FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: SHA 3600 B

Product name(s): LABAMBA

Chemical active substance:

Lambda cyhalothrin 10% CS, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Cropchem España S.L.

Submission date: March 2022

MS Finalisation date: June 2022, November 2022

Version history

When	What
April 2022	Aplicant's Evaluation
June 2022	zRMS evaluation of the ppp SHA 3600 B/Labamba
September 2022	Applicant's update
November 2022	Applicant's update
November 2022	zRMS's update after commenting period process

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9 Ecotoxicology (KCP 10)

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, Fpn 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. num-ber a) per use b) per crop/ season	Min. inter-val 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 arthropods	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
1	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Aphids	Foliar Spray	BBCH 41-43	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	3 (cabbage), 7 (Brussels sprouts, cauliflower)								
2	CEU	Brassicas (cabbage, Brussels sprouts, cauliflower)	F	Caterpillars	Foliar Spray	BBCH 41-43	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	3 (cabbage), 7 (Brussels sprouts, cauliflower)								
3	CEU	Tomato	F	Aphids	Foliar Spray	BBCH 51-85	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	300-1000	3								
4	CEU	Tomato	G	Whitefly	Foliar Spray	BBCH 51-85	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	300-1000	3								
5	CEU	Winter cereals (wheat, barley, rye, oats, triticale)	F	Aphids	Foliar Spray	BBCH 41-75	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-400	28								
6	CEU	Winter Oilseed rape	F	Aphids	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	35								
7	CEU	Winter Oilseed rape	F	Coleseed sawfly	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	35								
8	CEU	Winter Oilseed rape	F	Pollen beetle	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	35								
9	CEU	Winter Oilseed rape	F	Stem weevil	Foliar Spray	BBCH 50-59	a) 1 b) 1		a) 0.075 b) 0.075	a) 0.0075 b) 0.0075	200-600	35								
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)																				
Minor uses according to Article 51 (field uses)																				

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Minor uses according to Article 51 (interzonal uses)																				

* 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

zRMS comment:

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. The changes are introduced directly as text in blue. Not agreed or not relevant information is struck through and shaded for transparency.

9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

No unacceptable risks for birds were identified for an application of LABAMBA in respect of the GAP.
No acute risk for mammals is expected after the application of SHA 3600 B/LABAMBA. However, after Tier I assessment, long-term risk for mammals was observed for vole and lagomorph in brassicas and oilseed rape, for vole in winter cereals and for rat and vole in tomato.
Higher-tier assessment was done. ~~Regarding the long-term risk for mammals a potential risk was still identified for small herbivorous mammals "vole" in brassicas. Additionally, the relevance of vole was discussed.~~ A refinement of the risk was done by refining the DF and the TER values were above the trigger of 5.
Summarizing, no unacceptable risks for mammals is expected after the application of SHA 3600 B/LABAMBA in respect of the GAPNo acute risk for mammals is expected after the application of SHA 3600 B/LABAMBA. However, after Tier I assessment, long-term risk for mammals was observed for vole and lagomorph in brassicas and oilseed rape, for vole in winter cereals and for rat and vole in tomato.

~~9.1.1.2~~ Higher-tier assessment was done. Regarding the long-term risk for mammals a potential risk was ~~still identified for small herbivorous mammals "vole" in brassicas. Additionally, the relevance of vole was discussed.~~ A refinement of the risk was done by refining the DF and the TER values were above the trigger of 5.

Summarizing, no unacceptable risks for mammals is expected after the application of SHA 3600 B/LABAMBA in respect of the GAP.

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

No data available.

9.1.1.4 Effects on aquatic organisms (KCP 10.2)

After Step1/2 calculations a risk for all aquatic organisms except algae was determined for lambda cyhalothrin and for metabolite XV in all crops (except sediment organisms).

After Step 3 calculations, metabolite XV was shown to present no unacceptable risk to aquatic and sediment dwelling organisms, whereas lambda-cyhalothrin still presented a risk for aquatic organisms.
~~After application of mitigation and step 4 calculations it has been shown to present no unacceptable acute and chronic risk to sediment dwelling organisms and for aquatic organisms.~~
~~The risk is acceptable when the following risk mitigation measures are considered for:~~

~~Brassicas, tomato field, winter cereals, winter oilseed rape:~~
~~*Spe3: to protect aquatic organisms respect an unsprayed buffer zone of 5 m to non-agricultural land/surface water bodies*~~
For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, an acceptable risk was obtained with the following mitigation measures:

Brassicas:

Spe3 – *To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.*

Tomato (field and glasshouse uses):

Spe3 – *To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.*

Winter cereals

Spe3 – *To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

Winter oilseed rape

Spe3 – *To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

9.1.1.5 After Step1/2 calculations a risk for all aquatic organisms except algae was determined for lambda cyhalothrin and for metabolite XV in all crops (except sediment organisms).

After Step 3 calculations, metabolite XV was shown to present no unacceptable risk to aquatic and sediment dwelling organisms, whereas lambda-cyhalothrin still presented a risk for aquatic organisms.
~~After application of mitigation and step 4 calculations it has been shown to present no unacceptable acute and chronic risk to sediment dwelling organisms and for aquatic organisms.~~
~~The risk is acceptable when the following risk mitigation measures are considered for:~~

~~Brassicas, Tomato field, Winter cereals, Winter oilseed rape:~~
~~*Spe3: to protect aquatic organisms respect an unsprayed buffer zone of 5 m to non-agricultural land/surface water bodies*~~

For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, an acceptable risk was obtained with the following mitigation measures:

Brassicas:

For D3 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 5 m no spray buffer zone + nozzle reduction of 90% or 10 m no spray buffer zone + nozzle reduction of 75% or 20 m no spray buffer zone + nozzle reduction of 50% should be considered.
For D4 stream 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D6 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 30 m no spray buffer zone + nozzle reduction of 50% should be considered.

For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% or 50 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 75% is needed.
For R2 stream, 40 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.

> ***Spe3*** *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.*

Tomato:
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 stream 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed

Although scenarios D6, R2 and R4 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.

> ***Spe3*** *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.*

Winter cereals
For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% should be considered.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D1, D2, D6, R3 and R4 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.

> ***Spe3*** *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

Winter oilseed rape

For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D2, D5 and R3 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.

Spe3 *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

9.1.1.6 Effects on (KCP 10.3.1)

Hazard quotients showed that no acute oral risk to bees is expected, whereas acute contact risk to bees is expected after the application of Lambda cyhalothrin 10CS.
~~Higher tier studies (tunnel and field test) are available in the monograph as well as own studies to address the risk to bees.~~
~~In conclusion, although an acute contact risk on bees is expected after the application of Lamba cyhalothrin 10% CS, the results of the semi-field and field studies showed that at the application rate supported in the GAP, the noted effects were principally observed on the day of application. Therefore, the risk for bees after the application of Lambda cyhalothrin 10%CS at the proposed rate supported in the GAP could be considered as acceptable.~~
Honey bee semi-field (tunnel study) and field studies were available with two of the four representative formulations ('Karate 10CS' (or similar formulation) and 'Lambda-Cyhalothrin 100 CS') on flowering Phacelia tanacetifoliaor oilseed rape. Adult honey bee mortality was observed in the tunnel study performed with 'Lambda-Cyhalothrin 100 CS' but the magnitude and the duration of this effect was considered not relevant. The study included detailed bee brood assessments and no clear adverse effect was observed. Some effects on mortality were also observed in the field studies performed with the representative formulation 'Karate 10CS' (and similar formulation). On the basis of these studies, overall, a low risk to honey bees was concluded for the representative uses in spring and winter cereals (Northern and Southern Europe), potatoes and seed potatoes (Northern and Southern Europe) and field tomatoes (Northern and Southern Europe).
It should be noted that, due to the variation in toxicity observed in the available acute studies, the experts at the Pesticides Peer Review Experts' Meeting 107 did not consider appropriate to read-across the available higher tier data between the different formulations. Therefore, whist a low risk to bees was concluded for the representative field uses of lambda-cyhalothrin, further consideration of the risk posed by the plant protection products is required. In addition, it was not considered appropriate to extrapolate the studies performed on flowering Phacelia tanacetifolia and oilseed rape to crops other than field crops.
A low risk to honey bees was concluded for the representative uses in glasshouse tomatoes. No assessment of the risk to pollinators which may be used in glasshouses was available.
For formulation SHA 3600 B/LABAMBA, HQ values were below 50, indicating acceptable risk for bees.
The acute risk for bees for the a.s. is unacceptable but several semi-field studies are available and they are considered sufficient to conclude acceptable risk for bees with the following mitigations measure such as :

- **SPe8: Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present.**

The final risk mitigation measures to bees should be considered at MSs level.

9.1.1.7 Effects on arthropods other than bees (KCP 10.3.2)

The results of the risk assessment showed unacceptable in-field risk after the application of SHA 3600 B/LABAMBA according to the GAP. The off-field risk is acceptable when the following risk mitigation measures are considered for:

- ~~Brassicas, tomato (field), winter cereals and winter oilseed rape: 5m buffer zone with 90% nozzles reduction or 10m buffer zone with 75% nozzles reduction or 15m buffer zone with 75% nozzles reduction or 20m buffer zone with 50% nozzles reduction or 30m buffer zone with 50% nozzles reduction or 40m buffer zone;~~

Brassicas, tomato (field), winter cereals and winter oilseed rape:
Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles or an unsprayed buffer zone of 10m with 75% drift reducing nozzles or an unsprayed buffer zone of 20m with 50% drift reducing nozzles or an unsprayed buffer zone of 40m.

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

No acute and chronic risk for earthworms from lambda-cyhalothrin and the metabolites Ia, metabolite V and metabolite XV is expected since the TER values are above the trigger.
No chronic risk is expected for soil macrofauna since the TER values are above the trigger value of 5. Therefore, no risk for earthworms and soil macroorganisms is expected after the application of Lambda-cyhalothrin 10% CS according to the proposed uses.

9.1.1.9 Effects on soil microbial activity (KCP 10.5)

No risk for soil microorganisms is expected from exposure to metabolite XV since the PECsoil is below the max. conc. with effects ≤ 25%.
At 1.67 mg Lambda-cyhalothrin SHA 3600 B/LABAMBA /kg dw soil, the effects on soil microorganisms were ≤ 25%. This concentration is higher than the highest $PEC_{soil\ acc}$ obtained for the formulation SHA 3600 B/LABAMBA.
Therefore, based on these results, no risk for soil microorganisms is expected after the application of SHA 3600 B/LABAMBA according to the proposed GAP.

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

No risk for non-target terrestrial plants is expected after the application of LABAMBA.

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

Not required.

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).

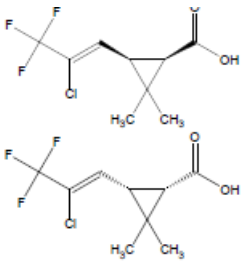
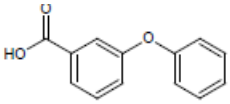
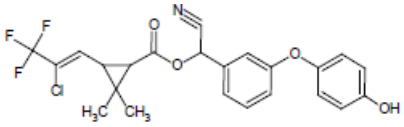
Table 9.1-2: Critical use pattern of SHA 3600 B/LABAMBA grouped according to criterion

Grouping according to criterion			
Group	**Intended uses**	**Relevant use parameters for grouping**	**Relevant parameter or value for sorting**
1	Brassicas (cabbage, Brussels sprouts, cauliflower)	1 applications, max app. Rate of 0.075 L./ha (equivalent to 7.5 g a.s./ha)	BBCH 41-43
2	Tomato	1 applications, max app. Rate of 0.075 L./ha (equivalent to 7.5 g a.s./ha)	BBCH 51-85
3	Tomato - greenhouse	1 applications, max app. Rate of 0.075 L./ha (equivalent to 7.5 g a.s./ha)	BBCH 51-85
4	Winter cereals (wheat, barley, rye, oats, triticale)	1 application, max app. Rate of 0.075 L./ha (equivalent to 7.5 g a.s./ha)	BBCH 41-75
5	Winter Oilseed rape	1 applications, max app. Rate of 0.075 L./ha (equivalent to 7.5 g a.s./ha)	BBCH 50-59

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 SHA 3600 B/LABAMBA is indicated in the table.

Table 9.1-3 Metabolites of lambda-cyhalothrin

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Metabolite 1a		242.5	Soil: 22.9 Water/Sediment: 29.4	Yes, aquatic and soil organisms
Metabolite V (PBA)		214.2	Soil: 31.4 (max observed in anaerobic soil, day 90) Water/Sediment: 28.5 (max observed in photolysis study in natural water, day 15)	Yes, aquatic and soil organisms
Metabolite XV		465.9	Soil: 12.1 Water/Sediment: 10.5	Yes, aquatic and soil organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with lambda-cyhalothrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on birds of SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin. However, the provision of further data on the SHA 3600 B/LABAMBA 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
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Acute oral toxicity	LD50 = 3950 mg/kg bw per day	EFSA Journal 2014;12(5):3677
Colinus virginianus (Bobwhite quail)	lambda-cyhalothrin	Short-term dietary toxicity	**LD50> 530 mg/kg bw per day** LD50>5300 mg/kg bw/feed	EFSA Journal 2014;12(5):3677
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Short-term dietary toxicity	LD50 = 3948 mg/kg bw/feed	EFSA Journal 2014;12(5):3677
Anas platyrhynchos (Mallard duck)	lambda-cyhalothrin	Long-term dietary/ reproduction toxicity	**NOAEL = 3.3 mg/kg bw per day** NOAEL = 30 mg/kg bw/feed	EFSA Journal 2014;12(5):3677

9.2.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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).

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.

Table 9.2-2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of SHA 3600 B/LABAMBA in brassicas

Intended use	**Brassicas**
Active substance/product	lambda-cyhalothrin
Application rate (g/ha)	1 × 7.5

Acute toxicity (mg/kg bw)	530				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Brassicas	Small omnivorous bird	158.8	1.0	1.19	445.0
Reprod. toxicity (mg/kg bw/d)	3.3				
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	Small omnivorous bird	64.8	1.0 × 0.53	0.26	12.81

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 SHA 3600 B/LABAMBA in tomato

Intended use	**Tomato**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	530				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Tomato	Small omnivorous bird	158.8	1.0	1.19	445.0
Reprod. toxicity (mg/kg bw/d)	3.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Tomato	Small omnivorous bird	64.8	1.0 × 0.53	0.26	12.81

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 SHA 3600 B/LABAMBA in winter cereals (wheat, barley, rye, oats, triticale)

Intended use	**Winter cereals (wheat, barley, rye, oats, triticale)**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	530				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter cereals	Small omnivorous bird	158.8	1.0	1.19	445.0
Reprod. toxicity (mg/kg bw/d)	3.3				
TER criterion	5				

Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter cereals	Small omnivorous bird	64.8	1.0 × 0.53	0.26	12.81

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 SHA 3600 B/LABAMBA in winter oilseed rape

Intended use	**Winter oilseed rape**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	530				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter oilseed rape	Small omnivorous bird	158.8	1.0	1.19	445.0
Reprod. toxicity (mg/kg bw/d)	3.3				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter oilseed rape	Small omnivorous bird	64.8	1.0 × 0.53	0.26	12.81

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.

According to the screening and first tier assessment, all the TER_a and TER_{lt} values for lambda-cyhalothrin are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 3600 B/LABAMBA presents no unacceptable acute and long-term risk to birds according to the intended uses.

zRMS comment:

Based on the Tier 1 risk assessment for birds all the TER_A and TER_{lt} values for lambda-cyhalothrin are greater than the Annex VI trigger of 10 and 5, respectively, indicating that SHA 3600 B/LABAMBA presents no unacceptable acute and long-term risk to birds according to the intended uses.

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 SHA 3600 B/LABAMBA 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 lambda-cyhalothrin via contaminated drinking water in leaf whorls

Intended use	**All crops**
Active substance	lambda-cyhalothrin
Application rate (g/ha)	1 × 7.5
Acute toxicity (mg/kg bw)	530
TER criterion	10

(Single) applic. 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	0.0075	0.46	0.0035	151428.57

$C_{spray-sol}$: 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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).
With a K(f)oc of ≥ 38000 mL/g, lambda-cyhalothrin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

Effective application rate (g/ha)	=	7.5	App. Rate x MAF = 7.5 x 1.0	
Acute toxicity (mg/kg bw)	=	530	quotient =	0.014
Reprod. Toxicity (mg/kg bw/d)	=	3.3	quotient =	2.27

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of lambda-cyhalothrin amounts to 5.5 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 measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Brassicas also covers the risk for birds from all other intended uses in groups (see 9.1.2).

Table 9.2-7: Assessment of the risk for earthworm-eating birds due to exposure to lambda-cyhalothrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in brassicas

Parameter	Lambda cyhalothrin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.003	PEC initial used as the worst case
log P_{ow} / P_{ow}	5.5 / 316228	LoEP
Koc	70100	LoEP
foc	0.02	Default
BCF_{worm}	2.707	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.008	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.0084	$DDD = PEC_{worm} \times 1.05$
NOEL (mg/kg bw/d)	3.3	LoEP
TER_{lt}	392.86	No risk, $TER_{lt} > 5$

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 water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of lambda-cyhalothrin in water.

Table 9.2-8: Assessment of the risk for fish-eating birds due to exposure to lambda-cyhalothrin via bioaccumulation in fish (secondary poisoning) for the intended use ~~in brassicas~~

Parameter	Lambda-cyhalothrin	comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00012	Max Step 1 value used as the worst case
BCF_{fish}	3635	LoEP
BMF	2	biomagnification factor (relevant for BCF ≥ 2000) default BMF for organis substances (Technical guidance document – EC, 2003)
PEC_{fish}	0.231	$PEC_{fish} = PEC_{water} \times BCF_{fish} \times TWA$
Daily dietary dose (mg/kg bw/d)	0.037	$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)	3.3	LoEP
TER_{lt}	89.77	No risk, $TER_{lt} > 5$

TER values shown in bold fall below the relevant trigger.

zRMS comment:

TER_{LT} for risk for earthworm-eating birds and fish-eating birds via secondary poisoning due to exposure to via bioaccumulation in earthworms (secondary poisoning) for the intended use is above trigger of 5.

9.2.2.5 Biomagnification in terrestrial food chains

The biomagnification in terrestrial food chains has been addressed by the following formula from EFSA (2009):
BAForganism, food = (α x FIR) / k2
With
α = fraction of ingested dose that is absorbed; available from toxicokinetc studies
k2 = ln(2)/T1/2 Rate constant for depuration (T1/2 = elimination half-life)
FIR = food intake rate relative to body weight

Parameter	lambda cyhalothrin	comments
α	0.25	EFSA 2014; 12(5):3677. In rat (based on excretion in urine)
FIR	2.26	Highest FIR/BW, for representative species in brassicas, used as worst case.
DT_{50} for depuration of vertebrates (days)	0.60	Calculated from 90% excretion within 48 h (EFSA 2014; 12(5):3677)
K_2	1.16	Rate constant for depuration
BAF	0.489	No potential of biomagnification

The BAF is < 1 and then it can be concluded that there is no potential of biomagnification.

zRMS comment:

No potential of biomagnification is indicated as BAF is < 1.

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

Not relevant.

9.2.4 Overall conclusions

No unacceptable risks for birds were identified for an application of SHA 3600 B/LABAMBA in respect of the GAP.

