

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 0100 Y

Product name: DECIDE

Chemical active substance:

Deltamethrin, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

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Version history

When	What
October 2020	Applicant update
March 2021	Applicant update
April 2021	The assessment of ppp Decide
July 2021	Applicant update
September 2021	The assessment of updated dRR for Decide
January 2022	Applicant update
April 2022	Final version after Consulting period with to regard the chronic studies for bees according to EU reg. 284/2013
May 2022	Final version corrected by zRMS on area of risk mitigation measures for aquatic organisms.

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9 Ecotoxicology (KCP 10)

zRMS comments:

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Not agreed or not relevant information is struck through. In blue corrected values or information were added by zRMS, if relevant.

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Gpn G, Gn, Gpn or I**	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ synergist per ha	Conclusion						
					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			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro- pods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	CEU	Brassicas (cab- bage, Brussels sprouts, cauli- flower)	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	-							
2	CEU	Brassicas (cab- bage, Brussels sprouts, cauli- flower)	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	-							
3	CEU	Strawberry	F	Aphids	Foliar Spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	3	-							
4	CEU	Strawberry	F	Lepidoptera	Foliar Spray	BBCH 11-81	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	200-600	3	-							
5	CEU	Tomato	F	Aphids	Foliar Spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	3	-							
6	CEU	Tomato	G	Whitefly	Foliar Spray	BBCH 11-85	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	3	-							
7	CEU	Ornamentals	F	Aphids	Foliar Spray	BBCH 10-89	a) 1 b) 1	-	a) 0.15 b) 0.15	a) 0.0075 b) 0.0075	300-1000	-	-							

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** 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

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

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

9.1.1 Overall conclusions

9.1.1.1 Effects on birds, Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

- **Birds**

According to the screening assessment, all TER_a and TER_{lt} 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. After first tier assessment for active substance Deltamethrin, the TER_{lt} values are lower than the Annex VI trigger of 5, for small herbivorous mammal “vole”, indicating that DECIDE presents an unacceptable long term risk to mammals. A refinement of the risk was done by refining the f_{twa} and the deposition factors and the TER_{lt} values were above the trigger showing no risk. Therefore, the acute and long term risk to mammals after the application of DECIDE according to the GAP is considered acceptable. Moreover, the risk for mammals due to uptake of contaminated drinking water was considered as low.~~

According to the screening assessment, all TER_a and TER_{lt} 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 mammals 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.

9.1.1.2 Effects on aquatic organisms (KCP 10.2)

For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Invertebrate ~~acute~~ **prolonged** as characterised by NOEC for *Daphnia magna* of 0.0041 µg/L in connection with an assessment factor of 10) in all FOCUS Step 1-3 scenarios. In fact, no acceptable risks were observed in all the assessed groups of aquatic organisms.

In that regard, first tier studies with fish may overestimate the toxicity of deltamethrin, especially when conducted as flowthrough exposure studies, as it is the case. This regime reflect exposure conditions which are not expected to be replicated under actual test item use in field, due to rapid dissipation of deltamethrin from water bodies. Taking also into consideration the interest of minimising the vertebrate testing it is concluded that the microcosm study is sufficient to establish that the risk to fish can be covered by the risk assessment for aquatic invertebrates.

Therefore, further 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 µg/L considering reduced exposure of surface water bodies. However, despite the above arguments, the risk assessment using fish endpoint (characterised by LC_{50} for *Oncorhynchus mykiss* of 0.26 µg/L in connection with an assessment factor of 100) was also included.

After Step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1. An accepta-

ble risk was obtained with the following mitigation measures:

Leafy vegetable (brassicas)

- For D3 ditch (1st season), D3 ditch (2nd season), D4 stream, R1 stream (1st season), R1 stream (2nd season), R2 stream (1st season), R2 stream (2nd season), R3 stream (1st season), R3 stream (2nd season), R4 stream (1st season) and R4 stream (2nd season) 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Fruiting vegetables (strawberry and tomato)

- For D4 stream, R2 stream, R3 stream and R4 stream 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Ornamentals (apple early BBCH 10)

- For D3 ditch 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction should be considered.
- For D4 pond 15 m no spray buffer zone OR 5 m with 50% nozzle reduction should be considered.
- For D4 stream and D5 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction should be considered.
- For D5 pond 10 m no spray buffer zone OR 5 m no spray buffer zone with 50% nozzle reduction should be considered.
- For R1 pond 10 m OR 5 m with 50% nozzle reduction should be considered.
- For R1 stream and R4 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle OR 10 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction should be considered.
- For R2 stream and R3 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR 15 m with 90% nozzle reduction OR 10 m with 95% nozzle reduction should be considered.
- For R3 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR 15 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction should be considered.

Ornamentals (apple late BBCH 85)

- For D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream 20 m no spray buffer zone OR 15 m with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For D5 stream and R3 stream 15 m no spray buffer zone with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.

Ornamentals (onion)

- For D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream and R4 stream 5 m no spray buffer zone should be considered.
- Although scenarios D6 (1st ditch) and D6 (2nd ditch) shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that these scenarios are not relevant under CEU conditions.

Strawberry (leafy vegetables 1st crop)

- For D3 ditch (1st season), D4 stream and R1 stream (1st season) 5 m no spray buffer zone should be considered.

Tomato (potato)

- For D3 ditch (1st season) and D4 stream 5 m no spray buffer zone should be considered.

Leafy vegetable (brassicas)

- For D3 ditch (1st season) and D3 ditch (2nd season) 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Fruiting vegetables (tomato)

- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions. The risk for aquatic organism for tomato was based on calculation of the PEC_{sw} for potato. Based on the PEC/RAC value for fish and PEC/ RAC for aquatic invertebrates the risk is considered as acceptable at STEP 3. No risk mitigation measures are required.

Ornamentals (apple early BBCH 10)

- For D3 ditch, D4 stream, D5 stream, R2 stream, R3 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction should be considered.
- For R1 stream and R4 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle OR 5 m with 90% nozzle reduction should be considered.

Ornamentals (apple late BBCH 85)

- For D4 stream, D5 stream, R2 stream and R3 stream 20 m no spray buffer zone OR 15 m with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For D3 ditch 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For R1 stream and R4 stream 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 75% nozzle reduction should be considered.

Ornamentals (onion)

- For D3 ditch 5 m no spray buffer zone should be considered.
- Although scenarios D6 (1st ditch) and D6 (2nd ditch) shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that these scenarios are not relevant under CEU conditions.

Strawberry (leafy vegetables 1st crop)

- For D3 ditch (1st season) 5 m no spray buffer zone should be considered.

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

Fruiting vegetables (strawberry and tomato) – 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 75% of nozzle reduction OR respect an unsprayed buffer zone of 15 m with 90% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 95% 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.~~

Conclusions of risk assessment to aquatic organism for the a.s. (field uses)

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.

Greenhouse uses (permanent use)

According to the new calculations using the new application rate, the risk in greenhouse permanent uses is considered acceptable.

However, the risk assessment for field uses covers all greenhouse uses for the product Decide.

Decide:

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 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)

The final risk mitigation measure should be applied at MSs level.

9.1.1.3 Effects on bees (KCP 10.3.1)

HQ values above the trigger were detected after the exposure to technical. However, first-tier assessments indicate that no unacceptable risk for bees exposed to Deltamethrin 5% CS is expected according to the intended uses. ~~Field studies carried out with Decis 25 EC formulation support the idea that exposure to the maximum proposed dose can be considered as “safe”~~

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 to 284 Reg. the chronic adult and chronic larvae studies ~~should be~~ were provided by the applicant during commenting period process. Further consideration of these studies should be provided by zRMS at national level.

9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2)

No endpoints are available for the representative species (*Typhlodromus pyri* and *Aphidius rhopalosiphii*), therefore the assessment is done using the results obtained from field studies. Risk reduction measures should be considered for arable crops at maximum field rate of 12.5 g/ha. At 5-10 m distance (or another comparable risk reduction measure), the risk for effects is considered to be low.

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of DECIDE. A potential of recovery of the in-field area have been demonstrated in a short period of time after application of a refined ~~MAF~~ DT₅₀ and according to the data from analogous submitted studies. In addition, an acceptable off-field risk was obtained with the application of the following risk mitigation measures:

~~Field crops (brassicae) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.~~

~~Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 20m OR 15m with 50% drift reduction nozzles OR 10m and 75% 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 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.~~

Field crops (brassicae) – 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.

The final risk mitigation measure should be applied at MSs level.

9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

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 and other soil macro- and mesofauna.

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.

9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6)

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.

However, based on the predicted rates of Deltamethrin in off-field areas, the TER values describing the risk for non-target plants following exposure to DECIDE according to the GAP are above acceptability criteria $TER \geq 5$.

9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

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).

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

Table 9.1-2: Critical use pattern of DECIDE (Deltamethrin 5% CS) grouped according to criterion

Grouping according to criterion			
Group	Intended uses	Relevant use parameters for grouping	Relevant parameter or value for sorting
Leafy vegetables	Brassicas (cabbage, Brussels sprouts, cauliflower)	Same application rate and number of applications	21 applications, 0.0125 kg a.s./ha at BBCH 11-43
Strawberries	Strawberry	Same number of applications	Worst case: 31 applications, 0.0125 kg a.s./ha at BBCH 11-81

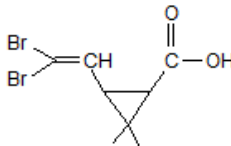
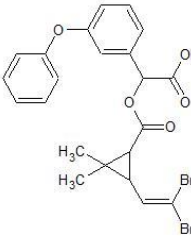
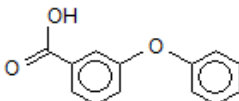
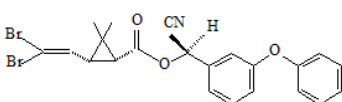
Fruiting vegetables	Tomato	Same application rate and number of applications	31 applications, 0.0125 0.0075 kg a.s./ha at BBCH 11-85
Ornamentals	Ornamentals	-	31 applications, 0.0125 0.0075 kg a.s./ha at BBCH 10-89
All crops	Brassicas (cabbage, Brussels sprouts, cauliflower), Strawberry, Tomato and Ornamentals	Worst case: application rate and number of applications	31 applications, 0.0125 0.0075 kg a.s./ha (Drinking water exposure)
All crops	Brassicas, strawberry, tomato and ornamentals	Maximum application rate and minimum interception (worst-case for PEC _{soil} calculations)	Ornamentals (onions) Maximum application rate: 31 x 12.5 7.5 g a.s./ha Minimum interception: 20%
All crops	Brassicas, strawberry, tomato and ornamentals	Maximum application rate (worst-case for PEC _{sw/sed} calculations)	Ornamentals (apple early) Maximum application rate: 31 x 12.5 7.5 g a.s./ha

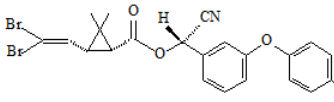
Application on tomato (use 6) was planned on greenhouse. However, same application was planned to be done also outdoors (use 5), hence the risk assessment is considered to be covered by field uses.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of Deltamethrin 5% CS is indicated in the table.

Table 9.1-3 Metabolites of Deltamethrin

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
Br ₂ CA (decamethrinic acid)	297.97 g/mol		Max in soil: 52%* Max in water: 53%**	No
D-COOH ((1R, cis)-α-[[[3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropyl]carbonyl]oxy]-3-phenoxy-benzeneacetic acid)	524.21 g/mol		Max in soil: 9%	No
mPBacid (3-phenoxy-benzoic acid)	214.22 g/mol		Max in water/sediment: 6% Max in water :26%***	No
α-R-deltamethrin	505.2 g/mol		Max in water/sediment: 24% Max in water: 46%**	No

Metabolite	Molar mass	Chemical structure	Maximum occurrence in compartments	Risk assessment required?
4'OH-deltamethrin	521.2 g/mol		Max in water/sediment: 8%	No

* Worst-case from anaerobic study

** From high tier studies

*** From photolysis study

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with Deltamethrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds of Deltamethrin 5% CS were not evaluated as part of the EU assessment of Deltamethrin. However, the provision of further data on DECIDE is not considered essential, because active substance data on toxicity to birds can be used.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Deltamethrin	Oral 14 d, Acute	LD ₅₀ > 2250 mg/kg bw	SANCO 6504/VI/99 (17 October 2002)
<i>Anas platyrhynchos</i>	Deltamethrin	Oral 8 d, Acute	LD ₅₀ > 4640 mg/kg bw	SANCO 6504/VI/99 (17 October 2002)
<i>Colinus virginianus</i>	Deltamethrin	Dietary 8 d, Short-term	LC ₅₀ > 5620 ppm LC ₅₀ > 562 mg/kg bw/d*	SANCO 6504/VI/99 (17 October 2002)
<i>Anas platyrhynchos</i>	Deltamethrin	Dietary 8 d, Short-term	LC ₅₀ = 8039 ppm LC ₅₀ = 803.9 mg/kg bw/d*	SANCO 6504/VI/99 (17 October 2002)
<i>Colinus virginianus</i> and <i>Anas platyrhynchos</i>	Deltamethrin	Dietary Reproductive tox	NOEL = 450 ppm NOEL = 45 mg/kg bw/d*	SANCO 6504/VI/99 (17 October 2002)

* estimated based on NOEC (ppm diet) x 0.1 in accordance (EFSA, 2009)

9.2.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones.

Selection of the endpoint used for acute risk assessment:

According to the Guidance EFSA/2009/1438, where the dietary LC₅₀ is lower than the acute LD₅₀, the dietary value should be used in the acute risk assessment. Therefore, LC₅₀ > 562 mg/kg bw/d was used in the acute risk assessment as worst-case for Deltamethrin.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Regarding the intended use of tomato for greenhouse, DECIDE is expected to apply in enclosed spaces. Therefore, according to the Regulation (EU) No 283/2013, the effects of the active substance on birds should not be considered.

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “leafy vegetables” also covers the risk for birds from both intended uses in “brassicas (cabbage, Brussels sprouts, cauliflower)” as the worst case within this crop. The assessment for the use group “strawberries” covers the risk from intended uses in “strawberries” as the worst case within this crop. The assessment for the use group “fruiting vegetables” also covers the risk from intended uses in “tomato”. The risk from the intended uses in “ornamentals” was assessed separately (see 9.1.2).

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DECIDE in leafy vegetables

Intended-use		Leafy vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		2 x 12.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Brassicac	Indicator species for screening	158.8	1.3	2.58	217.8	
Reprod. toxicity (mg/kg bw/d)		45				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m x TWA	DDD _m (mg/kg bw/d)	TER _{tt}	
Growth stage						
Brassicac	Indicator species for screening	64.8	1.5 x 0.53	0.64	69.9	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Leafy vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀	TER _a	

Growth stage				(mg/kg bw/d)	
Brassicas	Indicator species for screening	158.8	1.0	1.19	471.9
Reprod. toxicity (mg/kg bw/d)	45				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Brassicas	Indicator species for screening	64.8	1.0 x 0.53	0.26	174.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DECIDE in strawberry

Intended-use	Strawberry				
Active substance/product	Deltamethrin				
Application rate (g/ha)	3 x 12.5				
Acute toxicity (mg/kg bw)	562				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Strawberry	Indicator species for screening	158.8	1.5	2.98	188.8
Reprod. toxicity (mg/kg bw/d)	45				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Strawberry	Indicator species for screening	64.8	1.8 x 0.53	0.77	58.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use	Strawberry				
Active substance/product	Deltamethrin				
Application rate (g/ha)	1 x 7.5				
Acute toxicity (mg/kg bw)	562				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Strawberry	Indicator species for screening	158.8	1.0	1.19	471.9
Reprod. toxicity (mg/kg bw/d)	45				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Strawberry	Indicator species for screening	64.8	1.0 x 0.53	0.26	174.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-4: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DECIDE in fruiting vegetables

Intended-use		Fruiting vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Tomato	Indicator species for screening	158.8	1.5	2.98	188.8	
Reprod. toxicity (mg/kg bw/d)		45				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m x TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Tomato	Indicator species for screening	64.8	1.8 x 0.53	0.77	58.2	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Fruiting vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Tomato	Indicator species for screening	158.8	1.0	1.19	471.9	
Reprod. toxicity (mg/kg bw/d)		45				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Tomato	Indicator species for screening	64.8	1.0 x 0.53	0.26	174.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of DECIDE in ornamentals

Intended-use	Ornamentals				
Active substance/product	Deltamethrin				
Application rate (g/ha)	3 x 12.5				
Acute toxicity (mg/kg bw)	562				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Ornamentals	Indicator species for screening	46.8	1.5	0.88	640.5
Reprod. toxicity (mg/kg bw/d)	45				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Ornamentals	Indicator species for screening	18.2	1.8 x 0.53	0.22	207.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use	Ornamentals				
Active substance/product	Deltamethrin				
Application rate (g/ha)	1 x 7.5				
Acute toxicity (mg/kg bw)	562				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Ornamentals	Indicator species for screening	46.8	1.0	0.35	1601.1
Reprod. toxicity (mg/kg bw/d)	45				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Ornamentals	Indicator species for screening	18.2	1.0 x 0.53	0.07	622.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). zRMS agrees with the acute and chronic risk assessment for birds.

TER_a and TER_{LT} values are above trigger of 10 and 5, respectively, indicating acceptable risk.

9.2.2.2 Higher-tier risk assessment

Not required.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Leaf scenario

Since DECIDE is intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario must be considered.

Table 9.2-6: Assessment of the acute risk for birds due to exposure to Deltamethrin via contaminated drinking water in leaf whorls

Intended use		Leafy vegetables				
Active substance		Deltamethrin				
Application rate (g/ha)		2 x 12.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C_{spray-sol.} (g/L)	PEC_{leaf-whorl} = C_{spray-sol.}/5 (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER_a
12.5	200	0.0625	12.5	0.46	5.75	97.74

C_{spray-sol.}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Leafy vegetables				
Active substance		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		562				
TER criterion		10				
(Single) ap- plic. rate (g/ha)	Water applic. rate (L/ha)	C_{spray-sol.} (g/L)	PEC_{leaf-whorl} = C_{spray-sol.}/5 (mg/L)	DW uptake (L/kg bw/d)	Daily dose (mg/kg bw/d)	TER_a
7.5	200	0.0375	7.5	0.46	3.45	162.9

C_{spray-sol.}: concentration in spray solution; PEC_{leaf-whorl}: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (K_{oc} < 500 L/kg) or 3000 in the case of more sorptive substances (K_{oc} ≥ 500 L/kg).

With a K(f)_{oc} of 10.240.000 (SANCO, 2002; mean, n = 4), Deltamethrin belongs to the group of more sorptive substances.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for birds from all other intended uses (see 9.1.2).

Effective application rate (g/ha) =	22.5	AR = 12.5 x MAF = 12.5 x 1.8
Acute toxicity (mg/kg bw) =	562	quotient = 0.04
Reprod. toxicity (mg/kg bw/d) =	45	quotient = 0.50

Effective application rate (g/ha) =	7.5	
Acute toxicity (mg/kg bw) =	562	quotient = 0.01
Reprod. toxicity (mg/kg bw/d) =	45	quotient = 0.17

As the ratios do not exceed the value of 3000 for Deltamethrin, it is not necessary to conduct a drinking water risk assessment for birds.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Deltamethrin amounts to 4.6 (SANCO, 2002; at 25°C, pH 7.6) and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil and on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for birds from all other intended uses (see 9.1.2).

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to Deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in 'all crops'

Parameter	Deltamethrin	Comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.033 0.008	Worst-case PEC _{soil} on ornamentals (onions) – multiple application
log P_{ow} / P_{ow}	4.6 / 39810.72	
Koc	5751287	Geomean (n = 4)
Foc	0.02	Default
BCF _{worm}	0.004	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × P_{ow}) / foc × Koc
PEC _{worm}	0.0004 0.00003	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.0004 0.00003	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	45	
TER _{lt}	324675.3 1339285.7	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface.

Table 9.2-8: Assessment of the risk for fish-eating birds due to exposure to Deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in ‘all crops’

Parameter	Deltamethrin	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00009 0.00003	Worst-case (Step 1 2 scenario on apple early (ornamentals) (multiple application))
BCF _{fish}	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.13 0.04	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.02 0.01	DDD = PEC _{fish} × 0.159 x twa
NOEL (mg/kg bw/d)	45	
TER _{lt}	2246.2 6738.5	

TER values shown in bold fall below the relevant trigger.

zRMS comments:

We agree with the calculations provided for secondary poisoning for fish-eating birds due to exposure to Deltamethrin via bioaccumulation in fish (secondary poisoning) and for earthworm-eating birds due to exposure to Deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in ‘all crops’.

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.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

zRMS comments:

The studies on metabolism indicated that deltamethrin is rapidly eliminated in birds and mammals, thus biomagnification is not expected and no further assessment is required.

9.2.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

9.2.4 Overall conclusions

According to the screening assessment, all TER_a and TER_{lt} 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.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with Deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. However, the provision of further data on the formulation DECIDE is not considered essential, because endpoints obtained with the active substance are sufficient to evaluate the risk and new studies should not be conducted in regards of animal welfare (EFSA Journal 2009; 7(12):1438). The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Deltamethrin	Oral 1 d Acute	LD₅₀ = 87 mg/kg bw	SANCO 6504/VI/99 (17 October 2002)
Dogs	Deltamethrin	Long-term 13 weeks (neurotoxicity)	NOAEL = 2.5 mg/kg bw/d	SANCO 6504/VI/99 (17 October 2002)

9.3.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

Regarding the intended use of tomato for greenhouse, DECIDE is expected to apply in enclosed spaces. Therefore, according to the Regulation (EU) No 283/2013, the effects of the active substance on mammals should not be considered.

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group “leafy vegetables” also covers the risk for mammals from both intended uses in “brassicas (cabbage, Brussels sprouts, cauliflower)” as the worst case within this crop. The assessment for the use

group “strawberries” covers the risk from intended uses in “strawberries” as the worst case within this crop. The assessment for the use group “fruiting vegetables” also covers the risk from intended uses in “tomato”. The risk from the intended uses in “ornamentals” was assessed separately (see 9.1.2).

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DECIDE in leafy vegetables

Intended-use		Leafy vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		2 x 12.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Brassicaceae	Indicator species for screening	136.4	1.3	2.22	39.3	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}	
Growth stage						
Leafy vegetables—all season	Large herbivorous mammal ‘lagomorph’ Non-grass herbs 100% leaves	14.3	1.5 x 0.53	0.14	17.6	
Leafy vegetables—BBCH 10-19	Small insectivorous mammal ‘shrew’ ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.5 x 0.53	0.04	59.9	
Leafy vegetables—BBCH 10-49	Small omnivorous mammal ‘mouse’ Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.5 x 0.53	0.08	32.3	
Leafy vegetables—BBCH ≥ 20	Small insectivorous mammal ‘shrew’ ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.5 x 0.53	0.02	132.4	
Leafy vegetables—BBCH 40-49	Small herbivorous mammal ‘vole’ grass + cereals 100% grass	72.3	1.5 x 0.53	0.72	3.5	

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Leafy vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a	
Growth stage						

Brassicas	Indicator species for screening	136.4	1.0	1.02	85.0
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Brassicas	Indicator species for screening	72.3	1.0 x 0.53	0.29	8.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DECIDE in strawberry

Intended-use	Strawberries				
Active substance/product	Deltamethrin				
Application rate (g/ha)	3 x 12.5				
Acute toxicity (mg/kg bw)	87				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Strawberries	Indicator species for screening	118.4	1.5	2.2	39.2
Reprod. toxicity (mg/kg bw/d)	2.5				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Strawberries—BBCH 10-19	Small insectivorous mammal 'shrew' ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.8 x 0.53	0.05	49.9
Strawberries—BBCH 10-39	Large herbivorous mammal 'lagomorph' non-grass herbs 100% non-grass herbs	14.3	1.8 x 0.53	0.17	14.7
Strawberries—BBCH 10-39	Small omnivorous mammal 'mouse' Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.8 x 0.53	0.09	26.9
Strawberries—BBCH ≥20	Small insectivorous mammal 'shrew' ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.8 x 0.53	0.02	110.3
Strawberries—BBCH ≥40	Large herbivorous mammal 'lagomorph' non-grass herbs 100% non-grass herbs	5.7	1.8 x 0.53	0.07	36.8
Strawberries—BBCH ≥40	Small herbivorous mammal 'vole' grass + cereals 100% grass	28.9	1.8 x 0.53	0.34	7.3

Strawberries—BBCH ≥40	Small omnivorous mammal 'mouse' Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	3.1	1.8 x 0.53	0.04	67.6
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Strawberries			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5			
Acute toxicity (mg/kg bw)		87			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Strawberries	Indicator species for screening	118.4	1.0	0.89	98.0
Reprod. toxicity (mg/kg bw/d)		2.5			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Strawberries	Indicator species for screening	48.3	1.0 x 0.53	0.19	13.0

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DECIDE in fruiting vegetables

Intended-use		Fruiting-vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Tomato	Indicator species for screening	136.4	1.5	2.56	34.0	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Fruiting vegetables— BBCH 10-19	Small insectivorous mammal ‘shrew’ ground dwelling invertebrates without interception 100% ground arthropods	4.2	1.8 x 0.53	0.05	49.9	
Fruiting vegetables— BBCH 10-49	Small herbivorous mammal ‘vole’ grass + cereals 100% grass	72.3	1.8 x 0.53	0.86	2.9	
Fruiting vegetables— BBCH 10-49	Small omnivorous mammal ‘mouse’ Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.8 x 0.53	0.09	26.9	
Fruiting vegetables— BBCH ≥ 20	Small insectivorous mammal ‘shrew’ ground dwelling invertebrates with interception 100% ground arthropods	1.9	1.8 x 0.53	0.02	110.3	
Fruiting vegetables— BBCH ≥ 50	Small herbivorous mammal ‘vole’ grass + cereals 100% grass	21.7	1.8 x 0.53	0.26	9.7	
Fruiting vegetables— BBCH ≥ 50	Small omnivorous mammal ‘mouse’ Combination (invertebrates without interception) 25% weeds 50% weed seeds 25% ground arthropods	2.3	1.8 x 0.53	0.03	91.2	
Fruiting vegetables— Fruit stage BBCH 71-89	Frugivorous mammal ‘rat’ Gourds 100% fruit	25.2	1.8 x 0.53	0.30	8.3	

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Fruiting vegetables				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Tomato	Indicator species for screening	136.4	1.5	1.02	85.0	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Tomato	Indicator species for screening	72.3	1.0 x 0.53	0.29	8.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of DECIDE in ornamentals

Intended use		Ornamentals				
Active substance/product		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Ornamentals	Indicator species for screening	136.4	1.5	2.56	34.0	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Ornamentals and nursery—Application crop directed BBCH 40-49	Small omnivorous mammal ‘mouse’ Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	7.8	1.8 x 0.53	0.09	26.9	
Ornamentals and nursery—application crop directed BBCH ≥ 50	Small omnivorous mammal ‘mouse’ Combination (invertebrates with interception) 25% weeds 50% weed seeds 25% ground arthropods	3.9	1.8 x 0.53	0.05	53.8	
Ornamentals and nursery—BBCH ≥ 50	Small herbivorous mammal ‘vole’ grass + cereals 100% grass	36.1	1.8 x 0.53	0.43	5.8	
Ornamentals and nursery BBCH 40-49	Small herbivorous mammal ‘vole’ grass + cereals 100% grass	72.3	1.8 x 0.53	0.86	2.9	

Ornamentals and nursery— Application to plant— exposure to underlying ground	Small insectivorous mammal 'shrew' Ground-dwelling invertebrates with interception 100% ground arthropods	1.9	1.8 x 0.53	0.02	110.3
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Ornamentals				
Active substance/product		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Acute toxicity (mg/kg bw)		87				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Ornamentals	Indicator species for screening	136.4	1.0	1.02	85.0	
Reprod. toxicity (mg/kg bw/d)		2.5				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{tt}	
Growth stage						
Ornamentals	Indicator species for screening	72.3	1.0 x 0.53	0.29	8.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

9.3.2.2 Higher-tier risk assessment

Not relevant.

Higher-tier risk assessment for 'vole' – brassicas

DT₅₀ and TWA refinement

Initial residues were calculated according to EPPO. To take account of decline in residues, the mean DT₅₀ in lettuce and spinach was calculated to 2.8 days (in Martens and Schäfer, 1999, see table below). According to the Addendum to the Monograph (July, 2002), the same DT₅₀ can be applied also to young growing cereal shoots.

	Day	Measures residues (mg/kg)	Mean residues (mg/kg)	DT ₅₀ (r ²)	DT ₉₀
Lettuce (n=28)	0	0.03-0.5	0.17	2.7 days (1.0)	9 days
	3	0.02-0.2	0.079		
	5	0.005-0.2	0.046		
	7	0.005-0.08	0.029		
Spinach (n=11)	0	0.4-0.81	0.53	2.9 days (0.98)	10 days
	1	0.33-0.62 [†]	0.48		
	3	0.1-0.46	0.22		
	5	0.005-0.3	0.17		
	7	0.021-0.5	0.11		

The long-term assessment of the multiple application scenario has been refined, in the sense that decline of residues in plants (DT₅₀ 2.8 d) has been taken into account.

The f_{twa} was calculated based on the DT₅₀ of 2.8 days as following

$$f_{twa} = (1 - e^{-kt})/kt ; \text{ Where: } k = \ln 2 / DT_{50} \text{ (velocity constant)}$$

$$t = \text{averaging time (21 days)}$$

The DT_{50} was calculated to be 2.8 days, therefore, it results in the f_{twa} of 0.191.

Deposition factor (DF)

According to EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662), the FOCUS interception value for brassicas in BBCH 40-49 would be 70%, which would mean that 30% of the total applied product would end up in the ground and the intercepted 70% would remain in the crop.

Table 9.3-6: Higher-tier assessment of the long-term risk for mammals due to the use of DECIDE in leafy vegetables—refined parameters (*) are further described and justified in the text.

Intended-use		Leafy vegetables					
Active substance/product		Deltamethrin					
Application rate (g/ha)		2 x 12.5					
Reprod. toxicity (mg/kg bw/d)		2.5					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	RUD _m × DF* (mg/kg food)	MAF _m × TWA* TWA*	PT	DDD _m (mg/kg bw/d)	TER _{tt}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals 100% grass	1.33	54.2 x 0.3	1.5 x 0.191	4	0.08	32.3

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Conclusion:

After considering that growth stage dependent factor and the residue data, the TER_{tt} is higher than the trigger of 5, indicating that DECIDE presents no unacceptable long term risk to vole according to the intended uses on brassicas.

Higher-tier risk assessment for ‘vole’—Tomatoes

DT₅₀ and TWA refinement

The DT_{50} was calculated to be 2.8 days, therefore, it results in the f_{twa} of 0.191, as was specified in the higher tier risk assessment for ‘vole’ for brassicas (see above). Since similar results were obtained in both crops (lettuce and spinach) at the end of the study, the extrapolation to other crops is considered generally valid, when application is carried out at early growth stages with a following significant increase of plant mass.

Deposition factor (DF)

According to EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662), the FOCUS interception value for tomatoes in BBCH 10-49 would be from 50% to 80%. Taking 50% as the worst case, it would mean that 50% of the total applied product would end up in the ground and the intercepted 50% would remain in the crop.

Results of the higher tier risk assessment are presented in the table below:

Table 9.3-7: Higher-tier assessment of the long-term risk for mammals due to the use of DECIDE in tomato—refined parameters (*) are further described and justified in the text.

Intended-use		Fruiting vegetables					
Active substance/product		Deltamethrin					
Application rate (g/ha)		3 x 12.5					
Reprod. toxicity (mg/kg bw/d)		2.5					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	$RUD_m \times DF^*$ (mg/kg food)	$MAF_m \times TWA^*$	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals 100% grass	1.33	54.2 x 0.5	1.8 x 0.191	4	0.15	16.1

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Conclusion:

After considering that growth stage dependent factor and the residue data, the TER_{it} is higher than the trigger of 5, indicating that DECIDE presents no unacceptable long term risk to vole according to the intended uses on tomatoes.

Higher-tier risk assessment for ‘vole’—ornamentals

DT₅₀ and TWA refinement

The DT₅₀ was calculated to be 2.8 days, therefore, it results in the f_{TWA} of 0.191, as was specified in the higher tier risk assessment for ‘vole’ for brassicas and tomatoes (see above).

Deposition factor (DF)

According to EFSA Guidance Document to obtain DegT50 values (EFSA Journal 2014;12(5):3662), there is not a specific FOCUS interception value for ornamentals, hence surrogate species were considered in this regard. Surrogate crop for arbustive ornamentals would be apple and for herbaceous and ornamental flowers would be bulb vegetables, with 60 and 10% crop interception, respectively (see Section B8). Taking 10% as the worst case, the result of the higher tier risk assessment is as presented in the table below:

Table 9.3-8: Higher-tier assessment of the long-term risk for mammals due to the use of DECIDE in ornamentals—refined parameters (*) are further described and justified in the text.

Intended-use		Ornamentals					
Active substance/product		Deltamethrin					
Application rate (g/ha)		3 x 12.5					
Reprod. toxicity (mg/kg bw/d)		2.5					
TER criterion		5					
Focal species	Food category, % in diet	FIR/bw	$RUD_m \times DF^*$ (mg/kg food)	$MAF_m \times TWA^*$	PT	DDD_m (mg/kg bw/d)	TER_{it}
Common vole (<i>Microtus arvalis</i>)	Grass + cereals 100% grass	1.33	54.2 x 0.9	1.8 x 0.191	4	0.28	9.0

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold

~~fall below the relevant trigger.~~

Conclusion:

~~After considering that growth stage dependent factor and the residue data, the TER_{LT} is higher than the trigger of 5, indicating that DECIDE presents no unacceptable long term risk to vole according to the intended uses on ornamentals.~~

zRMS comments:

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438). zRMS agrees with the acute and chronic risk assessment for mammals.

TERa and TER_{LT} values are above trigger of 10 and 5, respectively, indicating acceptable risk.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 12.240.000, Deltamethrin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for mammals from all other intended uses (see 9.1.2).

Effective application rate (g/ha)=	12.5	AR = 12.5 x MAF = 12.5 x 1.8
Acute toxicity (mg/kg bw) =	87	quotient = 0.26
Reprod. toxicity (mg/kg bw/d) =	2.5	quotient = 3.00

Effective application rate (g/ha)=	7.5	
Acute toxicity (mg/kg bw) =	87	quotient = 0.09
Reprod. toxicity (mg/kg bw/d) =	2.5	quotient = 3.00

As the ratios do not exceed the value of 3000 for Deltamethrin, it is not necessary to conduct a drinking water risk assessment for mammals.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Deltamethrin amounts to 4.6 (at 25°C, pH 7.6) and thus exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil and on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for mammals from all other intended uses (see 9.1.2).

Table 9.3-9: Assessment of the risk for earthworm-eating mammals due to exposure to Deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in 'all crops'

Parameter	Deltamethrin	Comments
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.033 0.008	Worst-case PEC _{soil} on ornamentals (onions) – multiple application
log P _{ow} / P _{ow}	4.6 / 39810.72	
Koc	5751287	Geomean (n = 4)
Foc	0.02	Default
BCF _{worm}	0.004	BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × P _{ow}) / foc × Koc
PEC _{worm}	0.0004 0.00003	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.0002 0.00004	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	2.5	
TER _{lt}	14796.4 61035.2	

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for mammals from all other intended uses (see 9.1.2).

Table 9.3-10: Assessment of the risk for fish-eating mammals due to exposure to Deltamethrin via bioaccumulation in fish (secondary poisoning) for the intended use in 'all crops'

Parameter	Deltamethrin	Comments
PEC _{sw} (twa = 21 d) (mg/L)	0.00009 0.00003	Worst-case (Step 1 2 scenario on apple early (ornamentals) (multiple application))
BCF _{fish}	1400	
BMF	-	biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.13 0.04	PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.02 0.01	DDD = PEC _{fish} × 0.142 x twa
NOEL (mg/kg bw/d)	2.5	
TER _{lt}	139.7 419.2	

TER values shown in bold fall below the relevant trigger.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

zRMS comments:

We agree with the calculation provided for secondary poisoning for fish-eating mammals due to exposure to Deltamethrin via bioaccumulation in fish (secondary poisoning) and for earthworm-eating mammals due to exposure to Deltamethrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in 'all crops'.
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.

