report No. G13962 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.8.5.1.1	XXX B.	2020	Determination of the particle size by laser diffraction method. ICB Pharma, report ICB/76/2020 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 2.11	XXX V. S. M.	2018	Determination of effectiveness of cleaning by small scale jar test with Deltamethrin 5% CS Eurofins, report No. G13963 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 6.0-001	Anonymous	2019	Biological Assessment Dossier: Deltamethrin 5% CS (50 g/kg deltamethrin) – EU Central zone Sharda Cropchem España -, - Unpublished	N	Y	Study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 5.1.1/01	XXX, V.S.	2018	Accelerated storage stability test by heating at elevated temperature of Deltamethrin 5% CS. Advinus report no. G13965. GLP Unpublished	N	Y	Study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 5.2/01	XXX, R.	2013a	Method validation-Determination of residues of deltamethrin in soil and sediment. Battelle report no. YV/12/013 GLP Unpublished	N	Y	Study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 5.2/03	XXX, R.	2013b	Method validation-Determination of residues of deltamethrin in blood and liver.	N	Y	Study report never submitted before to Poland	Sharda Cropchem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Battelle report no. YV/12/007 GLP Unpublished				Ltd.
KCP 5.2/04	Anonymous	2014	Dutch mini-luke ("NL-") extraction method followed by LC and GC-MS/MS for multiresidue analysis of pesticides in fruits and vegetables. EURL-FV 2014 M12. Non GLP Published	N	Y	Study report never submitted before to Poland	Sharda Cropchem Ltd.
KCP 7.1.1	XXX XXX M.	2018	Acute oral toxicity study (acute toxic class method) of Deltamethrin 5% CS in Wistar rat Eurofins report No. G13190 GLP, Unpublished	Y	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.2	XXX XXX M.	2018	Acute dermal toxicity study of Deltamethrin 5% CS in Wistar rat Eurofins report No. G13191 GLP, Unpublished	Y	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.3	S. B. XXX XXX	2018	Deltamethrin 5% CS: Acute inhalation toxicity study in Wistar rats Eurofins report No. G13192 GLP, Unpublished	Y	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.4	P. S. XXX	2017	Deltamethrin 5% CS – <i>In vitro</i> skin corrosion: reconstructed human epidermis (RHE) test method Eurofins report No. G13193 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.4	P. S. XXX	2017	Deltamethrin 5% CS – <i>In vitro</i> skin irritation: Reconstructed human epidermis test method Eurofins report No. G13194 GLP, Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 7.1.6	S. B. XXX XXX	2018	Deltamethrin 5% CS: Local Lymph Node Assay (LLNA) in CBA/Ca mice Eurofins report No. G13195 GLP, Unpublished	Y	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.1	G. XXX	2021	Determination of the residues of deltamethrin in/on	N	Y	Study report never submitted before	SHARDA

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			strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R24 GLP Unpublished			to Poland	Cropchem Limited
KCP 8.3.1.2	S. XXX	2021	Determination of the Residues of Deltamethrin in/on Strawberries after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. DPL/169/2020 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.3	R. XXX	2021	Magnitude of the residue of deltamethrin in strawberry (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020 Report No. D-2020-23 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.1.4	G. XXX	2021	Magnitude of the residue of Deltamethrin in strawberry (Raw Agriculture Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and one decline curve trial in Northern Europe – Poland, 2020 Report No. DPL/170/2020 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.2.1	G. XXX	2021	Determination of the residues of Deltamethrin in/on tomato after three applications of Deltamethrin 5% CS in Northern Europe – Hungary in 2020. Report No. 065CPRHU20R25 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.2.2	G. XXX	2021	Magnitude of the residues of Deltamethrin in/on Tomato	N	Y	Study report never submitted before	SHARDA

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			after three applications of Deltamethrin 5% CS in Northern Europe – Hungary, 2020. Report No. DPL/174/2020 GLP Unpublished			to Poland	Cropchem Limited
KCP 8.3.2.3	R. XXX	2021	Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe. Report No. D-2020-24 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 8.3.2.4	S. XXX	2021	Magnitude of the residue of deltamethrin in tomato (Raw Agricultural Commodity – RAC) grown in open field conditions after three applications of formulated product Deltamethrin 5% CS – one harvest and two decline curve trials in Northern Europe – Poland, 2020 Report No. DPL/171/2020 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-01	B.V. XXX	2020	Deltamethrin 5% CS: Fish, acute toxicity test with rainbow trout. Eurofins Advinus Limited. G13391 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-02	B.V. XXX	2020	Deltamethrin 5% CS: Alga, growth inhibition test with <i>Raphidocelis subcapitata</i> (formerly <i>Pseudokirchneriella subcapitata</i>). Eurofins Advinus Limited. G13392 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.2.1-03	B.V. XXX	2020	Deltamethrin 5% CS: <i>Daphnia magna</i> , acute immobilization test.	N	Y	Study report never submitted before to Poland	SHARDA Cropchem