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 lambda-cyhalothrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.
Effects on mammals of SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin.
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	lambda-cyhalothrin	Acute oral toxicity	LD50 = 56 mg/kg bw *)	EFSA Journal 2014;12(5):3677
Mouse	lambda-cyhalothrin	Acute oral toxicity	LD50 = 19.9 mg/kg bw *)	EFSA Journal 2014;12(5):3677
Rat	cyhalothrin	Multi-generation reproduction	0.5 mg cyhalothrin/kg bw per day (equivalent to **0.25 mg lambda cyhalothrin/kg bw per day**)	EFSA Journal 2014;12(5):3677

*) geomean **33.4 mg/kg** bw is used for the risk assessment

9.3.1.1 Justification for new endpoints

The applicant proposed a higher ecotoxicological relevant NOAEL based on true reproductive effects as summarized below.
The NOAEL of 0.5 mg cyhalothrin/kg bw per day (corresponding to 10 ppm in the three-generation toxicity study by Milburn, 1984) is based on decrease of body weight gain (EFSA Conclusion, EFSA Journal 2014;12(5):3677). While weight gain can be considered relevant for the consumer risk assessment, ecologically it is not relevant for wild mammals (the resulting weight is more relevant). For example, male hares competing for females will not be more successful because they grew faster in the past, but because they are stronger or heavier in the present. Hence the present condition is ecologically relevant (remember that according to EFSA, 2014, weight gain was the relevant effect and not weight). Furthermore, weight gain is typically an endpoint whose calculation frequently results in a high proportion of false positives, i.e. due to the high number of statistical tests and because weight gain is based on two weight measurements, it is very common to observe significant differences in weight gain, even though there are no differences in weight (for this reason, new statistical methods have been proposed, which take account of the systematic error introduced by multiple testing, see e.g. Hoffmann et al., 20021). This has also been highlighted in a recent evaluation by the Syngenta Task Force (2016)2 of the three-generation toxicity study by Milburn (1984). In this detailed evaluation it has also been shown that observations at the next higher concentration above the NOAEL proposed by EFSA (2014) were not always consistent or that effects did not follow a clear dose response. Therefore, a more appropriate endpoint for wild mammal reproductive risk assessment of 2.6 mg cyhalothrin/kg/d (corresponding to 1.3 mg lambda-cyhalothrin/kg bw/d) is used in the following, which reflects the non-relevance of body weight gain and which is based on true reproductive effects.
The PPR 107 ecotoxicology expert meeting discussed the RMS proposal of 1.5 mg cyhalothrin/kg bw per day = 0.75 mg a.s./kg bw per day (in terms of lambda-cyhalothrin (based on the multi-generation study with rats by Milburn et al. (1984)) as ecotoxicological relevant NOEAL in the draft RAR. This endpoint was based on bodyweight effects in the F1 and F2 pups, and effects on litter size in F2 and F3 generation. The experts did not agree to the notifiers position above to consider the decrease of body weight gain not relevant for wild mammals. The three-generation toxicity study Milburn (1984) was later further discussed in the Mammalian toxicology meeting. The toxicological experts agreed that the body weight effects were relevant for the human health assessment and decided on an endpoint of 10 ppm for offspring toxicity based on a reduction in pup body-weight gain (= 0.5 mg cyhalothrin/kg bw per day). Overall, it was proposed that the effects on pup body-weight gain should be considered in the risk assessment for wild mammals. However, it was acknowledged that this is a conservative endpoint based on inconsistent effects with uncertainty as to whether these effects would be observed following the representative uses of the active substance. zRMS notes that in recent registration decisions for gamma-cyhalothrin products the same three-generation toxicity study of Milburn (1984) was relied upon to support an ecotoxicological relevant NOEAL of ca. 1 mg/kg bw/day which is more consistent with the NOAEL of 1.5 mg

cyhalothrin/kg bw per day = 0.75 mg a.s./kg bw per day as originally proposed by RMS Sweden. For reasons of consistency zRMS accepts a NOEAL of 0.75 mg a.s./kg bw/day as ecotoxicological relevant NOEAL.

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).

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.

Table 9.3-2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in Brassicas

Intended use	**Brassicas**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	33.4				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Brassicas- screening	Small herbivorous mammal	136.4	1.0	1.023	32.65
Reprod. toxicity (mg/kg bw/d)	0.25				
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 - screening	Small herbivorous mammal	72.3	1.0 x 0.53	0.287	**0.87**
Leafy vegetables BBCH> 20	Small insectivorous mammal “shrew”	1.9	1.0 x 0.53	0.008	31.25
Leafy vegetables BBCH 40-49	Small herbivorous mammal “vole”	72.3	1.0 x 0.53	0.287	**0.87**
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	1.0 x 0.53	0.057	**4.39**
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1.0 x 0.53	0.003	8.06

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 SHA 3600 B/LABAMBA in tomato

Intended use	**Tomato**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	33.4				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Tomato - screening	Small herbivorous mammal	136.4	1.0	1.023	32.65
Reprod. toxicity (mg/kg bw/d)	0.25				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Tomato - screening	Small herbivorous mammal	72.3	1.0 x 0.53	0.287	**0.87**
Fruiting Vegetables Fruit stage BBCH 71-89	Frugivorous mammal "rat"	25.2	1.0 x 0.53	0.1	**2.5**
Fruiting Vegetables BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.0 x 0.53	0.008	31.25
Fruiting Vegetables BBCH ≥ 50	Small herbivorous mammal "vole"	21.7	1.0 x 0.53	0.086	**2.91**
Fruiting Vegetables BBCH ≥ 50	Small omnivorous mammal "mouse"	2.3	1.0 x 0.53	0.009	27.78

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.

Tomato – greenhouse

According to the REGULATION (EU) No 283/2013, the effects of the active substance on birds and mammals should not be considered, as the product is intended to be used in the greenhouse.

Table 9.3-4: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in winter cereals

Intended use	**Winter cereals**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	33.4				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter cereals - screening	Small herbivorous mammal	118.4	1.0	0.888	37.61

Reprod. toxicity (mg/kg bw/d)	0.25				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter cereals - screening	Small herbivorous mammal	48.3	1.0 × 0.53	0.192	**1.30**
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.0 × 0.53	0.008	31.25
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.0 × 0.53	0.086	**2.91**
Cereals BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.0 × 0.53	0.009	27.78

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 SHA 3600 B/LABAMBA in winter oilseed rape

Intended use	**Winter oilseed rape**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Acute toxicity (mg/kg bw)	33.4				
TER criterion	10				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_{90}**	**MAF_{90}**	**DDD_{90} (mg/kg bw/d)**	**TER_a**
Winter oilseed rape-screening	Small herbivorous mammal	118.4	1.0	0.888	37.61
Reprod. toxicity (mg/kg bw/d)	0.25				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter oilseed rape-screening	Small herbivorous mammal	48.3	1.0 × 0.53	0.192	**1.30**
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.0 × 0.53	0.008	31.25
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.0 × 0.53	0.072	**3.47**
Oilseed rape All season	Large herbivorous mammal "lagomorph"	14.3	1.0 × 0.53	0.057	**4.39**
Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse"	1.9	1.5 × 0.53	0.008	31.25

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.

A low acute risk for mammals after application of SHA 3600 B/LABAMBA can be concluded for all uses in the screening step.

Regarding the long-term risk for mammals a potential risk was identified for large and small herbivorous mammals in brassicas, tomato, winter cereals and winter oilseed rape. For these uses a higher tier risk assessment is presented below.

9.3.2.2 Higher-tier risk assessment

1. Consideration of relevance of the EFSA endpoint
See under 9.3.1.1.

Table 9.3-6: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in brassicas

Intended use	**Brassicas**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Reprod. toxicity (mg/kg bw/d)	0.75				
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 - screening	Small herbivorous mammal	72.3	1.0 x 0.53	0.287	**2.61**
Leafy vegetables BBCH> 20	Small insectivorous mammal “shrew”	1.9	1.0 x 0.53	0.008	93.75
Leafy vegetables BBCH 40-49	Small herbivorous mammal “vole”	72.3	1.0 x 0.53	0.287	**2.61**
Leafy vegetables All season	Large herbivorous mammal “lagomorph”	14.3	1.0 x 0.53	0.057	13.16
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	7.8	1.0 x 0.53	0.003	24.19

Table 9.3-7: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in tomato

Intended use	**Tomato**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Reprod. toxicity (mg/kg bw/d)	0.75				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Tomato - screening	Small herbivorous mammal	72.3	1.0 x 0.53	0.287	**2.61**
Fruiting Vegetables Fruit stage BBCH 71-89	Frugivorous mammal “rat”	25.2	1.0 x 0.53	0.1	7.5
Fruiting	Small insectivorous mammal	1.9	1.0 x 0.53	0.008	93.75

Vegetables BBCH ≥ 20	"shrew"				
Fruiting Vegetables BBCH ≥ 50	Small herbivorous mammal "vole"	21.7	1.0 x 0.53	0.086	8.72
Fruiting Vegetables BBCH ≥ 50	Small omnivorous mammal "mouse"	2.3	1.0 x 0.53	0.009	83.33

Table 9.3-8: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in winter cereals

Intended use	**Winter cereals**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Reprod. toxicity (mg/kg bw/d)	0.75				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter cereals - screening	Small herbivorous mammal	48.3	1.0 × 0.53	0.192	**3.91**
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.0 × 0.53	0.008	93.75
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.0 × 0.53	0.086	8.72
Cereals BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3	1.0 × 0.53	0.009	83.33

Table 9.3-9: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in winter oilseed rape

Intended use	**Winter oilseed rape**				
Active substance/product	lambda-cyhalothrin				
Application rate (g/ha)	1 × 7.5				
Reprod. toxicity (mg/kg bw/d)	0.75				
TER criterion	5				
Crop scenario Growth stage	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Winter oilseed rape-screening	Small herbivorous mammal	48.3	1.0 × 0.53	0.192	**3.91**
Oilseed rape BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9	1.0 × 0.53	0.008	93.75
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.0 × 0.53	0.072	10.42
Oilseed rape All season	Large herbivorous mammal "lagomorph"	14.3	1.0 × 0.53	0.057	13.16

Oilseed rape BBCH ≥ 40	Small omnivorous mammal "mouse"	1.9	1.5 × 0.53	0.008	93.75

~~Regarding the long-term risk for mammals a potential risk was still identified for small herbivorous mammals "vole" in brassicas.~~
~~There are many reports from the literature that the optimum or prime habitat' of common voles is undisturbed grassland or set-aside at a vegetation height of minimum 20 cm (De Jonge and Dienske, 1979; Delattre et al., 1996; Butet and Leroux, 2001; Giraudoux et al., 1994; Gorman and Reynolds, 1993) or perennial crops like alfalfa (Truszkowski, 1982).~~
~~The preference for primary habitats is underlined by the findings of Briner et al. (2005), who demonstrated by using automatic radio tracking, that M. arvalis developed high population densities containing 90% of the total home range in wild flower strips neighbouring crop fields, but hardly ever entered the nearby crops, even when those were highly palatable. Also, Koks et al. (2007) showed that vole abundance was twice as high in set aside land and in high and dense vegetation than in neighbouring non fallow habitat types like plantations or cereals.~~
~~Therefore, it can be stated that~~
~~a.) When local population densities are low, Common voles are prone to spend much less time in crop fields, which only serve as transient habitats.~~
~~b.) Secondary populations of the Common vole in field (as opposed to the primary population in the margins) are also of little to no importance for the survival of the local populations, since harvest and ploughing will destroy their home range habitat at least once a year.~~
~~Since this species is so prolific, it can additionally be stated that a slight reduction in the growth potential of secondary populations in field crops will usually also be of little to no importance for the population of local predator species.~~
~~Therefore, it is may be more appropriate to consider the other small mammals, such as the wood mouse (Apodemus sylvaticus) and common shrew (Sorex araneus), as relevant focal species in crop habitats.~~
~~The risk assessment is considered to be covered through the assessment of other small mammalian species for the following reasons:~~
~~• High fecundity and population recuperation of the vole;~~
~~• Primary source of food outside crops fields for the vole;~~
~~• Necessity of population control measures since the vole is considered a crop pest when high population levels are reached;~~
~~• Other agricultural techniques being also means of population control~~

zRMS comment:

A low acute risk for mammals after application of SHA 3600 B/LABAMBA can be concluded for all uses in the screening step. Regarding the long-term risk for mammals a potential risk was identified for large and small herbivorous mammals in brassicas, tomato, winter cereals and winter oilseed rape.

After refinement the potential risk was still identified only for small herbivorous mammals "vole" in brassicas.

Therefore, further refinement is required for vole in brassicas.

DF refinement

Deposition factor (DF)
LABAMBA will be applied directly to crop. Since grass will be covered by the crop, an interception by the crop has to be taken into account. Therefore, the Applicant considers that a deposition factor for the refinement is justified. According to the values of EFSA Journal 2014;12(5):3662[1], brassicas (leafy vegetables) have assigned an interception factor of 70% (BBCH 40 - 89), which corresponds to a deposition factor of 0.3.

Table 9.3-10: Higher-tier assessment of the long-term/reproductive risk for mammals due to the use of SHA 3600 B/LABAMBA in brassicas

Intended use **Active substance/product** **Application rate (g/ha)**		**Brassicas** lambda-cyhalothrin 1 × 7.5			
Reprod. toxicity (mg/kg bw/d) **TER criterion**		0.75 5			
Crop scenario **Growth stage**	**Indicator/generic focal species**	**SV_m**	**MAF_m × TWA × DF**	**DDD_m (mg/kg bw/d)**	**TER_{lt}**
Leafy vegetables BBCH 40-49	Small herbivorous mammal "vole"	72.3	1.0 x 0.53 x 0.3	0.09	8.72

zRMS comment:

zRMS agrees with the refinement option presented by the Applicant.

After refinement the potential risk for small herbivorous mammals "vole" in brassicas is considered acceptable.

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 (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).
With a K(f)oc of ≥ 38000 mL/g, lambda-cyhalothrin belongs to the group of more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied.

[1] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil.

Effective application rate (g/ha)	=	7.5	App. Rate x MAF = 7.5 x 1.0	
Acute toxicity (mg/kg bw)	=	33.4	quotient	= 0.22
Reprod. toxicity (mg/kg bw/d)	=	0.25	quotient	= 30

9.3.2.4 Effects of secondary poisoning

The log Pow of lambda-cyhalothrin amounts to 5.5 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 measured/predicted concentrations in soil/porewater / is based on experimental data.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Brassicas also covers the risk for mammals from all other intended uses in groups (see 9.1.2).

Table 9.3-6: Assessment of the risk for earthworm-eating mammals due to exposure to lambda-cyhalothrin via bioaccumulation in earthworms (secondary poisoning) for the intended use in Brassicas

Parameter	lambda-cyhalothrin	comments
PEC_{soil} (twa = 21 d) (mg/kg soil)	0.003	PEC initial used as the worst case
log P_{ow} / P_{ow}	5.5 / 316228	LoEP
Koc	70100	LoEP
foc	0.02	Default
BCF_{worm}	2.707	$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw})$ $= (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC_{worm}	0.008	$PEC_{worm} = PEC_{soil} \times BCF_{worm/soil}$
Daily dietary dose (mg/kg bw/d)	0.01	$DDD = PEC_{worm} \times 1.28$
NOEL (mg/kg bw/d)	0.25	LoEP
TER_{lt}	25.0	

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 / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of lambda-cyhalothrin in water.

Table 9.3-7: Assessment of the risk for fish-eating mammals due to exposure lambda-cyhalothrin via bioaccumulation in fish (secondary poisoning) for the intended use ~~in Brassicas~~

Parameter	lambda-cyhalothrin	Comments
PEC_{sw} (twa = 21 d) (mg/L)	0.00007	Max Step 2. ~~21 d- $PEC_{sw,twa}$ value used~~
BCF_{fish}	3635	Whole fish

BMF	2	biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}	0.135	PECfish = PECwater × BCFfish × TWA
Daily dietary dose (mg/kg bw/d)	0.019	DDD = PECfish × 0.142
NOEL (mg/kg bw/d)	0.25	LoEP
TER_{lt}	13.05	No risk. TER_{lt}> 5

TER values shown in bold fall below the relevant trigger.

zRMS comment:

The risk assessment for fish-eating mammals and earthworm–eating mammals due to exposure lambda-cyhalothrin via bioaccumulation in fish and earthworm (secondary poisoning) provided for worst case in Brassicas, covering remaining uses in the GAP was considered acceptable.

9.3.2.5 Biomagnification in terrestrial food chains

The biomagnification in terrestrial food chains has been addressed by the following formula from EFSA (2009):
BAForganism, food = (α x FIR) / k2
With
α = fraction of ingested dose that is absorbed; available from toxicokinetic studies
k2 = ln(2)/T1/2 Rate constant for depuration (T1/2 = elimination half-life)
FIR = food intake rate relative to body weight

Parameter	lambda cyhalothrin	Comments
α	0.25	EFSA 2014; 12(5):3677. In rat (based on excretion in urine)
FIR	1.68	Highest FIR/BW, for representative species in brassicas, used as worst case.
DT_{50} for depuration of vertebrates (days)	0.60	Calculated from 90% excretion within 48 h (EFSA 2014; 12(5):3677)
K_2	1.16	Rate constant for depuration
BAF	0.364	The BAF is < 1 and then it can be concluded that there is no potential of biomagnification.

The BAF is < 1 and then it can be concluded that there is no potential of biomagnification.

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

Not relevant.

9.3.4 Overall conclusions

No acute risk for mammals is expected after the application of SHA 3600 B/LABAMBA. However, after Tier I assessment, long-term risk for mammals was observed for vole and lagomorph in brassicas and oilseed rape, for vole in winter cereals and for rat and vole in tomato.

Higher-tier assessment was done. ~~Regarding the long-term risk for mammals a potential risk was still identified for small herbivorous mammals "vole" in brassicas. Additionally, the relevance of vole was discussed.~~ A refinement of the risk was done by refining the DF and the TER values were above the trigger of 5.
Summarizing, no unacceptable risks for mammals is expected after the application of SHA 3600 B/LABAMBA in respect of the GAP.

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 lambda-cyhalothrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).
Effects on aquatic organisms of SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin. A new aquatic studies are currently ongoing and the final reports will be presented when it will be available.
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 – lambda-cyhalothrin and relevant metabolites

Species	Substance	Exposure System	Results	Reference
Leuciscus idus	Lambda-cyhalothrin	96 h	**EC_{50}: 0.078 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Lepomis macrochirus	Lambda-cyhalothrin	96 h	LC_{50}: 0.21 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oncorhynchus mykiss	Lambda-cyhalothrin	96 h	LC_{50}: 0.24 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Ictalurus punctatus	Lambda-cyhalothrin	96 h	LC_{50}: 0.16 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Gasterosteus aculeatus	Lambda-cyhalothrin	96 h	LC_{50}: 0.40 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Brachydanio rerio	Lambda-cyhalothrin	96 h	LC_{50}: 0.64 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Pimephales promelas	Lambda-cyhalothrin	96 h	LC_{50}: 0.70 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oryzias latipes	Lambda-cyhalothrin	96 h	LC_{50}: 1.4 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Poecilia reticulata	Lambda-cyhalothrin	96 h	LC_{50}: 2.3 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oncorhynchus mykiss	metabolite Ia	96h	**LC_{50}>10800 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Lepomis macrochirus	metabolite Ia	96h	LC_{50}>14000 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oncorhynchus mykiss	metabolite II	96h	**LC_{50}: 18.7 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Pimephales promelas	metabolite IV	96h	**LC_{50}: 60 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Oncorhynchus mykiss	metabolite V	96h	**LC_{50}: 13300 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Lepomis macrochirus	metabolite V	96h	LC_{50}: 36300 µg a.s./L_{mm}	EFSA 2014;12(5):3677

Species	Substance	Exposure System	Results	Reference
Oncorrynchus mykiss	metabolite XV	96h	**LC_{50}: 0.84 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Cyprinus carpio	Karate 10 CS (100 g a.s./L)	96h	LC_{50}: 1.17 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oncorrhynchus mykiss	CA 2352 (Kaiso sorbie 5% EG)	96h	LC_{50}: 0.395 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Cyprinus carpio	JF9509 (5% EC)	96h	LC_{50}: 0.5 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Oncorrynchus mykiss	Lambda-cyhalothrin 100 g/L CS formulation	96h	LC_{50}: 0.5 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Cyprinodon variegatus	Lambda-cyhalothrin	ELS 28d	NOEC:0.25 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Pimephales promelas	Lambda-cyhalothrin	FLC 300d	**NOEC: 0.031 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Higher tier endpoint: Refined acute RAC = 2.1 ng/L (based on EFSA method 2[e] i.e. the ranking method where data for additional species are available)				
Daphnia magna	Lambda-cyhalothrin	48h	EC_{50}: 0.23 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Cylclops sp.	Lambda-cyhalothrin	48h	EC_{50}: 0.195 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Hyallela azteca	Lambda-cyhalothrin	48h	**EC_{50}: 0.0018 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Chaoborus sp.	Lambda-cyhalothrin	48h	EC_{50}: 0.0022 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Cloeon dipterum	Lambda-cyhalothrin	48h	EC_{50}: 0.0264 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Gammarus pulex	Lambda-cyhalothrin	48h	EC_{50}: 0.011 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Corixa sp.	Lambda-cyhalothrin	48h	EC_{50}: 0.026 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Hydracarina	Lambda-cyhalothrin	48h	EC_{50}: 0.041 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Ischnura elegans	Lambda-cyhalothrin	48h	EC_{50}: 0.102 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Ostracoda	Lambda-cyhalothrin	48h	EC_{50}: 2.04 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Daphnia pulex	Metabolite Ia	48h	**EC_{50}: 105000 µg a.s./L_{nom}**	EFSA 2014;12(5):3677
Daphnia magna	Metabolite II	48h	**EC_{50}> 14.3µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Daphnia magna	Metabolite V	48h	**EC_{50}: 85000 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Daphnia magna	Metabolite XV	48h	**EC_{50}: 0.16 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Daphnia magna	Lambda-cyhalothrin 100 g/L CS formulation	48h	EC_{50}: 0.13 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Daphnia magna	Lambda-cyhalothrin 100 g/L CS formulation	48h	EC_{50}: 2.36 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Daphnia magna	Lambda-cyhalothrin 50 g/L EC formulation	48h	EC_{50}: 0.52 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Daphnia magna	Lambda-cyhalothrin CA 2352 50 g/L EG formulation	48h	EC_{50}: 0.25 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Gammarux pulex	Lambda-cyhalothrin CA 2352 50 g/L EG	48h	EC_{50}: 0.0026 µg a.s./L_{mm}	EFSA 2014;12(5):3677