9.3.3 Risk assessment for baits, pellets, granules, pills or treated seed

Not relevant.

zRMS comments:

The studies on metabolism indicated that deltamethrin is rapidly eliminated in birds and mammals, thus biomagnification is not expected and no further assessment is required.

9.3.4 Overall conclusions

~~According to the screening assessment, the TER_a value for the active substance Deltamethrin is greater than the Annex VI trigger of 10. After first tier assessment for active substance Deltamethrin, the TER_{lt} values are lower than the Annex VI trigger of 5, for small herbivorous mammal "vole", indicating that DECIDE presents an unacceptable long term risk to mammals. A refinement of the risk was done by refining the f_{twd} and the deposition factors and the TER_{lt} values were above the trigger showing no risk. Therefore, the acute and long term risk to mammals after the application of DECIDE according to the GAP is considered acceptable. Moreover, the risk for mammals due to uptake of contaminated drinking water was considered as low.~~

According to the screening assessment, all TER_a and TER_{lt} 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 mammals 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.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

No data available.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with Deltamethrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. **New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.**

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – Deltamethrin

Species	Substance	Exposure System	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	IS-002A	Acute, f 96 h	LC₅₀ = 0.26 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
<i>Oncorhynchus mykiss</i>	Deltamethrin	Chronic, f 28 d	NOEC < 0.032 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
Aquatic invertebrates				
<i>Daphnia magna</i>	Deltamethrin	24 h, f 48 h, f	EC ₅₀ > 1.3 µg a.s./L EC ₅₀ = 0.56 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
<i>Daphnia magna</i>	IS-002A	24 h, ss 48 h, ss	EC ₅₀ = 0.25 µg a.s./L EC₅₀ = 0.11 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
<i>Daphnia magna</i>	Deltamethrin	21 d, f	NOEC = 0.0041 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
Sediment-dwelling organisms				
<i>Chironomus tentans</i>	Deltamethrin	24 h, s	NOEC = 0.03-0.05 µg a.s./L EC ₁₀₀ = 3.5 µg a.s./L	Addendum to the Monograph Annex B, 2002
<i>Chironomus riparius</i>	Deltamethrin	28 d, s	NOEC = 0.010 µg a.s./L	SANCO 6504/VI/99 (17 October 2002)
Algae				
<i>S. capricornutum</i>	Deltamethrin	Acute/chronic, ss	Uncertain value, but probably only moderate toxicity	SANCO 6504/VI/99 (17 October 2002)
Higher-tier studies (micro- or mesocosm studies)				
Overall assessment: For invertebrates, including sediment-living organisms: EAC 3 x 0.0032 µg/L (Schanné and van der Kolk, 2001; Schanné, 2001 a,b) Toxicity to fish overestimates in laboratory studies; lowest NOEL in field studies was overspray at 10 g/ha and LOEL 50 g/ha (NOEL 3 g/ha and LOEL 15 g/ha when corrected to a standard depth of 0.3 m). Experimental ponds: At nominal concentration of 1 µg/L from overspray at 10 g/ha to 1 m deep water (= 3 g/ha to a 0.3 m deep water): No mortality in fish (<i>R. rutilus</i> and <i>C. carassius</i>) over 14 days, no conclusive data on invertebrates. At nominal concentration of 5 µg/L from overspray at 50 g/ha to 1 m deep water (= 15 g/ha to a 0.3 m deep water):				

Species	Substance	Exposure System	Results	Reference
<p>Severe fish mortality, severe effects on invertebrates indicated.</p> <p>Microcosm: At nominal concentration of 2.2 µg/L from overspray at 20 g/ha to 0.9 m deep water (= 6.7 g/ha to a 0.3 m deep water): no adverse effects in fish (<i>P. promelas</i>) over 7 days.</p> <p>Mesocosm: At nominal concentration of 3.2 µg/L from application of 10 g/ha just below the surface of 0.5 m deep water (=6 g/ha to a 0.3 m deep water): No short- or long-term mortality in fish (<i>P. promelas</i>).</p> <p>Natural ponds: At initial (1 h) concentration of 0.2-0.23 µg/L from overspray at 7.5 g/ha to natural ponds, up to 0.8 m deep: Severe effects on chironomidae; marked recovery in one pond within 4-6 weeks, in the other pond not until next spring (treatment done in June).</p> <p>Mesocosm study on tralomethrin: At nominal concentration of up to 10 x 0.27 µg/L (spray) + 5 x 0.87 µg/L (slurry) from overspray at rates up to 10 x 4.5 g/ha (spray) + 5 x 7.2 g/ha (slurry) to mesocosm approximately 1.75 m deep (= up to 10 x 0.8 g/ha (spray) + 5 x 1.2 g/ha (slurry) to a 0.3 m deep water): No short- or long-term adverse effects on fish (<i>L. macrochirus</i>), no effect on invertebrates inhabiting the hydrosol; effects on crustaceans could not be evaluated; no NOEC level for macroinvertebrates was obtained.</p> <p>Microcosm: At nominal concentration of 3 x 10 ng a.s./L (SI 7 days), applied under the water surface to static systems of 1 m depth: Effects on abundance were observed in 5 taxa (<i>Daphnia app</i> in free water; <i>Chaoborus</i> adults and larvae, Ephemeroptera larvae and <i>A. aquaticus</i>), but recovery indicated/demonstrated. At the next lower level, 3 x 3.2 ng/L, effects on <i>A. aquaticus</i> appeared only at very late sampling points, and the population growth observed earlier clearly indicates a potential for recovery. Ecologically Acceptable Concentration (EAC) for aquatic invertebrates, including sediment-dwellers, set to 3 x 0.0032 µg a.s./L (SI 7 days).</p>				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – DECIDE

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	DECIDE	96 h, s	LC ₅₀ = 1.34 mg/L _{nom}	KCP 10.2.1-01 B.V. XXX, 2020 G13391
<i>Raphidocelis subcapitata</i>	DECIDE	72 h, s	E _r C ₅₀ = 143.33 mg/L _{nom} E _y C ₅₀ = 53.29 mg/L _{nom}	KCP 10.2.1-02 B.V. XXX, 2020 G13392
<i>Daphnia magna</i>	DECIDE	48 h, s	EC ₅₀ = 0.0044 mg/L _{nom}	KCP 10.2.1-03 B.V. XXX, 2020 G13393
Higher-tier studies (micro- or mesocosm studies)				
-				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones.

According to R (EU) n° 284/2013: “Possible effects on aquatic species (fish, aquatic invertebrates, algae

and in the case of herbicides and plant growth regulators, aquatic macrophytes) shall be investigated except where the possibility that aquatic species will be exposed can be ruled out". DECIDE is an insecticide therefore the Applicant considers that studies on macrophytes with formulation is not mandatory.

The risk assessment with the metabolite Br2CA (decamethrinic acid) was not carried out due to the absence of aquatic endpoints from EU assessment.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009", as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PEC_{sw} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in leafy vegetable (brassicas)

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Sed.-dwell.-prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC <0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	<0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
-	0.12 / 0.23	46.154 / 88.462	37.500 / 71.875	109.091 / 209.091	292.683 / 560.976	120.000 / 230.000	37.500 / 71.875
Step 2							
S-Europe	0.12 / 0.10	46.154 / 38.462	37.500 / 31.250	109.091 / 90.909	292.683 / 243.902	120.000 / 100.000	37.500 / 31.250
N-Europe	0.11 / 0.10	42.308 / 38.462	34.375 / 31.250	100.000 / 90.909	268.293 / 243.902	110.000 / 100.000	34.375 / 31.250
Step 3							
D3/ditch (1 st -season)	0.0049 / 0.0042	1.885 / 1.615	1.531 / 1.313	4.455 / 3.818	11.951 / 10.244	4.900 / 4.200	1.531 / 1.313
D3/ditch (2 nd -season)	0.0049 / 0.0042	1.885 / 1.615	1.531 / 1.313	4.455 / 3.818	11.951 / 10.244	4.900 / 4.200	1.531 / 1.313
D4/pond	0.0001 / 0.0002	0.038 / 0.077	0.031 / 0.063	0.091 / 0.182	0.244 / 0.488	0.100 / 0.200	0.031 / 0.063
D4/stream	0.0037 / 0.0033	1.423 / 1.269	1.156 / 1.031	3.364 / 3.000	9.024 / 8.049	3.700 / 3.300	1.156 / 1.031
D6/ditch	0.0836 / 0.0834	32.154 / 32.077	26.125 / 26.063	76.000 / 75.818	203.902 / 203.415	83.600 / 83.400	26.125 / 26.063
R1/pond (1 st -season)	0.0001 / 0.0002	0.038 / 0.077	0.031 / 0.063	0.091 / 0.182	0.244 / 0.488	0.100 / 0.200	0.031 / 0.063
R1/pond (2 nd -season)	0.0001 / 0.0002	0.038 / 0.077	0.031 / 0.063	0.091 / 0.182	0.244 / 0.488	0.100 / 0.200	0.031 / 0.063
R1/stream (1 st -season)	0.0031 / 0.0026	1.192 / 1.000	0.969 / 0.813	2.818 / 2.364	7.561 / 6.341	3.100 / 2.600	0.969 / 0.813

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
R1/stream (2 nd season)	0.0031 / 0.0026	1.192 / 1.000	0.969 / 0.813	2.818 / 2.364	7.561 / 6.341	3.100 / 2.600	0.969 / 0.813
R2/stream (1 st season)	0.0042 / 0.0036	1.615 / 1.385	1.313 / 1.125	3.818 / 3.273	10.244 / 8.780	4.200 / 3.600	1.313 / 1.125
R2/stream (2 nd season)	0.0043 / 0.0036	1.654 / 1.385	1.344 / 1.125	3.909 / 3.273	10.488 / 8.780	4.300 / 3.600	1.344 / 1.125
R3/stream (1 st season)	0.0045 / 0.0038	1.731 / 1.462	1.406 / 1.188	4.091 / 3.455	10.976 / 9.268	4.500 / 3.800	1.406 / 1.188
R3/stream (2 nd season)	0.0045 / 0.0038	1.731 / 1.462	1.406 / 1.188	4.091 / 3.455	10.976 / 9.268	4.500 / 3.800	1.406 / 1.188
R4/stream (1 st season)	0.0031 / 0.0026	1.192 / 1.000	0.969 / 0.813	2.818 / 2.364	7.561 / 6.341	3.100 / 2.600	0.969 / 0.813
R4/stream (2 nd season)	0.0030 / 0.0026	1.154 / 1.000	0.938 / 0.813	2.727 / 2.364	7.317 / 6.341	3.000 / 2.600	0.938 / 0.813

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC < 0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
I	0.07	26.923	21.875	63.636	170.732	70.000	21.875
Step 2							
S-Europe	0.07	26.923	21.875	63.636	170.732	70.000	21.875
N-Europe	0.07	26.923	21.875	63.636	170.732	70.000	21.875
Step 3							
D3/ditch (1 st season)	0.0028	1.077	0.875	2.545	6.829	2.800	0.875
D3/ditch (2 nd season)	0.0028	1.077	0.875	2.545	6.829	2.800	0.875

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
D4/pond	<0.001	0.385	0.313	0.909	2.439	1.000	0.313
D4/stream	0.0021	0.808	0.656	1.909	5.122	2.100	0.656
D6/ditch	0.0836	32.154	26.125	76.000	203.902	83.600	26.125
R1/pond (1 st season)	<0.001	0.385	0.313	0.909	2.439	1.000	0.313
R1/pond (2 nd season)	<0.001	0.385	0.313	0.909	2.439	1.000	0.313
R1/stream (1 st season)	0.0017	0.654	0.531	1.545	4.146	1.700	0.531
R1/stream (2 nd season)	0.0018	0.692	0.563	1.636	4.390	1.800	0.563
R2/stream (1 st season)	0.0024	0.923	0.750	2.182	5.854	2.400	0.750
R2/stream (2 nd season)	0.0024	0.923	0.750	2.182	5.854	2.400	0.750
R3/stream (1 st season)	0.00254	0.977	0.794	2.309	6.195	2.540	0.794
R3/stream (2 nd season)	0.00255	0.981	0.797	2.318	6.220	2.550	0.797
R4/stream (1 st season)	0.0017	0.654	0.531	1.545	4.146	1.700	0.531
R4/stream (2 nd season)	0.0017	0.654	0.531	1.545	4.146	1.700	0.531

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in fruiting vegetables (~~strawberry and tomato~~)

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Sed.-dwell.-prolonged	Microcosms
Test species		<i>Oncorhynchus-mykiss</i>	<i>Oncorhynchus-mykiss</i>	<i>Daphnia-magna</i>	<i>Daphnia-magna</i>	<i>Chironomus-riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC <0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	<0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	NOEC	EAC
(µg/L)		0.26	< 0.032	0.11	0.0041	0.010	0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	0.07	26.923	21.875	63.636	170.732	70.000	21.875
Step 2							

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in ornamentals (apple early BBCH 10; apple tree scenario as a replacement plant for tall ornamental plants)

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Sed.-dwell.-prolonged	Microcosms
Test-species		<i>Oncorhynchus-mykiss</i>	<i>Oncorhynchus-mykiss</i>	<i>Daphnia-magna</i>	<i>Daphnia-magna</i>	<i>Chironomus-riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC ≤0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	≤0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							

Group		Fish-acute	Fish-prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
-	1.22 / 3.65	469.23 / 1403.85	381.25 / 1140.63	1109.09 / 3318.18	2975.61 / 8902.44	1220.00 / 3650.00	381.25 / 1140.63
Step 2							
S-Europe	1.22 / 1.00	469.23 / 384.62	381.25 / 312.50	1109.09 / 909.09	2975.61 / 2439.02	1220.00 / 1000.00	381.25 / 312.50
N-Europe	1.22 / 1.00	469.23 / 384.62	381.25 / 312.50	1109.09 / 909.09	2975.61 / 2439.02	1220.00 / 1000.00	381.25 / 312.50
Step 3							
D3/ditch	0.0770 / 0.0612	29.615 / 23.538	24.063 / 19.125	70.000 / 55.636	187.805 / 149.268	77.000 / 61.200	24.063 / 19.125
D4/pond	0.0035 / 0.0054	1.346 / 2.077	1.094 / 1.688	3.182 / 4.909	8.537 / 13.171	3.500 / 5.400	1.094 / 1.688
D4/stream	0.0724 / 0.0626	27.846 / 24.077	22.625 / 19.563	65.818 / 56.909	176.585 / 152.683	72.400 / 62.600	22.625 / 19.563
D5/pond	0.0035 / 0.0052	1.346 / 2.000	1.094 / 1.625	3.182 / 4.727	8.537 / 12.683	3.500 / 5.200	1.094 / 1.625
D5/stream	0.0763 / 0.0659	29.346 / 25.346	23.844 / 20.594	69.364 / 59.909	186.098 / 160.732	76.300 / 65.900	23.844 / 20.594
R1/pond	0.0035 / 0.0049	1.346 / 1.885	1.094 / 1.531	3.182 / 4.455	8.537 / 11.951	3.500 / 4.900	1.094 / 1.531
R1/stream	0.0609 / 0.0476	23.423 / 18.308	19.031 / 14.875	55.364 / 43.273	148.537 / 116.098	60.900 / 47.600	19.031 / 14.875
R2/stream	0.0830 / 0.0650	31.923 / 25.000	25.938 / 20.313	75.455 / 59.091	202.439 / 158.537	83.000 / 65.000	25.938 / 20.313
R3/stream	0.0893 / 0.0698	34.346 / 26.846	27.906 / 21.813	81.182 / 63.455	217.805 / 170.244	89.300 / 69.800	27.906 / 21.813
R4/stream	0.0613 / 0.0479	23.577 / 18.423	19.156 / 14.969	55.727 / 43.545	149.512 / 116.829	61.300 / 47.900	19.156 / 14.969

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	NOEC	EAC
(µg/L)		0.26	< 0.032	0.11	0.0041	0.010	0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Step 1							
I	0.73	280.77	228.13	663.64	1780.49	730.00	228.13
Step 2							
S-Europe	0.73	280.77	228.13	663.64	1780.49	730.00	228.13
N-Europe	0.73	280.77	228.13	663.64	1780.49	730.00	228.13
Step 3							
D3/ditch	0.0438	16.846	13.688	39.818	106.829	43.800	13.688
D4/pond	0.0019	0.731	0.594	1.727	4.634	1.900	0.594
D4/stream	0.0412	15.846	12.875	37.455	100.488	41.200	12.875
D5/pond	0.0019	0.731	0.594	1.727	4.634	1.900	0.594
D5/stream	0.0434	16.692	13.563	39.455	105.854	43.400	13.563
R1/pond	0.0019	0.731	0.594	1.727	4.634	1.900	0.594
R1/stream	0.0347	13.346	10.844	31.545	84.634	34.700	10.844
R2/stream	0.0473	18.192	14.781	43.000	115.366	47.300	14.781
R3/stream	0.0508	19.538	15.875	46.182	123.902	50.800	15.875
R4/stream	0.0349	13.423	10.906	31.727	85.122	34.900	10.906

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in ornamentals (apple late BBCH 85; apple tree scenario as a replacement plant for tall ornamental plants)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC <0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	<0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
-	0.66 / 1.97	253.85 / 757.69	206.25 / 615.63	600.00 / 1790.91	1609.76 / 4804.88	660.00 / 1970.00	206.25 / 615.63
Step 2							
S-Europe	0.66 / 0.46	253.85 / 176.92	206.25 / 143.75	600.00 / 418.18	1609.76 / 1121.95	660.00 / 460.00	206.25 / 143.75
N-Europe	0.66 / 0.46	253.85 / 176.92	206.25 / 143.75	600.00 / 418.18	1609.76 / 1121.95	660.00 / 460.00	206.25 / 143.75
Step 3							
D3/ditch	0.0338 / 0.0236	13.000 / 9.077	10.563 / 7.375	30.727 / 21.455	82.439 / 57.561	33.800 / 23.600	10.563 / 7.375
D4/pond	0.0011 / 0.0014	0.423 / 0.538	0.344 / 0.438	1.000 / 1.273	2.683 / 3.415	1.100 / 1.400	0.344 / 0.438
D4/stream	0.0330 / 0.0228	12.692 / 8.769	10.313 / 7.125	30.000 / 20.727	80.488 / 55.610	33.000 / 22.800	10.313 / 7.125
D5/pond	0.0011 / 0.0017	0.423 / 0.654	0.344 / 0.531	1.000 / 1.545	2.683 / 4.146	1.100 / 1.700	0.344 / 0.531
D5/stream	0.0369 / 0.0254	14.192 / 9.769	11.531 / 7.938	33.545 / 23.091	90.000 / 61.951	36.900 / 25.400	11.531 / 7.938
R1/pond	0.0011 / 0.0013	0.423 / 0.500	0.344 / 0.406	1.000 / 1.182	2.683 / 3.171	1.100 / 1.300	0.344 / 0.406
R1/stream	0.0252 / 0.0174	9.692 / 6.692	7.875 / 5.438	22.909 / 15.818	61.463 / 42.439	25.200 / 17.400	7.875 / 5.438
R2/stream	0.0349 / 0.0240	13.423 / 9.231	10.906 / 7.500	31.727 / 21.818	85.122 / 58.537	34.900 / 24.000	10.906 / 7.500

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
R3/stream	0.0368 / 0.0254	14.154 / 9.769	11.500 / 7.938	33.455 / 23.091	89.756 / 61.951	36.800 / 25.400	11.500 / 7.938
R4/stream	0.0252 / 0.0174	9.692 / 6.692	7.875 / 5.438	22.909 / 15.818	61.463 / 42.439	25.200 / 17.400	7.875 / 5.438

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	NOEC	EAC
(µg/L)		0.26	< 0.032	0.11	0.0041	0.010	0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
	0.39	150.00	121.88	354.55	951.22	390.00	121.88
Step 2							
S-Europe	0.39	150.00	121.88	354.55	951.22	390.00	121.88
N-Europe	0.39	150.00	121.88	354.55	951.22	390.00	121.88
Step 3							
D3/ditch	0.0192	7.385	6.000	17.455	46.829	19.200	6.000
D4/pond	0.0006	0.231	0.188	0.545	1.463	0.600	0.188
D4/stream	0.0188	7.231	5.875	17.091	45.854	18.800	5.875
D5/pond	0.0006	0.231	0.188	0.545	1.463	0.600	0.188
D5/stream	0.0209	8.038	6.531	19.000	50.976	20.900	6.531
R1/pond	0.0006	0.231	0.188	0.545	1.463	0.600	0.188
R1/stream	0.0144	5.538	4.500	13.091	35.122	14.400	4.500

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
R2/stream	0.0198	7.615	6.188	18.000	48.293	19.800	6.188
R3/stream	0.0209	8.038	6.531	19.000	50.976	20.900	6.531
R4/stream	0.0144	5.538	4.500	13.091	35.122	14.400	4.500

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in ornamentals (onion bulb vegetation as a replacement plant for low ornamental plants)

Group		Fish-acute	Fish-prolonged	Inverteb.-acute	Inverteb.-prolonged	Sed.-dwell.-prolonged	Microcosms
Test species		<i>Oncorhynchus-mykiss</i>	<i>Oncorhynchus-mykiss</i>	<i>Daphnia-magna</i>	<i>Daphnia-magna</i>	<i>Chironomus-riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC <0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	<0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
-	0.12 / 0.35	46.154 / 134.615	37.500 / 109.375	109.091 / 318.182	292.683 / 853.659	120.000 / 350.000	37.500 / 109.375
Step 2							
S-Europe	0.11 / 0.08	42.308 / 30.769	34.375 / 25.000	100.000 / 72.727	268.293 / 195.122	110.000 / 80.000	34.375 / 25.000
N-Europe	0.11 / 0.08	42.308 / 30.769	34.375 / 25.000	100.000 / 72.727	268.293 / 195.122	110.000 / 80.000	34.375 / 25.000
Step 3							
D3/ditch	0.0049 / 0.0035	1.885 / 1.346	1.531 / 1.094	4.455 / 3.182	11.951 / 8.537	4.900 / 3.500	1.531 / 1.094
D4/pond	0.0001 / 0.0002	0.038 / 0.077	0.031 / 0.063	0.091 / 0.182	0.244 / 0.488	0.100 / 0.200	0.031 / 0.063
D4/stream	0.0036 / 0.0026	1.385 / 1.000	1.125 / 0.813	3.273 / 2.364	8.780 / 6.341	3.600 / 2.600	1.125 / 0.813

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
D6-1 st /ditch	0.5368 / 0.5367	206.462 / 206.423	167.750 / 167.719	488.000 / 487.909	1309.268 / 1309.024	536.800 / 536.700	167.750 / 167.719
D6-2 nd /ditch	0.3425 / 0.3388	131.731 / 130.308	107.031 / 105.875	311.364 / 308.000	835.366 / 826.341	342.500 / 338.800	107.031 / 105.875
R1/pond	0.0001 / 0.0001	0.038 / 0.038	0.031 / 0.031	0.091 / 0.091	0.244 / 0.244	0.100 / 0.100	0.031 / 0.031
R1/stream	0.0031 / 0.0022	1.192 / 0.846	0.969 / 0.688	2.818 / 2.000	7.561 / 5.366	3.100 / 2.200	0.969 / 0.688
R2/stream	0.0042 / 0.0029	1.615 / 1.115	1.313 / 0.906	3.818 / 2.636	10.244 / 7.073	4.200 / 2.900	1.313 / 0.906
R3/stream	0.0045 / 0.0032	1.731 / 1.231	1.406 / 1.000	4.091 / 2.909	10.976 / 7.805	4.500 / 3.200	1.406 / 1.000
R4/stream	0.0030 / 0.0021	1.154 / 0.808	0.938 / 0.656	2.727 / 1.909	7.317 / 5.122	3.000 / 2.100	0.938 / 0.656

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	NOEC	EAC
(µg/L)		0.26	< 0.032	0.11	0.0041	0.010	0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 1							
I	0.07	26.92	21.88	63.64	170.73	70.00	21.88
Step 2							
S-Europe	0.07	26.92	21.88	63.64	170.73	70.00	21.88
N-Europe	0.07	26.92	21.88	63.64	170.73	70.00	21.88
Step 3							
D3/ditch	0.0027	1.038	0.844	2.455	6.585	2.700	0.844
D4/pond	<0.0001	0.038	0.031	0.091	0.244	0.100	0.031

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
D4/stream	0.0020	0.769	0.625	1.818	4.878	2.000	0.625
D6 1 nd /ditch	0.5368	206.462	167.750	488.000	1309.268	536.800	167.750
D6 2 nd /ditch	0.3397	130.654	106.156	308.818	828.537	339.700	106.156
R1/pond	<0.0001	0.038	0.031	0.091	0.244	0.100	0.031
R1/stream	0.0017	0.654	0.531	1.545	4.146	1.700	0.531
R2/stream	0.0023	0.885	0.719	2.091	5.610	2.300	0.719
R3/stream	0.0025	0.962	0.781	2.273	6.098	2.500	0.781
R4/stream	0.0017	0.654	0.531	1.545	4.146	1.700	0.531

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in strawberry (leafy vegetables 1st crop vegetation as a replacement plant for strawberry)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC < 0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 3							
D3(1 st season)/ditch	0.0049 / 0.0034	1.885 / 1.308	1.531 / 1.063	4.455 / 3.091	11.951 / 8.293	4.900 / 3.400	1.531 / 1.063
D4/pond	0.0001 / 0.0001	0.038 / 0.038	0.031 / 0.031	0.091 / 0.091	0.244 / 0.244	0.100 / 0.100	0.031 / 0.031
D4/stream	0.0037 / 0.0027	1.423 / 1.038	1.156 / 0.844	3.364 / 2.455	9.024 / 6.585	3.700 / 2.700	1.156 / 0.844
R1(1 st season)/pond	0.0001 / 0.0001	0.038 / 0.038	0.031 / 0.031	0.091 / 0.091	0.244 / 0.244	0.100 / 0.100	0.031 / 0.031
R1(1 st season)/stream	0.0031 / 0.0022	1.192 / 0.846	0.969 / 0.688	2.818 / 2.000	7.561 / 5.366	3.100 / 2.200	0.969 / 0.688

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC < 0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Step 3							
D3 1 st /ditch	0.0028	1.077	0.875	2.545	6.829	2.800	0.875
D4/pond	<0.001	0.385	0.313	0.909	2.439	1.000	0.313
D4/stream	0.0021	0.808	0.656	1.909	5.122	2.100	0.656
R1 1 st /pond	<0.001	0.385	0.313	0.909	2.439	1.000	0.313
R1 1 st /stream	0.0017	0.654	0.531	1.545	4.146	1.700	0.531

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of DECIDE in tomato (potato)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Sed. dwell. prolonged	Microcosms
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Chironomus riparius</i>	Invertebrate populations
Endpoint (µg/L)		LC ₅₀ 0.26	NOEC < 0.032	EC ₅₀ 0.11	NOEC 0.0041	NOEC 0.010	EAC 0.0032
AF		100	10	100	10	10	1
RAC (µg/L)		0.0026	< 0.0032	0.0011	0.00041	0.0010	0.0032
FOCUS Scenario	PEC _{gl-max} (µg/L)						
Step 3							
D3/ditch	0.0039 / 0.0028	1.500 / 1.077	1.219 / 0.875	3.545 / 2.545	9.512 / 6.829	3.900 / 2.800	1.219 / 0.875
D4/pond	0.0001 / 0.0002	0.038 / 0.077	0.031 / 0.063	0.091 / 0.182	0.244 / 0.488	0.100 / 0.200	0.031 / 0.063
D4/stream	0.0033 / 0.0023	1.269 / 0.885	1.031 / 0.719	3.000 / 2.091	8.049 / 5.610	3.300 / 2.300	1.031 / 0.719
R1/pond	0.0026 / 0.0002	1.000 / 0.077	0.813 / 0.063	2.364 / 0.182	6.341 / 0.488	2.600 / 0.200	0.813 / 0.063
R1/stream	0.0026 / 0.0018	1.000 / 0.692	0.813 / 0.563	2.364 / 1.636	6.341 / 4.390	2.600 / 1.800	0.813 / 0.563

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Invertebrate acute as characterised by NOEC for *Daphnia magna* of 0.0041 µg/L in connection with an assessment factor of 10) in all FOCUS Step 1-3 scenarios. In fact, no acceptable risks were observed in all the assessed groups of aquatic organisms.

In that regard, is important to point out that, in the case of fish groups, first tier studies may overestimate the toxicity of deltamethrin, especially when conducted as flowthrough exposure studies, as it is the case. This regime reflect exposure conditions which are not expected to be replicated under actual test item use in field, due to rapid dissipation of deltamethrin from water bodies. Higher-tier studies available in the monograph and its addendum (Addendum to the Monograph, Annex B, Rev. 2, July 2002) support this assumption and provide a different toxicity profile, which is obtained under more realistic exposure conditions (Tooby et al., 1980; Fackler, 1991; Muir, Rawn and Grift, 1985; Kennedy et al. 1989a, 1989b). Hence, it is unlikely that spray drift of deltamethrin will cause unacceptable effects in fish under natural conditions. Taking also into consideration the interest of minimising the vertebrate testing it is concluded that the microcosm study is sufficient to establish that the risk to fish can be covered by the risk assessment for aquatic invertebrates.

Therefore, further 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 µg/L. However, despite the above arguments, the risk assessment using fish endpoint (characterised by LC₅₀ for *Oncorhynchus mykiss* of 0.26 µg/L in connection with an assessment factor of 100) was also included.

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in leafy vegetables (brassicas)

Intended-use		Leafy vegetables (brassicas)	
Active substance		Deltamethrin	
Application rate (g/ha)		2 x 12.5	
Nozzle reduction	Vegetated filter strip (m)	None	
	No-spray buffer (m)	5	10
None	D3 ditch	0.0012 / 0.0010	—
50 %	(1 st season)	—	—
None	D3 ditch	0.0012 / 0.0010	—
50 %	(2 nd season)	—	—
None	D4 stream	0.0012 / 0.0010	—
50 %		—	—
None	D6 ditch	0.0836 / 0.0835	0.0836 / 0.0835
50 %		0.0836 / 0.0835	—
None	R1 stream	0.0010 / —	—
50 %	(1 st season)	—	—
None	R1 stream	0.0010 / —	—
50 %	(2 nd season)	—	—
None	R2 stream	0.0014 / 0.0011	—

50 %	(1 st season)	+	+
None	R2 stream	0.0014 / 0.0012	+
50 %	(2 nd season)	+	+
None	R3 stream	0.0015 / 0.0012	+
50 %	(1 st season)	+	+
None	R3 stream	0.0015 / 0.0012	+
50 %	(2 nd season)	+	+
None	R4 stream	0.0010 /	/
50 %	(1 st season)	/	/
None	R4 stream	0.0010 /	/
50 %	(2 nd season)	/	/
RAC (µg/L)		PEC/RAC ratio	
0.0032			
None	D3 ditch	0.375 / 0.3125	+
50 %	(1 st season)	+	+
None	D3 ditch	0.375 / 0.3125	+
50 %	(2 nd season)	+	+
None	D4 stream	0.375 / 0.3125	+
50 %		+	+
None	D6 ditch	26.125 / 26.094	26.125 / 26.094
50 %		26.125 / 26.094	+
None	R1 stream	0.313 /	/
50 %	(1 st season)	/	/
None	R1 stream	0.313 /	/
50 %	(2 nd season)	/	/
None	R2 stream	0.438 / 0.344	+
50 %	(1 st season)	+	+
None	R2 stream	0.438 / 0.375	+
50 %	(2 nd season)	+	+
None	R3 stream	0.469 / 0.375	+
50 %	(1 st season)	+	+
None	R3 stream	0.469 / 0.375	+
50 %	(2 nd season)	+	+
None	R4 stream	0.313 /	/
50 %	(1 st season)	/	/
None	R4 stream	0.313 /	/
50 %	(2 nd season)	/	/
RAC (µg/L)		PEC/RAC ratio	
0.0026			

None	D3 ditch	0.462/0.385	7
50 %	(1 st season)	7	7
None	D3 ditch	0.462/0.385	7
50 %	(2 nd season)	7	7
None	D4 stream	0.462/0.385	7
50 %		7	7
None	D6 ditch	32.154/32.115	32.154/32.115
50 %		32.154/32.115	7
None	R1 stream	0.385/	7
50 %	(1 st season)	7	7
None	R1 stream	0.385/	7
50 %	(2 nd season)	7	7
None	R2 stream	0.538/0.423	7
50 %	(1 st season)	7	7
None	R2 stream	0.538/0.462	7
50 %	(2 nd season)	7	7
None	R3 stream	0.577/0.462	7
50 %	(1 st season)	7	7
None	R3 stream	0.577/0.462	7
50 %	(2 nd season)	7	7
None	R4 stream	0.385/	7
50 %	(1 st season)	7	7
None	R4 stream	0.385/	7
50 %	(2 nd season)	7	7

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Leafy vegetables (brassicas)
Active substance		Deltamethrin
Application rate (g/ha)		1 x 7.5
Nozzle re- duction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D3 ditch 1 st st	0.0007
None	D3 ditch 2 nd	0.0007
None	D6 ditch	0.0836
RAC (µg/L)		
0.0032		PEC/RAC ratio
None	D3 ditch 1 st st	0.219
None	D3 ditch 2 nd	0.219
None	D6 ditch	26.125

RAC (µg/L)		
0.0026		PEC/RAC ratio
None	D3 ditch 1 st *	0.269
None	D3 ditch 2 nd	0.269
None	D6 ditch	32.154

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

* This scenario also covers Strawberry

Table 9.5-11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in fruiting vegetables (strawberry and tomato)

Intended use		Fruiting vegetables (strawberry and tomato)	
Active substance		Deltamethrin	
Application rate (g/ha)		3 x 12.5	
Nozzle reduction	Vegetated filter strip (m)	None	
	No-spray buffer (m)	5	10
None	D4 stream	0.0012 / —	—
50 %		—	—
None	D6 ditch	0.0112 / 0.0113	0.0113 / 0.0113
50 %		0.0112 / 0.0113	— / —
None	R2 stream	0.0014 / 0.0010	— / —
50 %		— / —	— / —
None	R3 stream	0.0015 / 0.0010	— / —
50 %		— / —	— / —
None	R4 stream	0.0010 / —	— / —
50 %		— / —	— / —
RAC (µg/L)			
0.0032		PEC/RAC ratio	
None	D4 stream	0.375 / —	— / —
50 %		— / —	— / —
None	D6 ditch	3.5000 / 3.5313	3.5313 / 3.5313
50 %		3.5000 / 3.5313	— / —
None	R2 stream	0.4375 / 0.3125	— / —
50 %		— / —	— / —
None	R3 stream	0.4688 / 0.3125	— / —
50 %		— / —	— / —

None	R4 stream	0.3125 /	/
50 %		/	/
RAC (µg/L)			
0.0026		PEC/RAC ratio	
None	D4 stream	0.462 /	/
50 %		/	/
None	D6 ditch	4.308 / 4.346	4.346 / 4.346
50 %		4.308 / 4.346	/
None	R2 stream	0.538 / 0.385	/
50 %		/	/
None	R3 stream	0.577 / 0.385	/
50 %		/	/
None	R4 stream	0.385 /	/
50 %		/	/

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Fruiting vegetables (tomato)
Active substance		Deltamethrin
Application rate (g/ha)		1 x 7.5
Nozzle re- duction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D6 ditch	0.0102
RAC (µg/L)		
0.0032		PEC/RAC ratio
None	D6 ditch*	3.188
RAC (µg/L)		
0.0026		PEC/RAC ratio
None	D6 ditch*	3.923

*Scenario not relevant for CEU zone.