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			Eurofins Advinus Limited. G13393 GLP Unpublished				Limited
KCP 10.3.1.1.1	B.V. XXX	2018	Deltamethrin 5% CS: Acute Oral Toxicity Test in Honey Bees Eurofins Advinus Limited. G13394 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.1.2	B.V. XXX	2018	Deltamethrin 5% CS: Acute Contact Toxicity Test in Honey Bees Eurofins Advinus Limited. G13395 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.2-01	XXX, K.	2021	Chronic Oral Toxicity Study of Deltamethrin 5% CS on adult honey bee (<i>Apis mellifera</i>) Report No.: 7969/2020 Bioscience Research Foundation GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.1.3-01	XXX, K.	2021	Effect of Deltamethrin 5% CS on larvae of honey bee, <i>Apis mellifera</i> (L.) following repeated exposure Report No.: 7970/2020 Bioscience Research Foundation GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-01	E. XXX	2011	A laboratory study to determine the effects of Poleci (deltamethrin 2.5% w/w) and DECIS EC 2,5 (deltamethrin 25g/L) on the non-target arthropod <i>Typhlodromus pyri</i> (Acari: Phytoseiidae). SynTech Research. 34SRFR11C2 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.1-02	E. XXX	2011	A laboratory study to determine the effects of Poleci (deltamethrin 2.5% w/w) and DECIS EC 2,5 (deltamethrin	N	Y	Study report never submitted before to Poland	SHARDA Cropchem

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			25g/L) on the non-target arthropod <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) SynTech Research. 34SRFR11C1 GLP Unpublished				Limited
KCP 10.3.2.2-01	P. XXX	2020	An extended laboratory test or evaluating the effects of Deltamethrin 5% CS on the predatory mite, <i>Typhlodromus pyri</i> (Scheuten) Bioscience Research Foundation. 6035/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.2-02	G. XXX	2019	A laboratory test for evaluating the effects of Deltamethrin 5% CS on the parasitic wasp <i>Aphidius rhopalosiphi</i> (De Stefani-Perez) Bioscience Research Foundation. 6034/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.2-03	M. XXX	2020	A laboratory test for evaluating the effects of Deltamethrin 5% CS on larvae of the green lacewing <i>Chrysoperla carnea</i> (L.) Bioscience Research Foundation. 6036/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.2-04	V. XXX	2020	An extended laboratory test for evaluating the effects of Deltamethrin 5% CS on the ladybird beetle, <i>Coccinella septempunctata</i> (L.) Bioscience Research Foundation. 6037/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.3.2.2-05	E. XXX	2011	A fresh and aged residue study to determine the effects of Poleci (deltamethrin 2.5% w/w) on the non-target arthropod <i>Typhlodromus pyri</i> (Acari: Phytoseiidae). SynTech Research. 34SRFR11C3 GLP	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited

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KCP 10.3.2.2-06	F. XXX	2021	Unpublished Deltamethrin 5 % CS: Toxicity to the aphid parasitoid <i>Aphidius rhopalosiphi</i> De Stefani Perez (Hymenoptera, Braconidae) after exposure to freshly applied and aged spray deposits under extended laboratory conditions Trialcamp S.L.U. Study code: S20-07841 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.1.1	B.V. XXX	2020	Deltamethrin 5% CS: Earthworm Reproduction Test Eurofins Advinus Limited. G13397 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-01	K. XXX	2020	Effect of Deltamethrin 5% CS on the reproduction of the collembolans (<i>Folsomia candida</i>) in artificial soil. Bioscience Research Foundation. 6942/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.4.2.1-02	V. XXX	2019	Effect of Deltamethrin 5% CS on the reproductive output of the predatory soil mite <i>Hypoaspis (Geolaelaps) aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil. Bioscience Research Foundation. 6031/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5-01	H. S. XXX	2019	Soil Microorganisms: Carbon Transformation Test of Deltamethrin 5% CS Eurofins Advinus Limited. G13398 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.5-02	H. S. XXX	2019	Soil Microorganisms: Nitrogen Transformation Test of Deltamethrin 5% CS Eurofins Advinus Limited. G13399 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited
KCP 10.6.2-01	S. XXX	2020	Effect of Deltamethrin 5% CS on seedling emergence and	N	Y	Study report never submitted before	SHARDA

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			seedling growth of terrestrial plants. Bioscience Research Foundation. 6032/2020 GLP Unpublished			to Poland	Cropchem Limited
KCP 10.6.2-02	S. XXX	2020	Effect of Deltamethrin 5% CS on vegetative vigour of terrestrial plants. Bioscience Research Foundation. 6033/2019 GLP Unpublished	N	Y	Study report never submitted before to Poland	SHARDA Cropchem Limited

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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