Species	Substance	Exposure System	Results	Reference
	formulation			
Mysidopsis bahia	Lambda-cyhalothrin	28 d	**NOEC: 0.00022 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Daphnia magna	Lambda-cyhalothrin	21 d	NOEC: 0.00198 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Higher tier endpoint: Refined acute RAC= 0.38 ng/L (based on EFSA method 1[e], i.e. the geometric mean of available acute data on aquatic invertebrates. Acute and chronic RAC = **0.3** ng/L. RAC was agreed on expert meeting and it is based on available laboratory data on lambda-cyhalothrin and gamma-cyhalothrin as well as field data on gamma-cyhalothrin. This RAC is only applicable for CS-formulations and when exposure to the aquatic environment is via spray drift only.				
Chironomus riparius	Lambda-cyhalothrin	48 h	EC_{50}: 1.5 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Chironomus riparius	Lambda-cyhalothrin	28 d	**NOEC: 0.13 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Chironomus riparius	Lambda-cyhalothrin	28 d	NOEC: 105 µg/kg sediment dw (mm)	EFSA 2014;12(5):3677
Chironomus riparius	Lambda-cyhalothrin	28 d	NOEC: 0.63 µg a.s./L_{mm} NOEC: 2.35 µg/kg sediment dw (mm)	EFSA 2014;12(5):3677
Chironomus riparius	Metabolite Ia	28d	**NOEC: 20800 µg a.s./L_{mm}**	EFSA 2014;12(5):3677
Chironomus riparius	Metabolite VI	28d	NOEC: 11000 µg a.s./L_{mm}	EFSA 2014;12(5):3677
Chironomus riparius	Metabolite XV	28d	**NOEC: 580 µg a.s./kg $_{mm}$**	EFSA 2014;12(5):3677
Pseudokirchneriella subcapitata	Lambda-cyhalothrin	72h	**E_rC_{50}: 5 µg a.s./L_{mm}** E_yC_{50}: 5 µg a.s./L_{mm}	EFSA 2014;12(5):3677

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

Species	Substance	Exposure System	Results	Reference
Cyprinus carpio	Karate 10 CS (100 g a.s./L)	96 h	LC_{50} = 1.17 µg a.s./L_{mm}	EFSA Conclusions EFSA Journal 2014:12(5):3677
Oncorrynchus mykiss	Lambda-cyhalothrin 100 g/L CS formulation	96 h	LC_{50} = 6.0 µg a.s./L_{mm}	EFSA Conclusions EFSA Journal 2014:12(5):3677
Daphnia magna	Lambda-cyhalothrin 100 g/L CS formulation	48 h	EC_{50} = 0.13 µg a.s./L_{mm}	EFSA Conclusions EFSA Journal 2014:12(5):3677
Daphnia magna	Lambda-cyhalothrin 100 g/L CS formulation	48 h	EC_{50} = 2.36 µg a.s./L_{mm}	EFSA Conclusions EFSA Journal 2014:12(5):3677

mm: based on mean measured concentrations.
*The representative formulation is similar to Labamba (please see in PART C for comparison both formulation)

9.5.1.1 Justification for new endpoints

The EU agreed endpoints were used.

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. PEC/RAC ratios above the relevant trigger of 1are shown in bold.

Table 9.5-3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in brassicas use no. 1&2

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**		**Sed. dwell. acute**	~~**Sed. dwell. pro-longed**~~	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***		***C. riparius***	~~***C. riparius***~~	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}		EC50	~~NOEC~~	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5		1.5	~~2.35~~	0.13
AF		100	10	100	10	10		100	10	10
RAC (µg/L)		0.0021*	0.0031	0.000018	0.000022	0.5		0.015	~~0.235~~	0.013
FOCUS Sce-nario	**PEC $_{gl\text{-}max}$ (µg/L)**						~~**PEC $_{gl\text{-}max}$ (µg/kg)**~~			
Step 1										
	0.12	**57.14**	**38.71**	**6666.67**	**5454.55**	0.24	~~18.39~~	**8**	~~**78.26**~~	**9.23**
Step 2										
N-Europe March-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	~~1.51~~	**4.66**	~~**6.43**~~	**5.38**
S-Europe March-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	~~2.59~~	**4.66**	~~**11.02**~~	**5.38**
N-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	~~1.51~~	**4.66**	~~**6.43**~~	**5.38**
S-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	~~2.05~~	**4.66**	~~**8.72**~~	**5.38**
Step 3										
D3***/ditch	0.0462	**22.00**	**14.90**	**2566.67**	**2100**	-/-	~~0.1129~~	0.11	~~0.48~~	0.12
D3****/ditch	0.0460	**21.90**	**14.84**	**2555.56**	**2090.91**	-/-	~~0.0941~~	**2.19**	~~0.40~~	**2.53**

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. acute	~~Sed. dwell. pro-longed~~	Sed. dwell. pro-longed
D4***/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-/-	~~0.0129~~	**3.07**	~~0.05~~	**3.54**
D4***/stream	0.0329	**15.67**	**10.61**	**1827.78**	**1495.45**	-/-	~~0.0162~~	0.12	~~0.07~~	0.14
D6***/ditch	0.0460	**21.9**	**14.84**	**2555.56**	**2090.91**	-/-	~~0.0937~~	0.13	~~0.40~~	0.15
R1***/pond	0.0018	0.86	0.58	**100.0**	**81.82**	-/-	~~0.0541~~	**2.04**	~~0.23~~	**2.35**
R1****/pond	0.0019	0.90	0.61	**105.56**	**86.36**	-/-	~~0.0575~~	**2.04**	~~0.24~~	**2.35**
R1***/stream	0.0306	**14.57**	**9.87**	**1700.0**	**1390.91**	-/-	~~0.7666~~	**2.73**	~~3.26~~	**3.15**
R1****/stream	0.0306	**14.57**	**9.87**	**1700.0**	**1390.91**	-/-	~~0.759~~	**2.73**	~~3.23~~	**3.15**
R2***/stream	0.0409	**19.48**	**13.19**	**2272.22**	**1859.09**	-/-	~~0.7366~~	**2.87**	~~3.13~~	**3.31**
R2****/stream	0.0409	**19.48**	**13.19**	**2272.22**	**1859.09**	-/-	~~2.081~~	**2.86**	~~8.86~~	**3.30**
R3***/stream	0.0430	**20.48**	**13.87**	**2388.89**	**1954.55**	-/-	~~2.108~~	**2.49**	~~8.97~~	**2.87**
R3****/stream	0.0429	**20.43**	**13.84**	**2383.33**	**1950.00**	-/-	~~1.659~~	**2.04**	~~7.06~~	**2.35**
R4***/stream	0.0373	**17.76**	**12.03**	**2072.22**	**1695.45**	-/-	~~0.8377~~	0.11	~~3.56~~	0.12
R4****/stream	0.0306	**14.57**	**9.87**	**1700.0**	**1390.91**	-/-	~~1.844~~	**2.19**	~~7.85~~	**2.53**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*****vegetables leafy 1st**
******vegetables leafy 2nd**
*according to EFSA, 2014

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in tomato use no. 3

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute		~~Sed. dwell. pro-longed~~	Sed. dwell. pro-longed
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***		~~*C. riparius*~~	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50		~~NOEC~~	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5		~~2.35~~	0.13

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute		~~Sed. dwell. pro-longed~~	Sed. dwell. pro-longed
AF		100	10	100	10	10	100		10	10
RAC (µg/L)		0.0021*	0.0031	0.000018	0.000022	0.5	0.015		~~0.235~~	0.013
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							~~PEC $_{gl-max}$ (µg/kg)~~		
Step 1										
	0.12	**57.14**	**38.71**	**6666.67**	**5454.55**	0.24	**8**	~~18.39~~	~~**78.26**~~	**9.23**
Step 2										
N-Europe March-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~2.59~~	~~**11.02**~~	**5.38**
S-Europe March-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.51~~	~~**6.43**~~	**5.38**
N-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.51~~	~~**6.43**~~	**5.38**
S-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~2.05~~	~~**8.72**~~	**5.38**
Step 3										
D3/ditch****	0.0462	**22.00**	**14.9**	**2566.67**	**2100.0**	-/-	**3.08**	~~0.1129~~	~~0.48~~	**3.55**
D4/pond****	0.0016	0.76	0.52	**88.89**	**72.73**	-/-	0.11	~~0.0129~~	~~0.05~~	0.12
D4/stream****	0.0329	**15.67**	**10.61**	**1827.78**	**1495.45**	-/-	**2.19**	~~0.0162~~	~~0.07~~	**2.53**
D6/ditch	0.0458	**21.81**	**14.77**	**2544.44**	**2081.82**	-/-	**3.05**	~~0.0855~~	~~0.36~~	**3.52**
R1/pond****	0.0018	0.86	0.58	**100.0**	**81.82**	-/-	0.12	~~0.0541~~	~~0.23~~	0.14
R1/stream****	0.0306	**14.57**	**9.87**	**1700.0**	**1390.91**	-/-	**2.04**	~~0.7666~~	~~**3.26**~~	**2.35**
R2/stream	0.0409	**19.48**	**13.19**	**2272.22**	**1859.09**	-/-	**2.73**	~~1.232~~	~~**5.24**~~	**3.15**
R3/stream	0.0431	**20.52**	**13.90**	**2394.44**	**1959.09**	-/-	**2.87**	~~0.5546~~	~~**2.36**~~	**3.32**
R4/stream	0.0297	**14.14**	**9.58**	**1650.0**	**1350**	-/-	**1.98**	~~1.0601~~	~~**4.51**~~	**2.28**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
**** National scenarios relevant for Poland are D3, D4 and R1. Due to fact that drainage scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for vegetables leafy 1st.

Table 9.5-65: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in winter cereals use no. 5

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**		**Sed. dwell. pro-longed**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***		~~***C. riparius***~~	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC_{50}		~~NOEC~~	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5		~~2.35~~	0.13
AF		100	10	100	10	10	100		~~10~~	10
RAC (µg/L)		0.0021*	0.0031	0.000018	0.000022	0.5	0.015		~~0.235~~	0.013
FOCUS Sce-nario	**PEC $_{gl\text{-}max}$ (µg/L)**							~~**PEC $_{gl\text{-}max}$ (µg/kg)**~~		
Step 1										
	0.12	**57.14**	**38.71**	**6666.67**	**5454.55**	0.24	8	~~18.39~~	~~**78.26**~~	**9.23**
Step 2										
N-Europe Mar-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-	**4.66**	1.51	**6.43**	**5.38**
S-Europe Mar-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-	**4.66**	2.59	**11.02**	**5.38**
N-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-	**4.66**	1.51	**6.43**	**5.38**
S-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-	**4.66**	2.05	**8.72**	**5.38**
Step 3										
D1/ditch	0.0467	**22.24**	**15.06**	**2594.44**	**2122.73**	-	**3.11**	~~0.2155~~	~~0.92~~	**3.59**

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute		Sed. dwell. pro-longed	Sed. dwell. pro-longed
D1/stream	0.0404	**19.24**	**13.03**	**2244.44**	**1836.36**	-	**2.69**	0.0808	0.34	**3.11**
D2/ditch	0.0467	**22.24**	**15.06**	**2594.44**	**2122.73**	-	**3.11**	0.2119	0.90	**3.59**
D2/stream	0.0413	**19.67**	**13.32**	**2294.44**	**1877.27**	-	**2.75**	0.1867	0.79	**3.18**
D3/ditch	0.0462	**22.00**	**14.90**	**2566.67**	**2100**	-	**3.08**	0.1135	0.48	**3.55**
D4/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-	0.11	0.0151	0.06	0.12
D4/stream	0.0363	**17.29**	**11.71**	**2016.67**	**1650**	-	**2.42**	0.0252	0.11	**2.79**
D5/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-	0.11	0.0157	0.07	0.12
D5/stream	0.0368	**17.52**	**11.87**	**2044.44**	**1672.73**	-	**2.45**	0.0206	0.09	**2.83**
D6/ditch	0.0461	**21.95**	**14.87**	**2561.11**	**2095.45**	-	**3.07**	0.1099	0.47	**3.55**
R1/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-	0.11	0.0236	0.10	0.12
R1/stream	0.0303	**14.43**	**9.77**	**1683.33**	**1377.27**	-	**2.02**	0.3165	**1.35**	**2.33**
R3/stream	0.0430	**20.48**	**13.87**	**2388.89**	**1954.55**	-	**2.87**	0.3589	**1.53**	**3.31**
R4/stream	0.0304	**14.48**	**9.81**	**1688.89**	**1381.82**	-	**2.03**	0.7329	**3.12**	**2.34**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
* refined acute RAC (EFSA Journal 2014;12(5):3677)
** based on the geometric mean of NOEC values for crustaceans (EFSA Journal 2014;12(5):3677, EFSA Journal 2013;11(7): 3290, Gonsior 2008)
*according to EFSA 2014

Table 9.5-~~7~~6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in winter oilseed rape use no. 6, 7, 8 &9

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**		**Sed. dwell. pro-longed**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***		***C. riparius***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50		NOEC	NOEC

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute		Sed. dwell. pro-longed	Sed. dwell. pro-longed
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5		2.35	0.13
AF		100	10	100	10	10	100		10	10
RAC (µg/L)		0.0021*	0.0031	0.000018	0.000022	0.5	0.015		0.235	0.013
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**							~~PEC $_{gl-max}$ (µg/kg)~~		
Step 1										
	0.12	**57.14**	**38.71**	**6666.67**	**5454.55**	0.24	8	~~18.39~~	~~**78.26**~~	**9.23**
Step 2										
N-Europe Mar-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.33~~	~~**5.66**~~	**5.38**
S-Europe Mar-May	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.78~~	~~**7.57**~~	**5.38**
N-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.33~~	~~**5.66**~~	**5.38**
S-Europe June-Sept	0.07	**33.33**	**22.58**	**3888.89**	**3181.82**	-/-	**4.66**	~~1.78~~	~~**7.57**~~	**5.38**
Step 3										
D2/ditch	0.0468	**22.29**	**15.10**	**2600**	**2127.27**	-/-	**3.12**	~~0.2125~~	~~0.90~~	**3.60**
D2/stream	0.0416	**19.81**	**13.42**	**2311.11**	**1890.91**	-/-	**2.77**	~~0.1891~~	~~0.80~~	**3.20**
D3/ditch	0.0462	**22.00**	**14.9**	**2566.67**	**2100**	-/-	**3.08**	~~0.1093~~	~~0.47~~	**3.55**
D4/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-/-	0.11	~~0.0155~~	~~0.07~~	0.12
D4/stream	0.0355	**16.90**	**11.45**	**1972.22**	**1613.64**	-/-	**2.37**	~~0.0233~~	~~0.10~~	**2.73**
D5/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-/-	0.11	~~0.0158~~	~~0.07~~	0.12
D5/stream	0.0374	**17.81**	**12.06**	**2077.78**	**1700**	-/-	**2.49**	~~0.0224~~	~~0.10~~	**2.88**
R1/pond	0.0016	0.76	0.52	**88.89**	**72.73**	-/-	0.11	~~0.0237~~	~~0.10~~	0.12

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute		Sed. dwell. pro-longed	Sed. dwell. pro-longed
R1/stream	0.0302	**14.38**	**9.74**	**1677.78**	**1372.73**	-/-	**2.01**	~~0.2465~~	~~**1.05**~~	**2.32**
R3/stream	0.0427	**20.33**	**13.77**	**2372.22**	**1940.91**	-/-	**2.85**	~~0.0965~~	~~0.41~~	**3.28**

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*according to EFSA 2014

For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several/all FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies.

The higher RAC of 0.0003 µg/L for aquatic invertebrates was agreed in the PPR 107 expert meeting. It is based on available laboratory data on lambda-cyhalothrin and gamma-cyhalothrin as well as field data on gamma-cyhalothrin. This RAC is only applicable for CS-formulations and when exposure to the aquatic environment is predominantly via spray drift. As demonstrated in Section B.8 the highest PEC_{sw} is related to a drift event for all scenarios with the highest PEC_{sw} from exposure via drift calculated for single application. The higher RAC of 0.0003 µg/L is therefore considered applicable for the CS-formulation SHA 3600 B / LABAMBA.

Table 9.5-8: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in brassicas

Intended use		Brassicas												
Active substance		Lambda-cyhalothrin												
Application rate (g/ha)		1 × 7.5												
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	None	5***	10	15****	20	20	20	20
	No spray buffer (m)	5	10	15	20	30	40	50	5	10	15	20	30	40	50
none	D3 ditch*	0.0125	0.0162	0.0045	0.0035	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D3 ditch**	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D4 pond*	0.0014	0.0010	0.0008	0.0007	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	0.0003	0.0002	-	-	-	-	-	-	-	-

75 %		0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.0120	0.0064	0.0044	0.0033	0.0022	0.0017	0.0014	-	-	-	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	0.0011	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0003	0.0002	-	-	-	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	0.0002	-	-	-	-	-	-	-	-	-
none	D6 ditch*	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	R1 pond*	0.0016	0.0014	0.0014	-	-	-	-	0.0015	0.0011	0.0008	0.0007	0.0005	0.0004	0.0004
50 %		0.0014	0.0014	-	-	-	-	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.0003	0.0003
75 %		0.0014	-	-	-	-	-	-	0.0009	0.0006	0.0004	0.0003	-	-	-
90 %		-	-	-	-	-	-	-	0.0009	0.0006	0.0004	-	-	-	-
none	R1 pond**	0.0017	0.0014	0.0014	0.0014	0.0014	0.0013	0.0013	0.0016	0.0011	0.0009	0.0007	0.0006	0.0005	0.0004
50 %		0.0014	0.0014	0.0013	0.0013	0.0013	0.0013	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.0003	0.0003
75 %		0.0013	0.0013	0.0013	0.0013	0.0013	-	-	0.0008	0.0006	0.0004	0.0003	-	-	-
90 %		0.0013	0.0013	-	-	-	-	-	0.0008	0.0006	0.0004	-	-	-	-
none	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0034	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0013
50 %		0.0056	0.0034	0.0034	0.0034	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0008
75 %		0.0034	0.0034	0.0034	-	-	-	-	0.0028	0.0016	0.0012	0.0008	0.0008	0.0008	0.0008
90 %		0.0034	-	-	-	-	-	-	0.0022	0.0016	0.0012	0.0008	0.0008	0.0008	-
none	R1 stream**	0.0112	0.0059	0.0041	0.0031	0.0026	0.0026	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0017
50 %		0.0056	0.0030	0.0026	0.0026	0.0026	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0007
75 %		0.0028	0.0026	0.0026	0.0026	-	-	-	0.0028	0.0015	0.0010	0.0008	0.0006	0.0006	0.0006

90 %		0.0026	0.0026	-	-	-	-	-	0.0017	0.0012	0.0009	0.0006	0.0006	0.0006	0.0006
none	R2 stream*	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013
50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R2 stream**	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013
50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R3 stream*	0.0157	0.0083	0.0057	0.0043	0.0029	0.0023	0.0023	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0017
50 %		0.0079	0.0042	0.0029	0.0023	0.0023	0.0023	0.0023	0.0079	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0023	0.0023	0.0023	0.0023	-	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0006	0.0006
90 %		0.0023	0.0023	0.0023	-	-	-	-	0.0016	0.0011	0.0008	0.0006	0.0006	0.0006	0.0006
none	R3 stream**	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0019	0.0157	0.0083	0.0057	0.0043	0.0029	0.002218	0.0017
50 %		0.0078	0.0042	0.0028	0.0022	0.0019	0.0019	0.0019	0.0078	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0021	0.0019	0.0019	0.0019	0.0019	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0005	0.0005
90 %		0.0019	0.0019	0.0019	0.0019	-	-	-	0.0016	0.0009	0.0007	0.0005	0.0005	0.0005	0.0005
none	R4 stream*	0.0109	0.0058	0.0045	0.0045	-	-	-	0.0109	0.0058	0.0040	0.0030	0.0020	0.0015	0.0013
50 %		0.0055	0.0045	0.0045	-	-	-	-	0.0055	0.0029	0.0020	0.0015	0.0011	0.0011	0.0011
75 %		0.0045	0.0045	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	0.0011	0.0011	0.0011
90 %		0.0045	-	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	-	-	-
none	R4 stream**	0.0112	0.0059	0.0044	0.0044	-	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0011	0.0011
50 %		0.0056	0.0044	0.0044	0.0044	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0011	0.0011	-
75 %		0.0044	0.0044	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	0.0011	-	-
90 %		0.0044	-	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	-	-	-