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in ornamentals (apple early BBCH 10)

Intended use		Ornamentals (apple early)					
Active substance		Deltamethrin					
Application rate (g/ha)		3 x 12.5					
Nozzle reduction	Vegetated strip (m)	None					
	No spray buffer (m)	5	10	15	20	30	40
None	D3 ditch	0.0590/0.0458	0.0345/0.0256	0.0143/0.0135	0.0068/0.0058	0.0023/0.0017	
50 %		0.0275/0.0213	0.0161/0.0119	0.0067/0.0063	0.0032/0.0027	+	
75 %		0.0128/0.0099	0.0075/0.0055	0.0031/0.0029	0.0015/0.0012	+	
90 %		0.0047/0.0036	0.0027/0.0020	0.0011/0.0011	+	+	
95 %		0.0022/0.0017	0.0013/				
None	D4 pond	0.0040/0.0062	0.0021/0.0033	-0.0016	+	+	
50 %		0.0019/0.0029	-0.0016	+	+	+	
75 %		-0.0014	+	+	+	+	
90 %		+	+	+	+	+	
95 %							
None	D4 stream	0.0612/0.0522	0.0358/0.0291	0.0148/0.0154	0.0070/0.0066	0.0024/0.0019	
50 %		0.0285/0.0243	0.0167/0.0136	0.0069/0.0072	0.0033/0.0031	+	
75 %		0.0133/0.0113	0.0078/0.0063	0.0032/0.0033	0.0015/0.0014	+	
90 %		0.0048/0.0041	0.0028/0.0023	0.0012/0.0012	+	+	
95 %		0.0023/0.0019	0.0013/				
None	D5 pond	0.0040/0.0059	0.0021/0.0032	-0.0016	+	+	
50 %		0.0019/0.0028	-0.0015	+	+	+	
75 %		-0.0013	+	+	+	+	
90 %		+	+	+	+	+	
95 %							
None	D5 stream	0.0645/0.0550	0.0377/0.0307	0.0156/0.0162	0.0074/0.0069	0.0026/0.0020	
50 %		0.0301/0.0256	0.0176/0.0143	0.0073/0.0076	0.0035/0.0032	+	
75 %		0.0140/0.0119	0.0082/0.0066	0.0034/0.0035	0.0016/0.0015	+	
90 %		0.0051/0.0043	0.0030/0.0024	0.0012/0.0013	+	+	
95 %		0.0024/0.0020	0.0014/				
None	R1 pond	0.0040/0.0055	0.0021/0.0030	-0.0015	+	+	
50 %		0.0019/0.0026	-0.0014	+	0.0003/0.0004	+	
75 %		-0.0012	+	+	0.0001/0.0002	+	

90 %		+	+	+	+	+	✓
95%		✓	✓	✓	✓	✓	✓
None		0.0515/0.0397	0.0301/0.0221	0.0125/0.0117	0.0059/0.0050	0.0020/0.0015	✓
50 %		0.0240/0.0185	0.0140/0.0103	0.0058/0.0055	0.0028/0.0023	+	✓
75 %	R1-stream	0.0112/0.0086	0.0065/0.0048	0.0027/0.0025	0.0013/-	+	✓
90 %		0.0041/0.0031	0.0024/0.0017	0.0010/-	+	+	✓
95%		0.0019/0.0015	✓	✓	✓	✓	✓
None		0.0702/0.0542	0.0411/0.0302	0.0170/0.0160	0.0081/0.0068	0.0028/0.0020	0.0013/-
50 %		0.0327/0.0252	0.0191/0.0141	0.0079/0.0076	0.0038/0.0032	0.0013/-	✓
75 %	R2-stream	0.0152/0.0118	0.0089/0.0066	0.0037/0.0035	0.0017/0.0015	+	✓
90 %		0.0055/0.0043	0.0032/0.0024	0.0013/0.0013	+	+	✓
95%		0.00258/0.0020	0.0015/-	✓	✓	✓	✓
None		0.0755/0.0582	0.0441/0.0325	0.0183/0.0172	0.0087/0.0073	0.0030/0.0022	0.0014/-
50 %		0.0352/0.0271	0.0206/0.0151	0.0085/0.0080	0.0040/0.0034	0.0014/-	✓
75 %	R3-stream	0.0164/0.0126	0.0096/0.0070	0.0040/0.0037	0.0019/0.0016	+	✓
90 %		0.0060/0.0046	0.0035/0.0026	0.0014/0.0014	+	+	✓
95%		0.0028/0.0021	0.0016/-	✓	✓	✓	✓
None		0.0519/0.0400	0.0303/0.0223	0.0126/0.0118	0.0060/0.0050	0.0021/0.0015	✓
50 %		0.0242/0.0186	0.0141/0.0104	0.0058/0.0055	0.0028/0.0023	+	✓
75 %	R4-stream	0.0113/0.0087	0.0066/0.0048	0.0027/0.0026	0.0013/-	+	✓
90 %		0.0041/0.0032	0.0024/0.0018	0.0010/-	+	+	✓
95%		0.0019/0.0015	✓	✓	✓	✓	✓
RAC (µg/L)							
0.0032		PEC/RAC ratio					
None		18.438/14.313	10.781/8.000	4.469/4.219	2.125/1.813	0.719/0.531	✓
50 %		8.594/6.656	5.031/3.719	2.094/1.969	1.000/0.844	+	✓
75 %	D3-ditch	4.000/3.094	2.344/1.719	0.969/0.906	0.469/0.375	+	✓
90 %		1.469/1.125	0.844/0.625	0.344/0.344	+	+	✓
95%		0.688/0.531	0.406/-	✓	✓	✓	✓
None		1.250/1.938	0.656/1.031	-/0.500	+	+	✓
50 %		0.594/0.906	-/0.500	+	+	+	✓
75 %	D4-pond	-0.438	+	+	+	+	✓
90 %		+	+	+	+	+	✓
95%		✓	✓	✓	✓	✓	✓
None		19.125/16.313	11.188/9.094	4.625/4.813	2.188/2.063	0.750/0.594	✓
50 %		8.906/7.594	5.219/4.250	2.156/2.250	1.031/0.969	+	✓
75 %	D4-stream	4.156/3.531	2.438/1.969	1.000/1.031	0.469/0.438	+	✓
90 %		1.500/1.281	0.875/0.719	0.375/0.375	+	+	✓

95%		0.719/0.594	0.406/-	7/-	7/-	7/-	7/-
None	D5-pond	1.250/1.844	0.656/1.000	-0.500	+	+	7/-
50 %		0.594/0.875	-0.469	+	+	+	7/-
75 %		-0.406	+	+	+	+	7/-
90 %		+	+	+	+	+	7/-
95%		7/-	7/-	7/-	7/-	7/-	7/-
None	D5-stream	20.156/17.188	11.781/9.594	4.875/5.063	2.313/2.156	0.813/0.625	7/-
50 %		9.406/8.000	5.500/4.469	2.281/2.375	1.094/1.000	+	7/-
75 %		4.375/3.719	2.563/2.063	1.063/1.094	0.500/0.469	+	7/-
90 %		1.594/1.344	0.938/0.750	0.375/0.406	+	+	7/-
95%		0.750/0.625	0.438/-	7/-	7/-	7/-	7/-
None	R1-pond	1.250/1.719	0.656/0.938	-0.469	+	+	7/-
50 %		0.594/0.813	-0.438	+	+	+	7/-
75 %		-0.375	+	+	+	+	7/-
90 %		+	+	+	+	+	7/-
95%		7/-	7/-	7/-	7/-	7/-	7/-
None	R1-stream	16.094/12.406	9.406/6.906	3.906/3.656	1.844/1.563	0.625/0.469	7/-
50 %		7.500/5.781	4.375/3.219	1.813/1.719	0.875/0.719	+	7/-
75 %		3.500/2.688	2.031/1.500	0.844/0.781	0.406-	+	7/-
90 %		1.281/0.969	0.750/0.531	0.313-	+	+	7/-
95%		0.594/0.469	7/-	7/-	7/-	7/-	7/-
None	R2-stream	21.938/16.938	12.844/9.438	5.313/5.000	2.531/2.125	0.875/0.625	0.406/-
50 %		10.219/7.875	5.969/4.406	2.469/2.375	1.188/1.000	0.406-	7/-
75 %		4.750/3.688	2.781/2.063	1.156/1.094	0.531/0.469	+	7/-
90 %		1.719/1.344	1.000/0.750	0.406/0.406	+	+	7/-
95%		0.806/0.625	0.469/-	7/-	7/-	7/-	7/-
None	R3-stream	23.594/18.188	13.781/10.156	5.719/5.375	2.719/2.281	0.938/0.688	0.438/-
50 %		11.000/8.469	6.438/4.719	2.656/2.500	1.250/1.063	0.438-	7/-
75 %		5.125/3.938	3.000/2.188	1.250/1.156	0.594/0.500	+	7/-
90 %		1.875/1.438	1.094/0.813	0.438/0.438	+	+	7/-
95%		0.875/0.656	0.500/-	7/-	7/-	7/-	7/-
None	R4-stream	16.219/12.500	9.469/6.969	3.938/3.688	1.875/1.563	0.656/0.469	7/-
50 %		7.563/5.813	4.406/3.250	1.813/1.719	0.875/0.719	+	7/-
75 %		3.531/2.719	2.063/1.500	0.844/0.813	0.406-	+	7/-
90 %		1.281/1.000	0.750/0.563	0.313-	+	+	7/-
95%		0.594/0.469	7/-	7/-	7/-	7/-	7/-
RAC (µg/L)							
0.0026		PEC/RAC ratio					
None	D3-ditch	22.692/17.615	13.269/9.846	5.500/5.192	2.615/2.231	0.885/0.654	7/-

50 %		10.577/8.192	6.192/4.577	2.577/2.423	1.231/1.038	/	/
75 %		4.923/3.808	2.885/2.115	1.192/1.115	0.577/0.462	/	/
90 %		1.808/1.385	1.038/0.769	0.423/0.423	/	/	/
95%		0.846/0.654	0.500/	/	/	/	/
None		1.538/2.385	0.808/1.269	/0.615	/	/	/
50 %	D4 pond	0.731/1.115	/0.615	/	/	/	/
75 %		/0.538	/	/	/	/	/
90 %		/	/	/	/	/	/
95%		/	/	/	/	/	/
None		23.538/20.077	13.769/11.192	5.692/5.923	2.692/2.538	0.923/0.731	/
50 %	D4 stream	10.962/9.346	6.423/5.231	2.654/2.769	1.269/1.192	/	/
75 %		5.115/4.346	3.000/2.423	1.231/1.269	0.577/0.538	/	/
90 %		1.846/1.577	1.077/0.885	0.462/0.462	/	/	/
95%		0.885/0.731	0.500/	/	/	/	/
None		1.538/2.269	0.808/1.231	/0.615	/	/	/
50 %	D5 pond	0.731/1.077	/0.577	/	/	/	/
75 %		/0.500	/	/	/	/	/
90 %		/	/	/	/	/	/
95%		/	/	/	/	/	/
None		24.808/21.154	14.500/11.808	6.000/6.231	2.846/2.654	1.000/0.769	/
50 %	D5 stream	11.577/9.846	6.769/5.500	2.808/2.923	1.346/1.231	/	/
75 %		5.385/4.577	3.154/2.538	1.308/1.346	0.615/0.577	/	/
90 %		1.962/1.654	1.154/0.923	0.462/0.500	/	/	/
95%		0.923/0.769	0.538/	/	/	/	/
None		1.538/2.115	0.808/1.154	/0.577	/	/	/
50 %	R1 pond	0.731/1.000	/0.538	/	/	/	/
75 %		/0.462	/	/	/	/	/
90 %		/	/	/	/	/	/
95%		/	/	/	/	/	/
None		19.808/15.269	11.577/8.500	4.808/4.500	2.269/1.923	0.769/0.577	/
50 %	R1 stream	9.231/7.115	5.385/3.962	2.231/2.115	1.077/0.885	/	/
75 %		4.308/3.308	2.500/1.846	1.038/0.962	0.500/	/	/
90 %		1.577/1.192	0.923/0.654	0.385/	/	/	/
95%		0.731/0.577	/	/	/	/	/
None		27.000/20.846	15.808/11.615	6.538/6.154	3.115/2.615	1.077/0.769	0.500/
50 %	R2 stream	12.577/9.692	7.346/5.423	3.038/2.923	1.462/1.231	0.500/	/
75 %		5.846/4.538	3.423/2.538	1.423/1.346	0.654/0.577	/	/
90 %		2.115/1.654	1.231/0.923	0.500/0.500	/	/	/
95%		0.992/0.769	0.577/	/	/	/	/

None		29.038/22.385	16.962/12.500	7.038/6.615	3.346/2.808	1.154/0.846	0.538/-
50 %		13.538/10.423	7.923/5.808	3.269/3.077	1.538/1.308	0.538/-	-
75 %	R3 stream	6.308/4.846	3.692/2.692	1.538/1.423	0.731/0.615	-	-
90 %		2.308/1.769	1.346/1.000	0.538/0.538	-	-	-
95%		1.077/0.808	0.615/-	-	-	-	-
None		19.962/15.385	11.654/8.577	4.846/4.538	2.308/1.923	0.808/0.577	-
50 %		9.308/7.154	5.423/4.000	2.231/2.115	1.077/0.885	-	-
75 %	R4 stream	4.346/3.346	2.538/1.846	1.038/1.000	0.500/-	-	-
90 %		1.577/1.231	0.923/0.692	0.385/-	-	-	-
95%		0.731/0.577	-	-	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Ornamentals (apple early)				
Active substance		Deltamethrin				
Application rate (g/ha)		1 x 7.5				
Nozzle reduction	Vegetated filter strip (m)	None				
	No-spray buffer (m)	5	10	15	20	30
None	D3 ditch	0.0336	0.0196	0.0081	0.0039	0.0013
50 %		0.0157	0.0091	0.0038	0.0018	-
75 %		0.0073	0.0042	0.0018	-	-
90 %		0.0027	0.0015	-	-	-
None	D4 stream	0.0348	0.0203	0.0084	0.0040	0.0013
50 %		0.0162	0.0095	0.0039	0.0019	-
75 %		0.0076	0.0044	0.0018	-	-
90 %		0.0028	0.0016	-	-	-
None	D5 stream	0.0368	0.0215	0.0089	0.0042	0.0014
50 %		0.0171	0.0100	0.0041	0.0020	-
75 %		0.0080	0.0046	0.0019	-	-
90 %		0.0029	0.0017	-	-	-
None	R1 stream	0.0293	0.0171	0.0071	0.0034	0.0012
50 %		0.0137	0.0080	0.0033	0.0016	-
75 %		0.0064	0.0037	0.0015	-	-
90 %		0.0023	0.0014	-	-	-
None	R2 stream	0.0400	0.0234	0.0096	0.0046	0.0016
50 %		0.0186	0.0109	0.0045	0.0021	-
75 %		0.0087	0.0050	0.0021	-	-
90 %		0.0032	0.0018	-	-	-
None	R3 stream	0.0430	0.0251	0.0104	0.0049	0.0017

50 %		0.0200	0.0117	0.0048	0.0023	-
75 %		0.0093	0.0054	0.0023	-	-
90 %		0.0034	0.0020	-	-	-
None		0.0295	0.0173	0.0072	0.0034	0.0012
50 %	R4 stream	0.0138	0.0080	0.0033	0.0016	-
75 %		0.0064	0.0037	0.0015	-	-
90 %		0.0023	0.0014	-	-	-
RAC (µg/L)						
0.0032		PEC/RAC ratio				
None		10.500	6.125	2.531	1.219	0.406
50 %	D3 ditch	4.906	2.844	1.188	0.563	-
75 %		2.281	1.313	0.563	-	-
90 %		0.844	0.469	-	-	-
None		10.875	6.344	2.625	1.250	0.406
50 %	D4 stream	5.063	2.969	1.219	0.594	-
75 %		2.375	1.375	0.563	-	-
90 %		0.875	0.500	-	-	-
None		11.500	6.719	2.781	1.313	0.438
50 %	D5 stream	5.344	3.125	1.281	0.625	-
75 %		2.500	1.438	0.594	-	-
90 %		0.906	0.531	-	-	-
None		9.156	5.344	2.219	1.063	0.375
50 %	R1 stream	4.281	2.500	1.031	0.500	-
75 %		2.000	1.156	0.469	-	-
90 %		0.719	0.438	-	-	-
None		12.500	7.313	3.000	1.438	0.500
50 %	R2 stream	5.813	3.406	1.406	0.656	-
75 %		2.719	1.563	0.656	-	-
90 %		1.000	0.563	-	-	-
None		13.438	7.844	3.250	1.531	0.531
50 %	R3 stream	6.250	3.656	1.500	0.719	-
75 %		2.906	1.688	0.719	-	-
90 %		1.063	0.625	-	-	-
None		9.219	5.406	2.250	1.063	0.375
50 %	R4 stream	4.313	2.500	1.031	0.500	-
75 %		2.000	1.156	0.469	-	-
90 %		0.719	0.438	-	-	-
RAC (µg/L)						
0.0026		PEC/RAC ratio				

None	D3 ditch	12.923	7.538	3.115	1.500	0.500
50 %		6.038	3.500	1.462	0.692	-
75 %		2.808	1.615	0.692	-	-
90 %		1.038	0.577	-	-	-
None	D4 stream	13.385	7.808	3.231	1.538	0.500
50 %		6.231	3.654	1.500	0.731	-
75 %		2.923	1.692	0.692	-	-
90 %		1.077	0.615	-	-	-
None	D5 stream	14.154	8.269	3.423	1.615	0.538
50 %		6.577	3.846	1.577	0.769	-
75 %		3.077	1.769	0.731	-	-
90 %		1.115	0.654	-	-	-
None	R1 stream	11.269	6.577	2.731	1.308	0.462
50 %		5.269	3.077	1.269	0.615	-
75 %		2.462	1.423	0.577	-	-
90 %		0.885	0.538	-	-	-
None	R2 stream	15.385	9.000	3.692	1.769	0.615
50 %		7.154	4.192	1.731	0.808	-
75 %		3.346	1.923	0.808	-	-
90 %		1.231	0.692	-	-	-
None	R3 stream	16.538	9.654	4.000	1.885	0.654
50 %		7.692	4.500	1.846	0.885	-
75 %		3.577	2.077	0.885	-	-
90 %		1.308	0.769	-	-	-
None	R4 stream	11.346	6.654	2.769	1.308	0.462
50 %		5.308	3.077	1.269	0.615	-
75 %		2.462	1.423	0.577	-	-
90 %		0.885	0.538	-	-	-

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in ornamentals (apple late BBCH 85)

Intended-use		Ornamentals (apple late)				
Active substance		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
Nozzle reduction	Vegetated filter strip (m)	None				
	No-spray buffer (m)	5	10	15	20	30

None	D3 ditch	0.0219 / 0.0156	0.0090 / 0.0067	0.0042 / 0.0031	0.0024 / 0.0017	✓
50 %		0.0102 / 0.0072	0.0042 / 0.0031	0.0020 / 0.0014	+	✓
75 %		0.0047 / 0.0034	0.0020 / 0.0014	+	+	✓
90 %		0.0017 / 0.0012	+	+	+	✓
None	D4 stream	0.0251 / 0.0175	0.0103 / 0.0075	0.0049 / 0.0035	0.0028 / 0.0019	0.0013 / ✓
50 %		0.0117 / 0.0082	0.0048 / 0.0035	0.0023 / 0.0016	0.0013 / +	✓
75 %		0.0054 / 0.0038	0.0022 / 0.0016	+	+	✓
90 %		0.0020 / 0.0014	+	+	+	✓
None	D5 stream	0.0281 / 0.0196	0.0115 / 0.0084	0.0054 / 0.0039	0.0032 / 0.0021	0.0015 / ✓
50 %		0.0131 / 0.0091	0.0054 / 0.0039	0.0025 / 0.0018	0.0015 / +	✓
75 %		0.0061 / 0.0042	0.0025 / 0.0018	+	+	✓
90 %		0.0022 / 0.0015	+	+	+	✓
None	R1 stream	0.0192 / 0.0134	0.0079 / 0.0058	0.0037 / 0.0027	0.0022 / 0.0015	✓
50 %		0.0089 / 0.0062	0.0037 / 0.0027	0.0017 / 0.0012	+	✓
75 %		0.0042 / 0.0029	0.0017 / 0.0012	+	+	✓
90 %		0.0015 / 0.0011	+	+	+	✓
None	R2 stream	0.0265 / 0.0185	0.0109 / 0.0080	0.0051 / 0.0037	0.0030 / 0.0020	0.0014 / ✓
50 %		0.0124 / 0.0086	0.0051 / 0.0037	0.0024 / 0.0017	0.0014 / +	✓
75 %		0.0057 / 0.0040	0.0024 / 0.0017	+	+	✓
90 %		0.0021 / 0.0015	+	+	+	✓
None	R3 stream	0.0280 / 0.0195	0.0115 / 0.0084	0.0054 / 0.0039	0.0032 / 0.0021	0.0015 / ✓
50 %		0.0131 / 0.0091	0.0054 / 0.0039	0.0025 / 0.0018	0.0015 / +	✓
75 %		0.0061 / 0.0042	0.0025 / 0.0018	+	+	✓
90 %		0.0022 / 0.0015	+	+	+	✓
None	R4 stream	0.0192 / 0.0134	0.0079 / 0.0058	0.0037 / 0.0027	0.0022 / 0.0015	✓
50 %		0.0089 / 0.0062	0.0037 / 0.0027	0.0017 / 0.0012	+	✓
75 %		0.0042 / 0.0029	0.0017 / 0.0012	+	+	✓
90 %		0.0015 / 0.0011	+	+	+	✓
RAC (µg/L)						
0.0032		PEC/RAC ratio				
None	D3 ditch	6.844/4.875	2.813/2.094	1.313/0.969	0.750/0.531	✓
50 %		3.188/2.250	1.313/0.969	0.625/0.438	+	✓
75 %		1.469/1.063	0.625/0.438	+	+	✓
90 %		0.531/0.375	+	+	+	✓
None	D4 stream	7.844/5.469	3.219/2.344	1.531/1.094	0.875/0.594	0.406 / ✓
50 %		3.656/2.563	1.500/1.094	0.719/0.500	0.406 / +	✓
75 %		1.688/1.188	0.688/0.500	+	+	✓
90 %		0.625/0.438	+	+	+	✓
None	D5 stream	8.781/6.125	3.594/2.625	1.688/1.219	1.000/0.656	0.469 / ✓

50 %		4.094/2.844	1.688/1.219	0.781/0.563	0.469/	/
75 %		1.906/1.313	0.781/0.563	+	+	/
90 %		0.688/0.469	+	+	+	/
None	R1 stream	6.000/4.188	2.469/1.813	1.156/0.844	0.688/0.469	/
50 %		2.781/1.938	1.156/0.844	0.531/0.375	+	/
75 %		1.313/0.906	0.531/0.375	+	+	/
90 %		0.469/0.344	+	+	+	/
None	R2 stream	8.281/5.781	3.406/2.500	1.594/1.156	0.938/0.625	0.438/
50 %		3.875/2.688	1.594/1.156	0.750/0.531	0.438/	/
75 %		1.781/1.250	0.750/0.531	+	+	/
90 %		0.656/0.469	+	+	+	/
None	R3 stream	8.750/6.094	3.594/2.625	1.688/1.219	1.000/0.656	0.469/
50 %		4.094/2.844	1.688/1.219	0.781/0.563	0.469/	/
75 %		1.906/1.313	0.781/0.563	+	+	/
90 %		0.688/0.469	+	+	+	/
None	R4 stream	6.000/4.188	2.469/1.813	1.156/0.844	0.688/0.469	/
50 %		2.781/1.938	1.156/0.844	0.531/0.375	+	/
75 %		1.313/0.906	0.531/0.375	+	+	/
90 %		0.469/0.344	+	+	+	/
RAC (µg/L)						
0.0026		PEC/RAC ratio				
None	D3 ditch	8.423/6.000	3.462/2.577	1.615/1.192	0.923/0.654	/
50 %		3.923/2.769	1.615/1.192	0.769/0.538	/	/
75 %		1.808/1.308	0.769/0.538	/	/	/
90 %		0.654/0.462	/	/	/	/
None	D4 stream	9.654/6.731	3.962/2.885	1.885/1.346	1.077/0.731	0.500/
50 %		4.500/3.154	1.846/1.346	0.885/0.615	0.500/	/
75 %		2.077/1.462	0.846/0.615	/	/	/
90 %		0.769/0.538	/	/	/	/
None	D5 stream	10.808/7.538	4.423/3.231	2.077/1.500	1.231/0.808	0.577/
50 %		5.038/3.500	2.077/1.500	0.962/0.692	0.577/	/
75 %		2.346/1.615	0.962/0.692	/	/	/
90 %		0.846/0.577	/	/	/	/
None	R1 stream	7.385/5.154	3.038/2.231	1.423/1.038	0.846/0.577	/
50 %		3.423/2.385	1.423/1.038	0.654/0.462	/	/
75 %		1.615/1.115	0.654/0.462	/	/	/
90 %		0.577/0.423	/	/	/	/
None	R2 stream	10.192/7.115	4.192/3.077	1.962/1.423	1.154/0.769	0.538/
50 %		4.769/3.308	1.962/1.423	0.923/0.654	0.538/	/

75 %		2.192/1.538	0.923/0.654	/	/	/
90 %		0.808/0.577	/	/	/	/
None		10.769/7.500	4.423/3.231	2.077/1.500	1.231/0.808	0.577/
50 %	R3 stream	5.038/3.500	2.077/1.500	0.962/0.692	0.577/	/
75 %		2.346/1.615	0.962/0.692	/	/	/
90 %		0.846/0.577	/	/	/	/
None		7.385/5.154	3.038/2.231	1.423/1.038	0.846/0.577	/
50 %	R4 stream	3.423/2.385	1.423/1.038	0.654/0.462	/	/
75 %		1.615/1.115	0.654/0.462	/	/	/
90 %		0.577/0.423	/	/	/	/

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Ornamentals (apple late)			
Active substance		Deltamethrin			
Application rate (g/ha)		1 x 7.5			
Nozzle reduction	Vegetated filter strip (m)	None			
	No-spray buffer (m)	5	10	15	20
None		0.0125	0.0051	0.0024	0.0014
50 %	D3 ditch	0.0058	0.0024	0.0011	!
75 %		0.0027	0.0011	!	!
90 %		0.0010	!	!	!
None		0.0143	0.0059	0.0028	0.0016
50 %	D4 stream	0.0067	0.0027	0.0013	!
75 %		0.0031	0.0013	!	!
90 %		0.0011	!	!	!
None		0.0156	0.0066	0.0031	0.0018
50 %	D5 stream	0.0074	0.0030	0.0014	!
75 %		0.0035	0.0014	!	!
90 %		0.0013	!	!	!
None		0.0109	0.0045	0.0021	0.0012
50 %	R1 stream	0.0051	0.0020	0.0010	!
75 %		0.0024	0.0010	!	!
90 %		0.0009	!	!	!
None		0.0151	0.0062	0.0029	0.0017
50 %	R2 stream	0.0070	0.0029	0.0014	!
75 %		0.0033	0.0013	!	!
90 %		0.0012	!	!	!
None	R3 stream	0.0160	0.0066	0.0031	0.0018

50 %		0.0074	0.0031	0.0014	-
75 %		0.0035	0.0014	-	-
90 %		0.0013	-	-	-
None		0.0109	0.0045	0.0021	0.0012
50 %	R4 stream	0.0051	0.0021	0.0010	-
75 %		0.0024	0.0010	-	-
90 %		0.0009	-	-	-
RAC (µg/L)					
0.0032		PEC/RAC ratio			
None		3.906	1.594	0.750	0.438
50 %	D3 ditch	1.813	0.750	0.344	-
75 %		0.844	0.344	-	-
90 %		0.313	-	-	-
None		4.469	1.844	0.875	0.500
50 %	D4 stream	2.094	0.844	0.406	-
75 %		0.969	0.406	-	-
90 %		0.344	-	-	-
None		4.875	2.063	0.969	0.563
50 %	D5 stream	2.313	0.938	0.438	-
75 %		1.094	0.438	-	-
90 %		0.406	-	-	-
None		3.406	1.406	0.656	0.375
50 %	R1 stream	1.594	0.625	0.313	-
75 %		0.750	0.313	-	-
90 %		0.281	-	-	-
None		4.719	1.938	0.906	0.531
50 %	R2 stream	2.188	0.906	0.438	-
75 %		1.031	0.406	-	-
90 %		0.375	-	-	-
None		5.000	2.063	0.969	0.563
50 %	R3 stream	2.313	0.969	0.438	-
75 %		1.094	0.438	-	-
90 %		0.406	-	-	-
None		3.406	1.406	0.656	0.375
50 %	R4 stream	1.594	0.656	0.313	-
75 %		0.750	0.313	-	-
90 %		0.281	-	-	-
RAC (µg/L)					
0.0026		PEC/RAC ratio			

None	D3 ditch	4.808	1.962	0.923	0.538
50 %		2.231	0.923	0.423	-
75 %		1.038	0.423	-	-
90 %		0.385	-	-	-
None	D4 stream	5.500	2.269	1.077	0.615
50 %		2.577	1.038	0.500	-
75 %		1.192	0.500	-	-
90 %		0.423	-	-	-
None	D5 stream	6.000	2.538	1.192	0.692
50 %		2.846	1.154	0.538	-
75 %		1.346	0.538	-	-
90 %		0.500	-	-	-
None	R1 stream	4.192	1.731	0.808	0.462
50 %		1.962	0.769	0.385	-
75 %		0.923	0.385	-	-
90 %		0.346	-	-	-
None	R2 stream	5.808	2.385	1.115	0.654
50 %		2.692	1.115	0.538	-
75 %		1.269	0.500	-	-
90 %		0.462	-	-	-
None	R3 stream	6.154	2.538	1.192	0.692
50 %		2.846	1.192	0.538	-
75 %		1.346	0.538	-	-
90 %		0.500	-	-	-
None	R4 stream	4.192	1.731	0.808	0.462
50 %		1.962	0.808	0.385	-
75 %		0.923	0.385	-	-
90 %		0.346	-	-	-

Table 9.5-14: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in ornamentals (onion)

Intended-use		Ornamentals (onion)
Active substance		Deltamethrin
Application rate (g/ha)		3 x 12.5
Nozzle reduction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D3 ditch	0.0011 / 0.0008
	D4 stream	0.0012 / -
	D6 1 st ditch	0.5368 / 0.5367
	D6 2 nd ditch	0.3425 / 0.3388
	R1 stream	0.0010 / -
	R2 stream	0.0014 / 0.0009
	R3 stream	0.0015 / -
	R4 stream	0.0010 / -
RAC (µg/L)		PEC/RAC ratio
0.0032		
None	D3 ditch	0.3438 / 0.2500
	D4 stream	0.3750 / -
	D6 1 st ditch	167.750 / 167.719
	D6 2 nd ditch	107.031 / 105.875
	R1 stream	0.3125 / -
	R2 stream	0.4375 / 0.2813
	R3 stream	0.4688 / -
	R4 stream	0.3125 / -
RAC (µg/L)		PEC/RAC ratio
0.0026		
None	D3 ditch	0.4231 / 0.3077
	D4 stream	0.4615 / -
	D6 1 st ditch	206.4615 / 206.4231
	D6 2 nd ditch	131.7308 / 130.3077
	R1 stream	0.3846 / -
	R2 stream	0.5385 / 0.3462
	R3 stream	0.5769 / -
	R4 stream	0.3846 / -

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration;
 PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Intended use		Ornamentals (onion)
Active substance		Deltamethrin
Application rate (g/ha)		1 x 7.5
Nozzle re- duction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D3 ditch	0.0007
	D6 ditch 1 st	0.5368
	D6 ditch 2 nd	0.3397
RAC (µg/L)		
0.0032		PEC/RAC ratio
None	D3 ditch	0.219
	D6 ditch 1 st	167.750
	D6 ditch 2 nd	106.156
RAC (µg/L)		
0.0026		PEC/RAC ratio
None	D3 ditch	0.269
	D6 ditch 1 st	206.462
	D6 ditch 2 nd	130.654

Table 9.5-15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC <1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in strawberry (leafy vegetables 1st crop)

Intended use		Strawberry (leafy vegetables 1 st crop)
Active substance		Deltamethrin
Application rate (g/ha)		3 x 12.5
Nozzle reduction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D3 ditch (1 st season)	0.0012 / 0.0008
	D4 stream	0.0012 / 0.0009
	R1 stream (1 st season)	0.0010 /
RAC (µg/L)		
0.0032		PEC/RAC ratio
None	D3 ditch (1 st season)	0.375 / 0.250
	D4 stream	0.375 /
	R1 stream (1 st season)	0.3125 /
RAC (µg/L)		
0.0026		PEC/RAC ratio
None	D3 ditch (1 st season)	0.4615 / 0.3077
	D4 stream	0.4615 / 0.3462
	R1 stream (1 st season)	0.3846 /

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC <1) for Deltamethrin based on FOCUS Step 4 calculations and toxicity data for invertebrate, including sediment living organisms with mitigation of spray drift and run-off for the use of DECIDE in tomato (potato)

Intended use		Tomato (potato)
Active substance		Deltamethrin
Application rate (g/ha)		3 x 12.5
Nozzle reduction	Vegetated filter strip (m)	None
	No-spray buffer (m)	5
None	D3 ditch (1 st season)	0.0012 / 0.0008
	D4 stream	0.0013 /
RAC (µg/L)		
0.0032		PEC/RAC ratio

None	D3 ditch (1 st season)	0.375 / 0.250
	D4 stream	0.406 / -
RAC (µg/L)		
0.0026		PEC/RAC ratio
None	D3 ditch (1 st season)	0.462 / 0.308
	D4 stream	0.500 / -

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Greenhouse uses

For greenhouse use GEM v3.3.2 for soilless scenarios has been used since the tomato crops are permanent and usually hydroponic. In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}) for single and multiple applications from GEM v3.3.2., and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use and organism group.

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin for each organism group based on GEM v3.3.2. calculations for the use of DECIDE in tomato

Group		Microcosms	Fish acute
Test species		Invertebrate populations	<i>Oncorhynchus mykiss</i>
Endpoint (µg/L)		EAC 0.0032	LC ₅₀ 0.26
AF		1	100
RAC (µg/L)		0.0032	0.0026
GEM Scenario	PEC _{gl-max} (µg/L)		
Soilless			
-	0.0005 / 0.0011	0.1563 / 0.3438	0.1923 / 0.4231

Group		Microcosms	Fish acute
Test species		Invertebrate populations	<i>Oncorhynchus mykiss</i>
Endpoint (µg/L)		EAC 0.0032	LC ₅₀ 0.26
AF		1	100
RAC (µg/L)		0.0032	0.0026
Scenario	PEC _{gl-max} (µg/L)		
I	0.0025	0.781	0.961

9.5.3 Overall conclusions

For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for Invertebrate ~~acute~~ **prolonged** as characterised by NOEC for *Daphnia magna* of 0.0041 µg/L in connection with an assessment factor of 10) in all FOCUS Step 1-3 scenarios. In fact, no acceptable risks were observed in all the assessed groups of aquatic organisms.

In that regard, first tier studies with fish may overestimate the toxicity of deltamethrin, especially when conducted as flowthrough exposure studies, as it is the case. This regime reflect exposure conditions which are not expected to be replicated under actual test item use in field, due to rapid dissipation of deltamethrin from water bodies. Taking also into consideration the interest of minimising the vertebrate testing it is concluded that the microcosm study is sufficient to establish that the risk to fish can be covered by the risk assessment for aquatic invertebrates.

Therefore, further 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 µg/L considering reduced exposure of surface water bodies. **However, despite the above arguments, the risk assessment using fish endpoint (characterised by LC₅₀ for *Oncorhynchus mykiss* of 0.26 µg/L in connection with an assessment factor of 100) was also included.**

After Step 4 calculations, the PEC/RAC ratio values calculated were below the trigger of 1. An acceptable risk was obtained with the following mitigation measures:

Leafy vegetable (brassicas)

- For D3 ditch (1st season), D3 ditch (2nd season), D4 stream, **R1 stream (1st season), R1 stream (2nd season), R2 stream (1st season), R2 stream (2nd season), R3 stream (1st season), R3 stream (2nd season), R4 stream (1st season) and R4 stream (2nd season)** 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Fruiting vegetables (strawberry and tomato)

- For D4 stream, R2 stream, R3 stream **and R4 stream** 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Ornamentals (apple early BBCH 10)

- For D3 ditch 30 m no spray buffer zone **OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction** should be considered.
- For D4 pond 15 m no spray buffer zone OR 5 m with 50% nozzle reduction should be considered.
- For D4 stream and D5 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction **OR 5 m with 95% nozzle reduction** should be considered.
- For D5 pond **10 m no spray buffer zone OR 5 m no spray buffer zone with 50% nozzle reduction** should be considered.
- For R1 pond 10 m OR 5 m with 50% nozzle reduction should be considered.
- For R1 stream and R4 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle OR 10 m with 90% nozzle reduction **OR 5 m with 95% nozzle reduction** should be considered.
- For R2 stream and R3 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR **15 10 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction** should be considered.