RAC (ng/L) 0.3		PEC/RAC ratio													
none	D3 ditch*	0.042	0.054	0.015	0.012	0.008	0.006	0.005	-	-	-	-	-	-	-
50 %		0.021	0.011	0.008	0.006	0.004	0.003	0.002	-	-	-	-	-	-	-
75 %		0.01	0.006	0.004	0.003	0.002	0.001	0.001	-	-	-	-	-	-	-
90 %		0.004	0.002	0.002	0.001	0.001	0.001	0.00	-	-	-	-	-	-	-
none	D3 ditch**	0.042	0.022	0.015	0.011	0.008	0.006	0.005	-	-	-	-	-	-	-
50 %		0.021	0.011	0.008	0.006	0.004	0.003	0.002	-	-	-	-	-	-	-
75 %		0.01	0.006	0.004	0.003	0.002	0.001	0.001	-	-	-	-	-	-	-
90 %		0.004	0.002	0.002	0.001	0.001	0.001	0.0003	-	-	-	-	-	-	-
none	D4 pond*	0.005	0.003	0.003	0.002	0.002	0.001	0.001	-	-	-	-	-	-	-
50 %		0.002	0.002	0.001	0.001	0.001	0.001	-	-	-	-	-	-	-	-
75 %		0.001	0.001	0.001	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.04	0.021	0.015	0.011	0.007	0.006	0.005	-	-	-	-	-	-	-
50 %		0.02	0.011	0.007	0.006	0.004	0.003	0.002	-	-	-	-	-	-	-
75 %		0.01	0.005	0.004	0.003	0.002	0.001	0.001	-	-	-	-	-	-	-
90 %		0.004	0.002	0.001	0.001	0.001	-	-	-	-	-	-	-	-	-
none	D6 ditch*	0.042	0.022	0.015	0.011	0.008	0.006	0.005	-	-	-	-	-	-	-
50 %		0.021	0.011	0.008	0.006	0.004	0.003	0.002	-	-	-	-	-	-	-
75 %		0.01	0.006	0.004	0.003	0.002	0.001	0.001	-	-	-	-	-	-	-
90 %		0.004	0.002	0.002	0.001	0.001	0.001	0.0003	-	-	-	-	-	-	-
none	R1 pond*	0.005	0.005	0.005	-	-	-	-	0.005	0.004	0.003	0.002	0.002	0.001	0.001
50 %		0.005	0.005	-	-	-	-	-	0.003	0.002	0.002	0.001	0.001	0.001	0.001
75 %		0.005	-	-	-	-	-	-	0.003	0.002	0.001	0.001	-	-	-

90 %		-	-	-	-	-	-	-	0.003	0.002	0.001	-	-	-	-
none	R1 pond**	0.006	0.005	0.005	0.005	0.005	0.004	0.004	0.005	0.004	0.003	0.002	0.002	0.002	0.001
50 %		0.005	0.005	0.004	0.004	0.004	0.004	-	0.003	0.002	0.002	0.001	0.001	0.001	0.001
75 %		0.004	0.004	0.004	0.004	0.004	-	-	0.003	0.002	0.001	0.001	-	-	-
90 %		0.004	0.004	-	-	-	-	-	0.003	0.002	0.001	-	-	-	-
none	R1 stream*	0.037	0.02	0.013	0.011	0.011	-	-	0.037	0.020	0.013	0.01	0.007	0.005	0.004
50 %		0.019	0.011	0.011	0.011	-	-	-	0.019	0.01	0.007	0.005	0.003	0.003	0.003
75 %		0.011	0.011	0.011	-	-	-	-	0.009	0.005	0.004	0.003	0.003	0.003	0.003
90 %		0.011	-	-	-	-	-	-	0.007	0.005	0.004	0.003	0.003	0.003	-
none	R1 stream**	0.037	0.02	0.014	0.01	0.009	0.009	-	0.037	0.02	0.013	0.01	0.007	0.005	0.006
50 %		0.019	0.01	0.009	0.009	0.009	-	-	0.019	0.01	0.007	0.005	0.003	0.003	0.002
75 %		0.009	0.009	0.009	0.009	-	-	-	0.009	0.005	0.003	0.003	0.002	0.002	0.002
90 %		0.009	0.009	-	-	-	-	-	0.006	0.004	0.003	0.002	0.002	0.002	0.002
none	R2 stream*	0.05	0.026	0.018	0.014	0.009	0.007	0.006	0.05	0.026	0.018	0.014	0.009	0.007	0.004
50 %		0.025	0.013	0.009	0.007	0.005	0.003	0.003	0.025	0.013	0.009	0.007	0.005	0.004	0.003
75 %		0.012	0.007	0.005	0.003	0.002	0.002	0.002	0.012	0.007	0.005	0.003	0.002	0.002	0.001
90 %		0.005	0.003	0.002	0.002	0.002	0.002	0.002	0.005	0.003	0.002	0.001	0.001	0.001	0.001
none	R2 stream**	0.05	0.026	0.018	0.014	0.009	0.007	0.006	0.05	0.026	0.018	0.014	0.009	0.007	0.004
50 %		0.025	0.013	0.009	0.007	0.005	0.003	0.003	0.025	0.013	0.009	0.007	0.005	0.004	0.003
75 %		0.012	0.007	0.005	0.003	0.002	0.002	0.002	0.012	0.007	0.005	0.003	0.002	0.002	0.001
90 %		0.005	0.003	0.002	0.002	0.002	0.002	0.002	0.005	0.003	0.002	0.001	0.001	0.001	0.001
none	R3 stream*	0.052	0.028	0.019	0.014	0.01	0.008	0.008	0.052	0.028	0.019	0.014	0.01	0.007	0.006
50 %		0.026	0.014	0.01	0.008	0.008	0.008	0.008	0.026	0.014	0.009	0.007	0.005	0.004	0.003
75 %		0.013	0.008	0.008	0.008	0.008	-	-	0.013	0.007	0.005	0.004	0.002	0.002	0.002
90 %		0.008	0.008	0.008	-	-	-	-	0.005	0.004	0.003	0.002	0.002	0.002	0.002

none	R3 stream**	0.052	0.028	0.019	0.014	0.01	0.007	0.006	0.052	0.028	0.019	0.014	0.01	0.007	0.006
50 %		0.026	0.014	0.009	0.007	0.006	0.006	0.006	0.026	0.014	0.009	0.007	0.005	0.004	0.003
75 %		0.013	0.007	0.006	0.006	0.006	0.006	-	0.013	0.007	0.005	0.004	0.002	0.002	0.002
90 %		0.006	0.006	0.006	0.006	-	-	-	0.005	0.003	0.002	0.002	0.002	0.002	0.002
none	R4 stream*	0.036	0.019	0.015	0.015	-	-	-	0.036	0.019	0.013	0.01	0.007	0.005	0.004
50 %		0.018	0.015	0.015	-	-	-	-	0.018	0.01	0.007	0.005	0.004	0.004	0.004
75 %		0.015	0.015	-	-	-	-	-	0.01	0.007	0.005	0.004	0.004	0.004	0.004
90 %		0.015	-	-	-	-	-	-	0.01	0.007	0.005	0.004	-	-	-
none	R4 stream**	0.037	0.02	0.015	0.015	-	-	-	0.037	0.02	0.013	0.01	0.007	0.004	0.004
50 %		0.019	0.015	0.015	0.015	-	-	-	0.019	0.01	0.007	0.005	0.004	0.004	-
75 %		0.015	0.015	-	-	-	-	-	0.01	0.007	0.005	0.004	0.004	-	-
90 %		0.015	-	-	-	-	-	-	0.01	0.007	0.005	0.004	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*vegetables leafy 1st
**vegetables leafy 2nd
***0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
****0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).
a) The PECsw units are in ng/L instead of µg/L

Table 9.5-7: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in brassicas (use no. 1 & 2)

Intended use		Brassicas													
Active substance		Lambda-cyhalothrin													
Application rate (g/ha)		1 × 7.5													
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	None	5***	10	15****	20	20	20	20

	No spray buffer (m)	5	10	15	20	30	40	50	5	10	15	20	30	40	50
none	D3 ditch*	0.0125	0.0162	0.0045	0.0035	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D3 ditch**	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D4 pond*	0.0014	0.0010	0.0008	0.0007	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	0.00025	0.0002	0.0002	-	-	-	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.0120	0.0064	0.0044	0.0033	0.0022	0.0017	0.0014	-	-	-	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	0.0011	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0004	0.0002	-	-	-	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-
none	D6 ditch*	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	R1 pond*	0.0016	0.0014	0.0014	-	-	-	-	0.0015	0.0011	0.0008	0.0007	0.0005	0.0004	0.0004
50 %		0.0014	0.0014	-	-	-	-	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.00029	0.00029
75 %		0.0014	-	-	-	-	-	-	0.0009	0.0006	0.0004	0.00029	0.000029	-	-
90 %		-	-	-	-	-	-	-	0.0009	0.0006	0.0004	-	-	-	-

none	R1 pond**	0.0017	0.0014	0.0014	0.0014	0.0014	0.0013	0.0013	0.0016	0.0011	0.0009	0.0007	0.0006	0.0005	0.0004
50 %		0.0014	0.0014	0.0013	0.0013	0.0013	0.0013	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.00029	0.00029
75 %		0.0013	0.0013	0.0013	0.0013	0.0013	-	-	0.0008	0.0006	0.0004	0.00029	0.00029	-	-
90 %		0.0013	0.0013	-	-	-	-	-	0.0008	0.0006	0.0004	-	-	-	-
none	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0034	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0013
50 %		0.0056	0.0034	0.0034	0.0034	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0008
75 %		0.0034	0.0034	0.0034	-	-	-	-	0.0028	0.0016	0.0012	0.0008	0.0008	0.0008	0.0008
90 %		0.0034	-	-	-	-	-	-	0.0022	0.0016	0.0012	0.0008	0.0008	0.0008	-
none	R1 stream**	0.0112	0.0059	0.0041	0.0031	0.0026	0.0026	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0017
50 %		0.0056	0.0030	0.0026	0.0026	0.0026	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0007
75 %		0.0028	0.0026	0.0026	0.0026	-	-	-	0.0028	0.0015	0.0010	0.0008	0.0006	0.0006	0.0006
90 %		0.0026	0.0026	-	-	-	-	-	0.0017	0.0012	0.0009	0.0006	0.0006	0.0006	0.0006
none	R2 stream*	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013
50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R2 stream**	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013
50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R3 stream*	0.0157	0.0083	0.0057	0.0043	0.0029	0.0023	0.0023	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0017
50 %		0.0079	0.0042	0.0029	0.0023	0.0023	0.0023	0.0023	0.0079	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0023	0.0023	0.0023	0.0023	-	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0006	0.0006
90 %		0.0023	0.0023	0.0023	-	-	-	-	0.0016	0.0011	0.0008	0.0006	0.0006	0.0006	0.0006
none	R3	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0019	0.0157	0.0083	0.0057	0.0043	0.0029	0.002218	0.0017

50 %	stream**	0.0078	0.0042	0.0028	0.0022	0.0019	0.0019	0.0019	0.0078	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0021	0.0019	0.0019	0.0019	0.0019	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0005	0.0005
90 %		0.0019	0.0019	0.0019	0.0019	-	-	-	0.0016	0.0009	0.0007	0.0005	0.0005	0.0005	0.0005
none	R4 stream*	0.0109	0.0058	0.0045	0.0045	-	-	-	0.0109	0.0058	0.0040	0.0030	0.0020	0.0015	0.0013
50 %		0.0055	0.0045	0.0045	-	-	-	-	0.0055	0.0029	0.0020	0.0015	0.0011	0.0011	0.0011
75 %		0.0045	0.0045	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	0.0011	0.0011	0.0011
90 %		0.0045	-	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	-	-	-
none	R4 stream**	0.0112	0.0059	0.0044	0.0044	-	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0011	0.0011
50 %		0.0056	0.0044	0.0044	0.0044	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0011	0.0011	-
75 %		0.0044	0.0044	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	0.0011	-	-
90 %		0.0044	-	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	-	-	-
RAC (µg/L) 0.0003		PEC/RAC ratio													
none	D3 ditch*	**41.667**	**54.000**	**15.000**	**11.667**	**7.667**	**6.000**	**4.667**	-	-	-	-	-	-	-
50 %		**21.000**	**11.000**	**7.667**	**5.667**	**4.000**	**3.000**	**2.333**	-	-	-	-	-	-	-
75 %		**10.333**	**5.667**	**3.667**	**3.000**	**2.000**	**1.333**	**1.333**	-	-	-	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	0.667	0.667	0.333	-	-	-	-	-	-	-
none	D3 ditch**	**41.667**	**22.000**	**15.000**	**11.333**	**7.667**	**6.000**	**4.667**	-	-	-	-	-	-	-
50 %		**20.667**	**11.000**	**7.667**	**5.667**	**4.000**	**3.000**	**2.333**	-	-	-	-	-	-	-
75 %		**10.333**	**5.667**	**3.667**	**3.000**	**2.000**	**1.333**	**1.333**	-	-	-	-	-	-	-
90 %		**4.000**	**2.333**	**1.667**	**1.000**	0.667	0.667	0.333	-	-	-	-	-	-	-
none	D4 pond*	**4.667**	**3.333**	**2.667**	**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	0.833	0.667	0.667	-	-	-	-	-	-	-
75 %		**1.000**	0.667	0.667	0.667	-	-	-	-	-	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-	-	-	-	-	-	-

none	D4 stream*	40.000	21.333	14.667	11.000	7.333	5.667	4.667	-	-	-	-	-	-	-
50 %		20.000	10.667	7.333	5.667	3.667	3.000	2.333	-	-	-	-	-	-	-
75 %		10.000	5.333	3.667	2.667	2.000	1.333	0.667	-	-	-	-	-	-	-
90 %		4.000	2.000	1.333	1.000	0.667	0.667	-	-	-	-	-	-	-	-
none	D6 ditch*	41.667	22.000	15.000	11.333	7.667	6.000	4.667	-	-	-	-	-	-	-
50 %		20.667	11.000	7.667	5.667	4.000	3.000	2.333	-	-	-	-	-	-	-
75 %		10.333	5.667	3.667	3.000	2.000	1.333	1.333	-	-	-	-	-	-	-
90 %		4.000	2.333	1.667	1.000	0.667	0.667	0.333	-	-	-	-	-	-	-
none	R1 pond*	5.333	4.667	4.667	-	-	-	-	5.000	3.667	2.667	2.333	1.667	1.333	1.333
50 %		4.667	4.667	-	-	-	-	-	3.000	2.000	1.667	1.333	1.000	0.967	0.967
75 %		4.667	-	-	-	-	-	-	3.000	2.000	1.333	0.967	0.967	-	-
90 %		-	-	-	-	-	-	-	3.000	2.000	1.333	-	-	-	-
none	R1 pond**	5.667	4.667	4.667	4.667	4.667	4.333	4.333	5.333	3.667	3.000	2.333	2.000	1.667	1.333
50 %		4.667	4.667	4.333	4.333	4.333	4.333	-	3.000	2.000	1.667	1.333	1.000	0.967	0.967
75 %		4.333	4.333	4.333	4.333	4.333	-	-	2.667	2.000	1.333	0.967	0.967	-	-
90 %		4.333	4.333	-	-	-	-	-	2.667	2.000	1.333	-	-	-	-
none	R1 stream*	37.333	19.667	13.333	11.333	11.333	-	-	37.333	19.667	13.333	10.333	7.000	5.333	4.333
50 %		18.667	11.333	11.333	11.333	-	-	-	18.667	10.000	6.667	5.000	3.333	2.667	2.667
75 %		11.333	11.333	11.333	-	-	-	-	9.333	5.333	4.000	2.667	2.667	2.667	2.667
90 %		11.333	-	-	-	-	-	-	7.333	5.333	4.000	2.667	2.667	2.667	-
none	R1 stream**	37.333	19.667	13.667	10.333	8.667	8.667	-	37.333	19.667	13.333	10.333	7.000	5.333	5.667
50 %		18.667	10.000	8.667	8.667	8.667	-	-	18.667	10.000	6.667	5.000	3.333	2.667	2.333
75 %		9.333	8.667	8.667	8.667	-	-	-	9.333	5.000	3.333	2.667	2.000	2.000	2.000
90 %		8.667	8.667	-	-	-	-	-	5.667	4.000	3.000	2.000	2.000	2.000	2.000
none	R2	50.000	26.333	18.000	13.667	9.333	7.000	5.667	50.000	26.333	18.000	13.667	9.333	7.000	4.333

50 %	stream*	**25.000**	**13.333**	**9.000**	**7.000**	**4.667**	**3.333**	**3.000**	**25.000**	**13.333**	**9.000**	**7.000**	**4.667**	**3.667**	**2.667**
75 %		**12.333**	**6.667**	**4.667**	**3.333**	**2.333**	**2.000**	**2.000**	**12.333**	**6.667**	**4.667**	**3.333**	**2.333**	**1.667**	**1.333**
90 %		**5.000**	**2.667**	**2.000**	**2.000**	**2.000**	**2.000**	**2.000**	**5.000**	**2.667**	**1.667**	**1.333**	**1.000**	0.667	0.667
none	R2 stream**	**49.667**	**26.333**	**18.000**	**13.667**	**9.333**	**7.000**	**5.667**	**49.667**	**26.333**	**18**	**13.667**	**9.333**	**7.000**	**4.333**
50 %		**25.000**	**13.333**	**9.000**	**7.000**	**4.667**	**3.333**	**3.000**	**25.000**	**13.333**	**9.000**	**7.000**	**4.667**	**3.667**	**2.667**
75 %		**12.333**	**6.667**	**4.667**	**3.333**	**2.333**	**2.000**	**2.000**	**12.333**	**6.667**	**4.667**	**3.333**	**2.333**	**1.667**	**1.333**
90 %		**5.000**	**2.667**	**2.000**	**2.000**	**2.000**	**2.000**	**2.000**	**5.000**	**2.667**	**1.667**	**1.333**	**1.000**	0.667	0.667
none	R3 stream*	**52.333**	**27.667**	**19.000**	**14.333**	**9.667**	**7.667**	**7.667**	**52.333**	**27.667**	**19.000**	**14.333**	**9.667**	**7.333**	**5.667**
50 %		**26.333**	**14.000**	**9.667**	**7.667**	**7.667**	**7.667**	**7.667**	**26.333**	**14.000**	**9.333**	**7.333**	**5.000**	**3.667**	**3.000**
75 %		**13.000**	**7.667**	**7.667**	**7.667**	**7.667**	-	-	**13.000**	**7.000**	**4.667**	**3.667**	**2.333**	**2.000**	**2.000**
90 %		**7.667**	**7.667**	**7.667**	-	-	-	-	**5.333**	**3.667**	**2.667**	**2.000**	**2.000**	**2.000**	**2.000**
none	R3 stream**	**52.333**	**27.667**	**19.000**	**14.333**	**9.667**	**7.333**	**6.333**	**52.333**	**27.667**	**19.000**	**14.333**	**9.667**	**7.393**	**5.667**
50 %		**26.000**	**14.000**	**9.333**	**7.333**	**6.333**	**6.333**	**6.333**	**26.000**	**14.000**	**9.333**	**7.333**	**5.000**	**3.667**	**3.000**
75 %		**13.000**	**7.000**	**6.333**	**6.333**	**6.333**	**6.333**	-	**13.000**	**7.000**	**4.667**	**3.667**	**2.333**	**1.667**	**1.667**
90 %		**6.333**	**6.333**	**6.333**	**6.333**	-	-	-	**5.333**	**3.000**	**2.333**	**1.667**	**1.667**	**1.667**	**1.667**
none	R4 stream*	**36.333**	**19.333**	**15.000**	**15.000**	-	-	-	**36.333**	**19.333**	**13.333**	**10.000**	**6.667**	**5.000**	**4.333**
50 %		**18.333**	**15.000**	**15.000**	-	-	-	-	**18.333**	**9.667**	**6.667**	**5.000**	**3.667**	**3.667**	**3.667**
75 %		**15.000**	**15.000**	-	-	-	-	-	**10.000**	**7.000**	**5.333**	**3.667**	**3.667**	**3.667**	**3.667**
90 %		**15.000**	-	-	-	-	-	-	**10.000**	**7.000**	**5.333**	**3.667**	-	-	-
none	R4 stream**	**37.333**	**19.667**	**14.667**	**14.667**	-	-	-	**37.333**	**19.667**	**13.333**	**10.333**	**7.000**	**3.667**	**3.667**
50 %		**18.667**	**14.667**	**14.667**	**14.667**	-	-	-	**18.667**	**10.000**	**6.667**	**5.000**	**3.667**	**3.667**	-
75 %		**14.667**	**14.667**	-	-	-	-	-	**9.667**	**6.667**	**5.333**	**3.667**	**3.667**	-	-
90 %		**14.667**	-	-	-	-	-	-	**9.667**	**6.667**	**5.333**	**3.667**	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*vegetables leafy 1st
**vegetables leafy 2nd
***0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).

****0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).
a) The PECsw units are in ng/L instead of µg/L

For the CEU relevant scenarios the Applicant proposes to use as refinement Parent Kfoc of 189959 mL/g (geometric mean, n=14) and 1/n of 0.97 (arithmetic mean, n=14). The results are given in Table 9.5-8 and 9.5-9 below.

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 3 calculations for the use of LABAMBA in brassicas use no. 1 & 2 after refinement

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5	0.13
AF		100	10	100	10	10	100	10
RAC (µg/L)		0.0021	0.0031	0.000018	0.000022	0.5	0.015	0.013
FOCUS Sce-nario	**PEC $_{gl-max}$ (µg/L)**							
Step 3								
D3*/ditch	0.0414	**19.714**	**13.355**	**2300.000**	**1881.818**	0.083	**2.760**	**3.185**
D3**/ditch	0.0412	**19.619**	**13.290**	**2288.889**	**1872.727**	0.082	**2.747**	**3.169**
D4*/pond	0.00143	0.681	0.461	**79.444**	**65.000**	0.003	0.095	0.110
D4*/stream	0.0295	**14.048**	**9.516**	**1638.889**	**1340.909**	0.059	**1.967**	**2.269**
R1*/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
R1**/pond	0.0015	0.714	0.484	**83.333**	**68.182**	0.003	0.100	0.115
R1*/stream	0.0008	0.381	0.258	**44.444**	**36.364**	0.002	0.053	0.062
R1**/stream	0.0006	0.286	0.194	**33.333**	**27.273**	0.001	0.040	0.046

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
***vegetables leafy 1st**
****vegetables leafy 2nd**

Table 9.5-9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in brassicas (use no. 1 & 2) after refinement

Intended use		Brassicas													
Active substance		Lambda-cyhalothrin													
Application rate (g/ha)		1 × 7.5													
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	None	5***	10	15****	20	20	20	20
	No spray buffer (m)	5	10	15	20	30	40	50	5	10	15	20	30	40	50
none	D3 ditch*	0.0112	0.0060	0.0041	0.0031	0.0021	0.0016	0.0013	-	-	-	-	-	-	-
50 %		0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0006	-	-	-	-	-	-	-
75 %		0.0028	0.0015	0.0010	0.0008	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D3 ditch**	0.0112	0.0059	0.0040	0.0031	0.0021	0.0008	0.0013	-	-	-	-	-	-	-
50 %		0.0056	0.0030	0.0020	0.0015	0.0010	0.0010	0.0006	-	-	-	-	-	-	-
75 %		0.0028	0.0015	0.0010	0.0008	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D4 pond*	0.0012	0.0009	0.0007	0.0006	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0006	0.0004	0.0004	0.000296	0.0002	0.0002	0.0002	-	-	-	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.0108	0.0057	0.0039	0.0030	0.0005	0.0015	0.0012	-	-	-	-	-	-	-
50 %		0.0054	0.0029	0.0019	0.0015	0.0010	0.0008	0.0006	-	-	-	-	-	-	-
75 %		0.0027	0.0014	0.0010	0.0007	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-

none	R1 pond*	0.0013	0.0009	0.0007	0.0006	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0006	0.0005	0.0004	0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	R1 pond**	0.0013	0.0009	0.0007	0.0006	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0006	0.0005	0.0004	0.0003	0.0002	0.0002	0.0002	-	-	-	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-
90 %		0.0002	-	-	-	-	-	-	-	-	-	-	-	-	-
none	R1 stream*	0.0100	0.0053	0.0036	0.0028	0.0019	0.0014	0.0011	0.0100	0.0053	0.0036	0.0028	0.0019	0.0014	0.0011
50 %		0.0050	0.0027	0.0018	0.0014	0.0009	0.0007	0.0006	0.0050	0.0027	0.0018	0.0014	0.0009	0.0007	0.0006
75 %		0.0025	0.0013	0.0009	0.0007	0.0005	0.0005	0.0005	0.0025	0.0013	0.0009	0.0007	0.0005	0.0004	0.00029
90 %		0.0010	0.0005	0.0005	0.0005	0.0005	0.0005	0.0005	0.0010	0.0005	0.0005	0.00028	0.0002	0.0001	-
none	R1 stream**	0.0100	0.0053	0.0036	0.0028	0.0019	0.0014	0.0011	0.0100	0.0053	0.0036	0.0028	0.0019	0.0014	0.0011
50 %		0.0050	0.0027	0.0018	0.0014	0.0009	0.0007	0.0006	0.0050	0.0027	0.0018	0.0014	0.0009	0.0007	0.0006
75 %		0.0025	0.0013	0.0009	0.0007	0.0005	0.0004	0.0004	0.0025	0.0013	0.0009	0.0007	0.0005	0.0004	0.00029
90 %		0.0010	0.0005	0.0004	0.0004	0.0004	0.0004	0.0004	0.0010	0.0005	0.0005	0.00028	0.0002	0.0001	-
RAC (µg/L) 0.0003		PEC/RAC ratio													
none	D3 ditch*	**37.333**	**20.000**	**13.667**	**10.333**	**7.000**	**5.333**	**4.333**	-	-	-	-	-	-	-
50 %		**18.667**	**10.000**	**6.667**	**5.000**	**3.333**	**2.667**	**2.000**	-	-	-	-	-	-	-
75 %		**9.333**	**5.000**	**3.333**	**2.667**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	**1.000**	0.667	0.667	0.333	-	-	-	-	-	-	-
none	D3 ditch**	**37.333**	**19.667**	**13.333**	**10.333**	**7.000**	**2.667**	**4.333**	-	-	-	-	-	-	-
50 %		**18.667**	**10.000**	**6.667**	**5.000**	**3.333**	**3.333**	**2.000**	-	-	-	-	-	-	-
75 %		**9.333**	**5.000**	**3.333**	**2.667**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-

90 %		**3.667**	**2.000**	**1.333**	**1.000**	0.667	0.667	0.333	-	-	-	-	-	-	-
none	D4 pond*	**4.000**	**3.000**	**2.333**	**2.000**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
50 %		**2.000**	**1.333**	**1.333**	0.987	0.667	0.667	0.667	-	-	-	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-	-	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	**36.000**	**19.000**	**13.000**	**10.000**	**1.667**	**5.000**	**4.000**	-	-	-	-	-	-	-
50 %		**18.000**	**9.667**	**6.333**	**5.000**	**3.333**	**2.667**	**2.000**	-	-	-	-	-	-	-
75 %		**9.000**	**4.667**	**3.333**	**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	**1.000**	0.667	0.667	0.333	-	-	-	-	-	-	-
none	R1 pond*	**4.333**	**3.000**	**2.333**	**2.000**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
50 %		**2.000**	**1.667**	**1.333**	**1.000**	0.667	0.667	0.667	-	-	-	-	-	-	-
75 %		**1.000**	0.667	0.667	0.667	-	-	-	-	-	-	-	-	-	-
90 %		0.667	-	-	-	-	-	-	-	-	-	-	-	-	-
none	R1 pond**	**4.333**	**3.000**	**2.333**	**2.000**	**1.667**	**1.333**	**1.000**	-	-	-	-	-	-	-
50 %		**2.000**	**1.667**	**1.333**	**1.000**	0.667	0.667	-	-	-	-	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	R1 stream*	**33.333**	**17.667**	**12.000**	**9.333**	**6.333**	**4.667**	**3.667**	**33.333**	**17.667**	**12.000**	**9.333**	**6.333**	**4.667**	**3.667**
50 %		**16.667**	**9.000**	**6.000**	**4.667**	**3.000**	**2.333**	**2.000**	**16.667**	**9.000**	**6.000**	**4.667**	**3.000**	**2.333**	**2.000**
75 %		**8.333**	**4.333**	**3.000**	**2.333**	**1.667**	**1.667**	**1.667**	**8.333**	**4.333**	**3.000**	**2.333**	**1.667**	**1.333**	0.967
90 %		**3.333**	**1.667**	**1.667**	**1.667**	**1.667**	**1.667**	**1.667**	**3.333**	**1.667**	**1.667**	0.933	0.667	0.333	-
none	R1 stream**	**33.333**	**17.667**	**12.000**	**9.333**	**6.333**	**4.667**	**3.667**	**33.333**	**17.667**	**12.000**	**9.333**	**6.333**	**4.667**	**3.667**
50 %		**16.667**	**9.000**	**6.000**	**4.667**	**3.000**	**2.333**	**2.000**	**16.667**	**9.000**	**6.000**	**4.667**	**3.000**	**2.333**	**2.000**
75 %		**8.333**	**4.333**	**3.000**	**2.333**	**1.667**	**1.333**	**1.333**	**8.333**	**4.333**	**3.000**	**2.333**	**1.667**	**1.333**	0.967
90 %		**3.333**	**1.667**	**1.333**	**1.333**	**1.333**	**1.333**	**1.333**	**3.333**	**1.667**	**1.667**	0.933	0.667	0.333	-

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

*vegetables leafy 1st
**vegetables leafy 2nd
***0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
****0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).
a) The PECsw units are in ng/L instead of µg/L

Table 9.5 10 9: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in tomato

Intended use **Active substance** **Application rate (g/ha)**		Tomato Lambda-cyhalothrin 1 × 7.5							
Nozzle reduction	**Vegetative strip (m)**	None	None	None	None	5**	10	15***	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch*	0.0125	0.0162	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond*	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream*	0.0120	0.0064	0.0044	0.0033	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	-	-	-	-

None	D6 ditch	0.0232	0.0123	0.0045	0.0034	-	-	-	-
50 %		0.0116	0.0033	0.0023	0.0032	-	-	-	-
75 %		0.0058	0.0016	0.0011	0.0016	-	-	-	-
90 %		0.0023	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond*	0.0016	0.0014	0.0014	0.0014	0.0015	0.0011	0.0008	0.0007
50 %		0.0014	0.0014	0.0014	0.0014	0.0009	0.0006	0.0005	0.0004
75 %		0.0014	0.0014	-	-	0.0009	0.0006	0.0004	0.0003
90 %		-	-	-	-	0.0009	0.0006	0.0004	-
None	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0112	0.0059	0.0040	0.0031
50 %		0.0056	0.0034	0.0034	0.0034	0.0056	0.0030	0.0020	0.0015
75 %		0.0034	0.0034	0.0034	-	0.0028	0.0016	0.0012	0.0008
90 %		0.0034	-	-	-	0.0022	0.0016	0.0012	0.0008
None	R2 stream	0.0149	0.0079	0.0054	0.0041	0.0149	0.0079	0.0054	0.0041
50 %		0.0075	0.0040	0.0027	0.0021	0.0109	0.0040	0.0027	0.0021
75 %		0.0037	0.0020	0.0014	0.0010	0.0037	0.0020	0.0014	0.0010
90 %		0.0015	0.0008	0.0008	0.0008	0.0015	0.0008	0.0005	0.0004
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0079	0.0042	0.0028	0.0022	0.0079	0.0042	0.0028	0.0022
75 %		0.0039	0.0021	0.0017	0.0017	0.0039	0.0021	0.0014	0.0011
90 %		0.0017	0.0017	0.0017	0.0017	0.0016	0.0008	0.0006	0.0004
None	R4 stream	0.0109	0.0058	0.0045	0.0045	0.0109	0.0058	0.0039	0.0030
50 %		0.0054	0.0045	0.0045	0.0045	0.0054	0.0029	0.0048	0.0015
75 %		0.0045	0.0045	-	-	0.0029	0.0020	0.0012	0.0011
90 %		0.0045	-	-	-	0.0029	0.0020	0.0011	0.0011
RAC (ng/L) 0.3		PEC/RAC							

None	D3 ditch*	0.042	0.054	0.015	0.012	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.01	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D4 pond*	0.005	0.003	0.003	0.002	-	-	-	-
50 %		0.002	0.002	0.001	0.001	-	-	-	-
75 %		0.001	0.001	0.001	0.001	-	-	-	-
90 %		0.0003	-	-	-	-	-	-	-
None	D4 stream*	0.04	0.021	0.015	0.011	-	-	-	-
50 %		0.02	0.011	0.007	0.006	-	-	-	-
75 %		0.01	0.005	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.001	0.001	-	-	-	-
None	D6 ditch	0.077	0.041	0.015	0.011	-	-	-	-
50 %		0.039	0.011	0.008	0.011	-	-	-	-
75 %		0.019	0.005	0.004	0.005	-	-	-	-
90 %		0.008	0.002	0.002	0.001	-	-	-	-
None	R1 pond*	0.005	0.005	0.005	0.005	0.005	0.004	0.003	0.002
50 %		0.005	0.005	0.005	0.005	0.003	0.002	0.002	0.001
75 %		0.005	0.005	-	-	0.003	0.002	0.001	0.001
90 %		-	-	-	-	0.003	0.002	0.001	-
None	R1 stream*	0.037	0.02	0.013	0.011	0.037	0.02	0.013	0.01
50 %		0.019	0.011	0.011	0.011	0.019	0.01	0.007	0.005
75 %		0.011	0.011	0.011	-	0.009	0.005	0.004	0.003
90 %		0.011	-	-	-	0.007	0.005	0.004	0.003
None	R2 stream	0.05	0.026	0.018	0.014	0.05	0.026	0.018	0.014

50 %		0.025	0.013	0.009	0.007	0.036	0.013	0.009	0.007
75 %		0.012	0.007	0.005	0.003	0.012	0.007	0.005	0.003
90 %		0.005	0.003	0.003	0.003	0.005	0.003	0.002	0.001
None	R3 stream	0.052	0.028	0.019	0.014	0.052	0.028	0.019	0.014
50 %		0.026	0.014	0.009	0.007	0.026	0.014	0.009	0.007
75 %		0.013	0.007	0.006	0.006	0.013	0.007	0.005	0.004
90 %		0.006	0.006	0.006	0.006	0.005	0.003	0.002	0.001
None	R4 stream	0.036	0.019	0.015	0.015	0.036	0.019	0.013	0.01
50 %		0.018	0.015	0.015	0.015	0.018	0.01	0.016	0.005
75 %		0.015	0.015	-	-	0.01	0.007	0.004	0.004
90 %		0.015	-	-	-	0.01	0.007	0.004	0.004

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*National scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for leafy vegetables 1st.
**0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
***0.7 and 0.9 was used for used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).a) The PECsw units are in ng/L instead of µg/L

Table 9.5-10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in tomato use No. 3

Intended use		Tomato							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	**Vegetative strip (m)**	None	None	None	None	5**	10	15***	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch*	0.0125	0.0162	0.0045	0.0035	-	-	-	-

50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond*	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream*	0.0120	0.0064	0.0044	0.0033	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	-	-	-	-
None	D6 ditch	0.0232	0.0123	0.0045	0.0034	-	-	-	-
50 %		0.0116	0.0033	0.0023	0.0032	-	-	-	-
75 %		0.0058	0.0016	0.0011	0.0016	-	-	-	-
90 %		0.0023	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond*	0.0016	0.0014	0.0014	0.0014	0.0015	0.0011	0.0008	0.0007
50 %		0.0014	0.0014	0.0014	0.0014	0.0009	0.0006	0.0005	0.0004
75 %		0.0014	0.0014	-	-	0.0009	0.0006	0.0004	0.00029
90 %		-	-	-	-	0.0009	0.0006	0.0004	-
None	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0112	0.0059	0.0040	0.0031
50 %		0.0056	0.0034	0.0034	0.0034	0.0056	0.0030	0.0020	0.0015
75 %		0.0034	0.0034	0.0034	-	0.0028	0.0016	0.0012	0.0008
90 %		0.0034	-	-	-	0.0022	0.0016	0.0012	0.0008
None	R2 stream	0.0149	0.0079	0.0054	0.0041	0.0149	0.0079	0.0054	0.0041
50 %		0.0075	0.0040	0.0027	0.0021	0.0109	0.0040	0.0027	0.0021

75 %		0.0037	0.0020	0.0014	0.0010	0.0037	0.0020	0.0014	0.0010
90 %		0.0015	0.0008	0.0008	0.0008	0.0015	0.0008	0.0005	0.0004
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0079	0.0042	0.0028	0.0022	0.0079	0.0042	0.0028	0.0022
75 %		0.0039	0.0021	0.0017	0.0017	0.0039	0.0021	0.0014	0.0011
90 %		0.0017	0.0017	0.0017	0.0017	0.0016	0.0008	0.0006	0.0004
None	R4 stream	0.0109	0.0058	0.0045	0.0045	0.0109	0.0058	0.0039	0.0030
50 %		0.0054	0.0045	0.0045	0.0045	0.0054	0.0029	0.0048	0.0015
75 %		0.0045	0.0045	-	-	0.0029	0.0020	0.0012	0.0011
90 %		0.0045	-	-	-	0.0029	0.0020	0.0011	0.0011
RAC (µg/L) 0.0003		PEC/RAC							
None	D3 ditch*	**41.667**	**54.000**	**15.000**	**11.667**	-	-	-	-
50 %		**21.000**	**11.000**	**7.667**	**5.667**	-	-	-	-
75 %		**10.333**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	D4 pond*	**4.667**	**3.333**	**2.667**	**2.333**	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**1.000**	0.667	0.667	0.667	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	D4 stream*	**40.000**	**21.333**	**14.667**	**11.000**	-	-	-	-
50 %		**20.000**	**10.667**	**7.333**	**5.667**	-	-	-	-
75 %		**10.000**	**5.333**	**3.667**	**2.667**	-	-	-	-
90 %		**4.000**	**2.000**	**1.333**	**1.000**	-	-	-	-
None	D6 ditch	**77.333**	**41.000**	**15.000**	**11.333**	-	-	-	-
50 %		**38.667**	**11.000**	**7.667**	**10.667**	-	-	-	-

75 %		**19.333**	**5.333**	**3.667**	**5.333**	-	-	-	-
90 %		**7.667**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	R1 pond*	**5.333**	**4.667**	**4.667**	**4.667**	**5.000**	**3.667**	**2.667**	**2.333**
50 %		**4.667**	**4.667**	**4.667**	**4.667**	**3.000**	**2.000**	**1.667**	**1.333**
75 %		**4.667**	**4.667**	-	-	**3.000**	**2.000**	**1.333**	0.967
90 %		-	-	-	-	**3.000**	**2.000**	**1.333**	-
None	R1 stream*	**37.333**	**19.667**	**13.333**	**11.333**	**37.333**	**19.667**	**13.333**	**10.333**
50 %		**18.667**	**11.333**	**11.333**	**11.333**	**18.667**	**10.000**	**6.667**	**5.000**
75 %		**11.333**	**11.333**	**11.333**	-	**9.333**	**5.333**	**4.000**	**2.667**
90 %		**11.333**	-	-	-	**7.333**	**5.333**	**4.000**	**2.667**
None	R2 stream	**49.667**	**26.333**	**18.000**	**13.667**	**49.667**	**26.333**	**18.000**	**13.667**
50 %		**25.000**	**13.333**	**9.000**	**7.000**	**36.333**	**13.333**	**9.000**	**7.000**
75 %		**12.333**	**6.667**	**4.667**	**3.333**	**12.333**	**6.667**	**4.667**	**3.333**
90 %		**5.000**	**2.667**	**2.667**	**2.667**	**5.000**	**2.667**	**1.667**	**1.333**
None	R3 stream	**52.333**	**27.667**	**19.000**	**14.333**	**52.333**	**27.667**	**19.000**	**14.333**
50 %		**26.333**	**14.000**	**9.333**	**7.333**	**26.333**	**14.000**	**9.333**	**7.333**
75 %		**13.000**	**7.000**	**5.667**	**5.667**	**13.000**	**7.000**	**4.667**	**3.667**
90 %		**5.667**	**5.667**	**5.667**	**5.667**	**5.333**	**2.667**	**2.000**	**1.333**
None	R4 stream	**36.333**	**19.333**	**15.000**	**15.000**	**36.333**	**19.333**	**13.000**	**10.000**
50 %		**18.000**	**15.000**	**15.000**	**15.000**	**18.000**	**9.667**	**16.000**	**5.000**
75 %		**15.000**	**15.000**	-	-	**9.667**	**6.667**	**4.000**	**3.667**
90 %		**15.000**	-	-	-	**9.667**	**6.667**	**3.667**	**3.667**

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*National scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for leafy vegetables 1st.
**0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
***0.7 and 0.9 was used for used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).a) The PECsw units are in ng/L instead of µg/L

For the CEU relevant scenarios the Applicant proposes to use as refinement Parent Kfoc of 189959 mL/g (geometric mean, n=14) and 1/n of 0.97 (arithmetic mean, n=14). The results are given in Table 9.5-11 and 9.5-12 below.