For R3 stream 30 m no spray buffer zone OR 20 m with 75% nozzle reduction OR 15 m with 90% nozzle reduction OR 5 m with 95% nozzle reduction should be considered.

Ornamentals (apple late BBCH 85)

- For D3 ditch, D4 stream, D5 stream, R1 stream, R2 stream, R3 stream and R4 stream 20 m no spray buffer zone OR 15 m with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For D5 stream and R3 stream 15 m no spray buffer zone with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.

Ornamentals (onion)

- For D3 ditch, D4 stream, R1 stream, R2 stream, R3 stream and R4 stream 5 m no spray buffer zone should be considered.
- Although scenarios D6 (1st ditch) and D6 (2nd ditch) shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that these scenarios are not relevant under CEU conditions.

Strawberry (leafy vegetables 1st crop)

For D3 ditch (1st season), D4 stream and R1 stream (1st season) 5 m no spray buffer zone should be considered.

Tomato (potato)

For D3 ditch (1st season) and D4 stream 5 m no spray buffer zone should be considered.

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Leafy vegetable (brassicas)

- For D3 ditch (1st season) and D3 ditch (2nd season) 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Fruiting vegetables (tomato)

- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

The risk for aquatic organism for tomato was based on calculation of the PEC_{sw} for potato. Based on the PEC/RAC value for fish and PEC/ RAC for aquatic invertebrates the risk is considered as acceptable at STEP 3. No risk mitigation measures are required.

Ornamentals (apple early BBCH 10)

- For D3 ditch, D4 stream, D5 stream, R2 stream, R3 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction should be considered.
- For R1 stream and R4 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle OR 5 m with 90% nozzle reduction should be considered.

Ornamentals (apple late BBCH 85)

- For D4 stream, D5 stream, R2 stream and R3 stream 20 m no spray buffer zone OR 15 m with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For D3 ditch 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.

- For R1 stream and R4 stream 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 75% nozzle reduction should be considered.

Ornamentals (onion)

- For D3 ditch 5 m no spray buffer zone should be considered.
- Although scenarios D6 (1st ditch) and D6 (2nd ditch) shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that these scenarios are not relevant under CEU conditions.

Strawberry (leafy vegetables 1st crop)

- For D3 ditch (1st season) 5 m no spray buffer zone should be considered.

Conclusions (field uses)

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

Fruiting vegetables (strawberry and tomato) – 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 75% of nozzle reduction OR respect an unsprayed buffer zone of 15 m with 90% of nozzle reduction OR respect an unsprayed buffer zone of 5 m with 95% 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.

Applicant update – July 2021

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.

Greenhouse uses (permanent use)

According to the new calculations and using the new application rate, the risk in greenhouse uses is considered acceptable.

zRMS comment:

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The calculations based on PEC_{sw}/RAC for active substance deltamethrin for field uses have been accepted by zRMS-PL, except using the combination STEP4 buffer zone +95% drift reduction nozzles. They cannot be used in the risk assessment for aquatic organisms, due to the possibility of exceeding the residual drift. It does not comply with European recommendations of FOCUS L&M GD (FOCUS, 2017).

GREENHOUSE USE (permanent use)

For glasshouse permanent use for tomato for Poland the risk assessment is provided below taking into account the agreed PEC_{sw} value from Section 8, Fate and Behaviour and the relevant RAC endpoints for fish and aquatic invertebrates.

Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Deltamethrin based on calculations for greenhouse uses for tomato the use of DECIDE.

Group		Microcosms	Fish acute
Test species		Invertebrate populations	<i>Oncorhynchus mykiss</i>
Endpoint		EAC	LC ₅₀
(µg/L)		0.0032	0.26
AF		1	100
RAC		0.0032	0.0026
(µg/L)			
	PEC _{gl-max} (µg/L)		
0.0025µg/L		0.0078	0.96

It should be also indicated that the calculations for field uses of tomato (based on the potato PEC_{sw} calculations at STEP 3) were considered as an acceptable.

In conclusion, the risk assessment for aquatic organism for greenhouse are covered by field uses for this crop. No risk mitigation are required.

Field USES- a.s.

Leafy vegetable (brassicas)

- For D3 ditch (1st season) and D3 ditch (2nd season) 5 m no spray buffer zone should be considered.
- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.

Fruiting vegetables (tomato)

- Although scenario D6 ditch shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that this scenario is not relevant under CEU conditions.
 The risk for aquatic organism for tomato was based on calculation of the PEC_{sw} for potato. Based on the PEC/RAC value for fish and PEC/ RAC for aquatic invertebrates the risk is con-

sidered as acceptable at STEP 3. No risk mitigation measures are required.

Ornamentals (apple early BBCH 10)

- For D3 ditch, D4 stream, D5 stream, R2 stream, R3 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle reduction OR 10 m with 90% nozzle reduction should be considered.
- For R1 stream and R4 stream 30 m no spray buffer zone OR 20 m with 50% nozzle reduction OR 15 m with 75% nozzle OR 5 m with 90% nozzle reduction should be considered.

Ornamentals (apple late BBCH 85)

- For D4 stream, D5 stream, R2 stream and R3 stream 20 m no spray buffer zone OR 15 m with 50% nozzle reduction OR 10 m with 75% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For D3 ditch 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 90% nozzle reduction should be considered.
- For R1 stream and R4 stream 15 m no spray buffer zone OR 10 m with 50% nozzle reduction OR 5 m with 75% nozzle reduction should be considered.

Ornamentals (onion)

- For D3 ditch 5 m no spray buffer zone should be considered.
- Although scenarios D6 (1st ditch) and D6 (2nd ditch) shown step 4 PEC_{sw} greater than the lowest RAC value for aquatic organisms, it should be considered that these scenarios are not relevant under CEU conditions.

Strawberry (leafy vegetables 1st crop)

- For D3 ditch (1st season) 5 m no spray buffer zone should be considered.

The risk assessment for formulation Decide for the most sensitive organism algae with 72 E_rC₅₀=4.4 µg formulation /L with RAC 0.44 formulation /L was provided below:

Nozzle reduction	PEC _{SW} [µg formulation /L]							
	Spray drift buffer zone[m]	FOCUS default	5	10	15	20	30	35
Endpoint 4.4 µg formulation/L								
Brassicas (cabbage); Strawberry and tomato; Ornamentals (onions)								
None	1 m (Drift 2.77%)	1.417	0.261	-	-	-	-	-
50 %		0.709	-	-	-	-	-	-
75 %		0.354	-	-	-	-	-	-
90 %		0.142	-	-	-	-	-	-
Ornamentals (Apple early)								
None	3 m (Drift 29.20%)	14.934	9.271	5.694	2.202	1.302	0.4979	0.345
50 %		7.467	4.636	2.849	1.101	0.6510	0.2489	-
75 %		3.733	2.318	1.434	0.326	-	-	-
90 %		1.493	0.937	0.569	0.220			
Ornamentals (Apple late)								
None	3 m (Drift 15.73%)	8.045	1.878	0.8392	0.379	-	-	-
50 %		4.023	0.039	0.4196	-	-	-	-
75 %		2.011	0.482	0.215	-	-	-	-

90 %		0.805	0.2154	-	-	-	-	-
In green PEC/RAC<1 indicating acceptable risk assessment								
Decide: To protect aquatic organism <u>for formulation</u> the following risk mitigation measures should be applied to surface water bodies: <ul style="list-style-type: none"> • 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) The final risk mitigation measures should be decided at MSs level.								

9.6 Effects on bees (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with Deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Deltamethrin	Oral	LD ₅₀ = 0.079 µg/bee	SANCO 6504/VI/99 (17 October 2002)
<i>Apis mellifera</i>	Deltamethrin	Contact	LD ₅₀ = 0.0015 µg/bee	SANCO 6504/VI/99 (17 October 2002)
<i>Apis mellifera</i>	DECIDE (Deltamethrin 5% CS)	Oral	LD ₅₀ = >100 µg/bee	KCP 10.3.1.1.1 XXX, B.V., 2018 G13394
<i>Apis mellifera</i>	DECIDE (Deltamethrin 5% CS)	Contact	LD ₅₀ = >100 µg/bee	KCP 10.3.1.1.2 XXX, B.V., 2018 G13395
<i>Apis mellifera</i>	DECIDE (Deltamethrin 5% CS)	Chronic 10d	LDD ₅₀ = 0.68 µg/bee/day NOEDD = 0.38 µg/bee/day	KCP 10.3.1.2-01 K. XXX, 2021 7969/2020*
<i>Apis mellifera</i>	DECIDE (Deltamethrin 5% CS)	Honeybee larvae study 22d	NOED larvae = 0.03 µg/larva	KCP 10.3.1.3-01 K. XXX, 2021 7970/2020*
Higher-tier studies (tunnel test, field studies)				

Species	Substance	Exposure System	Results	Reference
-				

* Study summaries are included in this dossier (see appendix 2). However, they have not been considered further as they are not relevant to the currently approved risk assessment scheme (SANCO/10329/2002).

9.6.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones. Studies were conducted with DECIDE and were also considered for the risk assessment.

9.6.2 Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group ‘all crops’ also covers the risk for bees from all other intended uses (see 9.1.2).

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of DECIDE in ‘all crops’

Intended use	All crops (brassicas / strawberry / tomato / ornamentals)		
Active substance	Deltamethrin		
Application rate (g/ha)	3 x 12.5		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	0.079	12.5	158.23
Contact toxicity	0.0015		8333.33
Product	DECIDE (Deltamethrin 5% CS)		
Application rate (g/ha)	3 x 0.25 L/ha (3 x 255.725 g/ha)		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	>100	255.725	2.56
Contact toxicity	>100		2.56

Intended use	All crops (brassicas / strawberry / tomato / ornamentals)		
Active substance	Deltamethrin		
Application rate (g/ha)	1 x 7.5		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	0.079	7.5	94.94

Contact toxicity	0.0015		5000
Product	DECIDE (Deltamethrin 5% CS)		
Application rate (g/ha)	1 x 0.15 L/ha (1 x 153.435 g/ha)		
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	>100	153.435	1.53
Contact toxicity	>100		1.53

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

* Considering a density of 1.0229 g/mL

9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies)

Although the exposure to the product Deltamethrin 5% CS did not pose a risk, as the HQ were well below the trigger, however, HQ values above the trigger were detected after the exposure to technical.

A comparison of the toxicity of Deltamethrin 5% CS to that of the representative formulation which was evaluated under Uniform Principles for the first approval of deltamethrin under Directive 91/414/EEC, Decis 25 EC, clearly indicates that oral and contact toxicity is much higher than that of Deltamethrin 5% CS.

Comparison between formulations

Endpoint	Decis 25 EC	Deltamethrin 5% CS
Oral LD ₅₀ (48h)	0.28 µg a.i./bee	>4.89 µg a.i./bee
Contact LD ₅₀ (48h)	0.01 µg a.i./bee	>4.89 µg a.i./bee

* LoEP refers to SANCO/6504/VI/99-final, 17 October 2002

Field studies conducted with Decis 25 EC were submitted for the first approval of deltamethrin under Directive 91/414/EEC since this will present a worst-case review of the toxicity of Deltamethrin 5% CS because of the higher oral and contact toxicity of Decis 25 EC.

A cage study included in the monograph showed that the toxicity of alfalfa samples sprayed with Decis at 22.4 g a.s./ha declined with time with an RT₂₅ < 8 hour. 24 hours old residues did not cause a mortality different from the control (Mayer, 1992).

Also, field study results included in monograph and compiled in a review by Soubrier, give more details about the effects of this product.

- With a dosing of **12.5 g/ha**, mortality remained small. A slower escape as the spraying-boom went by was observed compared to lower doses, but a repellent effect for 2 h was still noticed. Changed behavior was noted. However, this trial was disturbed by unfavorable climatic conditions and a second trial was therefore carried out.

The slower escape was confirmed in the second trial. The repellent effect lasted for at least 1 h. Mortality was still negligible (192 bees/ha in the field and 39-86 per day in 4 hives over the 4 days following application). No large behavioral changes. There was no treatment related decrease of weight of pollen collected. The authors concluded that 12.5 g/ha onto foraging bees is harmless (Roa and Bocquet, 1980).

- With a dosing of **17.5 g/ha**, no increase in mortality in the 4 hives: 38 dead bees found on the day of application, 9- 95 per day over the next three days. A slight increase in paths: from 144/ha the day of application to 768/ha three days after. Slightly modified behavior which lasted for 1 h. The repellent

effect was visible for 1-2 h, but it was less marked. The authors concluded that 17.5 g/ha was still harmless, but that the limit dose was approaching (Roa and Bocquet, 1980).

- The effects obtained with a dosing of **21.2 g/ha** were similar to 17.5 g/ha. The repellent effect was less pronounced. Immediately after treatment some bees were 'knocked-down' for 5-10 min. No mortality on the crop, low mortality at the hives: In 4 hives 119 dead bees were found on day of application, 88-133 per day over the next three days. In traps for dead bees, 10-31 bees per day were found (Roa and Bocquet, 1981).
- When **35 g/ha** was applied, a significant increased mortality in hives was observed: On the day of application, 365 dead bees were found in 4 hives, plus 97 in traps for dead bees. Over the next four days 108-231 dead bees were found in the hives, plus 53-90 in the traps. Numerous dead bees were observed outside the observation area. A significant aggressiveness was noted, as well as casting out of pupae. Changes in behavior, and a repellent effect still noted for 1 h. The authors concluded that 35 g/ha is toxic to bees (Roa and Bocquet, 1981).

Therefore, as can be inferred from the field results presented above, the toxic effects observed in bees are mild and the mortality is low or even equal to the control group when the product is applied at ~~the maximum proposed dose according to the GAP (i.e. of 12.5 g/ha)~~, which is higher than the maximum proposed dose according to the GAP (i.e. 7.5 g/ha). In fact, as studies at higher doses show, this application dose has to be increased around ~~two~~ **three** and even ~~three~~ **five** times to show significant mortality results. In addition, after risk assessment with formulated Deltamethrin 5% CS, HQ values were well below the trigger of 50 showing no unacceptable risk on honeybees.

For all reasons above, the Applicant considers that no unacceptable risk for bees exposed to Deltamethrin 5% CS is expected according to the intended uses.

zRMS comments:

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 the chronic adult and chronic larvae tests ~~should be~~ were provided by the applicant for the product Decide 5CS during Commenting period process and should be considered at MSs level.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

HQ values above the trigger were detected after the exposure to technical. However, first-tier assessments indicate that no unacceptable risk for bees exposed to Deltamethrin 5% CS is expected according to the intended uses. Field studies carried out with Decis 25 EC formulation support the idea that exposure to the maximum proposed dose can be considered as “safe”.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods were carried out with Deltamethrin (Decis EC). Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of Deltamethrin 5% CS were not evaluated as part of the EU assessment of Deltamethrin.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Coccinella septempunctata</i> (larvae)	Decis EC	Laboratory test glass plates (2D) 24 h mortality	At 1.5 g a.s./ha: 100% mortality (high mortality in the control: uncertain)	SANCO 6504/VI/99 (17 October 2002)
<i>Chrysoperla carnea</i> (larvae)	Decis EC	Laboratory test glass plates (2D) 4 w mortality	At 13.5 g a.s./ha: 98% mortality	SANCO 6504/VI/99 (17 October 2002)
<i>Chrysoperla carnea</i> (larvae)	Decis	Green lacewing 51 d overall impact	At 13.5 g a.s./ha: 48% overall impact (brief reporting, uncertain)	SANCO 6504/VI/99 (17 October 2002)
<i>Trichogramma cacoeciae</i> (adult)	Decis EC	Laboratory test glass plates (2D) 7 d parasitism capacity	At 13.5 g a.s./ha: 100% effect	SANCO 6504/VI/99 (17 October 2002)
<i>Typhlodromus pyri</i>	Deltamethrin 2.5 % EC	Laboratory test glass plates (2D)	LR ₅₀ (7d) = 0.002 g as/ha	KCP 10.3.2.1-01 XXX, E., 2011 34SRFR11C2
<i>Aphidius rhopalosiphi</i>	Deltamethrin 2.5 % EC	Laboratory test glass plates (2D)	LR ₅₀ (48h) = 0.019 g as/ha	KCP 10.3.2.1-02 XXX, E., 2011 34SRFR11C1

Species	Substance	Exposure System	Results	Reference																																				
<i>Typhlodromus pyri</i>	DECIDE	Extended (2D)	LR ₅₀ = 0.55 mL/ha (0.02789 g ai/ha) ER ₅₀ > 0.49 mL/ha (> 0.025 g ai/ha)	KCP 10.3.2.2-01 XXX, P., 2020 6035/2019																																				
<i>Aphidius rhopalosiphi</i>	DECIDE	Extended (3D)	LR ₅₀ = 0.20 L/ha (10.14 g ai/ha) ER ₅₀ < 0.18 L/ha (9.13 g ai/ha)	KCP 10.3.2.2-02 XXX, G., 2019 6034/2019																																				
<i>Chrysoperla carnea</i>	DECIDE	Extended (2D)	LR ₅₀ = 0.19 L/ha (9.63 g ai/ha) ER ₅₀ = 0.18 L/ha (9.13 g ai/ha)	KCP 10.3.2.2-03 XXX, M., 2020 6036/2019																																				
<i>Coccinella septempunctata</i>	DECIDE	Extended (2D)	LR ₅₀ = 0.0010 L/ha (0.051 g ai/ha) ER ₅₀ > 0.00078 L/ha (0.040 g ai/ha)	KCP 10.3.2.2-04 XXX, V., 2020 6037/2019																																				
<i>Typhlodromus pyri</i>	Deltamethrin 2.5 % EC, 7.5 g as/ha	Aged residue study	<table><tr><th>Residues aged for:</th><th>% mortality (7d)</th></tr><tr><td>0 DAA</td><td>100</td></tr><tr><td>21 DAA</td><td>93</td></tr><tr><td>35 DAA</td><td>86</td></tr><tr><td>49 DAA</td><td>31</td></tr></table> <p>49 DAA: When compared to the control group, no significant adverse effect on fecundity was noted indicating full recovery had occurred.</p>	Residues aged for:	% mortality (7d)	0 DAA	100	21 DAA	93	35 DAA	86	49 DAA	31	KCP 10.3.2.2-05 XXX, E., 2011 34SRFR11C3																										
Residues aged for:	% mortality (7d)																																							
0 DAA	100																																							
21 DAA	93																																							
35 DAA	86																																							
49 DAA	31																																							
<i>Aphidius rhopalosiphi</i>	DECIDE	Aged residue study	<p>0.58 L FP/ha [29.41 g a.i./ha]</p> <table><tr><th>Res. aged:</th><th>% mort.</th><th>% repr. red.</th></tr><tr><td>0 DAA1</td><td>65.8</td><td>-</td></tr><tr><td>14 DAA1</td><td>75.0</td><td>-</td></tr><tr><td>28 DAA1</td><td>57.5</td><td>-</td></tr><tr><td>42 DAA1</td><td>10.0</td><td>66.6</td></tr><tr><td>56 DAA1</td><td>25.0</td><td>48.4</td></tr></table> <p>0.68 L FP/ha [34.48 g a.i./ha]</p> <table><tr><th>Res. aged:</th><th>% mort.</th><th>% repr. red.</th></tr><tr><td>0 DAA1</td><td>73.7</td><td>-</td></tr><tr><td>14 DAA1</td><td>100.0</td><td>-</td></tr><tr><td>28 DAA1</td><td>100.0</td><td>-</td></tr><tr><td>42 DAA1</td><td>60.0</td><td>-</td></tr><tr><td>56 DAA1</td><td>50.0</td><td>49.0</td></tr></table> <p>56 DAA1: When compared to the control group, a fecundity reduction ≤ 50 % was observed at both application rates.</p>	Res. aged:	% mort.	% repr. red.	0 DAA1	65.8	-	14 DAA1	75.0	-	28 DAA1	57.5	-	42 DAA1	10.0	66.6	56 DAA1	25.0	48.4	Res. aged:	% mort.	% repr. red.	0 DAA1	73.7	-	14 DAA1	100.0	-	28 DAA1	100.0	-	42 DAA1	60.0	-	56 DAA1	50.0	49.0	KCP 10.3.2.2-06 XXX, F., 2021 S20-07841
Res. aged:	% mort.	% repr. red.																																						
0 DAA1	65.8	-																																						
14 DAA1	75.0	-																																						
28 DAA1	57.5	-																																						
42 DAA1	10.0	66.6																																						
56 DAA1	25.0	48.4																																						
Res. aged:	% mort.	% repr. red.																																						
0 DAA1	73.7	-																																						
14 DAA1	100.0	-																																						
28 DAA1	100.0	-																																						
42 DAA1	60.0	-																																						
56 DAA1	50.0	49.0																																						
Field or semi-field tests																																								

Species	Substance	Exposure System	Results	Reference
<p><u>Field studies carried out in cereals:</u></p> <p>6.25 g a.s./ha reduced population of Diptera and Linyphiidae; practically not in Carabidae and Staphylinidae. 6.25 g a.s./ha, effects on Linyphiidae, Lycosidae and parasitic Hymenoptera, not on Carabidae and Staphylinidae. 5.0 g a.s./ha, syrphids 43-75% of control, no evaluation possible for some taxa.</p> <p>2 x 12.5 g/ha adverse effects, especially on Linyphiid spiders, but also on Staphylinid beetles. 2 x 0.125 g/ha, temporary and less pronounced effects on spiders and possibly also Collembola. 2 x 0.0125 g/ha, few and limited effects observed, not clearly treatment-related, considered as NOAEL.</p> <p><u>Field study carried out in apple orchard:</u></p> <p>3 x 12.5 g/ha severe (> 50%) effects on numerous taxa (27/43), from which some mites and Coleopterans did not recover within the season.</p> <p>3 x 2 g/ha severe (> 50%) effects on several taxa (14/43), and long time (> 6 weeks) for recovery indicated for some of them, while two groups of mites did not recover within the season.</p> <p>3 x 0.6 g/ha severe (> 50%) effects were noted in some taxa (6/43), but of these, all except Phalacridae (Coleoptera) recovered within 6 weeks. In taxa where 20-50% effect was observed, recovery within a few weeks or within the season was indicated, except for three species of mites.</p> <p>3 x 0.1 g/ha severe (> 50%) effects observed in one Coleopteran genera and in Syrphidae larvae (Diptera). For most taxa (34/43) effects were < 25%. A rapid recovery was indicated for most of the taxa affected at > 25%.</p>				

9.7.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones. Endpoints from the DECIDE formulation were also used for the risk assessment.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the field studies described in the Addendum to the Monograph (Julio, 2002).

9.7.2.1 Risk assessment for in-field exposure

Not relevant.

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of DECIDE in all crops

Intended use		All crops	
Active substance/product		Deltamethrin	
Application rate (g/ha)		3 x 12.5	
MAF		2-3 (foliar)	
Test species	Rate with ≤ 50 % effect ^a	PER _{in-field}	PER _{in-field} below rate with ≤ 50 % effect ^a
Higher-tier	(g/ha)	(g/ha)	
<i>Epilodromus pyri</i>	0.025	28.75	no
<i>Aphidius rhopalosiphii</i>	0.13		no
<i>Chrysoperla carnea</i>	0.13		no

<i>Coccinella septempunctata</i>	0.040		no
Test species Higher tier	Rate with ≤ 50 % effect (g/ha) at 56 DALT	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	34.48	28.75	yes
Intended use	All crops		
Active substance/product	Deltamethrin		
Application rate (g/ha)	3 x 12.5 (3 x 10*)		
MAF	2.7 (soil)		
Test species Higher tier	Rate with ≤ 50 % effect* (g/ha)	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	27	no
<i>Aphidius rhopalosiphi</i>	9.13		no
<i>Chrysoperla carnea</i>	9.13		no
<i>Coccinella septempunctata</i>	0.040		no
Test species Higher tier	Rate with ≤ 50 % effect (g/ha) at 56 DALT	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	34.48	27	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.

Criteria values shown in bold breach the relevant trigger.

* Considering an interception factor of 20% for sunflower, as surrogate crop for herbaceous and ornamental flowers (worst case).

Intended use	All crops		
Active substance/product	Deltamethrin		
Application rate (g/ha)	1 x 7.5		
MAF	1		
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	7.5	no
<i>Aphidius rhopalosiphi</i>	9.13		yes
<i>Chrysoperla carnea</i>	9.13		yes
<i>Coccinella septempunctata</i>	0.040		no
Test species Higher-tier	Rate with ≤ 50 % effect (g/ha) at 56 DALT	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	34.48	7.5	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.

Criteria values shown in bold breach the relevant trigger.

9.7.2.2 Risk assessment for off-field exposure

Not relevant.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of DECIDE

Intended use	Field-crops (brassicaceae)
Active substance/product	Deltamethrin
Application rate (g/ha)	3 x 12.5

MAF		1.7 (foliar)			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.0238	0.051	24	no (0.2529)
<i>Aphidius rhopalosiphii</i>	9.13		0.506		yes (2.529)
<i>Chrysoperla carnea</i>	9.13		0.051		yes (0.2529)
<i>Coccinella septempunctata</i>	0.040		0.051		no (0.2529)
Intended use		Field crops (brassicas)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5			
MAF		1.0			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.0277	0.021	5	no (0.1039)
<i>Aphidius rhopalosiphii</i>	9.13		0.208		yes (1.0388)
<i>Chrysoperla carnea</i>	9.13		0.021		yes (0.1039)
<i>Coccinella septempunctata</i>	0.040		0.021		no (0.1039)

Intended use		Vegetables (tomato)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		3 x 12.5			
MAF		2,3 (foliar)			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.069	0.198	5	no (0.992)
<i>Aphidius rhopalosiphii</i>	9.13		1.984		no (0.919)
<i>Chrysoperla carnea</i>	9.13		0.198		yes (0.992)
<i>Coccinella septempunctata</i>	0.040		0.198		no (0.992)
Intended use		Vegetables (tomato)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5			
MAF		1.0			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.0802	0.060	5	no (0.3008)
<i>Aphidius rhopalosiphii</i>	9.13		0.602		yes (3.0075)
<i>Chrysoperla carnea</i>	9.13		0.060		yes (0.3008)

<i>Coccinella septempunctata</i>	0.040		0.060		no (0.3008)
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Intended use		Ornamentals and small fruits			
Active substance/product		Deltamethrin			
Application rate (g/ha)		3 x 12.5			
MAF		2-3 (foliar)			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.0201	0.058	2	no (0.289)
<i>Aphidius rhopalosiphii</i>	9.13		0.578		yes (2.889)
<i>Chrysoperla carnea</i>	9.13		0.058		yes (0.289)
<i>Coccinella septempunctata</i>	0.040		0.058		no (0.289)
Intended use		Ornamentals and small fruits			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5			
MAF		1.0			
vdf		10 (2D) / 1 (3D)			
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	Drift rate	PER _{off-field} (g/ha)	CF	corr. PER _{off-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	0.0277	0.021	5	no (0.1039)
<i>Aphidius rhopalosiphii</i>	9.13		0.208		yes (1.0388)
<i>Chrysoperla carnea</i>	9.13		0.021		yes (0.1039)
<i>Coccinella septempunctata</i>	0.040		0.021		no (0.1039)

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

The applicant proposes using residue data to refine MAF DT₅₀ value. Initial residues were calculated according to EPPO. To take account of decline in residues, the mean DT₅₀ in lettuce and spinach was calculated to 2.9 days (in Martens and Schäfer, 1999, see table below).

	Day	Measures residues (mg/kg)	Mean residues (mg/kg)	DT ₅₀ (r ²)	DT ₉₀
Lettuce (n=28)	0	0.03-0.5	0.17	2.7 days (1.0)	9 days
	3	0.02-0.2	0.079		
	5	0.005-0.2	0.046		
	7	0.005-0.08	0.029		
Spinach (n=11)	0	0.4-0.81	0.53	2.9 days (0.98)	10 days
	1	0.33-0.62 ¹	0.48		
	3	0.1-0.46	0.22		
	5	0.005-0.3	0.17		
	7	0.021-0.5	0.11		

Using a DT₅₀ value of 2.8 days for the active substance, an interval of 10 days and three applications as

worst case, the calculated MAF is 1.1.
Therefore, a DT50 value of 2.8 is used in further refined assessment.

IN-FIELD

Table 9.7-4: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of DECIDE in all crops—Refined MAF

Intended use	All crops		
Active substance/product	Deltamethrin		
Application rate (g/ha)	3 x 12.5		
MAF	1.1 (foliar)		
Test species Higher tier	Rate with $\leq 50\%$ effect ^a (g/ha)	PER _{in-field} (g/ha)	PER _{in-field} below rate with $\leq 50\%$ effect?
<i>Typhlodromus pyri</i>	0.025	13.75	no
<i>Aphidius rhopalosiphii</i>	0.13		no
<i>Chrysoperla carnea</i>	0.13		no
<i>Coccinella septempunctata</i>	0.040		no
Test species Higher tier	Rate with $\leq 50\%$ effect (g/ha) at 56 DALT	PER _{in-field} (g/ha)	PER _{in-field} below rate with $\leq 50\%$ effect?
<i>Aphidius rhopalosiphii</i>	34.48	13.75	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment.
Criteria values shown in bold breach the relevant trigger.

The MAF refinement did not implied an acceptable in-field risk and then further assessment would be needed.

The most sensitive species according to the extended laboratory studies with DECIDE is *T. pyri*. Sharda has an available aged residue study on *T.pyri* with a similar formulation, Poleci. A comparison of toxicities between formulations is shown below.

	DECIDE (5% CS)	Poleci 2.5% EC (deltamethrin 25 g/L)	Decis 25 EC (deltamethrin 25 g/L)
<i>T. pyri</i>	LR ₅₀ = 0.02789 g ai/ha NOER < 0.010 g ai/ha	LR ₅₀ = 0.002 g ai/ha NOER < 0.00064 g ai/ha	LR ₅₀ = 0.002 g ai/ha NOER < 0.00064 g ai/ha
<i>A. rhopalosiphii</i>	LR ₅₀ = 10.14 g ai/ha NOER < 9.13 g ai/ha	LR ₅₀ = 0.019 g ai/ha NOER < 0.019 g ai/ha	LR ₅₀ = 0.029 g ai/ha NOER < 0.019 g ai/ha

The laboratory study in *T. pyri*, which was the most affected species was presented with Poleci 2.5% EC formulation (deltamethrin 25 g/L (XXX E., 2011); KCP 10.3.2.1-01). As it can be observed from the table, the toxicity of DECIDE is not higher than the one from Poleci or Decis, and therefore reference to the aged study on *T. pyri* with Poleci was considered appropriate.

The results of the aged residue study in *T.pyri* (deltamethrin 25 g/L (XXX E., 2011); KCP 10.3.2.2-05) showed that after 49-days of ageing, the resulted mortality was 31.11% and there was no significant reduction of the reproductive capacity in the test item treatment, in comparison to the control, indicating that full recovery had occurred 49 days after application. Although The rate tested in the study was 7.5 g a.s./ha, lower than the PER_{in-field} (13.75 g a.s./ha) as the calculated PER_{in-field}, hence it is reasonable to expect that, as showed above the toxicity of DECIDE was not higher than the toxicity of Poleci, a poten-

tial of recovery is also expected for *T.pyri* after the application of DECIDE.

In addition, applicant has used the refined DT₅₀ value of 2.8 days to predict the amount of days until residue levels would decrease to acceptable levels based on the tier II laboratory data for *T. pyri* (ER₅₀ = 0.025 g a.s./ha). The following equation was used:

$$PER_{(t)} = PER_{initial}(e^{-kt})$$

Where:

t = time elapsed (days)

k = rate constant (ln2/DT₅₀)

PER = Predicted Environmental Rate

According to this equation, after a maximum of 26.24 days the PER (0.0220.020) would be below the most sensitive toxicity endpoint, marked by *T. pyri* ER₅₀. This approach supports the idea of a recovery in a time period even lower than the one obtained from the aged residue study.

Furthermore, a new aged residue study with *A. rhopalosiphi* (DECIDE (XXX, F., 2021); KCP 10.3.2.2-06), showed that after 56-days of ageing, the resulted mortality was 49.0% and the reduction of the reproductive capacity in the test item treatment was also <50% in comparison to the control. This period of time can be considered as more conservative, compared to above obtained days and supports the idea of a potential recovery of field arthropods. In addition, it must be emphasized that the dose tested in the study is significantly higher than the calculated PER (13.757.5 g a.s./ha), so we can consider that the conditions of this study are conservative and, therefore, it also supports the already mentioned recovery.

Finally, applicant would like to refer to the higher tier **field study** that was provided and reviewed for the first approval of deltamethrin under Directive 91/414/EEC. The first study, performed in England during 1999 in fields of winter barley, applied deltamethrin at three rates, 12.5, 0.125 and 0.0125 g a.s./ha. This was designed to determine the effects not just at the application rate of 12.5 g/ha but also at simulated treatment rates of the off-field areas by drift at 1% and 0.1% of the applied rate (Brown & Selby, 2000). Only ground-dwelling arthropods were sampled. However, earlier studies indicated that spiders were particularly vulnerable and the restricted sampling was accepted.

The treatment at 0.0125 g a.s./ha simulated a drift rate of 0.1%, which corresponds to a buffer zone of 20m. No treatment related effects were noted and this rate was considered as the NOER.

The treatment at 0.125 g a.s./ha simulated a drift rate of 1%, which corresponds to a buffer zone of <5m. At this rate, the effect on spiders was considered temporary.

The supported GAP for tomato, strawberry and ornamentals is 31 applications per crop at a maximum rate of 12.5 7.5 g a.s./ha. Since the PER_{off-field} will be below the treatment of 0.125 g a.s./ha, at which effects were considered temporary, with the implementation of mitigation measures (5m buffer zone) the recolonization of the in-field area is expected.

For all the above reasons, the in-field risk for effects is considered to be acceptable since recolonization of the in-field area is possible within 1 year.

OFF-FIELD

Table 9.7-5: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of DECIDE

Intended use		Field crops (brassiens)				
Active substance/product		Deltamethrin				
Application rate (g/ha)		2 x 12.5				
MAF		1:1 (foliar)				
vdt		10 (2D) / 1 (3D)				
Test species	Rate with ≤ 50 % effect ³²	Drift rate	PER _{off-field}	CF	corr. PER _{off-field} below	
Higher-tier	(g/ha)		(g/ha)		rate with ≤ 50 % effect?	
<i>Typhlodromus pyri</i>	0.025	0.0238	0.033	5	no (0.1636)	
<i>Aphidius rhopalosiph</i>	0.13		0.327		yes (1.6363)	
<i>Chrysoperla carnea</i>	0.13		0.033		yes (0.1636)	
<i>Coccinella septempunctata</i>	0.040		0.033		no (0.1636)	

Intended use		Vegetables (tomato)				
Active substance/product		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
MAF		1:1 (foliar)				
vdt		10 (2D) / 1 (3D)				
Test species	Rate with ≤ 50 % effect ³²	Drift rate	PER _{off-field}	CF	corr. PER _{off-field} below	
Higher-tier	(g/ha)		(g/ha)		rate with ≤ 50 % effect?	
<i>Typhlodromus pyri</i>	0.025	0.069	0.095	5	no (0.4744)	
<i>Aphidius rhopalosiph</i>	0.13		0.940		no (4.7438)	
<i>Chrysoperla carnea</i>	0.13		0.095		yes (0.4744)	
<i>Coccinella septempunctata</i>	0.040		0.095		no (0.4744)	

Intended use		Ornamentals and small fruits				
Active substance/product		Deltamethrin				
Application rate (g/ha)		3 x 12.5				
MAF		1:1 (foliar)				
vdt		10 (2D) / 1 (3D)				
Test species	Rate with ≤ 50 % effect ³²	Drift rate	PER _{off-field}	CF	corr. PER _{off-field} below	
Higher-tier	(g/ha)		(g/ha)		rate with ≤ 50 % effect?	
<i>Typhlodromus pyri</i>	0.025	0.0201	0.028	5	no (0.1382)	
<i>Aphidius rhopalosiph</i>	0.13		0.276		yes (1.3819)	
<i>Chrysoperla carnea</i>	0.13		0.028		yes (0.1382)	
<i>Coccinella septempunctata</i>	0.040		0.028		no (0.1382)	

MAF: Multiple application factor; vdt: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

9.7.2.4 Risk mitigation measures

A higher tier field study were provided and reviewed for the first approval of deltamethrin under Directive 91/414/EEC. The first study, performed in England during 1999 in fields of winter barley, applied deltamethrin at three rates, 12.5, 0.125 and 0.00125 g a.s./ha. This was designed to determine the effects not just at the application rate of 12.5 g/ha but also at simulated treatment rates of the off field areas by drift at 10% and 0.01% of the applied rate (Brown & Selby, 2000). Only ground-dwelling arthropods were sampled. However, earlier studies indicated that spiders were particularly vulnerable and the restricted-sampling was accepted.