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 3 calculations for the use of LABAMBA in tomato use no. 3 after refinement

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5	0.13
AF		100	10	100	10	10	100	10
RAC (µg/L)		0.0021	0.0031	0.000018	0.000022	0.5	0.015	0.013
FOCUS Sce-nario	**PEC $_{gl-max}$ (µg/L)**							
Step 3								
D3*/ditch	0.0414	**19.714**	**13.355**	**2300.000**	**1881.818**	0.083	**2.760**	**3.185**
D4*/pond	0.00143	0.681	0.461	**79.444**	**65.000**	0.003	0.095	0.110
D4*/stream	0.0295	**14.048**	**9.516**	**1638.889**	**1340.909**	0.059	**1.967**	**2.269**
R1*/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
R1*/stream	0.0008	0.381	0.258	**44.444**	**36.364**	0.002	0.053	0.062

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
***vegetables leafy 1st**
****vegetables leafy 2nd**

Table 9.5-12: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in tomato use No. 3 after refinement

Intended use		Tomato							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	**Vegetative strip (m)**	None	None	None	None	5**	10	15***	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch*	0.0112	0.0060	0.0041	0.0031	-	-	-	-
50 %		0.0056	0.0030	0.0020	0.0015	-	-	-	-
75 %		0.0028	0.0015	0.0010	0.0008	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	-	-	-	-
None	D4 pond*	0.0012	0.0009	0.0007	0.0006	-	-	-	-
50 %		0.0006	0.0004	0.0004	0.000296	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream*	0.0108	0.0057	0.0039	0.0030	-	-	-	-
50 %		0.0054	0.0029	0.0019	0.0015	-	-	-	-
75 %		0.0027	0.0014	0.0010	0.0007	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	-	-	-	-
None	R1 pond*	0.0013	0.0009	0.0007	0.0006	-	-	-	-
50 %		0.0006	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0002	-	-	-	-	-	-	-
None	R1 stream*	0.0100	0.0053	0.0036	0.0028	0.0100	0.0053	0.0036	0.0028

50 %		0.0050	0.0027	0.0018	0.0014	0.0050	0.0027	0.0018	0.0014
75 %		0.0025	0.0013	0.0009	0.0007	0.0025	0.0013	0.0009	0.0007
90 %		0.0010	0.0005	0.0005	0.0005	0.0010	0.0005	0.0005	0.00028
RAC (µg/L) 0.0003		PEC/RAC							
None	D3 ditch*	**37.333**	**20.000**	**13.667**	**10.333**	-	-	-	-
50 %		**18.667**	**10.000**	**6.667**	**5.000**	-	-	-	-
75 %		**9.333**	**5.000**	**3.333**	**2.667**	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	0.999	-	-	-	-
None	D4 pond*	**4.000**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**2.000**	**1.333**	**1.333**	0.987	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	D4 stream*	**36.000**	**19.000**	**13.000**	**10.000**	-	-	-	-
50 %		**18.000**	**9.667**	**6.333**	**5.000**	-	-	-	-
75 %		**9.000**	**4.667**	**3.333**	**2.333**	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	0.999	-	-	-	-
None	R1 pond*	**4.333**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**2.000**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**1.000**	0.667	0.667	0.667	-	-	-	-
90 %		0.667	-	-	-	-	-	-	-
None	R1 stream*	**33.333**	**17.667**	**12.000**	**9.333**	**33.333**	**17.667**	**12.000**	**9.333**
50 %		**16.667**	**9.000**	**6.000**	**4.667**	**16.667**	**9.000**	**6.000**	**4.667**
75 %		**8.333**	**4.333**	**3.000**	**2.333**	**8.333**	**4.333**	**3.000**	**2.333**
90 %		**3.333**	**1.667**	**1.667**	**1.667**	**3.333**	**1.667**	**1.667**	0.933

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*National scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed.

Presented calculation was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for leafy vegetables 1st.
**0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
***0.7 and 0.9 was used for used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).a) The PECsw units are in ng/L instead of µg/L

~~**Table 9.5-12 10: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothtin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter cereals**~~

~~**PEC_{sw} (ng/L)[a)]**~~	~~**Scenario**~~	~~**STEP 4 Lambda-cyhalothrin**~~							
~~Nozzle reduction~~	~~Vegetative strip (m)~~	~~None~~				~~5*~~	~~10~~	~~15**~~	~~20~~
	~~No spray buffer (m)~~	~~5~~	~~10~~	~~15~~	~~20~~	~~5~~	~~10~~	~~15~~	~~20~~
~~None~~	~~D1 ditch~~	~~0.0127~~	~~0.0067~~	~~0.0046~~	~~0.0035~~	~~-~~	~~-~~	~~-~~	~~-~~
~~50 %~~		~~0.0063~~	~~0.0034~~	~~0.0023~~	~~0.0017~~	~~-~~	~~-~~	~~-~~	~~-~~
~~75 %~~		~~0.0032~~	~~0.0017~~	~~0.0011~~	~~0.0009~~	~~-~~	~~-~~	~~-~~	~~-~~
~~90 %~~		~~0.0013~~	~~0.0007~~	~~0.0005~~	~~0.0003~~	~~-~~	~~-~~	~~-~~	~~-~~
~~None~~	~~D1 stream~~	~~0.0148~~	~~0.0078~~	~~0.0053~~	~~0.0041~~	~~-~~	~~-~~	~~-~~	~~-~~
~~50 %~~		~~0.0074~~	~~0.0039~~	~~0.0027~~	~~0.0020~~	~~-~~	~~-~~	~~-~~	~~-~~
~~75 %~~		~~0.0037~~	~~0.0020~~	~~0.0013~~	~~0.0010~~	~~-~~	~~-~~	~~-~~	~~-~~
~~90 %~~		~~0.0015~~	~~0.0008~~	~~0.0005~~	~~0.0004~~	~~-~~	~~-~~	~~-~~	~~-~~
~~None~~	~~D2 ditch~~	~~0.0127~~	~~0.0067~~	~~0.0046~~	~~0.0035~~	~~-~~	~~-~~	~~-~~	~~-~~
~~50 %~~		~~0.0063~~	~~0.0034~~	~~0.0023~~	~~0.0017~~	~~-~~	~~-~~	~~-~~	~~-~~
~~75 %~~		~~0.0032~~	~~0.0017~~	~~0.0011~~	~~0.0009~~	~~-~~	~~-~~	~~-~~	~~-~~
~~90 %~~		~~0.0013~~	~~0.0007~~	~~0.0005~~	~~0.0003~~	~~-~~	~~-~~	~~-~~	~~-~~

None	D2 stream	0.0151	0.0080	0.0055	0.0042	-	-	-	-
50 %		0.0075	0.0040	0.0027	0.0021	-	-	-	-
75 %		0.0038	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0005	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0133	0.0070	0.0048	0.0037	-	-	-	-
50 %		0.0066	0.0035	0.0024	0.0018	-	-	-	-
75 %		0.0033	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0135	0.0071	0.0049	0.0037	-	-	-	-

50 %		0.0067	0.0036	0.0024	0.0019	-	-	-	-
75 %		0.0034	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D6 ditch	0.0125	0.0066	0.0045	0.0034	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0005	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.0003	0.0003	-
90 %		0.0005	0.0005	0.0004	0.0004	0.0003	-	-	-
None	R1 stream	0.0111	0.0059	0.0040	0.0032	0.0111	0.0059	0.0040	0.0031
50 %		0.0055	0.0032	0.0032	0.0032	0.0055	0.0029	0.0020	0.0015
75 %		0.0032	0.0032	0.0032	0.0032	0.0028	0.0015	0.0011	0.0008
90 %		0.0032	0.0032	0.0032	0.0032	0.0021	0.0015	0.0011	0.0008
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0078	0.0042	0.0028	0.0024	0.0078	0.0042	0.0028	0.0022
75 %		0.0039	0.0024	0.0024	0.0024	0.0039	0.0021	0.0014	0.0011
90 %		0.0024	0.0024	0.0024	0.0024	0.0016	0.0011	0.0008	0.0006
None	R4 stream	0.0111	0.0059	0.0041	0.0041	0.0111	0.0059	0.0040	0.0031
50 %		0.0056	0.0041	0.0041	0.0041	0.0056	0.0029	0.0020	0.0015

75 %		0.0041	0.0041	0.0041	0.0041	0.0028	0.0019	0.0014	0.0010
90 %		0.0041	0.0041	0.0041	0.0041	0.0027	0.0019	0.0014	0.0010
RAC = 0.3 ng/L		PEC/RAC							
None	D1 ditch	0.042	0.022	0.015	0.012	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.011	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D1 stream	0.049	0.026	0.018	0.014	-	-	-	-
50 %		0.025	0.013	0.009	0.007	-	-	-	-
75 %		0.012	0.007	0.004	0.003	-	-	-	-
90 %		0.005	0.003	0.002	0.001	-	-	-	-
None	D2 ditch	0.042	0.022	0.015	0.012	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.011	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D2 stream	0.05	0.027	0.018	0.014	-	-	-	-
50 %		0.025	0.013	0.009	0.007	-	-	-	-
75 %		0.013	0.007	0.005	0.003	-	-	-	-
90 %		0.005	0.003	0.002	0.001	-	-	-	-
None	D3 ditch	0.042	0.022	0.015	0.012	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.01	0.006	0.004	0.003	-	-	-	-

90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D4 pond	0.005	0.003	0.003	0.002	-	-	-	-
50 %		0.002	0.002	0.001	0.001	-	-	-	-
75 %		0.001	0.001	0.001	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.044	0.023	0.016	0.012	-	-	-	-
50 %		0.022	0.012	0.008	0.006	-	-	-	-
75 %		0.011	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D5 pond	0.005	0.003	0.003	0.002	-	-	-	-
50 %		0.002	0.002	0.001	0.001	-	-	-	-
75 %		0.001	0.001	0.001	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.045	0.024	0.016	0.012	-	-	-	-
50 %		0.022	0.012	0.008	0.006	-	-	-	-
75 %		0.011	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D6 ditch	0.042	0.022	0.015	0.011	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.01	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-

None	R1 pond	0.005	0.003	0.003	0.002	0.005	0.003	0.003	0.002
50 %		0.002	0.002	0.002	0.002	0.002	0.002	0.001	0.001
75 %		0.002	0.002	0.002	0.002	0.001	0.001	0.001	-
90 %		0.002	0.002	0.001	0.001	0.001	-	-	-
None	R1 stream	0.037	0.02	0.013	0.011	0.037	0.02	0.013	0.01
50 %		0.018	0.011	0.011	0.011	0.018	0.01	0.007	0.005
75 %		0.011	0.011	0.011	0.011	0.009	0.005	0.004	0.003
90 %		0.011	0.011	0.011	0.011	0.007	0.005	0.004	0.003
None	R3 stream	0.052	0.028	0.019	0.014	0.052	0.028	0.019	0.014
50 %		0.026	0.014	0.009	0.008	0.026	0.014	0.009	0.007
75 %		0.013	0.008	0.008	0.008	0.013	0.007	0.005	0.004
90 %		0.008	0.008	0.008	0.008	0.005	0.004	0.003	0.002
None	R4 stream	0.037	0.02	0.014	0.014	0.037	0.02	0.013	0.01
50 %		0.019	0.014	0.014	0.014	0.019	0.01	0.007	0.005
75 %		0.014	0.014	0.014	0.014	0.009	0.006	0.005	0.003
90 %		0.014	0.014	0.014	0.014	0.009	0.006	0.005	0.003

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

Table 9.5-13: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter cereals use no. 5

Intended use		Winter cereals							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0032	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D1 stream	0.0148	0.0078	0.0053	0.0041	-	-	-	-
50 %		0.0074	0.0039	0.0027	0.0020	-	-	-	-
75 %		0.0037	0.0020	0.0013	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0005	0.0004	-	-	-	-
None	D2 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0032	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D2 stream	0.0151	0.0080	0.0055	0.0042	-	-	-	-

50 %		0.0075	0.0040	0.0027	0.0021	-	-	-	-
75 %		0.0038	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0005	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream	0.0133	0.0070	0.0048	0.0037	-	-	-	-
50 %		0.0066	0.0035	0.0024	0.0018	-	-	-	-
75 %		0.0033	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0135	0.0071	0.0049	0.0037	-	-	-	-
50 %		0.0067	0.0036	0.0024	0.0019	-	-	-	-

75 %		0.0034	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D6 ditch	0.0125	0.0066	0.0045	0.0034	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0005	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.00025	0.0002	0.0002
90 %		0.0005	0.0005	0.0004	0.0004	0.000296	-	-	-
None	R1 stream	0.0111	0.0059	0.0040	0.0032	0.0111	0.0059	0.0040	0.0031
50 %		0.0055	0.0032	0.0032	0.0032	0.0055	0.0029	0.0020	0.0015
75 %		0.0032	0.0032	0.0032	0.0032	0.0028	0.0015	0.0011	0.0008
90 %		0.0032	0.0032	0.0032	0.0032	0.0021	0.0015	0.0011	0.0008
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0078	0.0042	0.0028	0.0024	0.0078	0.0042	0.0028	0.0022
75 %		0.0039	0.0024	0.0024	0.0024	0.0039	0.0021	0.0014	0.0011
90 %		0.0024	0.0024	0.0024	0.0024	0.0016	0.0011	0.0008	0.0006
None	R4 stream	0.0111	0.0059	0.0041	0.0041	0.0111	0.0059	0.0040	0.0031
50 %		0.0056	0.0041	0.0041	0.0041	0.0056	0.0029	0.0020	0.0015
75 %		0.0041	0.0041	0.0041	0.0041	0.0028	0.0019	0.0014	0.0010

90 %		0.0041	0.0041	0.0041	0.0041	0.0027	0.0019	0.0014	0.0010
RAC = 0.0003 µg/L		PEC/RAC							
None	D1 ditch	**42.333**	**22.333**	**15.333**	**11.667**	-	-	-	-
50 %		**21.000**	**11.333**	**7.667**	**5.667**	-	-	-	-
75 %		**10.667**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	D1 stream	**49.333**	**26.000**	**17.667**	**13.667**	-	-	-	-
50 %		**24.667**	**13.000**	**9.000**	**6.667**	-	-	-	-
75 %		**12.333**	**6.667**	**4.333**	**3.333**	-	-	-	-
90 %		**5.000**	**2.667**	**1.667**	**1.333**	-	-	-	-
None	D2 ditch	**42.333**	**22.333**	**15.333**	**11.667**	-	-	-	-
50 %		**21.000**	**11.333**	**7.667**	**5.667**	-	-	-	-
75 %		**10.667**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	D2 stream	**50.333**	**26.667**	**18.333**	**14.000**	-	-	-	-
50 %		**25.000**	**13.333**	**9.000**	**7.000**	-	-	-	-
75 %		**12.667**	**6.667**	**4.667**	**3.333**	-	-	-	-
90 %		**5.000**	**2.667**	**1.667**	**1.333**	-	-	-	-
None	D3 ditch	**41.667**	**22.000**	**15.000**	**11.667**	-	-	-	-
50 %		**21.000**	**11.000**	**7.667**	**5.667**	-	-	-	-
75 %		**10.333**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-

None	D4 pond	**4.667**	**3.333**	**2.667**	**2.333**	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**1.000**	0.667	0.667	0.667	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	D4 stream	**44.333**	**23.333**	**16.000**	**12.333**	-	-	-	-
50 %		**22.000**	**11.667**	**8.000**	**6.000**	-	-	-	-
75 %		**11.000**	**6.000**	**4.000**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.333**	-	-	-	-
None	D5 pond	**4.667**	**3.333**	**2.667**	**2.333**	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	**45.000**	**23.667**	**16.333**	**12.333**	-	-	-	-
50 %		**22.333**	**12.000**	**8.000**	**6.333**	-	-	-	-
75 %		**11.333**	**6.000**	**4.000**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.333**	-	-	-	-
None	D6 ditch	**41.667**	**22.000**	**15.000**	**11.333**	-	-	-	-
50 %		**21.000**	**11.000**	**7.667**	**5.667**	-	-	-	-
75 %		**10.333**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	R1 pond	**4.667**	**3.333**	**2.667**	**2.333**	**4.667**	**3.333**	**2.667**	**2.333**

50 %		**2.333**	**2.000**	**1.667**	**1.667**	**2.333**	**1.667**	**1.333**	**1.000**
75 %		**1.667**	**1.667**	**1.667**	**1.667**	**1.333**	0.833	0.667	0.667
90 %		**1.667**	**1.667**	**1.333**	**1.333**	0.987	-	-	-
None	R1 stream	**37.000**	**19.667**	**13.333**	**10.667**	**37.000**	**19.667**	**13.333**	**10.333**
50 %		**18.333**	**10.667**	**10.667**	**10.667**	**18.333**	**9.667**	**6.667**	**5.000**
75 %		**10.667**	**10.667**	**10.667**	**10.667**	**9.333**	**5.000**	**3.667**	**2.667**
90 %		**10.667**	**10.667**	**10.667**	**10.667**	**7.000**	**5.000**	**3.667**	**2.667**
None	R3 stream	**52.333**	**27.667**	**19.000**	**14.333**	**52.333**	**27.667**	**19.000**	**14.333**
50 %		**26.000**	**14.000**	**9.333**	**8.000**	**26.000**	**14.000**	**9.333**	**7.333**
75 %		**13.000**	**8.000**	**8.000**	**8.000**	**13.000**	**7.000**	**4.667**	**3.667**
90 %		**8.000**	**8.000**	**8.000**	**8.000**	**5.333**	**3.667**	**2.667**	**2.000**
None	R4 stream	**37.000**	**19.667**	**13.667**	**13.667**	**37.000**	**19.667**	**13.333**	**10.333**
50 %		**18.667**	**13.667**	**13.667**	**13.667**	**18.667**	**9.667**	**6.667**	**5.000**
75 %		**13.667**	**13.667**	**13.667**	**13.667**	**9.333**	**6.333**	**4.667**	**3.333**
90 %		**13.667**	**13.667**	**13.667**	**13.667**	**9.000**	**6.333**	**4.667**	**3.333**

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

For the CEU relevant scenarios the Applicant proposes to use as refinement Parent Kfoc of 189959 mL/g (geometric mean, n=14) and 1/n of 0.97 (arithmetic mean, n=14). The results are given in Table 9.5-13 and 9.5-14 below.