The treatment at 0.00125 g a.s./ha simulated a drift rate of 0.01%, which corresponds to a buffer zone of >250m. No treatment related effects were noted and this rate was considered as the NOER.

The treatment at 0.125 g a.s./ha simulated a drift rate of 1%, which corresponds to a buffer zone of <5m. At this rate, the effect on spiders was considered temporary.

The supported GAP for tomato, strawberry and ornamentals is 3 applications per crop at a maximum rate of 12.5 g a.s./ha. Since the soil treatment 5m outside of crops field margins will be approximately 0.12 g a.s./ha (0.41% drift factor) it is considered that the risks to beneficial non-target arthropods at a distance of 5-10m of the field margins are acceptable. The populations inhabiting these areas will be able to repopulate the treated area allowing recolonisation well within 1 year of application.

Table 9.7-6: Assessment of the off-field risk for non-target arthropods due to the use of DECIDE in field crops considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Field crops (brassicas)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		2 x 12.5 g a.s./ha			
MAF		1-1 (foliar)			
vdI		10 (2D) / 1 (3D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
1	2.38	0.164	0.082	0.041	0.016
5	0.47	0.032	0.016	0.008	0.003
10	0.24	0.017	0.008	0.004	0.002
Higher tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER₅₀ = 0.025 g a.s./ha					
1		No	No	No	Yes
5		No	Yes	Yes	Yes
10		Yes	Yes	Yes	Yes

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Intended use	Field crops (brassicas)
Active substance/product	Deltamethrin
Application rate (g/ha)	1 x 7.5 g a.s./ha

MAF		1.0			
Vdf		10 (2D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
1	2.77	0.104	0.052	0.026	0.010
5	0.57	0.021	0.011	0.005	0.002
Higher-tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER₅₀ = 0.025 g s.a./ha					
1		No	No	No	Yes
5		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-7: Assessment of the off-field risk for non-target arthropods due to the use of DECIDE in vegetables considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Vegetables (tomato)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		3 x 12.5 g a.s./ha			
MAF		1.1 (foliar)			
Vdf		10 (2D) - 1 (3D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
3	6.9	0.474	0.237	0.119	0.047
5	3.07	0.211	0.106	0.053	0.021
10	1.02	0.070	0.035	0.018	0.007
15	0.54	0.037	0.019	0.009	0.004
20	0.34	0.023	0.012	0.006	0.002
Higher-tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER₅₀ = 0.025 g s.a./ha					
3		No	No	No	No
5		No	No	No	Yes
10		No	No	Yes	-
15		No	Yes	-	-
20		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Intended use		Vegetables (tomato)			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5 g a.s./ha			

MAF		1.0			
Vdf		10 (2D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
3	8.02	0.301	0.151	0.075	0.030
5	3.62	0.136	0.068	0.034	0.014
10	1.23	0.046	0.023	0.012	0.005
15	0.65	0.024	0.012	0.006	0.002
Higher-tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER ₅₀ = 0.025 g s.a./ha					
3		No	No	No	No
5		No	No	No	Yes
10		No	Yes	Yes	-
15		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Table 9.7-8: Assessment of the off-field risk for non-target arthropods due to the use of DECIDE in ornamentals and small fruits considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Ornamentals and small fruits			
Active substance/product		Deltamethrin			
Application rate (g/ha)		3 x 12.5 g a.s./ha			
MAF		1.1 (foliar)			
Vdf		10 (2D)/1 (3D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
1	0.01	0.138	0.069	0.035	0.014
5	0.41	0.028	0.014	0.007	0.003
10	0.2	0.014	0.007	0.003	0.001
Higher-tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER ₅₀ = 0.025 g s.a./ha					
1		No	No	No	Yes
5		No	Yes	Yes	-
10		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

Intended use		Ornamentals and small fruits			
Active substance/product		Deltamethrin			
Application rate (g/ha)		1 x 7.5 g a.s./ha			

MAF		1.0			
Vdf		10 (2D)			
Buffer strip (m)	Drift rate (%)	corr. PER_{off-field} (g/ha)	corr. PER_{off-field} 50 % drift red. (g/ha)	corr. PER_{off-field} 75 % drift red. (g/ha)	corr. PER_{off-field} 90 % drift red. (g/ha)
1	2.77	0.104	0.052	0.026	0.010
5	0.57	0.021	0.011	0.005	0.002
Higher-tier toxicity value		corr. PER_{off-field} below rate with ≤ 50 % effect			
ER₅₀ = 0.025 g s.a./ha					
1		No	No	No	Yes
5		Yes	-	-	-

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

According to the results after the MAF refinement, the next mitigation measures should be applied:

Field crops (brassicas): To protect non-target arthropods, respect an unsprayed buffer zone of 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.

Vegetables (tomato): To protect non-target arthropods, respect an unsprayed buffer zone of 20m OR 15m with 50% drift reduction nozzles OR 10m and 75% drift reduction nozzles OR 5m and 90% drift reduction nozzles to non-agricultural land.

Ornamentals and small fruits: To protect non-target arthropods, respect an unsprayed buffer zone of 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.

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

9.7.3 Overall conclusions

No endpoints are available for the representative species (*Typhlodromus pyri* and *Aphidius rhopalosiphii*), therefore the assessment is done using the results obtained from field studies. Risk reduction measures should be considered for arable crops at maximum field rate of 12.5 g/ha. At 5-10 m distance (or another comparable risk reduction measure), the risk for effects is considered to be low.

The results of the risk assessment for non-target arthropods showed an acceptable in-field and off-field risk after the application of DECIDE. A potential of recovery of the in-field area have been demonstrated in a short period of time after application of a refined MAF **DT₅₀** and according to the data from analogous submitted studies. In addition, an acceptable off-field risk was obtained with the application of the following risk mitigation measures:

~~Field crops (brassicae) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.~~

~~Vegetables (tomato) – Spe3: To protect non-target arthropods, respect an unsprayed buffer zone of 20m OR 15m with 50% drift reduction nozzles OR 10m and 75% 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 10m OR 5m with 50% drift reduction nozzles OR 1m and 90% drift reduction nozzles to non-agricultural land.~~

Field crops (brassicae) – 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.

zRMS comments:

Field uses:

Due to the well-known toxicity of deltamethrin on arthropods (see EU agreed endpoints), the risk assessment for in-field area showed high risk to non-target arthropods.

However, higher tier studies were submitted by the applicant to show that re-colonisation and recovery of the non-target population in the treated field is expected within one year (e.g. by deltamethrin residue decline in vegetables and aged residue studies on the most sensitive species - *T.pyri* and *Aphidius rhopalosiphi*). The short summary of evaluation made by zRMS is provided below:

The new aged residue study with *A. rhopalosiphi* (DECIDE (XXX, F., 2021); KCP 10.3.2.2-06), showed that after 56-days of ageing for application rate of 0.68 L product/ha (correspond to 34.48 g.a.s./ha) the resulted mortality was 50.0% and the reduction of the reproductive capacity in the test item treatment was also <50% in comparison to the control.

For lower dose tested 0.58 L product/ha (correspond to 29.41 g a.s./ha) the resulted mortality was 25% and the reduction of the reproductive capacity in the test item treatment was 48.5% in comparison to the control. Therefore, in the opinion of zRMS the value of 29.41 g a.s./ha is considered acceptable to use in the risk assessment.

The results of the **aged residue** study in *T.pyri* – the most sensitive organism tested (deltamethrin 25 g/L (XXX E., 2011); KCP 10.3.2.2-05) showed that after 49-days of ageing, the resulted mortality was 31.11% and there was no significant reduction of the reproductive capacity in the test item treatment, in comparison to the control, indicating that full recovery had occurred 49 days after application.

It should be noted that this study was carried out with ppp Poleci (with lower LR₅₀ value than for Decide).

The rate tested in the study was 7.5 g a.s./ha, the same as PERin-field (7.5 g a.s./ha).

Therefore, we can agree that this study covers the PERin-field up to 7.5 g a.s./ha for Decide.

In addition, applicant has used the refined value of 2.8 days to predict the amount of days until residue levels would decrease to acceptable levels based on the tier II laboratory data for *T. pyri* (ER₅₀ = 0.025 g a.s./ha). The following equation was used:

$$PER_{(t)} = PER_{initial} (e^{-kt})$$

Where:

t = time elapsed (days)

k = rate constant (ln2/DT₅₀)

PER = Predicted Environmental Rate

According to this equation, after a maximum of 26 days the PER (0.022) would be below the most sensitive toxicity endpoint, marked by *T. pyri* ER₅₀. This approach supports the idea of a recovery in a time period even lower than the one obtained from the aged residue study.

Table 9.7-9-1: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of DECIDE.

Intended use	Brassicas (cabbage, Brussels sprouts, cauliflower) and ornamentals		
Active substance/product	Deltamethrin		
Application rate (g/ha)	1x7.5		
MAF	1		
Test species Higher-tier	Rate with ≤ 50 % effect* (g/ha)	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Typhlodromus pyri</i>	0.025	7.5	no
<i>Aphidius rhopalosiphi</i>	9.13		yes
<i>Chrysoperla carnea</i>	9.13		yes
<i>Coccinella septempunctata</i>	0.040		no
Test species Higher-tier	Rate with ≤ 50 % effect (g/ha) at 56 DALT	PER_{in-field} (g/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Aphidius rhopalosiphi</i>	29.41	7.5	yes
<i>Typhlodromus pyri</i> (age residue study)	7.5 at 56 day	7.5	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

The risk for non-target arthropods is considered acceptable.

We agree with the risk assessment for off- field exposure of Decide provided by the applicant.

Therefore, the following risk mitigation measures should be applied:

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.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have

been carried out with Deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. **New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.**

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Deltamethrin	Mixed into substrate 14 d, acute	LC ₅₀ = >1290 mg/kg dw LC _{50,corr} = 645 mg/kg dw* 14-d NOEC = 447 mg/kg dw soil 14-d NOEC _{corr} = 223.5 mg/kg dw soil*	SANCO 6504/VI/99 (17 October 2002) And Addendum to Monograph (July 2002)
<i>Eisenia fetida</i>	Deltamethrin	Reproductive	data not required	SANCO 6504/VI/99 (17 October 2002)
<i>Eisenia fetida</i>	DECIDE	Mixed into substrate 28 d, chronic 5 % peat content	NOEC = 167.8 mg f.p./kg dw (corr. 83.90 mg f.p./kg dw) NOEC = 8.41 mg a.s./kg dw (corr. 4.21 mg a.s./kg dw)	KCP 10.4.1.1 B.V. XXX, 2020 G13397
<i>Folsomia candida</i>	DECIDE	Mixed into substrate 28 d, chronic 5 % peat content	NOEC >1000 mg f.p./kg dw (corr. 500 mg f.p./kg dw) NOEC = 49.28 mg a.s./kg dw (corr. 24.64 mg a.s./kg dw)	KCP 10.4.2.1-01 XXX, K., 2020 6942/2019
<i>Hypoaspis aculeifer</i>	DECIDE	Mixed into substrate 14 d, chronic 5 % peat content	NOEC >1000 mg f.p./kg dw (corr. 500 mg f.p./kg dw) NOEC = 49.28 mg a.s./kg dw (corr. 24.64 mg a.s./kg dw)	KCP 10.4.2.1-02 XXX, V., 2019 6031/2019
Field studies				
No data submitted.				
Litter bag test				
No data submitted.				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones, **except for formulation, corresponding to data proper to DECIDE formulation.**

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17,

2002).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-37. According to the assessment of environmental-fate data, multi-annual accumulation in soil does not need to be considered for Deltamethrin.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group 'all crops' also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses (see 9.1.2).

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of DECIDE in 'all crops'

Intended use	All crops (brassicas / strawberry / tomato / ornamentals)		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Deltamethrin	645	0.039 0.009	16538.5 71667
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Deltamethrin	223.5	0.039	5730.8
DECIDE	83.90 ¹	0.924 0.184	91.1 456.0
DECIDE ²	4.21 ¹	0.039 0.009	107.9 467.8
Chronic effects on other soil macro- and mesofauna			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
DECIDE (<i>Folsomia candida</i>)	500 ¹	0.924 0.184	542.9 2717.4
DECIDE ² (<i>Folsomia candida</i>)	24.64 ¹	0.039 0.009	631.8 2737.8
DECIDE (<i>Hypoaspis aculeifer</i>)	500 ¹	0.924 0.184	542.9 2717.4
DECIDE ² (<i>Hypoaspis aculeifer</i>)	24.64 ¹	0.039 0.009	631.8 2737.8

TER values shown in bold fall below the relevant trigger.

¹The endpoint was divided by 2 since log Kow>2

² Risk assessment based on an endpoint expressed as mg as/kg dw from DECIDE study.

zRMS comments:

The chronic endpoints for the active substance for earthworm and other soil macro organism are not available. However, TER_{LT} values for earthworms and other soil macro-organisms provided with the product Decide (expressed as mg a.s./kg dws) are above trigger value of 5, indicating an acceptable risk to these group of soil organism.

Therefore, it is concluded that Decide does not pose long-term risk to earthworms and other soil macro-

and mesofauna when applied according to the proposed uses rates.

Risk assessment for metabolite (Br₂CA) :

It should be noted that the only relevant, although transient, metabolite which has to be considered in soil ecosystems is Br₂CA detected in soil studies with a maximum of 23% AR,(Addendum to DAR.).

Nevertheless, it is unlikely that earthworms were at risk by exposure to this soil metabolite for the reasons explained below :

Cleavage of pyrethroids by esterases is one of the main detoxification pathways in animals. Ester cleavage of deltamethrin leads to the formation of Br₂CA, which can be considered to be less toxic and thus possess no more insecticidal activity comparatively to deltamethrin. This is well supported by the considerably lower acute oral toxicity of Br₂CA compared to deltamethrin in rats (LD₅₀ of Br₂CA m/f 1682/>2000 Ad-dendum) vs. 95/87 mg/kg b.w. (Addendum to DAR). Moreover, even the parent compound deltamethrin was shown to pose no unacceptable effects to soil organisms. Therefore, it can be concluded that no undue risk is posed by Br₂CA to earthworms.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

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 and other soil macro- and mesofauna.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with Deltamethrin. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of DECIDE were not evaluated as part of the EU assessment of Deltamethrin. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	Deltamethrin	28 d, aerobic soil type	At 375 g as/ha*, none or only slight deviations from controls	SANCO 6504/VI/99 (17 October 2002)
C-mineralisation	Deltamethrin	56 d, aerobic soil type	At 375 g as/ha*, none or only slight deviations from controls	SANCO 6504/VI/99 (17 October 2002)
N-mineralisation	DECIDE (Deltamethrin 5% CS)	28 d, aerobic soil type	Deviations <25% at maximum tested dose of 17.15 mg test item/kg dw (0.86 mg a.i. kg/dw)	KCP 10.5.1 XXX, H.S., 2019 G13399
C-mineralisation	DECIDE (Deltamethrin 5% CS)	56 d, aerobic soil type	Deviations <25% at maximum tested dose of 17.15 mg test item/kg dw (0.86 mg a.i. kg/dw)	KCP 10.5.2 XXX, H.S., 2019 G13398

* Conversion of g a.s./ha mg a.s./kg soil
 $375 \text{ g a.s./ha} = 375 / (100 \times \text{Soil depth (cm)} \times \text{Soil dry bulk density (g/cm}^3\text{)})$
 $= 375 / 750$
 $= 0.5 \text{ mg a.s./kg soil}$

9.9.1.1 Justification for new endpoints

The used endpoints were the EU agreed ones. Endpoints specific to the formulation have been used as per EU requirements.

9.9.2 Risk assessment

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

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-37 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group ‘all crops’ also covers the risk for the soil microorganisms from all other intended uses (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of DECIDE in ‘all crops’

Intended use	All crops (brassicas / strawberry / tomato / ornamentals)		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Deltamethrin	0.5 (at 28 d)	0.039 0.009	Yes
DECIDE	0.86 (at 28 d)	0.039 0.009	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Deltamethrin	0.5 (at 56 d)	0.039 0.009	Yes
DECIDE	0.86 (at 28 d)	0.039 0.009	Yes

9.9.3 Overall conclusions

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.

ZRMS comments:

Risk assessment is acceptable. Risk assessment with regard to /N-transformation was conducted on the basis of the worst-case application scenario for Decide. Effects within a range of ±25 % compared to the control were observed at exposure levels which clearly exceed the maximum PEC_{ini} in soil.

Therefore, the proposed uses pose a low and acceptable risk to the biological activity of micro-organisms in soil.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

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. However, studies on non-target terrestrial plants are included, together with the corresponding risk assessment.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
<i>Glycine max</i> ^d <i>Zea mays</i> ^m <i>Pisum sativum</i> ^d <i>Sinapis alba</i> ^d <i>Raphanus sativus</i> ^d <i>Solanum lycopersicon</i> ^d	DECIDE	14 d Seedling emergence	ER ₅₀ = 0.696 L f.p./ha (eq. to 35.294 g a.s./ha) <i>Zea mays</i> (shoot lenght)	KCP 10.6.2-01 XXX, S. 2020 6032/2019
<i>Glycine max</i> ^d <i>Zea mays</i> ^m <i>Pisum sativum</i> ^d <i>Sinapis alba</i> ^d <i>Raphanus sativus</i> ^d <i>Solanum lycopersicon</i> ^d	DECIDE	21 d Vegetative vigour	ER ₅₀ = 0.716 L f.p./ha (eq. to 36.308 g a.s./ha) <i>Sinapis alba</i> (shoot lenght)	KCP 10.6.2-02 XXX, S. 2020 6033/2019

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

Not relevant.

The data proper to DECIDE formulation is used for the assessments.

9.10.1.2 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.1.3 Tier-2 risk assessment (based on dose-response data)

Not relevant.

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

Table 9.10-2: Assessment of the risk for non-target plants due to the use of DECIDE in field crops (brassicas)

Intended use		Field crops (brassicas)		
Active substance/product		Delthamethrin / DECIDE		
Application rate (g/ha)		2 x 12.5 g a.s./ha		
MAF		1.2		
Test species	ER ₅₀ (g/ha)	Drift rate	PER _{off field} (g/ha)	TER criterion: TER > 5
Seedling emergence	35.294	0.38	9.51	69.8
Vegetative vigour	36.308			71.8

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Field crops (brassicas)		
Active substance/product		Delthamethrin / DECIDE		
Application rate (g/ha)		1 × 7.5 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Seedling emergence	35.294	2.38	0.18	197.7
Vegetative vigour	36.308			203.4

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-3: Assessment of the risk for non-target plants due to the use of DECIDE in fruiting vegetables (tomato)

Intended use		Fruiting vegetables (tomato)		
Active substance/product		Delthamethrin / DECIDE		
Application rate (g/ha)		3 × 12.5 g a.s./ha		
MAF		5.3		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Seedling emergence	35.294	6.9	1.98	17.8
Vegetative vigour	36.308			18.6

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Fruiting vegetables (tomato)		
Active substance/product		Delthamethrin / DECIDE		
Application rate (g/ha)		1 × 7.5 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Seedling emergence	35.294	6.9	0.52	68.2
Vegetative vigour	36.308			70.2

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.10-4: Assessment of the risk for non-target plants due to the use of DECIDE in small fruits (strawberries) and ornamentals

Intended use		Small fruits (strawberries) and ornamentals		
Active substance/product		Deltamethrin / DECIDE		
Application rate (g/ha)		3 × 12.5 g a.s./ha		
MAF		5.3		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Seedling emergence	35.294	2.01	9.58	61.1
Vegetative vigour	36.308			62.8

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Intended use		Small fruits (strawberries) and ornamentals		
Active substance/product		Deltamethrin / DECIDE		
Application rate (g/ha)		1 × 7.5 g a.s./ha		
MAF		1.0		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
Seedling emergence	35.294	2.01	0.15	234.1
Vegetative vigour	36.308			240.9

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

zRMS comments:

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SAN-CO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. The deterministic risk based on the ER₅₀ = 35.294 g/ha values and PER_{off-field} the risk is considered acceptable with TER_{LT} above trigger of 5 without using drift mitigation measures to non-crop land.

9.10.1.4 Higher-tier risk assessment

Not relevant.

9.10.1.5 Risk mitigation measures

No risk mitigation needed.

9.10.2 Overall conclusions

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.

However, based on the predicted rates of Deltamethrin in off-field areas, the TER values describing the risk for non-target plants following exposure to DECIDE according to the GAP are above acceptability criteria $TER \geq 5$.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Method

The effect of Deltamethrin (purity 99% w/w) on activated sludge was investigated in a respiration inhibition test in accordance with OECD guidelines 209. Tests concentration were 10, 32, 100, 320 and 1000 mg/L plus control. Duplicate samples were incubated for 3 hours. Dichlorophenol was use as a toxic reference.

Results

At the two highest test concentrations, 4% inhibition was observed, compared to the control. The 3 hours EC_{50} was concluded to be > 1000 mg/L. NOEC was set to 1000 mg/L.

Conclusion

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*).

9.12 Monitoring data (KCP 10.8)

Not relevant.

9.13 Classification and Labelling

	DECIDE
Common name	Deltamethrin 5% CS
Classification and proposed labelling	
With regards to ecotoxicological endpoints (according to the criteria Reg. 1272/2008, as amended)	Hazards classe(s): Aquatic Acute 1 Aquatic Chronic 1 Code(s) for hazard pictogram(s): GHS09 Signal word: Warning Hazard statement(s): H400 H410 Precautionary statement: EUH401

ZRMS comments:

We agree with the proposed classification and labelling

Appendix 1 Lists of data considered in support of the evaluation

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	Owner
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	Y	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
KCP 10.2.1-03	B.V. XXX	2020	Deltamethrin 5% CS: <i>Daphnia magna</i> , acute immobilization test. Eurofins Advinus Limited. G13393 GLP Unpublished	N	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
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 25g/L) on the non-target arthropod <i>Aphidius rhopalosiphi</i> (Hymenoptera: Braconidae) SynTech Research. 34SRFR11C1 GLP Unpublished	N	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.
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 Unpublished	N	Sharda Cropchem Ltd.
KCP 10.3.2.2-06	F. XXX	2021	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	Sharda Cropchem Ltd.
KCP 10.4.1.1	B.V. XXX	2020	Deltamethrin 5% CS: Earthworm Reproduction Test Eurofins Advinus Limited. G13397 GLP Unpublished	N	Sharda Cropchem Ltd.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
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	Sharda Cropchem Ltd.
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</i> (<i>Geolaelaps</i>) <i>aculeifer</i> Canestrini (Acari: Laelapidae) in artificial soil. Bioscience Research Foundation. 6031/2019 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5-01	H. S. XXX	2019	Soil Microorganisms: Carbon Transformation Test of Deltamethrin 5% CS Eurofins Advinus Limited. G13398 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.5-02	H. S. XXX	2019	Soil Microorganisms: Nitrogen Transformation Test of Deltamethrin 5% CS Eurofins Advinus Limited. G13399 GLP Unpublished	N	Sharda Cropchem Ltd.
KCP 10.6.2-01	S. XXX	2020	Effect of Deltamethrin 5% CS on seedling emergence and seedling growth of terrestrial plants. Bioscience Research Foundation. 6032/2020 GLP Unpublished	N	Sharda Cropchem Ltd.
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	Sharda Cropchem Ltd.

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	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	Owner
-	-	-	-	-	-

List of data relied on 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	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2 Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> There was no mortality in the negative control at the end of the test which is less than 10% at the end of the test. The pH of the test solutions was ranged from 7.68 to 7.75 and the temperature of the test solutions was 13.4 to 13.9 °C. The dissolved oxygen saturation of the test solutions ranged from 87 to 96 % which is more than 60% of the air saturation value throughout the test. The concentration of the test item in all tested concentrations was between 84.22 and 105.14 % of the nominal concentrations which was within $\pm 20\%$ during the test. <p>Agreed endpoints: 96 h LC₅₀ for Deltamethrin 5% CS =1.34 mg test item/L or 0.07 mg Deltamethrin/L</p>
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Reference:

KCP 10.2.1 - 01

Report

"Deltamethrin 5% CS: Fish, Acute Toxicity Test with Rainbow Trout".

XXX XXX XXX XXX (2020), Report No. G13391. Eurofins Advinus Limited

Guideline(s): Yes, OECD Guideline No. 203 (1992)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Yes

Materials and methods

Test item:

Description: Deltamethrin 5% CS
 Production batch: SCL - 12589
 A.i. content: Deltamethrin: 50.71 g/L

Test system:

Species: Rainbow trout (*Oncorhynchus mykiss*)
 Strain: -
 Age: -
 Average weight: 12.2103 g
 Average length: 3.8 to 4.7 cm
 Source: Deputy Director of Fisheries Patlikuhl, District Kullu, Himachal Pradesh.
 Acclimation period: 12 days
 Diet: 3 times per week

Experimental conditions:

Temperature: 13.4 – 13.9°C
 Dissolved O₂: 87 – 96%
 Hardness: 250 as mg CaCO₃/L
 pH: 7.68 – 7.75
 Light and photoperiod: 16h light and 8h dark
 Loading: 0.43 g fish/L test solution
 Test procedure: Static
 Experimental period: 96h

Test design and treatment

Static system (96 hours, one replicate of seven fish for each test item concentration and the control).

The range finding test was carried out with test concentrations of 0.001, 0.01, 0.1, 1, 10 and 100 mg/L of the test medium along with negative control in a semi-static mode (renewal of test solution at every 24h interval). Three fish per group were used in the test.

The definitive test was carried out using nominal test concentrations 0.2, 0.4, 0.9, 2.1, 4.5 and 10 mg/L plus a control in a static mode. Seven fish were used for each test solution with single replicate per test concentration. The fish were observed for mortalities and visible abnormalities up to 96 h.

The concentrations of the active substances were chemically determined using a validated analytical method in Analytical R & D Department of Eurofins Advinus Limited. The stability test results concluded that the test item was stable in the test medium at 97 h at 0.001006 and 50.30 mg/L nominal concentrations. The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration

was in the range of 91.15 to 105.14% (RSD was 2.36 to 11.56%) at the start of the test and 84.22 to 99.73% (RSD was 2.03 to 16.83%) at the end of the test (96 hour) indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of $\leq 20\%$).

Calculations with the Probit method of Finney (1971) using in-house developed and validated computer programme were made.

Results

In the range finding test, there was no mortality of fish in the negative control and the tested concentrations of 0.001, 0.01 and 0.1 mg/L, and there was 66.67, 100 and 100% mortality of fish observed at the tested concentrations of 1, 10 and 100 mg/L at 96h exposure, respectively.

On the definitive test, there was no mortality of fish in the negative control and at the tested concentrations of 0.2 and 0.4 mg/L at 96 h exposure. There was 42.86, 57.14, 85.71 and 100% at the tested concentrations of 0.9, 2.1, 4.5 and 10 mg/L respectively.

The LC₅₀ value for Deltamethrin 5% CS at 72 h was 2.55 mg test item/L or 0.13 mg Deltamethrin/L with fiducial limits at 95 per cent being 31.856 to 5.969 based on nominal concentrations.

The LC₅₀ value for Deltamethrin 5% CS at 96 h was 1.34 mg test item/L or 0.07 mg Deltamethrin/L with fiducial limits at 95 per cent being 0.21 to 2.44 based on nominal concentrations.

On the basis of the observations made during test, the LOEC (Low Observed Effect Concentration) was 0.9 mg test item/L or 0.04 mg Deltamethrin/L.

On the basis of the observations made during test, the NOEC (No Observed Effect Concentration) was 0.4 mg test item/L or 0.02 mg Deltamethrin/L.

Conclusion

The LC₅₀ value for Deltamethrin 5% CS at 96 h was 1.34 mg test item/L or 0.07 mg Deltamethrin/L with fiducial limits at 95 per cent being 0.21 to 2.44 based on nominal concentrations.

On the basis of the observations made during test, the LOEC (Low Observed Effect Concentration) was 0.9 mg test item/L or 0.04 mg Deltamethrin/L.

On the basis of the observations made during test, the NOEC (No Observed Effect Concentration) was 0.4 mg test item/L or 0.02 mg Deltamethrin/L.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.		
	<ul style="list-style-type: none"> There was an increase in cell concentration of the negative control culture by a factor of 78.46 which is more than the required factor limit of at least 16 at the end of the test. The mean coefficient of variation for section by section specific growth rates in the negative control cultures during the course of the test was 26.44 % which is within the required limit of 35%. The coefficient of variation of average growth rate between replicate cultures of negative control was 0.19% which is within the required limit of 7 %. 		
	Agreed endpoints:		
	Observations	EC values (mg test item/L)	EC values (mg Deltamethrin/L)
	24 hours	E _r C ₅₀	148.79 (88.21-282.26)
		E _r C ₂₀	66.37 (39.35-125.91)
		E _r C ₁₀	43.52 (25.80-82.56)
		E _y C ₅₀	99.19 (86.63-113.57)
		E _y C ₂₀	41.94 (36.63-48.02)
		E _y C ₁₀	26.74 (23.36-30.62)
		LOEC	63
		NOEC	25
	48 hours	E _r C ₅₀	166.01 (72.80-612.02)
		E _r C ₂₀	73.02 (32.02-269.20)
		E _r C ₁₀	47.53 (20.84-175.23)
		E _y C ₅₀	92.10 (53.01-165.03)

		E _y C ₂₀	36.56 (21.04-65.51)	1.80 (1.04-3.23)
		E _y C ₁₀	22.56 (12.98-40.42)	1.11 (0.64-1.99)
		LOEC	64	3.11
		NOEC	25	1.23
	72 hours	E _r C ₅₀	143.33 (80.29-292.73)	7.07 (3.96-14.43)
		E _r C ₂₀	62.58 (35-06-127.81)	3.09 (1.73-6.30)
		E _r C ₁₀	40.58 (22.73-82.88)	2.00 (1.12-4.09)
		E _y C ₅₀	53.29 (46.35-61.28)	2.63 (2.29-3.02)
		E _y C ₂₀	22.76 (19.79-26.17)	1.12 (0.98-1.29)
		E _y C ₁₀	14.59 (12.69-16.77)	0.72 (0.63-0.83)
		LOEC	10	0.49
		NOEC	<10	<0.49
	Note: 1) E _r C refers to growth rate, E _y C refers to yield. 2) Range mentioned after EC value refers to 95% fiducial limits.			

Reference: KCP 10.2.1-02

Report “Deltamethrin 5% CS: Alga, Growth Inhibition Test with *Raphidocelis subcapitata* (Formerly *Pseudokirchneriella subcapitata*”, XXX XXX XXX XXX (2020), Report No. G13392. Eurofins Advinus Limited

Guideline(s): OECD Guideline No. 201 (2006)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The effect of Deltamethrin 5% CS was tested on the growth of freshwater unicellular green alga *Raphidocelis subcapitata* (formerly *Pseudokirchneriella subcapitata*) for 72 hours.

Range finding test was conducted to select the test concentrations for the definitive test with a negative control and test item concentrations at 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 mg/L. Each group had single replicate.

The alga was exposed to the test item at the test concentrations of 10, 25, 63, 158 and 395 mg/L along with a negative control. Six replicates were maintained for the negative control and three replicates for the test concentrations. The initial cell density of algal cells at the start of exposure was 1×10^4 /mL. the cell growth was measured at 24, 48 and 72 hours after the initiation of the test using a haemocytometer (microscopic observation).

The test item was recoverable at the concentrations of 0.001004 and 502.0 mg/L in the vehicle. The active ingredient concentration analysis in all test concentration showed that the recovery with the nominal concentration was from 93.19 to 103.19 at the start of the test (RSD was 0.24 to 4.11%), 95.25 to 100.57% at 24 hour (RSD was 0.18 to 3.31%), 90.78 to 96.45% at 48 hour (RSD was 1.09 to 4.25%) and 90.16 to 103.59% at the end of the test (72 hour) (RSD was 2.12 to 10.11%) indicating that the results were within the acceptable limit (80% to 120% of the nominal concentration with an RSD of $\leq 20\%$).

Results

Preliminary test

The test item exhibited 0, 0.25, 0.49, 0.49, 0.82, 2.49 and 16.53% cell reduction at the tested concentrations of 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 mg/L.

Table 10.2.1-03.1 Average cell biomass, preliminary test (non-GLP)

Nominal test item concentration [mg/L]	Average cell counts ($\times 10^4$ cells/mL)				% Reduction at end of test
	0 h	24 h	48 h	72 h	
Control	1	6.75	26.25	73.00	—
0.0001	1	6.25	25.00	73.50	-0.15*
0.001	1	6.50	21.00	71.25	0.25
0.01	1	7.25	21.25	70.50	0.49
0.1	1	6.00	17.75	70.50	0.49
1	1	5.75	13.00	69.75	0.82
10	1	2.75	8.75	64.75	2.49
100	1	2.75	8.50	35.50	16.53

* to be considered as 0

Definitive test

At the end of the test (72 hours), the cell biomass in the test item solutions decreased with the increase in test concentration.

At test concentration of 10, 25, 63, 158 and 395 mg/L, the observed inhibition in the percent growth rate of algal biomass was 1.16, 7.01, 16.57, 40.77 and 100% and the percent yield inhibition was 5.00, 26.73, 51.12, 84.19 and 100% respectively when compared to that of the negative control during the test period.

Table X.2 Growth rate and yield inhibition, definitive test

Nominal test item concentration [mg/L]	% inhibition after 72 h of expo- sure (growth rate)	% inhibition after 72 h of expo- sure (yield)
Control	—	—
10	1.16	5.00
25	7.01	26.73
63	16.57	52.12
158	40.77	84.19
395	100	101.29*

* To be considered as 100

Validity criteria

In the definitive test, the following validity criteria specified in OECD Guideline No. 201 (2006) were met:

- There was an increase in cell concentration of the negative control culture by a factor of 78.46 which is more than the required factor limit of at least 16 at the end of the test.
- The mean coefficient of variation for section by section specific growth rates in the negative control cultures during the course of the test was 26.44 % which is within the required limit of 35%.
- The coefficient of variation of average growth rate between replicate cultures of negative control was 0.19% which is within the required limit of 7 %.

Conclusion

The endpoint values determined for growth rate and yield at 24, 38 and 72 hours are presented below based on nominal concentration.

Observations		EC values (mg test item/L)	EC values (mg Deltamethrin/L)
24 hours	E _r C ₅₀	148.79 (88.21-282.26)	7.33 (4.32-13.92)
	E _r C ₂₀	66.37 (39.35-125.91)	3.27 (1.94-6.21)
	E _r C ₁₀	43.52 (25.80-82.56)	2.15 (1.27-4.07)
	E _y C ₅₀	99.19 (86.63-113.57)	4.89 (4.72-5.60)
	E _y C ₂₀	41.94 (36.63-48.02)	2.07 (1.81-2.37)
	E _y C ₁₀	26.74 (23.36-30.62)	1.32 (1.15-1.51)
	LOEC	63	3.11
	NOEC	25	1.23

48 hours	E _r C ₅₀	166.01 (72.80-612.02)	8.18 (3.59-30.18)
	E _r C ₂₀	73.02 (32.02-269.20)	3.60 (1.58-13.27)
	E _r C ₁₀	47.53 (20.84-175.23)	2.34 (1.03-8.64)
	E _y C ₅₀	92.10 (53.01-165.03)	4.54 (2.62-8.14)
	E _y C ₂₀	36.56 (21.04-65.51)	1.80 (1.04-3.23)
	E _y C ₁₀	22.56 (12.98-40.42)	1.11 (0.64-1.99)
	LOEC	64	3.11
	NOEC	25	1.23
72 hours	E _r C ₅₀	143.33 (80.29-292.73)	7.07 (3.96-14.43)
	E _r C ₂₀	62.58 (35.06-127.81)	3.09 (1.73-6.30)
	E _r C ₁₀	40.58 (22.73-82.88)	2.00 (1.12-4.09)
	E _y C ₅₀	53.29 (46.35-61.28)	2.63 (2.29-3.02)
	E _y C ₂₀	22.76 (19.79-26.17)	1.12 (0.98-1.29)
	E _y C ₁₀	14.59 (12.69-16.77)	0.72 (0.63-0.83)
	LOEC	10	0.49
	NOEC	<10	<0.49

Note: 1) E_rC refers to growth rate, E_yC refers to yield.
 2) Range mentioned after EC value refers to 95% fiducial limits.