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 3 calculations for the use of LABAMBA in winter cereals use no. 5 after refinement

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5	0.13
AF		100	10	100	10	10	100	10
RAC (µg/L)		0.0021	0.0031	0.000018	0.000022	0.5	0.015	0.013
FOCUS Sce-nario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 3								
D3/ditch	0.0414	**19.714**	**13.355**	**2300.000**	**1881.818**	0.083	**2.760**	**3.185**
D4/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
D4/stream	0.0325	**15.476**	**10.484**	**1805.556**	**1477.273**	0.065	**2.167**	**2.500**
R1/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
R1/stream	0.0272	**12.952**	**8.774**	**1511.111**	**1236.364**	0.054	**1.813**	**2.092**

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 9.5-15: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter cereals use no. 5 after refinement

Intended use		Winter cereals							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.0112	0.0060	0.0041	0.0031	-	-	-	-
50 %		0.0056	0.0030	0.0020	0.0015	-	-	-	-
75 %		0.0028	0.0015	0.0010	0.0008	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	-	-	-	-
None	D4 pond	0.0012	0.0009	0.0007	0.0006	-	-	-	-
50 %		0.0006	0.0004	0.0004	0.000297	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream	0.0119	0.0063	0.0043	0.0033	-	-	-	-
50 %		0.0059	0.0032	0.0022	0.0016	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	-	-	-	-
None	R1 pond	0.0012	0.0009	0.0007	0.0006	-	-	-	-

50 %		0.0006	0.0004	0.0004	0.000297	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	R1 stream	0.0099	0.0053	0.0036	0.0027	0.0099	0.0053	0.0036	0.0027
50 %		0.0050	0.0026	0.0018	0.0014	0.0050	0.0026	0.0018	0.0014
75 %		0.0025	0.0013	0.0009	0.0007	0.0025	0.0013	0.0009	0.0007
90 %		0.0010	0.0005	0.0005	0.0005	0.0010	0.0005	0.0004	0.00027
RAC = 0.0003 µg/L		PEC/RAC							
None	D3 ditch	**37.333**	**20.000**	**13.667**	**10.333**	-	-	-	-
50 %		**18.667**	**10.000**	**6.667**	**5.000**	-	-	-	-
75 %		**9.333**	**5.000**	**3.333**	**2.667**	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	0.999	-	-	-	-
None	D4 pond	**4.000**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**2.000**	**1.333**	**1.333**	0.990	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	D4 stream	**39.667**	**21.000**	**14.333**	**11.000**	-	-	-	-
50 %		**19.667**	**10.667**	**7.333**	**5.333**	-	-	-	-
75 %		**10.000**	**5.333**	**3.667**	**2.667**	-	-	-	-
90 %		**4.000**	**2.000**	**1.333**	0.999	-	-	-	-
None	R1 pond	**4.000**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**2.000**	**1.333**	**1.333**	0.990	-	-	-	-

75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	R1 stream	**33.000**	**17.667**	**12.000**	**9.000**	**33.000**	**17.667**	**12.000**	**9.000**
50 %		**16.667**	**8.667**	**6.000**	**4.667**	**16.667**	**8.667**	**6.000**	**4.667**
75 %		**8.333**	**4.333**	**3.000**	**2.333**	**8.333**	**4.333**	**3.000**	**2.333**
90 %		**3.333**	**1.667**	**1.667**	**1.667**	**3.333**	**1.667**	**1.333**	0.900

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

Table 9.5-14 11: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter oilseed rape

Intended use		winter oilseed rape							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0076	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D2 stream	0.0152	0.0081	0.0055	0.0042	-	-	-	-
50 %		0.0076	0.0040	0.0028	0.0021	-	-	-	-
75 %		0.0020	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0006	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-

None	D4 stream	0.0130	0.0069	0.0047	0.0036	-	-	-	-
50 %		0.0065	0.0034	0.0023	0.0018	-	-	-	-
75 %		0.0017	0.0017	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0137	0.0073	0.0050	0.0038	-	-	-	-
50 %		0.0068	0.0036	0.0025	0.0019	-	-	-	-
75 %		0.0018	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0014	0.0007	0.0005	0.0004	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0006	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.0003	0.0002	-
90 %		0.0005	0.0005	0.0005	-	0.0004	-	-	-
None	R1 stream	0.0110	0.0058	0.0040	0.0033	0.0110	0.0058	0.0040	0.0030
50 %		0.0055	0.0033	0.0033	0.0033	0.0055	0.0029	0.0020	0.0015
75 %		0.0033	0.0033	0.0033	-	0.0028	0.0015	0.0011	0.0008
90 %		0.0033	-	-	-	0.0028	0.0015	0.0011	0.0008
None	R3 stream	0.0156	0.0083	0.0056	0.0043	0.0156	0.0083	0.0056	0.0043
50 %		0.0078	0.0041	0.0028	0.0020	0.0078	0.0041	0.0028	0.0021
75 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0021	0.0014	0.0011
90 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0010	0.0008	0.0005
RAC = 0,3 ng/L		PEC/RAC							
None	D2 ditch	0.042	0.022	0.015	0.012	-	-	-	-

50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.006	0.025	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D2 stream	0.051	0.027	0.018	0.014	-	-	-	-
50 %		0.025	0.013	0.009	0.007	-	-	-	-
75 %		0.007	0.007	0.005	0.003	-	-	-	-
90 %		0.005	0.003	0.002	0.001	-	-	-	-
None	D3 ditch	0.042	0.022	0.015	0.012	-	-	-	-
50 %		0.021	0.011	0.008	0.006	-	-	-	-
75 %		0.006	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D4 pond	0.005	0.003	0.003	0.002	-	-	-	-
50 %		0.002	0.002	0.001	0.001	-	-	-	-
75 %		0.001	0.001	0.001	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.043	0.023	0.016	0.012	-	-	-	-
50 %		0.022	0.011	0.008	0.006	-	-	-	-
75 %		0.006	0.006	0.004	0.003	-	-	-	-
90 %		0.004	0.002	0.002	0.001	-	-	-	-
None	D5 pond	0.005	0.003	0.003	0.002	-	-	-	-
50 %		0.002	0.002	0.001	0.001	-	-	-	-
75 %		0.001	0.001	0.001	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.046	0.024	0.017	0.013	-	-	-	-
50 %		0.023	0.012	0.008	0.006	-	-	-	-
75 %		0.006	0.006	0.004	0.003	-	-	-	-

90 %		0.005	0.002	0.002	0.001	-	-	-	-
None	R1 pond	0.005	0.003	0.003	0.002	0.005	0.003	0.003	0.002
50 %		0.002	0.002	0.002	0.002	0.002	0.002	0.001	0.001
75 %		0.002	0.002	0.002	0.002	0.001	0.001	0.001	-
90 %		0.002	0.002	0.002	-	0.001	-	-	-
None	R1 stream	0.037	0.019	0.013	0.011	0.037	0.019	0.013	0.01
50 %		0.018	0.011	0.011	0.011	0.018	0.01	0.007	0.005
75 %		0.011	0.011	0.011	-	0.009	0.005	0.004	0.003
90 %		0.011	-	-	-	0.009	0.005	0.004	0.003
None	R3 stream	0.052	0.028	0.019	0.014	0.052	0.028	0.019	0.014
50 %		0.026	0.014	0.009	0.007	0.026	0.014	0.009	0.007
75 %		0.008	0.008	0.008	0.008	0.013	0.007	0.005	0.004
90 %		0.008	0.008	0.008	0.008	0.013	0.003	0.003	0.002

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
a) The PECsw units are in ng/L instead of µg/L
*0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
*0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).

Table 9.5-16: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter oilseed rape use no. 6, 7, 8 & 9

Intended use		winter oilseed rape							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5*	10	15**	20

	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0076	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D2 stream	0.0152	0.0081	0.0055	0.0042	-	-	-	-
50 %		0.0076	0.0040	0.0028	0.0021	-	-	-	-
75 %		0.0020	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0006	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	0.0002	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0130	0.0069	0.0047	0.0036	-	-	-	-
50 %		0.0065	0.0034	0.0023	0.0018	-	-	-	-
75 %		0.0017	0.0017	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-

None	D5 stream	0.0137	0.0073	0.0050	0.0038	-	-	-	-
50 %		0.0068	0.0036	0.0025	0.0019	-	-	-	-
75 %		0.0018	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0014	0.0007	0.0005	0.0004	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0006	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.00025	0.0002	0.0002
90 %		0.0005	0.0005	0.0005	-	0.0004	-	-	-
None	R1 stream	0.0110	0.0058	0.0040	0.0033	0.0110	0.0058	0.0040	0.0030
50 %		0.0055	0.0033	0.0033	0.0033	0.0055	0.0029	0.0020	0.0015
75 %		0.0033	0.0033	0.0033	-	0.0028	0.0015	0.0011	0.0008
90 %		0.0033	-	-	-	0.0028	0.0015	0.0011	0.0008
None	R3 stream	0.0156	0.0083	0.0056	0.0043	0.0156	0.0083	0.0056	0.0043
50 %		0.0078	0.0041	0.0028	0.0020	0.0078	0.0041	0.0028	0.0021
75 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0021	0.0014	0.0011
90 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0010	0.0008	0.0005
RAC = 0.0003 µg/L		PEC/RAC							
None	D2 ditch	**42.333**	**22.333**	**15.333**	**11.667**	-	-	-	-
50 %		**21.000**	**11.333**	**7.667**	**5.667**	-	-	-	-
75 %		**5.667**	**25.333**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	D2 stream	**50.667**	**27.000**	**18.333**	**14.000**	-	-	-	-
50 %		**25.333**	**13.333**	**9.333**	**7.000**	-	-	-	-
75 %		**6.667**	**6.667**	**4.667**	**3.333**	-	-	-	-
90 %		**5.000**	**2.667**	**2.000**	**1.333**	-	-	-	-
None	D3 ditch	**41.667**	**22.000**	**15.000**	**11.667**	-	-	-	-

50 %		**21.000**	**11.000**	**7.667**	**5.667**	-	-	-	-
75 %		**5.667**	**5.667**	**3.667**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.000**	-	-	-	-
None	D4 pond	**4.667**	**3.333**	**2.667**	**2.333**	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**0.667**	0.667	0.667	0.667	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	**43.333**	**23.000**	**15.667**	**12.000**	-	-	-	-
50 %		**21.667**	**11.333**	**7.667**	**6.000**	-	-	-	-
75 %		**5.667**	**5.667**	**4.000**	**3.000**	-	-	-	-
90 %		**4.333**	**2.333**	**1.667**	**1.333**	-	-	-	-
None	D5 pond	**4.667**	**3.333**	**2.667**	**2.333**	-	-	-	-
50 %		**2.333**	**1.667**	**1.333**	**1.000**	-	-	-	-
75 %		**0.667**	0.667	0.667	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	**45.667**	**24.333**	**16.667**	**12.667**	-	-	-	-
50 %		**22.667**	**12.000**	**8.333**	**6.333**	-	-	-	-
75 %		**6.000**	**6.000**	**4.000**	**3.000**	-	-	-	-
90 %		**4.667**	**2.333**	**1.667**	**1.333**	-	-	-	-
None	R1 pond	**4.667**	**3.333**	**2.667**	**2.333**	**4.667**	**3.333**	**2.667**	**2.333**
50 %		**2.333**	**2.000**	**2.000**	**1.667**	**2.333**	**1.667**	**1.333**	**1.000**
75 %		**1.667**	**1.667**	**1.667**	**1.667**	**1.333**	0.833	0.667	0.667
90 %		**1.667**	**1.667**	**1.667**	-	**1.333**	-	-	-
None	R1 stream	**36.667**	**19.333**	**13.333**	**11.000**	**36.667**	**19.333**	**13.333**	**10.000**
50 %		**18.333**	**11.000**	**11.000**	**11.000**	**18.333**	**9.667**	**6.667**	**5.000**
75 %		**11.000**	**11.000**	**11.000**	-	**9.333**	**5.000**	**3.667**	**2.667**

90 %		**11.000**	-	-	-	**9.333**	**5.000**	**3.667**	**2.667**
None	R3 stream	**52.000**	**27.667**	**18.667**	**14.333**	**52.000**	**27.667**	**18.667**	**14.333**
50 %		**26.000**	**13.667**	**9.333**	**6.667**	**26.000**	**13.667**	**9.333**	**7.000**
75 %		**7.667**	**7.667**	**7.667**	**7.667**	**13.000**	**7.000**	**4.667**	**3.667**
90 %		**7.667**	**7.667**	**7.667**	**7.667**	**13.000**	**3.333**	**2.667**	**1.667**

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
a) The PECsw units are in ng/L instead of µg/L
*0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
*0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).

For the CEU relevant scenarios the Applicant proposes to use as refinement Parent Kfoc of 189959 mL/g (geometric mean, n=14) and 1/n of 0.97 (arithmetic mean, n=14). The results are given in Table 9.5-17 and 9.5-18 below.

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for each organism group based on FOCUS Steps 3 calculations for the use of LABAMBA in winter oilseed rape use no. 6, 7, 8 & 9 after refinement

Group		**Fish acute**	**Fish pro-longed**	**Inverteb. acute**	**Inverteb. pro-longed**	**Algae**	**Sed. dwell. acute**	**Sed. dwell. pro-longed**
Test species		***L. idus***	***P. promelas***	***H. azteca***	***M. bahia***	***P. subcapi-tata***	***C. riparius***	***C. riparius***
Endpoint		LC_{50}	NOEC	EC_{50}	NOEC	E_rC_{50}/E_yC_{50}	EC50	NOEC
(µg/L)		0.078	0.031	0.0018	0.00022	5	1.5	0.13
AF		100	10	100	10	10	100	10
RAC (µg/L)		0.0021	0.0031	0.000018	0.000022	0.5	0.015	0.013
FOCUS Sce-nario	**PEC $_{gl\text{-}max}$ (µg/L)**							
Step 3								
D3/ditch	0.0414	**19.714**	**13.355**	**2300.000**	**1881.818**	0.083	**2.760**	**3.185**
D4/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
D4/stream	0.0317	**15.095**	**10.226**	**1761.111**	**1440.909**	0.063	**2.113**	**2.438**

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. acute	Sed. dwell. pro-longed
R1/pond	0.0014	0.667	0.452	**77.778**	**63.636**	0.003	0.093	0.108
R1/stream	0.0270	**12.857**	**8.710**	**1500.000**	**1227.273**	0.054	**1.800**	**2.077**

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 9.5-18: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin based on FOCUS Step 4 calculations and toxicity data for invertebrates - acute with mitigation of spray drift and run-off for the use of LABAMBA in winter oilseed rape use no. 6, 7, 8 & 9 after refinement

Intended use		winter oilseed rape							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch	0.0112	0.0060	0.0041	0.0031	-	-	-	-
50 %		0.0020	0.0030	0.0020	0.0015	-	-	-	-
75 %		0.0028	0.0015	0.0010	0.0008	-	-	-	-
90 %		0.0011	0.0006	0.0004	0.0003	-	-	-	-
None	D4 pond	0.0012	0.0009	0.0007	0.0006	-	-	-	-
50 %		0.0004	0.0004	0.0004	0.000296	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream	0.0116	0.0062	0.0042	0.0032	-	-	-	-
50 %		0.0021	0.0031	0.0021	0.0016	-	-	-	-
75 %		0.0029	0.0015	0.0011	0.0008	-	-	-	-

90 %		0.0012	0.0006	0.0004	0.0003	-	-	-	-
None	R1 pond	0.0012	0.0009	0.0007	0.0006	-	-	-	-
50 %		0.0004	0.0004	0.0004	0.000298	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	R1 stream	0.0099	0.0052	0.0036	0.0027	0.0099	0.0052	0.0036	0.0027
50 %		0.0018	0.0026	0.0018	0.0014	0.0049	0.0026	0.0009	0.0014
75 %		0.0025	0.0013	0.0009	0.0007	0.0025	0.0013	0.0009	0.0007
90 %		0.0010	0.0005	0.0005	0.0005	0.0010	0.0005	0.0004	0.00027
RAC = 0.0003 µg/L		PEC/RAC							
None	D3 ditch	**37.333**	**20.000**	**13.667**	**10.333**	-	-	-	-
50 %		**6.667**	**10.000**	**6.667**	**5.000**	-	-	-	-
75 %		**9.333**	**5.000**	**3.333**	**2.667**	-	-	-	-
90 %		**3.667**	**2.000**	**1.333**	0.999	-	-	-	-
None	D4 pond	**4.000**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**1.333**	**1.333**	**1.333**	0.987	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-
None	D4 stream	**38.667**	**20.667**	**14.000**	**10.667**	-	-	-	-
50 %		**7.000**	**10.333**	**7.000**	**5.333**	-	-	-	-
75 %		**9.667**	**5.000**	**3.667**	**2.667**	-	-	-	-
90 %		**4.000**	**2.000**	**1.333**	0.999	-	-	-	-
None	R1 pond	**4.000**	**3.000**	**2.333**	**2.000**	-	-	-	-
50 %		**1.333**	**1.333**	**1.333**	0.993	-	-	-	-
75 %		**1.000**	0.667	0.667	-	-	-	-	-
90 %		0.333	-	-	-	-	-	-	-

None	R1 stream	**33.000**	**17.333**	**12.000**	**9.000**	**33.000**	**17.333**	**12.000**	**9.000**
50 %		**6.000**	**8.667**	**6.000**	**4.667**	**16.333**	**8.667**	**3.000**	**4.667**
75 %		**8.333**	**4.333**	**3.000**	**2.333**	**8.333**	**4.333**	**3.000**	**2.333**
90 %		**3.333**	**1.667**	**1.667**	**1.667**	**3.333**	**1.667**	**1.333**	0.900

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
*0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).

zRMS comment:

The-Applicant at the begining of the evaluation Labamba did not provide further refinement of acute and long-term risk for fish with PEC_{sw} FOCUS STEP4 calculations. However, after commenting period process the Applicant recalculated the risk assessment again with consideration PEC_{sw} FOCUS STEP4 values provided in the Tables above (in green).

Fish

Based on the results it should be noted that the fish chronic risk assessment with $RAC_{chronic}$= 0.0031 microgram/L is covered by risk mitigation for acute risk assessment with RAC = 0.0021 microgram/L.

Risk for aquatic invertebrates:

For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several/all FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and higher RAC of 0.0003 µg a .s./L for aquatic invertebrates. RAC value is based on available laboratory data on lambda-cyhalothrin and gamma-cyhalothrin as well as field data on gamma-cyhalothrin. It should be noted that this RAC is only applicable for CS-formulations and when exposure to the aquatic environment is predominantly via spray drift. As demonstrated in Section B.8 the highest PEC_{sw} in FOCUS STEP 3 is related to a drift event for all scenarios with the highest PEC_{sw} from exposure via drift calculated for single application. Higher RAC of 0.0003 µg a.s./L is therefore considered applicable for the CS-formulation SHA 3600 B / LABAMBA. After Step 4 calculations, an acceptable risk was obtained. It should be noted that during commenting process the applicant provided the recalculation of the risk assessment for aquatic invertebrates in the Table above (in green).

Based on RAC= 0.0003 µg a.s./L for aquatic invertebrates the following risk mitigation measures should be applied:

Brassicas:
For D3 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 5 m no spray buffer zone + nozzle reduction of 90% or 10 m no spray buffer zone + nozzle reduction of 75% or 20 m no spray buffer zone + nozzle reduction of 50% should be considered.
For D4 stream 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D6 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 30 m no spray buffer zone + noz-zle reduction of 50% should be considered.

For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% or 50 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 75% is needed.
For R2 stream, 40 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle re-duction.

Tomato (field and glasshouse uses):
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 stream 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed

Although scenarios D6, R2 and R4 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.
Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.

Winter cereals
For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.

For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% should be considered.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D1, D2, D6, R3 and R4 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.

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction

Winter oilseed rape
For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D2, D5 and R3 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.

Spe3 – To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction
The field use for tomato covers glasshouse uses.

It should be noted the risk mitigation measures based on RAC=0.0003 µg a.s./L for aquatic invertebrates covers the risk mitigation measures for all aquatic species.

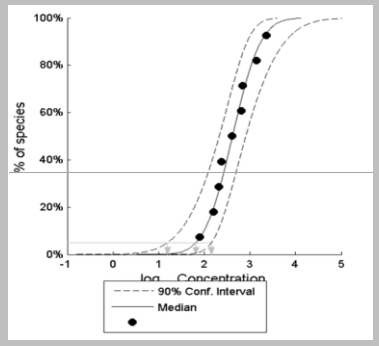
~~In zRMS's opinion acute toxicity SSD HC_5 RAC for fish following the EFSA (2013)[2] Tier 2B approach can be used as a refinement option of acute risk assessmet to fish. The dataset of EU-agreed acute toxicity endpoints for fish comprises bound LC_{50} values for nine species exposed to *lambda*-cyhalothrin under comparable~~

[2] EFSA PPR Panel 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp.

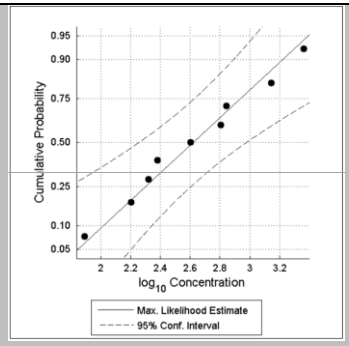
flow-through test conditions. Since sufficient (≥5) reliable values are available they have been used to construct a species sensitivity distribution (SSD) using the Webfram (DEFRA, UK) model to derive a refined acute toxicity endpoint for fish.

The input data set and the corresponding goodness-of-fit parameters are presented in the tables and figures below.

Species	96 h LC_{50} (µg a.s./L)
Fish	
Leuciscus idus	0.078
Lepomis macrochirus	0.21
Oncorhynchus mykiss	0.24
Ictalurus punctatus	0.16
Gasterosterus aculeatus	0.40
Brachydanio rerio	0.64
Pimephales promelas	0.70
Oryzias latipes	1.4
Poecilia reticulata	2.3



Webfram SSD plots for the acute toxicity of *lambda*-cyhalothrin to fish.



~~Goodness-of-fit test outcomes for the SSD for the acute toxicity of *lambda*-cyhalothrin to fish~~

~~P-values~~	~~Critical values for test statistic~~	~~Calculated test statistic~~	~~Accepted or rejected~~
~~Kolmogorov Smirnov~~			
~~0.1~~	~~0.819~~	~~0.4520~~	~~Accepted~~
~~0.05~~	~~0.895~~	~~0.4520~~	~~Accepted~~
~~0.025~~	~~0.995~~	~~0.4520~~	~~Accepted~~
~~0.01~~	~~1.035~~	~~0.4520~~	~~Accepted~~
~~Cramer Von Mises~~			
~~0.1~~	~~0.104~~	~~0.0131~~	~~Accepted~~
~~0.05~~	~~0.126~~	~~0.0131~~	~~Accepted~~
~~0.025~~	~~0.148~~	~~0.0131~~	~~Accepted~~
~~0.01~~	~~0.179~~	~~0.0131~~	~~Accepted~~
~~Anderson Darling~~			
~~0.1~~	~~0.631~~	~~-~~	~~Accepted~~
~~0.05~~	~~0.752~~	~~-~~	~~Accepted~~
~~0.025~~	~~0.873~~	~~-~~	~~Accepted~~
~~0.01~~	~~1.035~~	~~-~~	~~Accepted~~

The goodness-of-fit parameters are acceptable and the SSD may therefore be considered to be valid. The HC_5 median LC_{50} calculated from the SSD is 65.4 ng a.s./L, with lower and upper 95% confidence limits of 15.6 and 142 ng a.s./L, respectively. According to EFSA (2013) guidance, the default assessment factor (AF) to be applied to the SSD-derived median LC_{50} endpoint is 9. The refined acute **SSD-RAC** is therefore **65.4/9 = 7.27 ng a.s./L (0.00727 microgram/L).**

zRMS recalculated the acute risk assessment for fish taking into account RAC= 0.0021 microgram/L (according to recommendation given in EFSA 2014) and SSD - RAC= 0.00727 microgram/L (refined option) in the Tables below:

Table 9.5-8-1: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for fish (acute) based on FOCUS Step 4 calculations with mitigation of spray drift and run-off for the use of LABAMBA in brassicas.