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids. The dissolved oxygen concentration at the end of the test was more than ≥ 3 mg/L in negative control and other test vessels. <p>Agreed endpoints:</p> <p>The 48 h EC₅₀ for Deltamethrin 5% CS = 0.0044 mg test item/L or 0.00022 mg Deltamethrin/L</p>
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Reference: KCP 10.2.1-03

Report "Deltamethrin 5% CS: *Daphnia magna*, Acute Immobilization Test", XXX XXX XXX XXX (2020), Report No. G13393. Eurofins Advinus Limited

Guideline(s): OECD Guideline No. 202 (2004)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) Not relevant

Materials and methods

The acute immobilization effect of the test item Deltamethrin 5% CS was studied on *Daphnia magna* for 48 hours.

Neonates of *Daphnia* were tested for immobility in test concentrations of Deltamethrin 5% CS at 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 mg/L along with a negative control.

In definitive test, *Daphnia magna* less than 24 hours old were exposed to the nominal concentrations of

0.003, 0.009, 0.019, 0.043, 0.094 0.21, 0.45 and 1.0 mg/L along with a negative control. Four replicates were maintained for both negative control and test concentrations. The number of daphnia immobilized was recorded at 24 and 48 hours exposure.

All the test concentrations along with the negative control were analysed for the test item concentration at the beginning and end of test. For analysis, single composite sample was drawn from prepared test concentrations. Analysis was conducted using a validated analytical method in Analytical R & D Department of Eurofins Advinus Limited. The stability test results concluded that the test item was stable in the test medium at 97 h at 0.001006 and 50.30 mg/L nominal concentrations. The active ingredient concentration analysis in all test concentrations showed that the percent agreement with claimed concentration was in the range of 86.71 to 105.09% (RSD was 0.35 to 7.57%) at the start of the test and 81.61 to 119.47% at the end of the test (48 hour) (RSD was 1.17 to 15.16%) indicating that the results were within the acceptable limit (80 to 120% of the claimed concentration with an RDS of $\leq 20\%$).

Results

Preliminary test

In the preliminary test there was no immobility of the daphnids observed at the tested concentrations of 0.0001, 0.001 mg/L and in the negative control at 24 and 48 hour exposure.

There was 50, 60, 70, 90 and 100% at 24 hour and 60, 70, 100, 100 and 100% immobility of the daphnia observed at 48 hour at the tested concentrations of 0.01, 0.1, 1, 10 and 100 mg/L.

Definitive test

In the definitive test there was no immobility of daphnia in the negative control and at the tested concentration of 0.004 mg/L and at 24 and 48 hour exposure. The immobilization of daphnia was 50, 60, 75, 80, 85, 90 and 100% at 48 h exposure at 0.009, 0.019, 0.043, 0.094, 0.21, 0.45 and 1.0 mg/L.

Table 10.2.1-02-01 Immobilization of *Daphnia magna*, definitive test

Treatment [mg/L]	Number of <i>Daphnia</i> immobilized (5 <i>Daphnia</i> per replicate)								% Immobilization	
	24 h				48 h					
	Replicates								24 h	48 h
	R1	R2	R3	R4	R1	R2	R3	R4		
Negative control	0	0	0	0	0	0	0	0	0	0
0.004	0	0	0	0	0	0	0	0	0	0
0.009	2	3	3	2	3	4	3	2	50	60*
0.019	3	3	4	2	4	3	4	3	60	70*
0.043	4	3	3	3	4	3	4	4	65	75*
0.094	4	4	4	2	4	5	4	3	70	80*
0.21	4	2	4	5	4	4	4	5	75	85*
0.45	4	3	3	5	5	4	5	4	75	90*
1.0	5	4	5	2	5	5	5	5	80	100*

*Statistically significantly higher compared to the control group (Cochran-Armitage test one sided greater, $\alpha=0.05$)

Validity criteria

In the definitive test the validity criteria were met according to OECD Guideline No. 202 (2004):

- There was no immobilization of daphnia in the negative control during the test period, which is within the allowed 10 percent immobilization of daphnids.
- The dissolved oxygen concentration at the end of the test was more than ≥ 3 mg/L in negative control and other test vessels.

Conclusion

The EC₅₀ value for Deltamethrin 5% CS at 24 hours was 0.01 mg test item/L or 0.00049 mg Deltame-

thrin/L with fiducial limits at 95 percent being 0 to 0.027 mg/L based on nominal concentrations. The EC₅₀ value for Deltamethrin 5% CS at 48 hours was 0.0044 mg test item/L or 0.00022 mg Deltamethrin/L with fiducial limits at 95 percent being 0.00086 to 0.02233 mg/L based on nominal concentrations.

On the basis of the observations made during this test, the LOEC (Lowest Observed Effect Concentration) was 0.0004 mg test item/L or 0.0002 mg Deltamethrin/L.

On the basis of the observations made during this test, the NOEC (No Observed Effect Concentration) was 0.004 mg test item/L or 0.0002 mg Deltamethrin/L.

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> No mortality was observed in control and is within the specified 10 per cent limit at the end of the test. The LD₅₀ of the positive control, Dimethoate at 24 and 48 hours was 0.13 µg a.i./bee, which met the reported range of 0.10 to 0.35 µg a.i./bee. <p>The absence of adverse effects with the test item (up to 100 µg/bee) suggests a large discrepancy compared to the studies reported in the monograph and in the list of endpoints (showing that the active substance is dangerous to bees).</p> <p>Agreed endpoints:</p> <p>The 48 h LD₅₀ for Deltamethrin 5% CS > 100 µg a.i./bee.</p>
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Reference: KCP 10.3.1.1.1

Report “Deltamethrin 5% CS: Acute Oral Toxicity Test in Honey Bees”. B.V. XXX, 2018, G13394. Eurofins Advinus Limited

Guideline(s): Yes, OECD Guideline No. 213 (1998)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication Yes

(if vertebrate study)

Materials and methods

Test item:

Description: Deltamethrin 5% CS
Production batch: SCL - 89521
A.i. content: Deltamethrin 50.71 g/L

Test system:

Species: *Apis mellifera*
Strain: -
Age: Active adult foraging workers
Average weight: -
Average length: -
Source: A colony maintained at Eurofins Advinus Limited, India
Acclimation period: -
Diet: 50% (w/v) aqueous sucrose solution

Experimental conditions:

Temperature: 23 – 25°C
Humidity: 62 – 66%
Hardness: -
pH: -
Light and photoperiod: 24h darkness (except during observations).
Loading: -
Test procedure: For the oral toxicity test, the test substance was added to a 50% w/v sucrose solution reaching the concentration of 100 µg a.i./bee. Feeders were filled with the dilution. Bees were kept unfed for approximately 2 hours. The bees were then fed for 4 hours and observed on a period of 48 hours.

Experimental period: 48h

Test design and treatment

Stainless steel cages with an opening on each side to allow the feeding with glass tubes. The bees were observed for mortality and behavioural abnormalities after 4, 24 and 48 h of exposure.

A preliminary test was conducted with doses of 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 µg of a.i./bee. According to the results, the following nominal test item concentrations were used: 6.25, 12.5, 25.0, 50.0 and 100.0 µg a.i./bee in the oral test.

The mortality data was analysed with the statistical method of Probit analysis using an in-house developed and validated computer program. The dose response curves were plotted and the LD₅₀ calculation was calculated using a validated computer program.

Results

The condition of the test system was observed at 4, 24 and 48 hours after treatment. The following tables show the mortality/treatment group of the honeybees.

Oral toxicity test results

Dosage	Number of bees tested	Mortality after 48 h		LD ₅₀ after 48 h
Active ingredient [µg/bee]		no.	%	Active ingredient [µg/bee]

Control	30	0	0.0	Above 100.0
6.25	30	0	0.0	
12.5	30	0	0.0	
25.0	30	0	0.0	
50.0	30	0	0.0	
100.0	30	0	0.0	

Conclusion

There was no mortality and behavioural changes of bees observed in the control group during 4, 24 and 48 hours post treatment.

There was no mortality and behavioural changes of bees observed at the tested concentrations of 6.25, 12.5, 25.0, 50.0 and 100.0 µg a.i./bee at 4, 24 and 48 hours post treatment.

The percent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 13.33, 26.67 and 30.0 at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee respectively. The percent mortalities at 24 h and 48 h post treatment were 16.67, 66.67 and 86.67 % at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee respectively.

The LD₅₀ value of the test item, Deltamethrin 5% CS at 48 h is higher than 100 µg a.i./bee.

The LD₅₀ value of toxic standard, Dimethoate at 24 h and 48 h was 0.13 µg a.i./bee with fiducial limits at 95% ranging from 0.108 to 0.160 µg a.i./bee.

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> There was no mortality in control and is within the specified 10 per cent limit at the end of the test. The LD₅₀ of the positive control, Dimethoate at 24 hours was 0.13 µg a.i./bee, which met the reported range of 0.10 to 0.30 µg a.i./bee. <p>The absence of adverse effects with the test item (up to 100 µg/bee) suggests a large discrepancy compared to the studies reported in the monograph and in the list of endpoints (showing that the active substance is dangerous to bees).</p> <p>Agreed endpoints:</p> <p>The 48 h LD₅₀ for Deltamethrin 5% CS =0.13 µg a.i./bee</p>
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Reference: KCP 10.3.1.1.2

Report “Deltamethrin 5% CS: Acute Contact Toxicity Test in Honey Bees”. B.V. XXX, 2018, G13395. Eurofins Advinus Limited

Guideline(s): Yes, OECD Guideline No. 214 (1998)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item:

Description: Deltamethrin 5% CS
Production batch: SCL - 89521
A.i. content: Deltamethrin 50.71g/L

Test system:

Species: *Apis mellifera*
Strain:
Age: Active adult foraging workers
Average weight: -
Average length: -
Source: A colony maintained at Eurofins Advinus Limited, India
Acclimation period: 20 hours
Diet: 50% (v/v) honey and sugar solution

Experimental conditions:

Temperature: 23.4 – 24.9°C
Humidity: 60 – 62%
Hardness: -
pH: -
Light and photoperiod: 24h darkness (except during observations).
Loading: -
Test procedure: The honeybees were anaesthetized with carbon dioxide, transferred to plastic trays and dosed on the dorsal side of the thorax with 1 µl of test solution containing the test substance or reference substance.

Experimental period: 48h

Test design and treatment

Stainless steel cages with an opening on each side to allow the feeding with glass tubes.

A preliminary test was done at the dose of 0.0001, 0.001, 0.01, 0.1, 1, 10 and 100 µg a.i./bee. According to the results, the following nominal test item concentrations were used: 6.25, 12.5, 25, 50 and 100 µg a.i./bee. The honeybees were observed for mortality and behavioural abnormalities after 4, 24 and 48 h of exposure.

The mortality data was analysed with the statistical method of Probit analysis using an in-house developed and validated computer program. The dose response curves were plotted and the LD₅₀ calculation was calculated using a validated computer program.

Results

The condition of the test system was observed at 4, 24 and 48 hours after treatment. The following tables show the mortality/treatment group of the honeybees.

Contact toxicity test results

Dosage	Number of bees tested	Mortality after 48 h		LD ₅₀ after 48 h
Active ingredient [µg/bee]		no.	%	Active ingredient [µg/bee]
Control	30	0	0.0	0.13 (0.109 – 0.152)
6.15	30	0	0.0	
12.5	30	0	0.0	
25.0	30	0	0.0	
50.0	30	0	0.0	
100.0	30	0	0.0	

Conclusion

There was no mortality and behavioural changes of bees observed in the control group during 4, 24 and 48 hours post treatment.

There was no mortality and behavioural changes of bees at the tested concentrations of 6.25, 12.5, 25.0, 50 and 100 µg/bee during 4, 24 and 48 hours post treatment.

The percent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 16.67, 23.33 and 40.0 at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee respectively. The percent mortalities at 24 h and 48 h post treatment were 20.0, 53.33 and 100.0% respectively.

The LD₅₀ value of the test item, Deltamethrin 5% CS at 24 h and 48 h was 0.13 µg a.i./bee with fiducial limits at 95% ranging from 0.109 to 0.152 µg a.i./bee.

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

Comments of zRMS:	<p>The study was considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> The mean mortality in the control was ≤ 15 % at the end of the test (actual 0.00 % for control). The mean mortality in the reference item group was ≥50 % at the end of the test (actual 70 %) Reference substance study: the mortality of reference substance 0.8 mg a.i./kg was found to be 70% between the stipulated range of 0.5 – 1.0 mg a.i./kg for 10 days exposure on <i>Apis mellifera</i>. <p>Agreed endpoints:</p> <p>LD₅₀ of Deltamethrin 5% CS = 0.64 ± 0.048 µg/bee, which is equivalent to 0.030 µg deltamethrin/bee.</p> <p>LC₅₀ = 31.78 ± 2.40 mg/kg food which is equivalent to 1.57 mg deltamethrin/kg food.</p> <p>Based on feed consumption (test item intake) LDD₅₀ = 0.68 ± 0.02 µg/bee which is equivalent to 0.03 µg deltamethrin/bee.</p> <p>The NOEC = 14.81 mg/kg which is equivalent to 0.73 mg deltamethrin/kg. NOEDD = 0.38 µg/bee = 0.02 µg deltamethrin/bee.</p>
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Reference:

KCP 10.3.1.2-01

Report

“Chronic Oral Toxicity Study of Deltamethrin 5% CS on adult honey bee (*Apis mellifera*)”, K. XXX, 2021, Study code 7969/2020. Bioscience Research Foundation

Guideline(s):	Yes, OECD Guideline No. 245.
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The aim of the study was to determine the effects of the test item Deltamethrin 5% CS (Batch SCL-12589) on the honey bee *Apis mellifera* L. from chronic feeding exposure, the median Lethal Concentration (LC₅₀) and the median Lethal Dietary Dose (LDD₅₀) after 10 days of exposure, as well as the No Observed Effect Concentration and the No Observed Effect Dietary Dose (NOEC/NOEDD) were determined.

The test species was honey bee (*Apis mellifera* L.), young adult bees (not older than 48 hours) originating from commercial bee hive maintained at BRF test facility.

The test was conducted as a dose-response test with an exposure phase duration of 10 days. The test concentrations were: 1 control group, 5 test item group 0.20, 0.30, 0.44, 0.67 and 1.00 µg/bee/day concentrations in 50% w/v sucrose solution, corresponding to daily doses of 9.88, 14.81, 22.22, 33.33 and 50.00 mg/kg food; 1 reference item group with 0.8 mg/kg food. Three replicates of 10 bees each were used for each group. Mortality and behavioural abnormalities were assessed daily over the 10 days test period. Control groups and treated groups were exposed concurrently to identical conditions.

The test conditions were: Air temperature: Min / Max: 31.7 – 32.9 °C, Relative air humidity: Min / Max: 52 % - 63 % RH, Exposure to light: Constant darkness except during the observations.

Results and discussions

Table 1: Cumulative mortality, overall mean consumption of feeding solution, dietary dose (DD), accumulated mean uptake, NOEC, NOEDD, LC₅₀ and LDD₅₀

Initial		Consumed		No. of tested bees	Mortality		LC ₅₀	LDD ₅₀
Concentration	Dose	Concentration	Dose		Total			
[mg/kg of food]	[µg/20 mg/bee day]	[mg/kg of food]	[µg/bee/day]		No. of bees [%]			
Deltamethrin 5% CS								
	0.0 control			30	0	0.00	31.78 ± 2.40	0.68 ± 0.02
9.88	0.20	9.88	0.27	30	2	6.67		
14.81	0.30	14.81	0.38	30	3	10.00		
22.22	0.44	22.22	0.54	30	5	16.67		
33.33	0.67	33.33	0.77	30	13	43.33		
50.00	1.00	50.00	0.80	30	27	90.00		
Dimethoate								
0.8	0.016	0.8	0.012	30	21	70	Not determined	
Deltamethrin 5% CS	NOEC [mg/kg]				14.81			
	NOEDD [µg/bee/day]				0.38			

Findings:

- The maximum mortality which was observed in the highest test item treatment concentration, 50 mg/kg feeding solution was 90% after 10 days.
- At the concentrations of 9.88, 14.81, 22.22, 33.33 and 50.00 mg/kg feeding solution 6.67, 10.00, 16.67, 43.33 and 90.00% mortality was observed.

- The **NOEC** for mortality after 10 days of continuous exposure was determined to be 14.81 mg/kg feeding solution. The corresponding **NOEDD**, based on the actual consumption of the feeding solutions, was determined to be 0.38 µg/bee/day.
- After 10 days of continuous exposure, the **LC₅₀** with 95 % confidence intervals was determined to be 31.78 ± 2.40 mg/kg feeding solution. The corresponding **LDD₅₀** with 95 % confidence intervals, based on the actual consumption of the feeding solutions, was determined to be 0.68 ± 0.02 µg/bee/day.

The following validity criteria were met during the test:

- The mean mortality in the control was ≤ 15 % at the end of the test (actual 0.00 % for control).
- The mean mortality in the reference item group was ≥ 50 % at the end of the test (actual 70 %).

Conclusion

Based on the experimental results, the **LD₅₀** of Deltamethrin 5% CS was 0.64 ± 0.048 µg/bee, which is equivalent to 0.030 µg deltamethrin/bee.

LC₅₀ was determined as 31.78 ± 2.40 mg/kg food which is equivalent to 1.57 mg deltamethrin/kg food.

Based on feed consumption (test item intake) **LDD₅₀** was calculated to be 0.68 ± 0.02 µg/bee which is equivalent to 0.03 µg deltamethrin/bee.

The **NOEC** was determined as 14.81 mg/kg which is equivalent to 0.73 mg deltamethrin/kg.

NOEDD was determined as 0.38 µg/bee which is equivalent to 0.02 µg deltamethrin/bee.

Reference substance study: the mortality of reference substance 0.8 mg a.i./kg was found to be 70% between the stipulated range of 0.5 – 1.0 mg a.i./kg for 10 days exposure on *Apis mellifera*.

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Comments of zRMS:	<p>The study was considered valid. All validity criteria were met.</p> <ul style="list-style-type: none"> • Larval mortality in the controls: ≤ 15% for larvae across all control replicates (between D3 and D8 – 0% and 2.78%. • Adult emergence rate: ≥ 70% for bees across all control replicates (between D3 and D22) – 91.67%. • Larval mortality in the reference item: ≥ 50% for larvae exposed to 7.39 µg/larva across all reference replicates (between D3 and D8 – 87.88% on D8). <p>Agreed endpoints:</p> <p>ED₅₀ (successful adult emergence up to D22) = 0.10 µg/larva (i.e., 0.0049 µg deltamethrin/larva), which is equivalent to an EC₅₀ of 0.65 mg/kg food (i.e., 0.0320 mg deltamethrin/kg food).</p> <p>ED₁₀ = 0.52 µg/larva (i.e., 0.0256 µg deltamethrin/larva), which is equivalent to an EC₁₀ of 3.3 mg/kg food (i.e., 0.1626 mg deltamethrin/kg food).</p> <p>ED₂₀ = 0.29 µg/larva (i.e., 0.0143 µg deltamethrin/larva), which is equivalent to an EC₂₀ of 1.9 mg/kg (i.e., 0.0936 mg deltamethrin/kg food).</p>
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	The NOED was 0.03 µg/larva (i.e., 0.0015 µg/delta
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Reference: KCP 10.3.1.3-01

Report “Effect of Deltamethrin 5% CS on larvae of honey bee, *Apis mellifera* (L.) following repeated exposure”, K. XXX, 2021, Study code 7970/2020. Bioscience Research Foundation.

Guideline(s): Yes, Guidance Document on Honey Bee Larval Toxicity Test Following Repeated Exposure, Series on Testing and Assessment, No. 239, OECD (2016).

Deviations: No

GLP: Yes

Acceptability: Yes

Materials and methods

The purpose of this study was to determine the chronic toxicity (e.g., ED₅₀, EC₅₀, NOED and NOEC, adult emergence up to day 22) of Deltamethrin 5% CS (Batch number: SCL-12589) applied to the honey bee, *Apis mellifera* L strain: carnica, larvae in an *in vitro* test after repeated oral diet administration.

The test species was honey bee (*Apis mellifera* L.), synchronized first instar (L1) larvae originating from bee hive maintained at BRF test facility.

The test was carried out under laboratory conditions, honeybee larvae by repeatedly exposed (22 days) to Deltamethrin 5% CS. Based on the results of range finding study the toxicity of the Deltamethrin 5% CS was determined at doses of 0.03, 0.06, 0.13, 0.25 and 0.50 µg/larva.

The concentration of test item in the diet was 0.20, 0.41, 0.81, 1.63 and 3.25 mg/kg food. Additionally, honeybee larvae were treated with Dimethoate technical as reference item at a dose of 7.39 µg dimethoate/larva (test concentration 48 mg/kg) of diet and with an untreated diet as control.

One day old honeybee larvae (D1) of *Apis mellifera* L (first instar) were transferred from brood combs to polystyrene grafting cells in 48-well cell culture plates before start of the treatment (3 days). On 4 successive days (D3 to D6) the larvae were repeatedly exposed to Deltamethrin 5% CS diluted in the larval food (aqueous sugar solution mixed with royal jelly). After the applications no additional feedings provided to the larvae.

The test carried out with 5 treatment groups were as: 5 dose of the test item, 1 untreated control group and 1 dose of the reference item with 3 replicates per dose and 12 larvae per replicate.

Assessments of cumulated larval mortality were done on days (D4, D5, D6, D7 and D8). Additionally, other observations were reported on D8 such as small body size or large quantities of remaining food. Pupal mortality was assessed at D15 and emergence of adults was evaluated at D22 respectively.

The concentration of the active substance in the test item solution and in the control was determined by analytical verification.

Results and discussion

Table 1: Toxicity of test item to larvae of *Apis mellifera* L.

Treatment group	Test solution (ID)	Dose [$\mu\text{g}/\text{larva}$]	Conc. [$\text{mg}/\text{kg food}$]	On D ₈			On D ₁₅		On D ₂₂		
				Larval mortality D3 to D8		Mean OO	Pupae stage D8 to D15		Total mortality D3-D22		Adult emergence rate %
				mor. (%)	corr. (%)	(%)	mor. (%)	corr. (%)	mor. (%)	corr. (%)	(%)
Control	A1	–	–	2.78	–	0	2.78	0	8.33	0	91.67
Test Item	T1	0.03	0.20	8.33	5.71	0	2.78	0.00	22.22	15.15	77.78
	T2	0.06	0.41	11.11	8.57	0	5.56	2.86	30.56	24.24	69.44
	T3	0.13	0.81	19.44	17.14	0	11.11	8.57	52.78	48.48	47.22
	T4	0.25	1.63	38.89	37.14	0	25.00	22.86	77.78	75.76	22.22
	T5	0.5	3.25	47.22	45.71	0	30.56	28.57	91.67	90.91	8.33
Ref. Item	R1	7.39	48	52.78	51.43	0	16.67	14.29	88.89	87.88	11.11

Note: D-Day, Mor- Mortality, corr.-Corrected Mortality, OO-Other observation

Results are averages based on 3 replicates, containing 12 larvae each

corr.: corrected mortality (according to SCHNEIDER-ORELLI 1947); reference item was corrected by A1 and test item was corrected by A2;

negative values are set to "0"; calculations are performed with non-rounded values; CL.: confidence limit

OO: Other observations (e.g. remaining food)

1 Average% of pupal mortality was calculated according to the following formula:

Sum of dead between D8 and D22 / Sum of living larvae on D8 x 100%

2 Adult emergence [%] = 100 [%] – Mortality of D22 [%]

Table 2: Endpoint values

Treatment	Endpoint	Up to D22
		Value based on nominal dose
Test item doses	ED ₁₀ [$\mu\text{g}/\text{larva}$] (95% CL)	0.52 (0.0256 $\mu\text{g a.i.}/\text{larva}$)
	ED ₂₀ [$\mu\text{g}/\text{larva}$] (95% CL)	0.29 (0.0143 $\mu\text{g a.i.}/\text{larva}$)
	ED ₅₀ [$\mu\text{g}/\text{larva}$] (95% CL)	0.10 (0.0049 $\mu\text{g a.i.}/\text{larva}$)
	NOED [$\mu\text{g}/\text{larva}$]	0.03 (0.0015 $\mu\text{g a.i.}/\text{larva}$)
Test item concentrations	ED ₁₀ [$\text{mg}/\text{kg food}$] (95% CL)	3.3 (0.1626 $\text{mg a.i.}/\text{kg}$)
	ED ₂₀ [$\text{mg}/\text{kg food}$] (95% CL)	1.9 (0.0936 $\text{mg a.i.}/\text{kg}$)
	ED ₅₀ [$\text{mg}/\text{kg food}$] (95% CL)	0.65 (0.0320 $\text{mg a.i.}/\text{kg}$)
	NOED [$\text{mg}/\text{kg food}$]	0.20 (0.0099 $\text{mg a.i.}/\text{kg}$)

The following **validity criteria** were met during the test:

- Larval mortality in the controls: $\leq 15\%$ for larvae across all control replicates (between D3 and D8 – 0% and 2.78%.
- Adult emergence rate: $\geq 70\%$ for bees across all control replicates (between D3 and D22) – 91.67%.
- Larval mortality in the reference item: $\geq 50\%$ for larvae exposed to 7.39 $\mu\text{g}/\text{larva}$ across all reference replicates (between D3 and D8 – 87.88% on D8).

Conclusion

In a repeated exposure larval toxicity study with Deltamethrin 5% CS, the ED₅₀ (successful adult emergence up to D22) was calculated to be 0.10 $\mu\text{g}/\text{larva}$ (i.e., 0.0049 μg deltamethrin/larva), which is equivalent to an EC₅₀ of 0.65 $\text{mg}/\text{kg food}$ (i.e., 0.0320 mg deltamethrin/kg food).

ED₁₀ was calculated to be 0.52 $\mu\text{g}/\text{larva}$ (i.e., 0.0256 μg deltamethrin/larva), which is equivalent to an

EC₁₀ of 3.3 mg/kg food (i.e., 0.1626 mg deltamethrin/kg food).

ED₂₀ was calculated to be 0.29 µg/larva (i.e., 0.0143 µg deltamethrin/larva), which is equivalent to an EC₂₀ of 1.9 mg/kg (i.e., 0.0936 mg deltamethrin/kg food).

The NOED was 0.03 µg/larva (i.e., 0.0015 µg/deltamethrin/larva) and the corresponding NOEC was 0.20 mg/kg food (i.e., 0.0099 mg deltamethrin/kg food).

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.3.2 KCP 10.3.2 Effects on non-target arthropods other than bees

A 2.3.2.1 KCP 10.3.2.1 Standard laboratory testing for non-target arthropods

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> - mean mortality rate did not exceed 20% in control after 7 days (actual value: 8%). - mean mortality rate (corrected for control) in the reference item was > 50% after 7 days (actual value: 96%). - cumulative mean number of eggs per female > 4 in the control (actual value: 5.21 eggs). <p>Agreed endpoints:</p> <p>The LR₅₀ = 0.002 g a.s/ha for Deltamethrin 2.5% EC (Poleci) and Decis 25 EC indicating that the toxicity of Deltamethrin 2.5% EC is similar to Decis 25 EC.</p> <p>For Deltamethrin 2.5% EC (Poleci) the LOER = 0.0016 g a.s/ha and for Decis = 0.00064 g a.s/ha.</p> <p>The NOER for Deltamethrin 2.5% EC (Poleci) is 0.00064 g a.s/ha and for Decis it is <0.00064 g a.s/ha.</p>
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Reference: KCP 10.3.2.1-01

Report "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 *Typhlodromus pyri* (Acari: Phytoseiidae)". XXX, E (2011), 34SRFR11C2. SynTech Research France S.A.S.

Guideline(s): Yes, Blümel, *et al* (2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Objective:

The study assessed the effects (mortality and fecundity) of fresh dried residues of both Deltamethrin 2.5% EC and Decis 25 EC on the predatory mite *Typhlodromus pyri* in a 7-day test under worst-case laboratory conditions (i.e. glass plates as substrate) according to the guidelines of Blümel *et al* (2000).

Material and method:

The test item rates were 0.00064, 0.0016, 0.004, 0.01 and 0.025 g as/ha. A control (deionized water) and a reference item (Dimethoate 400 g/L) were tested in parallel. Four replicates per test item treatment, control and reference item treatment were set up. Mortality values of the control as well as mortality values of the reference item treatment were within the study validity criteria.

Results:

Application rate (g as/ha)	Corrected Mortality (%)		Eggs/female		Fecundity effects (%)	
	POLECI deltamethrin 2.5%w/w)	DECIS deltamethrin 2.5%w/v)	POLECI deltamethrin 2.5%w/w)	DECIS deltamethrin 2.5%w/v)	POLECI deltamethrin 2.5%w/w)	DECIS deltamethrin 2.5%w/v)
0 (control)	0		5.21			
0.00064	3.26	31.52*	1.06*	1.26*	-79.64*	-75.75*
0.0016	48.91*	46.74*	1.05*	0.86*	-79.91*	-83.56*
0.004	88.04*	66.30*				
0.01	100*	100*				
0.025	100*	100*				
LR50 (g as/ha)	0.002	0.002				
LOER (g as/ha)	0.0016	0.00064				
NOER (g as/ha)	0.00064	<0.00064				

Poleci, 24.8 kg deltamethrin/kg), EC
Decis2.5 EC (25 g deltamethrin/l), EC

Conclusion:

The LR50 was calculated to be 0.002 g as/ha for Deltamethrin 2.5% EC and Decis 2.5 EC indicating that the toxicity of Deltamethrin 2.5% EC is similar to Decis 2.5 EC. For Deltamethrin 2.5% EC the LOER is 0.0016 g as/ha and for Decis 2.5 EC it is 0.00064 g as/ha. The NOER for Deltamethrin 2.5% EC is 0.00064 g as/ha and for Decis it is <0.00064 g as/ha.

Comments of zRMS	The study is considered acceptable. All validity criteria were met.
	<p>The mortality and fecundity phases of this study are valid, because:</p> <ul style="list-style-type: none"> - mean mortality rate did not exceed 13% in control after 48 hours (actual value: 0%). - mean mortality rate (corrected for control) in the reference item was > 75% after 48 hours (actual value: 92.5%). - cumulative mean number of mummies per female was > 5 in the control (actual value: 16.33 mummies), and fewer than 2 females produced no mummies in control (actual value: 0 female). <p>Agreed endpoints:</p> <p>The LR50 =0.019 g as/ha for Deltamethrin 2.5% EC (Poleci) and 0.029 g as/ha for Decis 25 EC.</p> <p>For both test items the LOER = 0.019 and the NOER <0.019, indicating that the toxicity of Deltamethrin 2.5% EC (poleci) is similar to Decis 25 EC.</p>

Reference:

KCP 10.3.2.1-02

Report “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 *Aphidius rhopalosiphi* (Hymenoptera: Braconidae)”. XXX, E (2011), 34SRFR11C1. SynTech Research France S.A.S.

Guideline(s): Yes, Mead-Briggs *et al* (2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Objective:

The study assessed the effects (mortality and fecundity) of fresh dried residues of both Deltamethrin 2.5% EC and Decis 25 EC on the parasitoid wasp *Aphidius rhopalosiphi* in a 48 hour test under worst-case laboratory conditions (i.e. glass plates as substrate) according to the guidelines of Mead-Briggs *et al* (2000).

Material and method:

The test item rates were 0.019, 0.061, 0.20, 0.68, 2.25 and 7.5 g as/ha. A control (deionized water) and a reference item (Dimethoate 400 g/L) were tested in parallel. Four replicates per test item treatment, control and reference item treatment were set up. Mortality values of the control as well as mortality values of the reference item treatment were within the study validity criteria.

Results:

Application rate (g as/ha)	Mortality (%)		Mummies/female		Fecundity effects (%)	
	POLECI deltamethrin 2.5%w/w	DECIS deltamethrin 2.5%w/v	POLECI deltamethrin 2.5%w/w	DECIS deltamethrin 2.5%w/v	POLECI deltamethrin 2.5%w/w	DECIS deltamethrin 2.5%w/v
0 (control)	0		16.33			
0.019	47.5*	25.0*	13.89	16.69	-14.97	+2.77
0.061	95.0*	92.5*				
0.20	97.5*	95.0*				
0.68	100*	100*				
2.25	100*	100*				
7.5	100*	100*				
LR50 (g as/ha)	0.019	0.029				
LOER (g as/ha)	0.019	0.019				
NOER (g as/ha)	<0.019	<0.019				

Poleci, 24.8 kg deltamethrin/kg), EC
Decis2.5 EC (25 g deltamethrin/l), EC

Conclusion:

The LR50 was calculated to be 0.019 g as/ha for Deltamethrin 2.5% EC and 0.029 g as/ha for Decis 25 EC. For both test items the LOER is 0.019 and the NOER is <0.019, indicating that the toxicity of Deltamethrin 2.5% EC is similar to Decis 25 EC.

A 2.3.2.2 KCP 10.3.2.2 Extended laboratory testing, aged residue with non-target arthropods

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
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	<ul style="list-style-type: none"> mortality of the control group was 0.0% on day 7 of exposure (criterion: a maximum of 20%) mortality of the mites exposed to the reference item at the rate of 5.0 mL/ha was 100.0% on day 7 of exposure (criterion: from 50 to 100%) the mean number of eggs per female in the control group was 4.01 (required: ≥ 4 eggs per female).
	<p>Agreed endpoints:</p> <p>The ER₅₀ >0.49 mL Deltamethrin 5% CS/ha, i.e. >25 mg Deltamethrin/ha</p> <p>The NOER_{reproduction} <0.19 mL Deltamethrin 5% CS/ha, i.e. <10 mg Deltamethrin/ha</p>

Reference:	KCP 10.3.2.2-01
Report	“An extended laboratory test or evaluating the effects of Deltamethrin 5% CS on the predatory mite, <i>Typhlodromus pyri</i> (Scheuten)”. Ms. P. XXX, 2019, 6035/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 Guidance Document (Barrett K.L. et al., 1994) ESCORT 2 Guidance Document (Candolfi M.P. et al., 2001) Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Blumel S. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	Not relevant

Materials and methods

An extended laboratory laboratory test for evaluating the effects of Deltamethrin 5% CS on mortality and reproduction of the predatory mite *T. pyri* (Scheuten) was carried out at the rates 0.19, 0.31, 0.49, 0.78 and 1.25 mL of the test item/ha. At 24 hours old (protonymphal stage) the predatory mites were exposed to the test item applied on bean leaf discs and fed with pine pollen (*Pinus* sp.) during the experimental period.

Mortality was observed after 7 days of post treatment of the test item. Observations of reproduction in the control and other groups treated with the test item were made after 8, 11 and 14 days post treatment of the test item.

Mortality of *T. pyri* was 7 days and reproduction reduction (Pr) after 14 days of the treatment were test endpoints.

To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide ROGOHIT (30% dimethoate, w/w) was used as a reference item. The rate of the reference item was 5.0 mL/ha (1.5 g dimethoate/ha). The control group was treated with distilled water.

Results

The effects of Deltamethrin 5% CS on mortality and reproduction of *Typhlodromus pyri* in the definitive test are summarized below.

Mortality and reproduction of *T. pyri* in the laboratory test

Study group (application rate) (test item mL/ha)	Parameter (endpoint)				
	Mortality		Fecundity		
	Total [%]	LR ₅₀	Mean no. of mummies/female (Rr) [No]	Reproduction reduction Pr [%]	ER ₅₀
mL test item/ha (g a.i./ha)		mL test item/ha (g a.i./ha)			
Control	0.0	-	4.01	-	-
Deltamethrin 5% CS					
0.19	3.3	0.55 mL/ha (27.89 mg a.i./ha)	3.27	18.49 ⁺	>0.49 mL/ha (>25 mg a.i./ha)
0.31	18.3		2.59	35.42 ⁺	
0.49	45.0		2.83	29.48 ⁺	
0.78	63.3		-*	-*	
1.25	95.0		-*	-*	
NOER _{mortality}		0.19 mL/ha (10 mg a.i./ha)	NOER _{reproduction}		<0.19 mL/ha (<10 mg a.i./ha)
ROGOHIT	Mortality after 7 days				
5.0 mL/ha	100%				

+: statistically insignificant differences at $p < 0.05$

*: the reproduction was not determined due to the mortality higher than 50% in comparison with the control group

Findings

- Mortality of the control group after 48 hours of exposure was 0.0%. After 7 days of exposure to Deltamethrin 5% CS at rates of 0.19, 0.31, 0.49, 0.78 and 1.25 mL test item/ha, the percentages of *T. pyri* mortalities were 3.3, 18.3, 45.0, 63.3 and 95.0% respectively. There were statistically significant differences in mortality between group treated with the test item at all rates of 0.31, 0.49, 0.78 and 1.25 mL test item/ha and the control group.
- On the basis of the obtained mortality results, the LR₅₀ value is equal to 0.55 mL Deltamethrin 5% CS/ha, i.e. 27.89 mg Deltamethrin/ha. The NOER_{mortality} value is equal to 0.19 mL Deltamethrin 5% CS/ha, i.e. 10 mg Deltamethrin/ha.
- For the reference item Rogorin (Dimethoate 30% EC, w/w), the mortality of wasps after 7 days of exposure at the rate of 5.0 mL/ha was 100%, hence the criterion specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.
- The mean reproduction rate (Rr) in the control group was 4.01 eggs/female. The mean reproduction rates (Rr) after 14 days of exposure to Deltamethrin 5% CS at rates of 0.19, 0.31 and 0.49 mL test item/ha was 3.27, 2.59 and 2.83 eggs/female respectively. The percentages of reproduction reduction (Pr) caused by rates of 0.19, 0.31 and 0.49 mL test item/ha was 18.49, 35.42 and 29.48 respectively. The reproduction rate at the rates of 0.78 and 1.25 mL/ha was not determined due to the mortality higher than 50% in comparison with the control group. There were statistically significant differences in fecundity between the group treated with Deltamethrin 5% CS at the rates of 0.19, 0.31 and 0.49 mL/ha and the control group.
- On the basis of the obtained fecundity results, the ER₅₀ value is equal to >0.49 mL Deltamethrin 5% CS/ha, i.e. >25 mg Deltamethrin/ha. The NOER_{reproduction} value is equal to <0.19 mL Deltamethrin 5% CS/ha, i.e. <10 mg Deltamethrin/ha.

Conclusion

On the basis of the obtained results it can be concluded that Deltamethrin 5% CS had adverse effects on mortality and reproduction of the predatory mite, *T. pyri* at all rates of 0.19, 0.31, 0.49, 0.78 and 1.25 mL test item/ha.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
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	<ul style="list-style-type: none"> • after 48 hours, mortality of the control group was 0.0% (criterion: a maximum of 10.0%), • after 48 hours, mortality of the group treated with the reference item at the rate of 5.0 mL/ha was 90% (criterion: a minimum of 50%), • all wasps survived the 24-hour oviposition period (criterion: only wasps that survive oviposition can be examined for fecundity), • the mean number of mummies per female in the control group was 26.9 (criterion: a minimum of 5.0 mummies/female), • all wasps in the control group gave offspring (criterion: a maximum of 2 females giving no offspring). <p>Agreed endpoints: LR₅₀=0.2 L/ha (10.14 g a.s./ha) ER₅₀<0.18 L/ha (9.13 g a.s./ha) NOER_{rep}< 0.18 L/ha (<9.13 g a.s./ha)</p>
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Reference: KCP 10.3.2.2-02

Report “A extended laboratory test for evaluating the effects of Deltamethrin 5% CS on the parasitic wasp *Aphidius rhopalosiphi* (De Stefani-Perez)”. Ms. G. XXX, 2019, 6034/2019. Bioscience Research Foundation

Guideline(s): ESCORT 1 Guidance Document (Barrett et al., 1994)
 ESCORT 2 Guidance Document (Candolfi M.P. et al., 2000)
 Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Mead-Briggs M.A. et al., 2000; Mead-Briggs M.A. et al., 2010)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication Not relevant
 (if vertebrate study)

Materials and methods

A laboratory test for evaluating the effects of Deltamethrin 5% CS on mortality and fecundity of *Aphidius rhopalosiphi* was carried out at the rates 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha. Adult female wasps were exposed to the test item applied to bean leafs.

Observations of settling behaviour were made during the initial 3 hours of exposure. The aims were to determine repellent effects of Deltamethrin 5% CS and to check if the test insects had contact with barley plants sprayed with the test item. Settling behaviour of females from each replicates was observed five times.

Mortality was determined 2, 24 and 48 hours after the release of the wasps to the test arenas.

Females which survived 48-hour exposure to test item and the ones from the control group were subjected to fecundity assessments. To allow the oviposition, fifteen female wasps from the groups treated with Deltamethrin 5% CS and the control group were individually introduced into fecundity units containing barley plants infested with the aphid *Rhopalosiphum padi*. After 24 hour oviposition, the wasps were removed from the test arenas and the number of mummies (parasitized aphids in which wasps in pupae were developing) was recorded after 12 days.

Mortality of the wasps after 48 hour of exposure and the percentage of fecundity reduction (Pr) 12 days after the oviposition were the endpoints.

To verify the sensitivity of the biological test system and the precision of the test procedure, the insecticide ROGOHITN (30% dimethoate, w/w) was used as a reference item. The rate of the reference item was 5.0 mL/ha (1.5 g dimethoate/ha). The control group was treated with distilled water.

Results

Results		Parameter (endpoint)			
Study group (application rate) [L/ha]	Mortality after 48h of exposure		Fecundity		
	Total [%]	LR ₅₀	Mean no. of mummies/female	Fecundity re- duction Pr [%]	ER ₅₀
		[g test ítem/ha] [g a.i./ha]			[g test ítem/ha] [g a.i./ha]
Control	0.0	-	36.9	-	-
Captan 80% WG-Deltametrin 5 CS					
0.18	40 ⁺	0.20 L/ha (10.14 ^a g a.i./ha)	12.2	54.6 ⁺	<0.18 L/ha (9.13 ^a g a.i./ha)
0.29	63.3 ⁺		8.5	68.4 ⁺	
0.47	100 ⁺		0.7	97.4 ⁺	
0.75	100 ⁺		0.1	99.6 ⁺	
1.20	100 ⁺		0.0	100 ⁺	
NOER _{mortality}		<0.18 L/ha (9.13 ^a g a.i./ha)	NOER _{reproduction}		<0.18 L/ha (9.13 ^a g a.i./ha)
Reference item [mL/ha]		ROGORITH			
5.0 mL/ha	90	-	-	-	-

+: statistically significant differences at p < 0.05

a: Deltamethrin 5% CS

The validity criterion for mortality was met, because mortality of the control group after 48 hours of exposure was 0.0% whereas mortality of the wasps after 48 hours of exposure to Deltamethrin 5% CS at rates of 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 40, 63.3, 100, 100 and 100% respectively.

There were statistically significant differences in mortality between group treated with the test item at rates of 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha and the control group.

On the basis of the obtained mortality results, the LR₅₀ value is 0.20 L/ha, i.e. 10.14 g Deltamethrin/ha. The NOER_{mortality} value is <0.18 L/ha, i.e. 9.13 g Deltamethrin/ha.

For the reference item Rogohit (Dimethoate 30% EC, w/w), the mortality of wasps after 24 hours of exposure at the rate of 5.0 mL/ha was 90%, hence the criterion specified in the method description was met.

The results showed that the test organisms were sensitive to dimethoate.

The fecundity assessment showed that the mean number of mummies per female in the control group was 26.9 whereas in the group treated with Deltamethrin 5% CS at rates of 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 12.2, 8.5, 0.7, 0.1 and 0.0 respectively.

Fecundity reduction (Pr) in the group treated with Deltamethrin 5% CS at rates of 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 54.6, 68.4, 97.4, 99.6 and 100% respectively. There were no statistically significant differences in fecundity between the group treated and the control group.

On the basis of the obtained fecundity results, the ER₅₀ value is <0.18 L/ha, i.e. 9.13 g Deltamethrin/ha. The NOER_{reproduction} value is <0.18/ha, i.e. 9.13 g Deltamethrin/ha.

Conclusion

On the basis of the obtained results, it can be concluded that Deltamethrin 5% CS has adverse effects on mortality and fecundity of *Aphidius rhopalosiphi* at rates of 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha.

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met.</p> <ul style="list-style-type: none"> mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted) in the control: 6.67% (a criterion: $\leq 20\%$, fecundity (mean number of eggs per female per day) in the control 37.70 (criterion: ≥ 15), fertility (mean hatching rate) in the control: 98.52% (criterion: $\geq 70\%$). mortality in the reference item treatment was 100% (criterion: $> 50\%$). <p>Agreed endpoint:</p> <p>ER₅₀ = 0.18 L Deltamethrin 5% CS/ha, i.e. 9.13 g Deltamethrin/ha NOER_{fecundity} > 0.07 L Deltamethrin 5% CS/ha, i.e. < 3.56 g Deltamethrin/ha</p>
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Reference: KCP 10.3.2.2-03

Report "A laboratory test for evaluating the effects of Deltamethrin 5% CS on larvae of the green lacewing *Chrysoperla carnea* (L.)". Dr. M. XXX, 2020, 6036/2019. Bioscience Research Foundation

Guideline(s): ESCORT 1 (Barrett K.L. *et al.*, 1994)
 ESCORT 2 (Candolfi M.P. *et al.*, 2000)
 Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Vogt H. *et al.*, 2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item: Deltamethrin 5% CS; Batch Number SCL-12589; active substance: deltamethrin 50.71 g/L

Test species: *Chrysoperla carnea* (L.), Neuroptera, Chrysopidae from the BFR insectary. The larvae used in the study were 2 – 3 days old.

Diet: *ad libitum*

Study design: Number of replicates: 30 replicates for mortality, 10 replicates for reproduction

Number of larvae: 1/replicate

Test duration: until pupation

The test item was applied with a laboratory track sprayer on bean plants at seven application rates. ROGOHIT (Dimethoate 30%) was used as reference item whereas deionised water was used as control. After treatment, the treated leaves were transferred to a reproduction unit.

Application rates: Control, 0.07, 0.11, 0.18, 0.29, 0.47, 0.75, 1.20 L of the test item/ha (3.56, 5.70, 9.13, 14.71, 23.83, 38.03, 60.85 g deltamethrin/ha)

Test conditions: Temperature: 24.0 – 27.0 °C; humidity: 63.0 – 80.0%; lighting: 16 h light : 8 h dark; light intensity: 1100 – 1800 lux

Statistical analysis: LR₅₀ and NOER for mortality and ER₅₀ and NOER for reproduction were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System)

and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.

Endpoints: LR₅₀, NOER
ER₅₀, NOER

Results and Conclusions

The effects of Deltamethrin 5% CS on mortality and fecundity of *Chrysoperla carnea* in the extended laboratory test are summarized below:

Study group (application rate) (L/ha)	Mortality		Reproduction			
	Total (%)	Corrected# (%)	Fecundity (No)	Fecundity reduction (%)	Fertility (%)	Fertility re- duction (%)
Control						
0.0	6.67	-	37.70	-	98.52	-
Deltamethrin 5% CS						
0.07	33.33	28.57	28.00	25.73+	97.54	0.99
0.11	40	35.71	21.40	43.24+	95.82	2.74
0.18	50	46.43	19.10	49.34+	95.40	3.14
0.29	60	57.14	15.20	59.68+	92.14	6.48+
0.47	70	67.86	12.30	67.37+	90.64	8.00+
0.75	83.33	82.14	8.60	77.19+	85.58	13.13+
1.20	100	100	0	100.00	0	100.00
LR50mortality	0.19 L/ha (0.18 – 0.20 L/ha) (9.63 g/ha*) (8.89 – 10.32 g/ha)		ER50fecundity	0.18 L/ha (0.17 – 0.19 L/ha) (9.13 g/ha*) (8.39 – 9.87 g/ha)		
NOERmortality	0.07 L/ha (3.56 g/ha*)		NOERfecundity	>0.07 L/ha (<3.56 g/ha*)		
Reference item – ROGOHIT (DIMETHOATE 30% EC)						
0.65	100	100	-	-	-	-

#: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

+ : statistically significant difference between the control and the treatment group at $p < 0.05$

*: Deltamethrin

The validity criterion for mortality was met, because mortality of the control group after 10 days of exposure was 6.67% (criterion: $\leq 20\%$), whereas corrected mortality of *C. carnea* after 10 days of exposure to Deltamethrin 5% CS at rates of 0.07, 0.11, 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 28.57, 35.71, 46.43, 57.14, 67.86, 82.14 and 100% respectively.

There were statistically significant differences in mortality between groups treated with the test item at all the rates used and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained mortality results, the LR₅₀ value is 0.19 L Deltamethrin 5% CS/ha, i.e. 9.63 g Deltamethrin/ha. The NOER_{mortality} value is 0.07 L Deltamethrin 5% CS/ha, i.e. 3.56 g Deltamethrin/ha. For the reference item Rogohit (Dimethoate 30% EC, w/w), the corrected mortality of *C. carnea* after exposure at the rate of 0.65 L/ha was 100%, hence the criterion ($>50\%$) specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.

The validity criterion for fecundity was met, because the mean number of eggs per female per day in the control group was 37.70 (criterion: ≥ 15), whereas in the group treated with Deltamethrin 5% CS at rates of 0.07, 0.11, 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 28, 21.40, 19.10, 15.20, 12.30, 8.60 and 0 respectively. Fecundity reduction in the group treated with Deltamethrin 5% CS at rates of 0.07, 0.11, 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 25.73, 43.24, 49.34, 59.68, 67.37, 77.19 and 100% respectively in comparison with the control group.

There were no statistically significant difference between groups treated with the test item at all the rates used and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained fecundity results, the ER_{50} value is 0.18 L Deltamethrin 5% CS/ha, i.e. 9.13 g Deltamethrin/ha. The $NOER_{fecundity}$ value is >0.07 L Deltamethrin 5% CS/ha, i.e. <3.56 g Deltamethrin/ha. The validity criterion for fecundity was met, because the mean hatching rate in the control group was 98.52 (criterion: $\geq 70\%$), whereas in the group treated with Deltamethrin 5% CS at rates of 0.07, 0.11, 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 97.54, 95.82, 95.40, 92.14, 90.64, 85.58 and 0 respectively. Fertility reduction in the group treated with Deltamethrin 5% CS at rates of 0.07, 0.11, 0.18, 0.29, 0.47, 0.75 and 1.20 L/ha was 0.99, 2.74, 3.17, 6.48, 8.00, 13.3 and 100% respectively in comparison with the control group.

There were no statistically significant difference between group treated with the test item at all the rates used and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained results, it can be concluded that Deltamethrin 5% CS had adverse effects on mortality and fecundity of *C.carnea* at all the rates used, i.e. 0.07 – 1.20 L/ha.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	<ul style="list-style-type: none"> The average mortality of the larvae in the control group was 2.5% or 1 larvae (criterion: less than 20%). The average mortality of the larvae in the reference group was 94.87% (criterion: 50–100%). The average number of viable eggs laid by the adult control ladybirds per day was 108.4 (criterion: ≥ 2 fertile eggs per viable female per day).
	<p>Agreed endpoints:</p> <p>$ER_{50} > 0.00078$ L Deltamethrin 5% CS/ha, i.e. >0.040 g Deltamethrin/ha</p> <p>$NOER_{fecundity} = 0.00031$ L Deltamethrin 5% CS/ha, i.e. 0.015 g Deltamethrin/ha</p>

Reference: KCP 10.3.2.2-04

Report “An extended laboratory test for evaluating the effects of Deltamethrin 5% CS on the ladybird beetle, *Coccinella septempunctata* (L.)”. Dr. V. XXX, 2020, 6037/2019. Bioscience Research Foundation

Guideline(s): ESCORT 1 (Barrett K.L. *et al.*, 1994)
ESCORT 2 (Candolfi M.P. *et al.*, 2000)
Guidelines developed by the IOBC, BART and EPPO Joint Initiative (Mead-Briggs M.A. *et al.*, 2000; Mead-Briggs M.A. *et al.*, 2010)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item: Deltamethrin 5% CS; Batch Number SCL-12589; active substance: deltamethrin 50.71 g/L

Test species: *Coccinella septempunctata* (L.), Coleoptera, *Coccinellidae* from the BFR insectary. The larvae used in the study were 4 days old.

Diet:	<i>ad libitum</i>
Study design:	Number of replicates: 4 Number of larvae: 40/replicate for mortality, 10/replicate for fecundity Test duration: 21 days exposure phase, 14 days pre-reproduction phase, 14 days reproduction phase The test item was applied with a laboratory track sprayer on bean plants at seven application rates. ROGOHIT (Dimethoate 30%) was used as reference item whereas deionised water was used as control.
Application rates:	Control, 0.00031, 0.00049, 0.00078, 0.00125, 0.00200 L of the test item/ha (0.015, 0.025, 0.040, 0.063 and 0.101 g deltamethrin/ha)
Test conditions:	Temperature: 24.3 – 25.0 °C; humidity: 73 – 80%; lighting: 16 h light : 8 h dark; light intensity: 980 – 1075 lux
Statistical analysis:	LR ₅₀ and NOER for mortality and ER ₅₀ and NOER for reproduction were determined by using a Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviations were calculated using validated Excel sheets.
Endpoints:	LR ₅₀ , NOER ER ₅₀ , NOER

Results and Conclusions

The effects of Deltamethrin 5% CS on mortality and fecundity of *Coccinella septempunctata* in the extended laboratory test are summarized below:

Study group (application rate) (L/ha)	Mortality		Reproduction					
	Total (%)	Corrected ^a (%)	Mean num- ber of eggs laid/day	Eggs hatched/day		Mean num- ber of eggs laid/viable female/day	Mean number of viable eggs laid/viable female/day	Fecundity reduction ^b (%)
				Mean [No]	Mean [%]			
Control	2.5	-	114.5	108.4	94.6	3.6	3.4	-
Deltamethrin 5% CS								
0.00031	7.5	5.13	104.5	89.0	84.3	3.4	3.0	5.56
0.00049	20.0	17.95	82.2	64.9	79.2	3.2	2.5	11.11 ⁺
0.00078	47.5	46.15 ⁺	39.6	26.0	65.6	2.2	1.4	38.89 ⁺
0.00125 ^c	65.0	64.10 ⁺	-	-	-	-	-	-
0.00200 ^c	80.0	79.49 ⁺	-	-	-	-	-	-
LR ₅₀ mortality	0.0010 L/ha (0.051 g a.i./ha*)		ER ₅₀ fecundity	>0.00078 L/ha (0.040 g a.i./ha*)				
NOERmortality	0.00049 L/ha (0.025 g a.i./ha*)		NOERfecundity	0.00031 L/ha (0.015 g a.i./ha*)				
Reference item – ROGOHIT (DIMETHOATE 30% EC)								
5.0 mL/ha	95.0	94.87 ⁺	-	-	-	-	-	-

a: Mortality corrected according to Abbott's formula:

Corrected mortality [%] = ((Mt – Mc) / (100 – Mc)) x 100; Mt = Mortality treated, Mc = Mortality control

b: based on the mean number of eggs laid/viable female/day obtained for treatments in relation to the control group

c: reproduction phase was not performed due to mortality higher than 50% in comparison with the control group

+ : statistically significant difference between the control and the treatment group at $p < 0.05$

*: Deltamethrin

The validity criterion for mortality was met, because mortality of the control group was 2.5% (criterion: ≤20%), whereas corrected mortality of *C. septempunctata* after 10 days of exposure to Deltamethrin 5% CS at rates of 0.00031, 0.00049, 0.00078, 0.00125 and 0.00200 L/ha was 5.13, 17.95, 46.15, 64.10 and 79.49% respectively.

There were statistically significant differences in mortality between group treated with the test item at all the rates used and the control group (one-way ANOVA, $p < 0.05$).

On the basis of the obtained mortality results, the LR₅₀ value is 0.0010 L Deltamethrin 5% CS/ha, i.e. 0.051 g Deltamethrin/ha. The NOER_{mortality} value is 0.00049 L Deltamethrin 5% CS/ha, i.e. 0.025 g Deltamethrin/ha.

For the reference item Rogohit (Dimethoate 30% EC, w/w), the corrected mortality of *C. septempunctata* after exposure at the rate of 0.65 L/ha was 94.87%, hence the criterion (>50%) specified in the method description was met. The results showed that the test organisms were sensitive to dimethoate.

The validity criterion for fecundity was met, because the mean number of eggs per female per day in the control group was 37.70 (criterion: ≥ 15), whereas in the group treated with Deltamethrin 5% CS at rates of 0.00031, 0.00049 and 0.00078 L/ha was 3.4, 3.2 and 2.2 respectively.

There were no statistically significant difference between group treated with the test item at the rate of 0.00031 L/ha and the control group (one-way ANOVA, $p < 0.05$).
 On the basis of the obtained fecundity results, the ER_{50} value is >0.00078 L Deltamethrin 5% CS/ha, i.e. 0.051 g Deltamethrin/ha. The $NOER_{fecundity}$ value is 0.00031 L Deltamethrin 5% CS/ha, i.e. 0.015 g Deltamethrin/ha.

On the basis of the obtained results, it can be concluded that Deltamethrin 5% CS had no adverse effects on mortality and fecundity of *Coccinella septempunctata* at the rates of 0.00031 L/ha.

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

The mortality and fecundity phases of this study are valid, because:

- mean mortality rate did not exceed 20% in control after 7 days for each bioassay occasion (actual values: 11% at 0DAA, 16% at 21DAA, 12% at 35DAA and 10% at 49DAA).
- mean mortality rate (corrected for control) in the reference item was > 50% after 7 days for each bioassay occasion (actual values: 64.04% at 0DAA, 86.90% at 21DAA, 95.45% at 35DAA and 97.78% at 49DAA).
- cumulative mean number of eggs per female was > 4 in the control during the last bioassay occasion (49DAA; actual value: 5.66 eggs). Fecundity assessments were not carried out in previous bioassays since mortalities were > 50% in the test item.

Agreed endpoints:

Application rate (g as/ha)	Corrected Mortality after 7 days (%)				Fecundity 49DAA	
	0 DAA	21 DAA	35 DAA	49 DAA	Eggs/female	Effects (%)
0 (control)	0	0	0	0	5.66	-
7.5	100*	92.86*	87.5*	31.11*	6.00	+6.14

The corrected mean mortality in the bioassay initiated 49 days after application of the test item was calculated to be 31.11%. In the fecundity phase of the 49 day bioassay, there was no significant reduction of the reproductive capacity in the test item treatment, in comparison to the control.

Reference: KCP 10.3.2.2-05

Report "A fresh and aged residue study to determine the effects of Poleci (deltamethrin 2.5% w/w) on the non-target arthropod *Typhlodromus pyri* (Acari: Phytoseiidae)." XXX, E (2011), 34SRFR11C3. SynTech Research France S.A.S.

Guideline(s): Blümel, *et al* (2000)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication No
(if vertebrate study)

Objective:

The study assessed the magnitude and duration of effects (mortality and fecundity) of fresh and aged residues of Deltamethrin 2.5% EC on the predatory mite *Typhlodromus pyri* following one application on apple tree leaves at a field rate of 7.5 g as/ha according to the guidelines of Blümel *et al* (2000).

Material and method:

The test item rate was 7.5 g as/ha. A control (deionized water) and a reference item (Dimethoate 400 g/L) were tested in parallel. Apple leaves (*Malus domestica*) were treated with the test item and the mites were introduced after aging the residues for 0 (fresh), 21, 35 and 49 days. There were four replicates per test item treatment, control and reference item treatment. Mortality values of the control as well as mortality values of the reference item treatment were within the study validity criteria.

Results:

Application rate (g as/ha)	Corrected Mortality after 7 days (%)				Fecundity 49DAA	
	0 DAA	21 DAA	35 DAA	49 DAA	Eggs/female	Effects (%)
0 (control)	0	0	0	0	5.66	-
7.5	100*	92.86*	87.5*	31.11*	6.00	+6.14

Conclusion:

There were significant effects when Deltamethrin 2.5% EC was applied at 7.5 g as/ha on the mortality of *Typhlodromus pyri*. Corrected mean mortality in the bioassay initiated 49 days after application of the test item was calculated to be 31.11%. In the fecundity phase of the 49 day bioassay, there was no significant reduction of the reproductive capacity in the test item treatment, in comparison to the control, indicating that full recovery had occurred 49 days after application.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.		
	<ul style="list-style-type: none"> - Maximum mortality in the control was 5.0 % (exposure 0 DAA1). - Mortality (corrected to control) in the toxic reference was 100 % with 0, 14, 28, 42 and 56-day old residues. - Wasps in the control produced an average of 30.8 mummies per female with fresh and dry residues (exposure 42 DAA1) as minimum value. - One female produced zero mummies in the exposure of 42 DAA1. 		
	Agreed endpoints:		
	Rate ^a	48-h Mortality ≤ 50 %	Reduction Fecundity ≤ 50 %
	0.58 L FP/ha [Deltamethrin 5% CS] [29.41 g a.i./ha]	From 42 DAA1 ^b	From 56 DAA1 ^{b, c}
(a) :Rate in L of formulated product /ha and the equivalent active ingredient based on the analysed content: Deltamethrin 50.71 g/L (b): [DAA1; days after the application of water and test item] (c): Reproduction in T1 (exposure 56 DAA1) studied with surviving females after the 48h mortality period: 11 females (10 survivors and 1 moribund after the 24h parasitism period)			

Reference: KCP 10.3.2.2-06

Report "Deltamethrin 5 % CS: Toxicity to the Aphid Parasitoid *Aphidius rhopalosiphii* De Stefani Perez (Hymenoptera, Braconidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions". Francisco XXX, 2021. Study code: S20-07841. Trialcamp S.L.U.

Guideline(s): IOBC (Mead-Briggs et al., 2000) relative to assessments and exposures.

Mead-Briggs and Longley (1997), cited in Grimm et al. (2002), relative to exposure units design and Ternes et al. (2001) relative to the vegetal substrate

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Summary

The aim of the study was to evaluate the extent and persistence of effects on the survival and reproduction of the formulation “Deltamethrin 5% CS” to *Aphidius rhopalosiphi* DeStephani Perez (Hymenoptera: Braconidae), exposing the test organisms to Bean plants after different periods of ageing of the residues under outdoors conditions (with a roof closed only when it rains). The effects were evaluated 0, 14, 28, 42 and 56 days after the application of the rates of 0.58 and 0.68 L/ha of Formulated product (equivalent to 29.41 and 34.48 g of active substance (a.s.)/ha, respectively).

Material and methods

Test item: Deltamethrin 5% CS: content: 50/50.71 g Deltamethrin /L; Batch No.: SCL-12589; manufacturing date: May 20th, 2019; expiry date: May 19th, 2021.

Reference item: Dimethoate 40% EC: content: 400/414 g Dimethoate /L

Biological test system: The parasitoid *A. rhopalosiphi* DeStephani Perez (Hymenoptera: Braconidae)

- Age: adult wasps not older than 48 hours
- Source: TRIALCAMP S.L.U. – Valencia, (Spain)

Experimental design:

Treatment code	Product	Rate g a.s. ⁽¹⁾ /ha	Rate L FP ⁽²⁾ /ha
C	Tap Water	-	-
T1	Deltamethrin 5% CS	29.41	0.58
T2		34.48	0.68
R	Dimethoate 40 % w/v EC	186.3	0.45 L product /ha ⁽³⁾

(1): “a.s.” = active substance; Deltamethrin.

(2): Rate of the formulated product (FP) according to the certificate of analysis: Deltamethrin, 50 g/L

(3): Reference product at the maximum rate for intended use: 0.45 L FP /ha. It was applied at the beginning of the study (0 DAA) and just before the exposure of 42 DAA. Rate of active substance (186.3 g a.s./ha).

4 replicates/treatment; 10 adults/replicate

Bean plants (*Phaseolus vulgaris* L., Fabaceae) were used for trial purposes. Four plots were used with 24 plants in 8 pots per plot; 3 plants per pot: One plot for water treated control, one plot for each rate of the test item and one plot for the toxic reference.

Application was performed using a compressed air knapsack sprayer and one nozzle simulating an application in field (volume 600 L/ha), working at pressure of 4 bars and applying the plants outdoors.

After application, plants were maintained outdoors. The reference item was applied at the same time as the test item using a similar method.

Test conditions

- Temperature: 19.8 – 20.7°C
- Relative air humidity: 77.6 – 84.8%
- Photoperiod: 16 hours light (mortality: 1145 – 2047 lx; parasitisation: 2148 – 2504 lx; dev. of mummies: 9086 - 15336 lx); 8 hours dark

Statistics: Chi² 2x2 Test, Chi-square Test and Fisher`s Exact Binomial Test (mortality assessment), Shapiro-Wilk`s test and Levene`s (reproduction), STUDENT-t (fecundity).

Endpoints:

- Mortality (lethal effect) at 48 hours after exposure to aged residues on leaf disks of applied bean plants for the following periods: 0, 14 and 28 ± 1 days after application (DAA1); actual periods were 0, 14, 28, 42 and 56 DAA1.
- Reproduction (fecundity) of the surviving females for 11 days after a 24 hour parasitisation period in presence of their host aphids for the aforementioned ageing periods.
- The ageing period of the residues at the tested rates with effects below 50 %, relative to the control, was determined.

Results

Mortality

Exposures to the residues (bioassays) were performed 0, 14, 28, 42 and 56 days after application (DAA).

The effect on mortality was below the trigger value of 50 % at the rate of 0.58 L FP/ha of the test item Deltamethrin 5 % CS in the exposures of 42 and 56 DAA1. The effect on mortality was equal to the trigger value of 50 % at the rate of 0.68 L FP/ha of the test item Deltamethrin 5 % CS only in the exposure of 56 DAA1.

Mortality with the rate of 0.58 L FP/ha of the test item was significantly different to the control from the exposure of 0 DAA1 (dry and fresh residues) to the exposure 28 DAA1, and in the exposure of 56 DAA1 again (25 % mortality).

Mortality with the rate of 0.68 L FP/ha of the test item was significantly different to the control from the exposure of 0 DAA1 (dry and fresh residues) to the exposure 56 DAA1.

Signs of intoxication in surviving wasps (uncoordinated movements compared to the control) were observed after the introduction of wasps into the test units with the two tested rates of the item at every exposure from 0 to 56 DAA1.

The mortality in the reference item was higher than 50 % (corrected to control) in the five performed exposures; 100 % in the exposures of 0, 14, 28, 42 and 56 DAA1.

Treatment ^(a)	[%] Mortality ^(b)				
	Exposure +0 DAA1	Exposure +14 DAA1	Exposure +28 DAA1	Exposure +42 DAA1	Exposure +56 DAA1
C ; Water Control	5.0 ± 5.8	5.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Deltamethrin 5% CS at 0.58 L FP/ha	67.5 ± 33.0 ^{sd}	75.0 ± 20.8 ^{sd}	57.5 ± 50.6 ^{sd}	10.0 ± 14.1	25.0 ± 20.8 ^{sd}
Deltamethrin 5% CS at 0.68 L FP/ha	75.0 ± 20.8 ^{sd}	100.0 ± 0.0 ^{sd}	100.0 ± 0.0 ^{sd}	60.0 ± 14.1 ^{sd}	50.0 ± 21.6 ^{sd}
Dimethoate 40% EC at 0.45 L FP/ha	100.0 ± 0.0	100.0 ± 0.0	100.0 ± 0.0	100.0 ± 0.0	100.0 ± 0.0

	[%] Corrected Mortality				
C : Water Control	--	--	--	--	--
Deltamethrin 5% CS at 0.58 L FP/ha	65.8	75.0	57.5	10.0	25.0
Deltamethrin 5% CS at 0.68 L FP/ha	73.7	100.0	100.0	60.0	50.0
Dimethoate 40% EC at 0.45 L FP/ha	100.0	100.0	100.0	100.0	100.0

(a): Rate of the test product in L Formulated Product/ha.

(b): DAA1 = Days after application.

(c): sd: Statistically significantly increased compared to the control (Chi2 2x2 Test, one-sided greater, $\alpha = 0.05$ at 0 to 28 DAA1 and 56DAA1, Fisher's Exact Binomial Test (one-sided greater, $\alpha = 0.05$ at 42 DAA1))

Reproduction

For sub-lethal effects, the fecundity rate as mummies per female (number of offspring) after 24 hours of parasitisation was studied for the test item group at rate of 0.58 L FP/ha for the exposures 42 and 56 DAA1, since more than 50 % mortality (corrected to the control) was obtained for 0, 14 and 28 DAA1 exposures.

For sub-lethal effects, the fecundity rate as mummies per female (number of offspring) after 24 hours of parasitisation was studied for the test item group at rate of 0.68 L FP/ha for the exposure 56 DAA1, since more than 50 % mortality (corrected to the control) was obtained for 0, 14, 28 and 42 DAA1 exposures.

For the rate of 0.58 L FP/ha, in the exposure of 42 DAA1, fifteen surviving females of the mortality test period were used to study the reproduction capacity over a 24 h parasitisation period. One female among these 15 females died during the parasitization period.

For the rate of 0.58 L FP/ha, in the exposure of 56 DAA1, only eleven surviving females of the mortality test period were used to study the reproduction capacity over a 24 h parasitisation period. One female among these 11 females was observed as moribund during the parasitization period, therefore it was discarded to calculate the mean value of mummies per female. For the rate of 0.68 L FP/ha, in the exposure of 56 DAA1, only five surviving females of the mortality test period were used to study the reproduction capacity over a 24h parasitisation period.

In the exposure of 42 DAA1, the reduction in reproduction for the test item at the rate of 0.58 L FP/ha was above the trigger value of 50 %, 66.6 %, which was significantly different to the control.

In the exposure of 56 DAA1, the reduction in reproduction for the test item at the rates of 0.58 and 0.68 L FP/ha was below the trigger value of 50 %, 48.4 and 49.0 % respectively. However, no statistical analyses were performed since less than 15 females were recovered from the mortality tests.

	m/f (Average) ^(b)				
Treatment (a)	Exposure +0 DAA1	Exposure +14 DAA1	Exposure +28 DAA1	Exposure +42 DAA1	Exposure +56 DAA1
C : Water Control	Not studied	Not studied	Not studied	30.8 ± 14.2	49.4 ± 22.5
Deltamethrin 5% CS at 0.58 L FP/ha	Not studied	Not studied	Not studied	10.3 ± 11.7 ^{sd}	25.5 ^d ± 19.4
Deltamethrin 5% CS at 0.68 L FP/ha	Not studied	Not studied	Not studied	Not studied	25.2 ^c ± 11.9
	[%] R ^(c)				
C : Water Control	--	--	--	--	--
Deltamethrin 5% CS at 0.58 L FP/ha	--	--	--	66.6	48.4
Deltamethrin 5% CS at 0.68 L FP/ha	--	--	--	--	49.0

(a): Rate of the test product in L Formulated Product/ha.

(b): DAA1 = Days after application; "m/f"= mummies per female;
(c): [%] R= % Reduction in reproduction relative to control. Negative value indicates an increase compared to the control.
(d): sd = Statistically significantly decreased compared to the control (Student-t Test for homogeneous variances, one-sided smaller, $\alpha = 0.05$)
(e): Reproduction in T1 (exposure 56 DAA1) studied with surviving females after the 48h mortality period: 11 females (10 survivors and 1 moribund after the 24h parasitism period)
(f): Reproduction in T2 (exposure 56 DAA1) studied with surviving females after the 48h mortality period: 5 females (5 survivors after the 24h parasitism period)

Test validity criteria

All mortality and reproduction tests were considered to be valid as:

- Maximum mortality in the control was 5.0 % (exposure 0 DAA1).
- Mortality (corrected to control) in the toxic reference was 100 % with 0, 14, 28, 42 and 56-day old residues.
- Wasps in the control produced an average of 30.8 mummies per female with fresh and dry residues (exposure 42 DAA1) as minimum value.
- One female produced zero mummies in the exposure of 42 DAA1.

Conclusion

Rate ^a	48-h Mortality ≤ 50 %	Reduction Fecundity ≤ 50 %
0.58 L FP/ha [Deltamethrin 5% CS] [29.41 g a.i./ha]	From 42 DAA1 ^b	From 56 DAA1 ^{b, c}
0.68 L FP/ha [Deltamethrin 5% CS] [34.48 g a.i./ha]	From 56 DAA1 ^b	From 56 DAA1 ^{b, d}

(a) :Rate in L of formulated product /ha and the equivalent active ingredient based on the analysed content: Deltamethrin 50.71 g/L

(b): [DAA1; days after the application of water and test item]

(c): Reproduction in T1 (exposure 56 DAA1) studied with surviving females after the 48h mortality period: 11 females (10 survivors and 1 moribund after the 24h parasitism period)

(d): Reproduction in T2 (exposure 56 DAA1) studied with surviving females after the 48h mortality period: 5 females (5 survivors after the 24h parasitism period)

A 2.3.2.3 KCP 10.3.2.3 Semi-field studies with non-target arthropod

Not required.

A 2.3.2.4 KCP 10.3.2.4 Field studies with non-target arthropods

Not required.

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
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	<ul style="list-style-type: none">• Each replicate (containing 10 adults) produced minimum of 40 juveniles by the end of the test (acceptable criterion: each replicate containing 10 adults to have produced ≥ 30 juveniles by the end of the test).• The coefficient of variation of reproduction is 2.6 % (acceptable criterion: the coefficient of variation of reproduction to be ≤ 30 %).• There was no mortality of the earthworms in the control during the experimental period of 28 days (acceptable criterion: adult mortality over the initial 4 weeks of the test to be ≤ 10 %).									
	Agreed endpoints: <table><tr><th>Endpoint</th><th>Nominal Concentration of Test Item (mg/kg dry soil)</th><th>Nominal Concentration of Active Ingredient(mg deltamethrin/kg dry soil)</th></tr><tr><td>NOEC</td><td>167.8</td><td>8.41</td></tr><tr><td>EC₁₀</td><td>94.80</td><td>4.75</td></tr></table>	Endpoint	Nominal Concentration of Test Item (mg/kg dry soil)	Nominal Concentration of Active Ingredient(mg deltamethrin/kg dry soil)	NOEC	167.8	8.41	EC ₁₀	94.80	4.75
Endpoint	Nominal Concentration of Test Item (mg/kg dry soil)	Nominal Concentration of Active Ingredient(mg deltamethrin/kg dry soil)								
NOEC	167.8	8.41								
EC ₁₀	94.80	4.75								

Reference: KCP 10.4.1.1

Report "Deltamethrin 5% CS: Earthworm Reproduction Test". XXX XXX XXX XXX, 2020, G13397. Eurofins Advinus Limited

Guideline(s): OECD Guideline No. 222 (2004)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication (if vertebrate study) No

Materials and methods

Test item: Deltamethrin 5% CS; Batch Number SCL-89521; active substance: 50.71 g/L

Test species: *Eisenia fetida* bred at test facility: Ecotoxicology Laboratory, Eurofins Advinus limited, Bengaluru 560 058, India. 4.5 to 5 month adults.

Soil: 5% sphagnum peat, 20% kaolin clay, 75% industrial sand

Study design: Number of replicates: 4 replicates / concentration + 8 replicates / control

Number of earthworms: 10 earthworms/replicate

Test duration: 8 weeks

Application rates: Control, 8.9, 16.0, 28.8, 51.8, 93.2, 167.8m 302.0 and 543.6 mg/kg dry soil

Test conditions: Temperature: 19.7 – 20.5 °C; humidity: 27.1 – 28.1%; lighting: 16 h light 8 h dark; light intensity: 512 – 559 lux; pH: 6.90 – 6.99

Statistical analysis: The statistical analysis of the earthworm bodyweight and juvenile production data was carried out using licensed copies of SYSTAT Statistical package Ver.12.0. The body weight of adult earthworms at the end of first 4 week test and juvenile production data collected at the end of second 4 week test was tested for normality (Shapiro-Wilk test) and homogeneity of variances (Levene's test) within the group before performing a one-factor ANOVA modeling by treatment groups. Non-optimal (non-normal or heteroschedastic) data was transformed, before ANOVA was performed. Comparison of means between treatment groups and control group was done using Mann-Whitney test (when data was not normal). Regression analysis was made for body weight of adult earthworms and juvenile production data. The EC₁₀ and EC₅₀ value evaluations together with relevant fiducial limits were calculated using four parameter method (GraphPad Prism 8.0).

Endpoints: EC₁₀, EC₅₀, LC₅₀, LOEC, NOEC

Results and Conclusions

On the range finding test, there was no mortality of earthworms at the tested concentrations of 1, 10, 100, 750 and 1000 mg/kg dry soil on Day 28. No pathological and behavioral symptoms were observed during the test period in the control and treated groups. There was no reduction in the body weight of earthworms in test item treated groups (except G6-1000 mg/kg) as compared with the control.

On the definitive test, there was no mortality of earthworms in control and at the tested concentrations of 8.9, 15.0, 28.8, 51.8, 93.2 and 167.8 mg/kg (except 302.0, 543.6 mg/kg and reference substance groups) on Day 28. No pathological and behavioral symptoms were observed during the test period in the control and treated groups (including reference substance). No statistically significant reduction in body weight was observed in treated groups (except G8-302.0 mg/kg, G9-543.6 mg/kg and reference substance test group) as compared with the control.

No pathological and behavioral symptoms were observed in juveniles on Day 56 in the control and treated groups. No statistically significant reduction in juvenile production was observed in treated groups (except G8-302.0 mg/kg, G9-543.6 mg/kg and reference substance test group) as compared with the control. Cocoons were present in all the groups and maximum numbers of cocoons were observed in the reference substance test group.

The results of active ingredient analysis of test concentrations of 8.9, 51.8 and 543.6 mg/kg dry soil showed that overall recovery was as below:

Active ingredient	Analyzed content of active compound (% nominal)		
	Day 0	Day 28	Day 56
Deltamethrin	(108.08 – 117.42)	(100.17 – 108.80)	(100.90 – 109.60)

Reference substance (Carbendazim) group exhibited statistically significant reduction in juvenile production at 3 mg a.i./kg dry soil as compared with the control. Hence the test has met the validity acceptance criteria that significant effects should be observed between 1 and 5 mg a.i./kg dry soil in a test. This result infers that the obtained results during this test are valid and hence test is acceptable.

The LC₅₀ of Deltamethrin 5% CS on Adult earthworms on Day 28 is more than 543.6 mg test item or 27.23 mg deltamethrin/kg.

The reproduction LOEC of Deltamethrin 5% CS is 302.8 mg test item/kg or 15.17 mg deltamethrin/kg.

The reproduction NOEC of Deltamethrin 5% CS is 167.8 mg test item/kg or 8.41 mg deltamethrin/kg.

The reproduction EC₁₀ of Deltamethrin 5% CS is 94.80 mg test item/kg or 4.75 mg deltamethrin/kg dry soil with fiducial limits at 95 per cent ranging from 40.67 to 183.3 mg test item/kg.

The reproduction EC₅₀ of Deltamethrin 5% CS is 324.8 mg test item/kg or 16.27 mg deltamethrin/kg dry soil with fiducial limits at 95 per cent ranging from 252.3 to 434.4 mg test item/kg.

Endpoint	Nominal Concentration of Test Item (mg/kg dry soil)	Nominal Concentration of Active Ingredient (mg deltamethrin/kg dry soil)
NOEC	167.8	8.41
EC ₁₀	94.80	4.75

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.																			
	<ul style="list-style-type: none"> mean adult mortality: 0.0% (criterion: $\leq 20\%$), the mean number of juveniles per vessel at the end of the test: 792.75 (criterion: ≥ 100 juveniles at the end of the test), the coefficient of variation calculated for the number of juveniles: 0.91 (criterion: $\leq 30\%$). 																			
	Agreed endpoints: <table border="1"> <thead> <tr> <th>Endpoint</th><th>Value [mg test item/kg dry soil]</th><th>Value [mg of active substance/kg dry soil]</th></tr> </thead> <tbody> <tr> <td>EC₁₀</td><td>> 1000 (n.d.)</td><td>49.28 (n.d.)</td></tr> <tr> <td>EC₂₀</td><td>> 1000 (n.d.)</td><td>49.28 (n.d.)</td></tr> <tr> <td>EC₅₀</td><td>> 1000 (n.d.)</td><td>49.28 (n.d.)</td></tr> <tr> <td>NOEC</td><td>> 1000</td><td>49.28</td></tr> <tr> <td>LOEC</td><td>> 1000</td><td>49.28</td></tr> </tbody> </table>		Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]	EC ₁₀	> 1000 (n.d.)	49.28 (n.d.)	EC ₂₀	> 1000 (n.d.)	49.28 (n.d.)	EC ₅₀	> 1000 (n.d.)	49.28 (n.d.)	NOEC	> 1000	49.28	LOEC	> 1000	49.28
Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]																		
EC ₁₀	> 1000 (n.d.)	49.28 (n.d.)																		
EC ₂₀	> 1000 (n.d.)	49.28 (n.d.)																		
EC ₅₀	> 1000 (n.d.)	49.28 (n.d.)																		
NOEC	> 1000	49.28																		
LOEC	> 1000	49.28																		
	n.d. – not determined																			

Reference: KCP 10.4.2.1-01

Report "Effect of Deltamethrin 5% CS on reproduction of the collembolans (*Folsomia candida*) in artificial soil." Mr. K. XXX, 2019, 6942/2019. BIOSCIENCE RESEARCH FOUNDATION

Guideline(s): OECD 232 (2016)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication
(if vertebrate study) No

Materials and methods

Test item: Deltamethrin 5% CS; Batch code: SCL-12589; active substance: 50.91 g/L

Test species: *Folsomia candida* from a culture maintained at BFR, India, juveniles (9 - 12 days).

Soil: 5% sphagnum peat; 20% kaolin clay; 75% industrial sand

Study design: Number of replicates: 4 replicates / concentration + 8 replicates / control
Number of collembolans: 10 / replicate

Test duration: 28 days

Application rates: Control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg test item/kg soil dry weight

Test conditions: Temperature: 19.6 – 21.7 °C; humidity: 45.98 – 48.67 % of maximum WHC; lighting: 16 h light; 8 h dark; light intensity: 555 – 625 lux; pH: 5.66 – 5.98

Statistical analysis: The number of the surviving adults and juvenile collembolans was assessed 4 weeks after introduction.

The endpoint values for mortality and reproduction were determined by using Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way

ANOVA using Graphpad Prism 8.0.
Endpoints: EC₅₀, EC₂₀, EC₁₀, NOEC, LOEC
LC₅₀

Results and Conclusions

Mortality at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil ranged from 0.0 to 7.5%. As for the control group, it was 0.0%.

The concentration of the test item causing a 50% mortality of adults within the exposure period (LC₅₀) is >1000 mg/kg dry weight of the artificial soil (i.e. >49.28 mg Deltamethrin/kg dry weight of the artificial soil).

The endpoint values showing the impact of the test item on the survival of adult collembolans are presented in Table given below:

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
LC ₁₀	> 1000 (n.d.)	49.28 (n.d.)
LC ₂₀	> 1000 (n.d.)	49.28 (n.d.)
LC ₅₀	> 1000 (n.d.)	49.28 (n.d.)
NOEC	> 1000	49.28
LOEC	> 1000	49.28

n.d. – not determined

After the exposure of collembolans to the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 773.25 and 759.00 per replicate. As for the control group, the number of juveniles was equal to 792.75 per replicate.

The endpoint values showing the impact of the test item on reproduction of *Folsomia candida* are presented in Table given below:

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
EC ₁₀	> 1000 (n.d.)	49.28 (n.d.)
EC ₂₀	> 1000 (n.d.)	49.28 (n.d.)
EC ₅₀	> 1000 (n.d.)	49.28 (n.d.)
NOEC	> 1000	49.28
LOEC	> 1000	49.28

n.d. – not determined

Comments of
zRMS:

The study is considered acceptable. All validity criteria were met.

- mean adult mortality: 2.5% (criterion: ≤ 20%),
- the mean number of juveniles per replicate at the end of the test: 130.0 (criterion: ≥ 50 juveniles at the end of the test),
- the coefficient of variation for the number of juveniles: 2.85 (criterion: ≤ 30%).

Agreed endpoints:

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
EC ₁₀	> 1000 (n.d.)	> 49.28 (n.d.)
EC ₂₀	> 1000 (n.d.)	> 49.28 (n.d.)

	EC ₅₀	> 1000 (n.d.)	> 49.28 (n.d.)
	NOEC	≥ 1000	≥ 49.28
	LOEC	> 1000	> 49.28
	n.d. – not determined		

Reference: KCP 10.4.2.1 - 02

Report “Effect of Deltamethrin 5% CS on the reproductive output of the predatory soil mite *Hypoaspis (Geolaelaps) aculeifer* Canestrini (Acari: Laelapidae) in artificial soil”. Dr. V. XXX, 2019, 6031/2019. Bioscience Research Foundation

Guideline(s): OECD Guideline No. 226 (2016)

Deviations: No

GLP: Yes

Acceptability: Yes

Duplication
(if vertebrate study) No

Materials and methods

Test item: Deltamethrin 5% CS; Batch Number SCL-12589; active substance: deltamethrin 50.71 g/L

Test species: *Hypoaspis aculeifer* from BFR insectary. The collembolans used in the study were adult females (i.e. 33rd day after the parental females have started egg laying).

Soil: 5% sphagnum peat; 20% kaolin clay; 75% air-dried industrial sand

Study design: Number of replicates: 4 replicates / concentration + 8 replicates / control
Number of collembolans: 10 females / replicate
Test duration: 14 days

Application rates: Control, 5.04, 9.07, 16.33, 29.40, 52.92, 95.26, 171.47, 308.64, 555.56 and 1000 mg of the test item/kg of dry weight of the artificial soil

Test conditions: Temperature: 21.0 – 21.6°C; humidity: 19.85 – 21.44 % water content; lighting: 16 h light, 8 h dark; light intensity: 480 – 545 lux; pH: 6.16 – 6.35

Statistical analysis: Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0,

Endpoints: LCx/ECx-values for the reproductive output and adult survival
LOEC/NOEC for the reproductive output and adult survival

Results and Conclusions

Mortality at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil ranged from 0.0 to 10.0. As for the control group, it was 2.5%.

The concentration of Deltamethrin 5% CS causing a 50% mortality of adults within the exposure period (LC₅₀) is >1000 mg/kg dry weight of the artificial soil, i.e. >49.28 mg Deltamethrin/kg dry weight of the artificial soil.

The endpoint values showing the impact of the test item on the survival of adult *Hypoaspis aculeifer* are presented in Table given below.

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
LC ₁₀	> 1000 (n.d.)	> 49.28 (n.d.)
LC ₂₀	> 1000 (n.d.)	> 49.28 (n.d.)
LC ₅₀	> 1000 (n.d.)	> 49.28 (n.d.)
NOEC	≥ 1000	≥ 49.28
LOEC	> 1000	> 49.28

After the exposure of *Hypoaspis aculeifer* to the test item at the concentrations ranging from 5.04 to 1000 mg/kg dry weight of the artificial soil, the mean number of juveniles was between 121.25 and 129.25 per replicate. As for the control group, the number of juveniles was equal to 130.00 per replicate. The endpoint values showing the impact of the test item on reproductive output of *Hypoaspis aculeifer* are presented in Table given below.

Endpoint values

Endpoint	Value [mg test item/kg dry soil]	Value [mg of active substance/kg dry soil]
EC ₁₀	> 1000 (n.d.)	> 49.28 (n.d.)
EC ₂₀	> 1000 (n.d.)	> 49.28 (n.d.)
EC ₅₀	> 1000 (n.d.)	> 49.28 (n.d.)
NOEC	≥ 1000	≥ 49.28
LOEC	> 1000	> 49.28

n.d. – not determined

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	<p>The study is considered acceptable. All validity criteria were met. The variations between results of replicate control samples were within ±15% on every occasion tested.</p> <p>Agreed endpoints:</p> <p>After 28 days of incubation, the lowest treatment group deviated by -0.3% and the highest treatment group deviated by -3.5% from control with respect to the glucose induced respiration rates which was below the threshold value of < 25%. Based on the experiment results, it can be concluded that the test item, Deltamethrin 5% CS does not have long-term influence on carbon transformation in soil microorganisms.</p>
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Reference:	KCP 10.5-01
Report	“Soil Microorganisms: Carbon Transformation Test of Deltamethrin 5% CS”, H. S. XXX, M. Sc., 2019, G13398. Analytical R & D Department Eurofins Advinus Limited, India.
Guideline(s):	OECD Guideline No. 217 (2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication	-

(if vertebrate study)

Materials and methods

Materials

Test item:

Description: Deltamethrin 5% CS
Production batch: SCL – 89521
Active ingredients content: Deltamethrin 50.71 g/L

Vehicle and control:

Distilled water

Test system:

Species: Microorganisms

Source: From a site where no crop protection products have been applied for a minimum of one year before sampling and no organic fertilizer have been applied for at least six months before

Experimental conditions:

Temperature: 19.9 – 20.2°C
Humidity: 43.98 – 45.94% MWHC
Air changes: -
Light and photoperiod: Dark (24/24h)

Study design and methods

Experimental period: 18/02/2019 – 25/04/2019

Test design and treatment: 3 portions of soil weighing 25 g for each of the untreated and treated groups. Test duration: 28 days.

Concentrations of the test material:

Control; 5.15 mg of the test item/kg soil (3 x PEC) and 17.15 mg of the test item/kg soil (10 x PEC).

The glucose induced respiration rate in the treated soil samples was compared with that in the control, and the percent deviation of the treated from the control was calculated after 0, 7, 14, and 28 days of incubation.

Statistics: The statistical analysis of the experimental data was carried out using licensed copies of SYSTAT Statistical Package Ver.12.0. The quantitative variable (CO₂, mg/kg/day) was tested using ANOVA. Comparison of means between treatment groups and control group was done.

Results

The calculated % deviations in the glucose induced respiration rates (i.e., carbon dioxide released rates) between treated and control are < 25%.

After 28 days of incubation, the lowest treatment group deviated by -0.3% and the highest treatment group deviated by -3.5% from control with respect to the glucose induced respiration rates (carbon dioxide released rates). The variations between results of replicate control samples were within $\pm 15\%$ on every occasion tested. The difference in respiration rates between the treated and the control was <35% on day 28 and hence, the experiment was concluded after 28 days interval.

The 28 day analysis data was analysed and comparisons were evaluated at the 5% ($p < 0.05$) level and the statistical data showed that $p = 0.76$, at 5% level of significance (i.e. $\alpha = 0.05$) and hence, there was no significant difference between control vs high dose and low dose.

Mean Glucose induced respiration rate - deviations from the control [%]:

Day	Sample details	Mean Glucose induced respiration rate (mg/kg/hr)	% of Deviation from control
0	Control	62.58	NA
	Lower Concentration	64.98	3.8
	Higher Concentration	65.70	5.0
7	Control	60.46	NA
	Lower Concentration	63.79	5.5
	Higher Concentration	61.54	1.8
14	Control	61.59	NA
	Lower Concentration	64.36	4.5
	Higher Concentration	66.74	8.4
28	Control	64.13	NA
	Lower Concentration	63.94	-0.3
	Higher Concentration	61.91	-3.5

Conclusion

The effect of the test item on carbon transformation activity of soil microorganisms was investigated in a sandy clay loam soil. The test was performed at $20 \pm 2^\circ\text{C}$ for 28 days and the average recorded maximum and minimum temperatures were 20.2°C and 19.9°C , respectively. The application rates of test item were control (only Milli-Q water), low concentration level of 5.15 mg test item/kg dry weight of soil and as a.s.: 0.26 mg a.s./kg dry weight of soil and high concentration level of 17.15 mg test item/kg dry weight of soil and as a.s.: 0.86 mg a.s./kg dry weight of soil.

The variations between results of replicate control samples were within 15%. After 28 days of incubation, the lowest treatment group deviated by -0.3% and the highest treatment group deviated by -3.5% from control with respect to the glucose induced respiration rates which was below the threshold value of < 25%. Hence the experiment was concluded after 28 days of incubation.

Based on the experiment results, it can be concluded that the test item, Deltamethrin 5% CS does not have long-term influence on carbon transformation in soil microorganisms.

Comments of zRMS:	The study is considered acceptable. All validity criteria were met.
	The calculated % variations between results of replicate control samples were less than 15% indicating the validity of the test on all the intervals.

	<p>Agreed endpoints:</p> <p>After 28 days of incubation, the lowest treatment group deviated by 0.59 % and the highest treatment group deviated by 1.48% from control with respect to the nitrate content. The obtained results of 28 day data were analysed and comparisons were evaluated at the 5% ($p < 0.05$) level. It was found that $p = 0.12$, at 5% level of significance (i.e. $\alpha = 0.05$) and hence, there was no significant difference between control vs high dose and low dose.</p> <p>Based on the experiment results, it can be concluded that the test item, Deltamethrin 5% CS does not have long-term influence on nitrogen transformation in soil microorganisms.</p>
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Reference Report	KCP 10.5-02 “Soil Microorganisms: Nitrogen Transformation Test of Deltamethrin 5% CS”. H. S. XXX, M. Sc, 2019. STUDY CODE: G13399. Analytical R & D Department Eurofins Advinus Limited, India
Guideline(s)	OECD Guideline No. 216 (2000)
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Material and methods

Test material	Deltamethrin 5% CS
Soil	Agricultural soil collected from a site where no crop protection products have been applied for a minimum of one year before sampling and no organic fertilizer have been applied for at least six months before.
Test design	Three portions of soil (3 x 75 g), i.e. one control group and two treated groups. Every portion was divided into three replicates (3 x 25 g). The soil was enriched with the organic substrate, i.e. lucerne at dose of 5 g/kg dry weight of soil. Test duration: 28 days.
Concentrations of the test material	Control; 5.15 mg of test item/kg of soil (0.26 mg a.i./kg of dry weight of soil) and 17.15 mg of test item/kg of soil (0.86 mg a.i./kg of dry weight of soil).
Test conditions	Temperature: 19.9 – 20.2°C, soil moisture: -
Endpoints	The concentration of nitrate ions [mg/kg dry soil] after 0, 7, 14 and 28 days of incubation and percent deviation from the control in nitrate formation.
Statistical analysis	- SYSTAT Statistical Package Ver.12.0., - ANOVA

Study design

The aim of the study was to detect long-term adverse effects of Deltamethrin 5% CS on the processes of nitrogen transformation in aerobic surface soils.

Sandy clay loam soil was used. It was manually cleared of large objects and sieved to a particle size of 2 mm. The concentrations of the test item were 5.15 (3 x PEC) and 17.15 (15 x PEC) mg of test item/kg of soil. The treated and the control soils were divided into three replicates. On days 0, 7, 14 and 28 of incubation, soil samples were collected to determine the quantities of nitrates.

The method involves a measurement of the nitrate ion concentration in a soil extract obtained by using 0.1 M KCl, then adding 6 N Hydrochloric acid and Chromotropic acid (0.0125%) reagent. The absorbance of the solution was measured at 362 nm.

The nitrate formation rate in each treated group was compared with that in the control and the percent deviation of the treated from the control was calculated.

Results

After 28 days of incubation, the lowest treatment group deviated by 0.59% and the highest treatment group deviated by 1.48% from control with respect to the nitrate content. The calculated % variations between results of replicate control samples were less than 15% indicating the validity of the test on all the intervals.

The difference between nitrate content of the treated and the control samples after 28 day interval were less than 25% indicating that the test item does not have a long term influence on Nitrogen transformation in soil microorganisms. The obtained results of 28 day data were analysed and comparisons were evaluated at the 5% ($p < 0.05$) level. It was found that $p = 0.12$, at 5% level of significance (i.e. $\alpha = 0.05$) and hence, there was no significant difference between control vs high dose and low dose.

Nitrate content in soil - deviations from the control [%]:

Day	Sample details	Nitrate content in soil (mg/kg/day)	% of Deviation from control
0	Control	92.20 \pm 0.20	NA
	Lower Concentration	92.58 \pm 0.31	0.41
	Higher Concentration	82.23 \pm 0.19	0.03
7	Control	13.20 \pm 0.04	NA
	Lower Concentration	13.71 \pm 0.19	3.86
	Higher Concentration	14.10 \pm 0.27	6.82
14	Control	6.48 \pm 0.05	NA
	Lower Concentration	6.73 \pm 0.12	3.86
	Higher Concentration	6.88 \pm 0.12	6.17
28	Control	3.38 \pm 0.02	NA
	Lower Concentration	3.40 \pm 0.03	0.59
	Higher Concentration	3.43 \pm 0.02	1.48

Conclusions

The effect of the test item on nitrogen transformation activity of soil microorganisms was investigated in a sandy clay loam soil. The test was performed at $20 \pm 2^\circ\text{C}$ for 28 days and the average recorded maximum and minimum temperatures were 20.2°C and 19.9°C , respectively.

The results of the measurement of nitrate content for control (soil treated with Mili-Q water), low concentration level of 5.15 mg test item/kg dry weight of soil and as deltamethrin 0.26 mg a.i./kg dry weight of soil and high concentration level of 17.15 mg test item/kg dry weight of soil and as deltamethrin 0.86 mg a.i./kg dry weight of soil after each of 0, 7, 14 and 28 day intervals.

After 28 days of incubation, the lowest treatment group deviated by 0.59 % and the highest treatment group deviated by 1.48% from control with respect to the nitrate content. The obtained results of 28 day data were analysed and comparisons were evaluated at the 5% ($p < 0.05$) level. It was found that $p = 0.12$, at 5% level of significance (i.e. $\alpha = 0.05$) and hence, there was no significant difference between control vs high dose and low dose.

Based on the experiment results, it can be concluded that the test item, Deltamethrin 5% CS does not have long-term influence on nitrogen transformation in soil microorganisms.

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- the seedling emergence in the control (validity criterion: at least 70%) was as follows:
 - 95.2% – soybean,
 - 95.2% – corn,
 - 95.2% – pea,
 - 95.2% – white mustard,
 - 95.2% – radish,
 - 95.2% – tomato,
- the mean survival of the emerged control seedlings was 100% in case of all the experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Agreed endpoints:

Endpoint value	Soybean (<i>Glycine max</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	White mustard (<i>Sinapis alba</i>)	Radish (<i>Raphanus sativus</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number						
ER ₅₀	L/ha ^a	0.727	0.727	0.727	0.727	0.727
	g/ha ^b	36.866	36.866	36.866	36.866	36.866
NOER	L/ha ^a	0.19	0.19	0.19	0.19	0.19
	g/ha ^b	9.63	9.63	9.63	9.63	9.63
Shoot length (plants without roots)						
ER ₅₀	L/ha ^a	0.702	0.696	0.723	0.724	0.709
	g/ha ^b	35.598	35.294	36.663	36.724	35.953
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56
Plant dry weight (plants without roots)						
ER ₅₀	L/ha ^a	0.698	0.745	0.708	0.704	0.721
	g/ha ^b	35.396	37.779	35.903	35.700	36.562
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56

a: value for the test item, i.e., deltamethrin 50.71 g/L expressed as L/ha
b: value for the active substance, i.e. deltamethrin as g/ha

Reference:	KCP 10.6.2-01
Report	“Effect of Deltamethrin 5% CS on seedling emergence and seedling growth of terrestrial plants”. Dr. S. XXX, 2020, 6032/2020. Bioscience Research Foundation
Guideline(s):	OECD Guideline No. 208 (2003)
Deviations:	Study finished in June 2020, not January 2020, as it had been planned. This deviation did not affect the study results.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:	Deltamethrin 5% CS; Batch Number SCL-12589; active substance: deltamethrin 50.71 g/L
Test species:	Soybean (<i>Glycine max</i>), Corn (<i>Zea mays</i>), radish (<i>Raphanus sativus</i>), pea (<i>Pisum</i>

	<i>sativum</i>), tomato (<i>Solanum lycopersicon</i>) and white mustard (<i>Sinapsis alba</i>)
Soil:	Sandy loam soil containing 1.2% organic carbon
Study design:	number of rates: 5 application rates + control number of replicates: 7 pots/application rate and 3 seeds/plot. test termination: 14 days after the emergence of 50% of the control seedlings
Application rates:	Water control, 0.09, 0.19, 0.38, 0.75 and 1.50 L test item/ha Volume of distilled water used to prepare the highest rate: 300 L water/ha.
Test conditions:	temperature: 21.7 – 22.8°C, humidity: 55.1 – 66.4%, lighting: 16 h light : 8 h dark; light intensity: 362 – 400 µE/m ² /s; carbon dioxide concentration: 351 – 370 ppm
Statistical analysis:	The ER ₁₀ , ER ₂₅ , ER ₅₀ and NOER values were determined by using a Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0, respectively.
Endpoints:	ER ₁₀ , ER ₂₅ , ER ₅₀ , NOER

The number of seeds per pot and the total number of seeds per application rate were as follow:

- Soybean - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Corn - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Radish - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Pea - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- White mustard - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Tomato- 3 seeds/pot – 21 seeds/application rate (7 pots/application rate).

Results and Conclusions

The test item, i.e. Deltamethrin 5% CS applied at rates ranging from 0.09 to 1.50 L/ha had a varied impact on seedling emergence and seedling growth of all the plants species tested. The impact depended on the rate of the test item and species used. After the application of the test item, seedling emergence was delayed at rates ranging from 0.38 to 1.50 L/ha in comparison with the control. The phytotoxic symptoms for all the plant species tested were observed at all rates of the test item used on day 14 after the emergence of 50% of the control seedlings. There were phytotoxic symptoms observed for all the six plant species. The following phytotoxic symptoms were observed:

- Soybean, corn and mustard: chlorosis, leaf deformation, stem deformation or stunted growth
- Peas, radish and tomato: chlorosis, necrosis, leaf deformation or stem deformation

The endpoint values showing the impact of the test item on seedling emergence and seedling growth of the plant species tested are presented in table given below.

Endpoint value		Soybean (<i>Glycine max</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	White mustard (<i>Sinapsis alba</i>)	Radish (<i>Raphanus sativus</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number							
ER ₅₀	L/ha ^a	0.727	0.727	0.727	0.727	0.727	0.727
	g/ha ^b	36.866	36.866	36.866	36.866	36.866	36.866
NOER	L/ha ^a	0.19	0.19	0.19	0.19	0.19	0.19
	g/ha ^b	9.63	9.63	9.63	9.63	9.63	9.63
Shoot length (plants without roots)							
ER ₅₀	L/ha ^a	0.702	0.696	0.723	0.724	0.709	0.743
	g/ha ^b	35.598	35.294	36.663	36.724	35.953	37.678
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56
Plant dry weight (plants without roots)							
ER ₅₀	L/ha ^a	0.698	0.745	0.708	0.704	0.721	0.738
	g/ha ^b	35.396	37.779	35.903	35.700	36.562	37.424
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56

a: value for the test item, i.e., deltamethrin 50.71 g/L expressed as L/ha

b: value for the active substance, i.e. deltamethrin as g/ha

Comments of zRMS:

The study is considered acceptable. All validity criteria were met.

- the seedling emergence (validity criterion: at least 70%) was as follows:
 - 100% – soybean,
 - 100% – corn,
 - 100% – pea,
 - 100% – radish,
 - 100% – white mustard,
 - 100% – tomato,
- the mean survival of the emerged control seedlings was 100% in case of all experimental species (validity criterion: at least 90%),
- the control seedlings did not exhibit any visible phytotoxic symptoms,
- environmental conditions for all plants belonging to the same species were identical.

Agreed endpoints:

Endpoint value		Soybean (<i>Glycine max</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	White mustard (<i>Sinapsis alba</i>)	Radish (<i>Raphanus sativus</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number							
ER ₅₀	L/ha ^a	0.716	0.716	0.716	0.716	0.716	0.716
	g/ha ^b	36.308	36.308	36.308	36.308	36.308	36.308
NOER	L/ha ^a	0.19	0.19	0.19	0.19	0.19	0.19
	g/ha ^b	9.63	9.63	9.63	9.63	9.63	9.63
Shoot length (plants without roots)							
ER ₅₀	L/ha ^a	0.725	0.742	0.726	0.723	0.724	0.734
	g/ha ^b	36.750	37.627	36.815	36.663	36.714	37.221
NOER	L/ha ^a	< 0.09	< 0.09	0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	4.56	< 4.56	< 4.56	< 4.56
Plant dry weight (plants without roots)							
ER ₅₀	L/ha ^a	0.745	0.736	0.745	0.744	0.736	0.742
	g/ha ^b	37.779	37.323	37.779	37.728	37.323	37.627
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56

a: value for the test item, i.e., deltamethrin 5% cs expressed as L/ha

b: value for the active substance, i.e. deltamethrin as g/ha

Reference:

KCP 10.6.2-02

Report

“Effect of Deltamethrin 5% CS on vegetative vigour of terrestrial plants”.
Dr. S. XXX, 2020, Report number 6033/2019. Bioscience Research Foundation

Guideline(s):

OECD Guideline No. 227 (2006)

Deviations:

Study finished in June 2020, not in January 2020, as it had been planned.
This deviation did not affect the study results.

GLP:

Yes

Acceptability:

Yes

**Duplication
(if vertebrate study)**

No

Materials and methods

Test item:	Deltamethrin 5% CS; Batch Number SCL-12589; active substance: deltamethrin 50.71 g/L
Test species:	Soybean (<i>Glycine max</i>), Corn (<i>Zea mays</i>), radish (<i>Raphanus sativus</i>), pea (<i>Pisum sativum</i>), tomato (<i>Solanum lycopersicon</i>) and white mustard (<i>Sinapsis alba</i>)

Soil:	Sandy loam soil containing 1.2% organic carbon
Study design:	number of rates: 5 application rates + control number of replicates: 7 pots/application rate and 3 seeds/plot. test termination: 21 days after the spraying.
Application rates:	Water control, 0.09, 0.19, 0.38, 0.75 and 1.5 L test item/ha Volume of deionised water used to prepare the highest rate: 300 L water/ha
Test conditions:	temperature: 22.7 – 22.8°C, humidity: 55.1 – 66.4%, light – dark cycles (16h:8h), light intensity: 336 – 400 µE/m ² /s, carbon dioxide concentration: 351 – 370 ppm.
Statistical analysis:	The EC ₁₀ , EC ₂₅ , EC ₅₀ and NOEC values were determined by using a Probit analysis in the NCSS (Number Cruncher Statistical System) and one-way ANOVA using GraphPad Prism 8.0.
Endpoints:	EC ₁₀ , EC ₂₅ , EC ₅₀ and NOEC

- Soybean - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Corn - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Radish - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Pea - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- White mustard - 3 seeds/pot – 21 seeds/application rate (7 pots/application rate),
- Tomato- 3 seeds/pot – 21 seeds/application rate (7 pots/application rate).

Results and Conclusions

The test item, i.e. Deltamethrin 5% CS applied at rates ranging from 0.09 to 1.5 L test item/ha had a varied impact on vegetative vigour of all the plant species tested. The impact depended on the rate of the test item and species used.

There was mortality observed for all the plant species tested at rates ranging from 0.09 to 1.5 L test item/ha. The phytotoxic symptoms for all plant species tested were observed at all the rates of the test item used. The following phytotoxic symptoms were observed on 21 days after the test item application: chlorosis, necrosis, wilting, leaf deformation, stem deformation or death.

The endpoint values showing the impact of the test item on vegetative vigour of the plant species tested are presented in table given below:

Endpoint value		Soybean (<i>Glycine max</i>)	Corn (<i>Zea mays</i>)	Pea (<i>Pisum sativum</i>)	White mustard (<i>Sinapsis alba</i>)	Radish (<i>Raphanus sativus</i>)	Tomato (<i>Solanum lycopersicon</i>)
Plant number							
ER ₅₀	L/ha ^a	0.716	0.716	0.716	0.716	0.716	0.716
	g/ha ^b	36.308	36.308	36.308	36.308	36.308	36.308
NOER	L/ha ^a	0.19	0.19	0.19	0.19	0.19	0.19
	g/ha ^b	9.63	9.63	9.63	9.63	9.63	9.63
Shoot length (plants without roots)							
ER ₅₀	L/ha ^a	0.725	0.742	0.726	0.723	0.724	0.734
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NOER	L/ha ^a	< 0.09	< 0.09	0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	4.56	< 4.56	< 4.56	< 4.56
Plant dry weight (plants without roots)							
ER ₅₀	L/ha ^a	0.745	0.736	0.745	0.744	0.736	0.742
	g/ha ^b	37.779	37.323	37.779	37.728	37.323	37.627
NOER	L/ha ^a	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09	< 0.09
	g/ha ^b	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56	< 4.56

a: value for the test item, i.e., deltamethrin 5% cs expressed as L/ha

b: value for the active substance, i.e. deltamethrin as g/ha

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data