Intended use **Active substance** **Application rate (g/ha)**		**Brassicas** **Lambda-cyhalothrin** **1 × 7.5**													
Nozzle reduction	Vegetative strip (m)	None	None	None	None	None	None	None	5***	10	15****	20	20	20	20
	No spray buffer (m)	5	10	15	20	30	40	50	5	10	15	20	30	40	50
none	D3 ditch*	0.0125	0.0162	0.0045	0.0035	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D3 ditch**	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	D4 pond*	0.0014	0.0010	0.0008	0.0007	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	0.0003	0.0002	-	-	-	-	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-

none	D4 stream*	0.0120	0.0064	0.0044	0.0033	0.0022	0.0017	0.0014	-	-	-	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	0.0011	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0003	0.0002	-	-	-	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	0.0002	-	-	-	-	-	-	-	-	-
none	D6 ditch*	0.0125	0.0066	0.0045	0.0034	0.0023	0.0018	0.0014	-	-	-	-	-	-	-
50 %		0.0062	0.0033	0.0023	0.0017	0.0012	0.0009	0.0007	-	-	-	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	0.0006	0.0004	0.0004	-	-	-	-	-	-	-
90 %		0.0012	0.0007	0.0005	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
none	R1 pond*	0.0016	0.0014	0.0014	-	-	-	-	0.0015	0.0011	0.0008	0.0007	0.0005	0.0004	0.0004
50 %		0.0014	0.0014	-	-	-	-	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.0003	0.0003
75 %		0.0014	-	-	-	-	-	-	0.0009	0.0006	0.0004	0.0003	-	-	-
90 %		-	-	-	-	-	-	-	0.0009	0.0006	0.0004	-	-	-	-
none	R1 pond**	0.0017	0.0014	0.0014	0.0014	0.0014	0.0013	0.0013	0.0016	0.0011	0.0009	0.0007	0.0006	0.0005	0.0004
50 %		0.0014	0.0014	0.0013	0.0013	0.0013	0.0013	-	0.0009	0.0006	0.0005	0.0004	0.0003	0.0003	0.0003
75 %		0.0013	0.0013	0.0013	0.0013	0.0013	-	-	0.0008	0.0006	0.0004	0.0003	-	-	-
90 %		0.0013	0.0013	-	-	-	-	-	0.0008	0.0006	0.0004	-	-	-	-
none	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0034	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0013
50 %		0.0056	0.0034	0.0034	0.0034	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0008
75 %		0.0034	0.0034	0.0034	-	-	-	-	0.0028	0.0016	0.0012	0.0008	0.0008	0.0008	0.0008
90 %		0.0034	-	-	-	-	-	-	0.0022	0.0016	0.0012	0.0008	0.0008	0.0008	-
none	R1 stream**	0.0112	0.0059	0.0041	0.0031	0.0026	0.0026	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0016	0.0017
50 %		0.0056	0.0030	0.0026	0.0026	0.0026	-	-	0.0056	0.0030	0.0020	0.0015	0.0010	0.0008	0.0007
75 %		0.0028	0.0026	0.0026	0.0026	-	-	-	0.0028	0.0015	0.0010	0.0008	0.0006	0.0006	0.0006
90 %		0.0026	0.0026	-	-	-	-	-	0.0017	0.0012	0.0009	0.0006	0.0006	0.0006	0.0006
none	R2 stream*	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0150	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013
50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R2 stream**	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0017	0.0149	0.0079	0.0054	0.0041	0.0028	0.0021	0.0013

50 %		0.0075	0.0040	0.0027	0.0021	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0021	0.0014	0.0011	0.0008
75 %		0.0037	0.0020	0.0014	0.0010	0.0007	0.0006	0.0006	0.0037	0.0020	0.0014	0.0010	0.0007	0.0005	0.0004
90 %		0.0015	0.0008	0.0006	0.0006	0.0006	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002
none	R3 stream*	0.0157	0.0083	0.0057	0.0043	0.0029	0.0023	0.0023	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0017
50 %		0.0079	0.0042	0.0029	0.0023	0.0023	0.0023	0.0023	0.0079	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0023	0.0023	0.0023	0.0023	-	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0006	0.0006
90 %		0.0023	0.0023	0.0023	-	-	-	-	0.0016	0.0011	0.0008	0.0006	0.0006	0.0006	0.0006
none	R3 stream**	0.0157	0.0083	0.0057	0.0043	0.0029	0.0022	0.0019	0.0157	0.0083	0.0057	0.0043	0.0029	0.002218	0.0017
50 %		0.0078	0.0042	0.0028	0.0022	0.0019	0.0019	0.0019	0.0078	0.0042	0.0028	0.0022	0.0015	0.0011	0.0009
75 %		0.0039	0.0021	0.0019	0.0019	0.0019	0.0019	-	0.0039	0.0021	0.0014	0.0011	0.0007	0.0005	0.0005
90 %		0.0019	0.0019	0.0019	0.0019	-	-	-	0.0016	0.0009	0.0007	0.0005	0.0005	0.0005	0.0005
none	R4 stream*	0.0109	0.0058	0.0045	0.0045	-	-	-	0.0109	0.0058	0.0040	0.0030	0.0020	0.0015	0.0013
50 %		0.0055	0.0045	0.0045	-	-	-	-	0.0055	0.0029	0.0020	0.0015	0.0011	0.0011	0.0011
75 %		0.0045	0.0045	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	0.0011	0.0011	0.0011
90 %		0.0045	-	-	-	-	-	-	0.0030	0.0021	0.0016	0.0011	-	-	-
none	R4 stream**	0.0112	0.0059	0.0044	0.0044	-	-	-	0.0112	0.0059	0.0040	0.0031	0.0021	0.0011	0.0011
50 %		0.0056	0.0044	0.0044	0.0044	-	-	-	0.0056	0.0030	0.0020	0.0015	0.0011	0.0011	-
75 %		0.0044	0.0044	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	0.0011	-	-
90 %		0.0044	-	-	-	-	-	-	0.0029	0.0020	0.0016	0.0011	-	-	-
RAC (ng/L) 7.27		**PEC/RAC ratio**													
none	D3 ditch*	0.0017	0.0022	0.0006	0.0005	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	0.0002	0.0001	0.0001	-	-	-	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	-	-	-	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	0.0000	0.0000	0.0000	-	-	-	-	-	-	-
none	D3 ditch**	0.0017	0.0009	0.0006	0.0005	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	0.0002	0.0001	0.0001	-	-	-	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	-	-	-	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	0.0000	0.0000	0.0000	-	-	-	-	-	-	-

none	D4 pond*	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0000	-	-	-	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	0.0000	0.0000	-	-	-	-	-	-	-	-
75 %		0.0000	0.0000	0.0000	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.0017	0.0009	0.0006	0.0005	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
50 %		0.0008	0.0004	0.0003	0.0002	0.0002	0.0001	0.0001	-	-	-	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	0.0001	0.0000	0.0000	-	-	-	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	0.0000			-	-	-	-	-	-	-
none	D6 ditch*	0.0017	0.0009	0.0006	0.0005	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	0.0002	0.0001	0.0001	-	-	-	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	-	-	-	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	0.0000	0.0000	0.0000	-	-	-	-	-	-	-
none	R1 pond*	0.0002	0.0002	0.0002	-	-	-	-	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001
50 %		0.0002	0.0002	-	-	-	-		0.0001	0.0001	0.0001	0.0001	0.0000	0.0000	0.0000
75 %		0.0002	-	-	-	-	-	-	0.0001	0.0001	0.0001	0.0000	-	-	-
90 %		-	-	-	-	-	-	-	0.0001	0.0001	0.0001	-	-	-	-
none	R1 pond**	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001
50 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	-	0.0001	0.0001	0.0001	0.0001	0.0000	0.0000	0.0000
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	-	-	0.0001	0.0001	0.0001	0.0000	-	-	-
90 %		0.0002	0.0002	-	-	-	-	-	0.0001	0.0001	0.0001	-	-	-	-
none	R1 stream*	0.0015	0.0008	0.0006	0.0005	0.0005	-	-	0.0015	0.0008	0.0006	0.0004	0.0003	0.0002	0.0002
50 %		0.0008	0.0005	0.0005	0.0005	-	-	-	0.0008	0.0004	0.0003	0.0002	0.0001	0.0001	0.0001
75 %		0.0005	0.0005	0.0005	-	-	-	-	0.0004	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001
90 %		0.0005	-	-	-	-	-	-	0.0003	0.0002	0.0002	0.0001	0.0001	0.0001	-
none	R1 stream**	0.0015	0.0008	0.0006	0.0004	0.0004	0.0004	-	0.0015	0.0008	0.0006	0.0004	0.0003	0.0002	0.0002
50 %		0.0008	0.0004	0.0004	0.0004	0.0004	-	-	0.0008	0.0004	0.0003	0.0002	0.0001	0.0001	0.0001
75 %		0.0004	0.0004	0.0004	0.0004	-	-	-	0.0004	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001
90 %		0.0004	0.0004	-	-	-	-	-	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001
none	R2 stream*	0.0021	0.0011	0.0007	0.0006	0.0004	0.0003	0.0002	0.0021	0.0011	0.0007	0.0006	0.0004	0.0003	0.0002

50 %		0.0010	0.0006	0.0004	0.0003	0.0002	0.0001	0.0001	0.0010	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001
75 %		0.0005	0.0003	0.0002	0.0001	0.0001	0.0001	0.0001	0.0005	0.0003	0.0002	0.0001	0.0001	0.0001	0.0001
90 %		0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001	0.0000	0.0000	0.0000
none	R2 stream**	0.0020	0.0011	0.0007	0.0006	0.0004	0.0003	0.0002	0.0020	0.0011	0.0007	0.0006	0.0004	0.0003	0.0002
50 %		0.0010	0.0006	0.0004	0.0003	0.0002	0.0001	0.0001	0.0010	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001
75 %		0.0005	0.0003	0.0002	0.0001	0.0001	0.0001	0.0001	0.0005	0.0003	0.0002	0.0001	0.0001	0.0001	0.0001
90 %		0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001	0.0000	0.0000	0.0000
none	R3 stream*	0.0022	0.0011	0.0008	0.0006	0.0004	0.0003	0.0003	0.0022	0.0011	0.0008	0.0006	0.0004	0.0003	0.0002
50 %		0.0011	0.0006	0.0004	0.0003	0.0003	0.0003	0.0003	0.0011	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001
75 %		0.0005	0.0003	0.0003	0.0003	0.0003	-	-	0.0005	0.0003	0.0002	0.0002	0.0001	0.0001	0.0001
90 %		0.0003	0.0003	0.0003	-	-	-	-	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001
none	R3 stream**	0.0022	0.0011	0.0008	0.0006	0.0004	0.0003	0.0003	0.0022	0.0011	0.0008	0.0006	0.0004	0.0003	0.0002
50 %		0.0011	0.0006	0.0004	0.0003	0.0003	0.0003	0.0003	0.0011	0.0006	0.0004	0.0003	0.0002	0.0002	0.0001
75 %		0.0005	0.0003	0.0003	0.0003	0.0003	0.0003	-	0.0005	0.0003	0.0002	0.0002	0.0001	0.0001	0.0001
90 %		0.0003	0.0003	0.0003	0.0003	-	-	-	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
none	R4 stream*	0.0015	0.0008	0.0006	0.0006	-			0.0015	0.0008	0.0006	0.0004	0.0003	0.0002	0.0002
50 %		0.0008	0.0006	0.0006	-	-	-	-	0.0008	0.0004	0.0003	0.0002	0.0002	0.0002	0.0002
75 %		0.0006	0.0006	-	-	-	-	-	0.0004	0.0003	0.0002	0.0002	0.0002	0.0002	0.0002
90 %		0.0006	-	-	-	-	-	-	0.0004	0.0003	0.0002	0.0002	-	-	-
none	R4 stream**	0.0015	0.0008	0.0006	0.0006	-	-	-	0.0015	0.0008	0.0006	0.0004	0.0003	0.0002	0.0002
50 %		0.0008	0.0006	0.0006	0.0006	-	-	-	0.0008	0.0004	0.0003	0.0002	0.0002	0.0002	-
75 %		0.0006	0.0006	-	-	-	-	-	0.0004	0.0003	0.0002	0.0002	0.0002	-	-
90 %		0.0006	-	-	-	-	-	-	0.0004	0.0003	0.0002	0.0002	-	-	-
RAC (ng/L) 2.1		**PEC/RAC ratio**													
none	D3 ditch*	0.0060	0.0077	0.0021	0.0017	0.0011	0.0009	0.0007	-	-	-	-	-	-	-
50 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0004	0.0003	-	-	-	-	-	-	-
75 %		0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	0.0001	0.0001	0.0000	-	-	-	-	-	-	-
none	D3 ditch**	0.0060	0.0031	0.0021	0.0016	0.0011	0.0009	0.0007	-	-	-	-	-	-	-

50 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0004	0.0003	-	-	-	-	-	-	-
75 %		0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	0.0001	0.0001	0.0000	-	-	-	-	-	-	-
none	D4 pond*	0.0007	0.0005	0.0004	0.0003	0.0002	0.0002	0.0001	-	-	-	-	-	-	-
50 %		0.0003	0.0002	0.0002	0.0001	0.0001	0.0001	-	-	-	-	-	-	-	-
75 %		0.0001	0.0001	0.0001	-	-	-	-	-	-	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-	-	-	-	-	-	-
none	D4 stream*	0.0057	0.0030	0.0021	0.0016	0.0010	0.0008	0.0007	-	-	-	-	-	-	-
50 %		0.0029	0.0015	0.0010	0.0008	0.0005	0.0004	0.0003	-	-	-	-	-	-	-
75 %		0.0014	0.0008	0.0005	0.0004	0.0003	0.0001	0.0001	-	-	-	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	0.0001			-	-	-	-	-	-	-
none	D6 ditch*	0.0060	0.0031	0.0021	0.0016	0.0011	0.0009	0.0007	-	-	-	-	-	-	-
50 %		0.0030	0.0016	0.0011	0.0008	0.0006	0.0004	0.0003	-	-	-	-	-	-	-
75 %		0.0015	0.0008	0.0005	0.0004	0.0003	0.0002	0.0002	-	-	-	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	0.0001	0.0001	0.0000	-	-	-	-	-	-	-
none	R1 pond*	0.0008	0.0007	0.0007	-	-	-	-	0.0007	0.0005	0.0004	0.0003	0.0002	0.0002	0.0002
50 %		0.0007	0.0007	-	-	-	-	-	0.0004	0.0003	0.0002	0.0002	0.0001	0.0001	0.0001
75 %		0.0007	-	-	-	-	-	-	0.0004	0.0003	0.0002	0.0001	-	-	-
90 %		-	-	-	-	-	-	-	0.0004	0.0003	0.0002	-	-	-	-
none	R1 pond**	0.0008	0.0007	0.0007	0.0007	0.0007	0.0006	0.0006	0.0008	0.0005	0.0004	0.0003	0.0003	0.0002	0.0002
50 %		0.0007	0.0007	0.0006	0.0006	0.0006	0.0006	-	0.0004	0.0003	0.0002	0.0002	0.0001	0.0001	0.0001
75 %		0.0006	0.0006	0.0006	0.0006	0.0006	-	-	0.0004	0.0003	0.0002	0.0001	-	-	-
90 %		0.0006	0.0006	-	-	-	-	-	0.0004	0.0003	0.0002	-	-	-	-
none	R1 stream*	0.0053	0.0028	0.0019	0.0016	0.0016	-	-	0.0053	0.0028	0.0019	0.0015	0.0010	0.0008	0.0006
50 %		0.0027	0.0016	0.0016	0.0016	-	-	-	0.0027	0.0014	0.0010	0.0007	0.0005	0.0004	0.0004
75 %		0.0016	0.0016	0.0016	-	-	-	-	0.0013	0.0008	0.0006	0.0004	0.0004	0.0004	0.0004
90 %		0.0016	-	-	-	-	-	-	0.0010	0.0008	0.0006	0.0004	0.0004	0.0004	-
none	R1 stream**	0.0053	0.0028	0.0020	0.0015	0.0012	-	-	0.0053	0.0028	0.0019	0.0015	0.0010	0.0008	0.0008
50 %		0.0027	0.0014	0.0012	0.0012	0.0012	-	-	0.0027	0.0014	0.0010	0.0007	0.0005	0.0004	0.0003

75 %		0.0013	0.0012	0.0012	0.0012	-	-	-	0.0013	0.0007	0.0005	0.0004	0.0003	0.0003	0.0003
90 %		0.0012	0.0012	-	-	-	-	-	0.0008	0.0006	0.0004	0.0003	0.0003	0.0003	0.0003
none	R2 stream*	0.0071	0.0038	0.0026	0.0020	0.0013	0.0010	0.0008	0.0071	0.0038	0.0026	0.0020	0.0013	0.0010	0.0006
50 %		0.0036	0.0019	0.0013	0.0010	0.0007	0.0005	0.0004	0.0036	0.0019	0.0013	0.0010	0.0007	0.0005	0.0004
75 %		0.0018	0.0010	0.0007	0.0005	0.0003	0.0003	0.0003	0.0018	0.0010	0.0007	0.0005	0.0003	0.0002	0.0002
90 %		0.0007	0.0004	0.0003	0.0003	0.0003	0.0003	0.0003	0.0007	0.0004	0.0002	0.0002	0.0001	0.0001	0.0001
none	R2 stream**	0.0071	0.0038	0.0026	0.0020	0.0013	0.0010	0.0008	0.0071	0.0038	0.0026	0.0020	0.0013	0.0010	0.0006
50 %		0.0036	0.0019	0.0013	0.0010	0.0007	0.0005	0.0004	0.0036	0.0019	0.0013	0.0010	0.0007	0.0005	0.0004
75 %		0.0018	0.0010	0.0007	0.0005	0.0003	0.0003	0.0003	0.0018	0.0010	0.0007	0.0005	0.0003	0.0002	0.0002
90 %		0.0007	0.0004	0.0003	0.0003	0.0003	0.0003	0.0003	0.0007	0.0004	0.0002	0.0002	0.0001	0.0001	0.0001
none	R3 stream*	0.0075	0.0040	0.0027	0.0020	0.0014	0.0011	0.0011	0.0075	0.0040	0.0027	0.0020	0.0014	0.0010	0.0008
50 %		0.0038	0.0020	0.0014	0.0011	0.0011	0.0011	0.0011	0.0038	0.0020	0.0013	0.0010	0.0007	0.0005	0.0004
75 %		0.0019	0.0011	0.0011	0.0011	0.0011	-	-	0.0019	0.0010	0.0007	0.0005	0.0003	0.0003	0.0003
90 %		0.0011	0.0011	0.0011	-	-	-	-	0.0008	0.0005	0.0004	0.0003	0.0003	0.0003	0.0003
none	R3 stream**	0.0075	0.0040	0.0027	0.0020	0.0014	0.0010	0.0009	0.0075	0.0040	0.0027	0.0020	0.0014	0.0011	0.0008
50 %		0.0037	0.0020	0.0013	0.0010	0.0009	0.0009	0.0009	0.0037	0.0020	0.0013	0.0010	0.0007	0.0005	0.0004
75 %		0.0019	0.0010	0.0009	0.0009	0.0009	0.0009	-	0.0019	0.0010	0.0007	0.0005	0.0003	0.0002	0.0002
90 %		0.0009	0.0009	0.0009	0.0009	-	-	-	0.0008	0.0004	0.0003	0.0002	0.0002	0.0002	0.0002
none	R4 stream*	0.0052	0.0028	0.0021	0.0021	-	-	-	0.0052	0.0028	0.0019	0.0014	0.0010	0.0007	0.0006
50 %		0.0026	0.0021	0.0021	-	-	-	-	0.0026	0.0014	0.0010	0.0007	0.0005	0.0005	0.0005
75 %		0.0021	0.0021	-	-	-	-	-	0.0014	0.0010	0.0008	0.0005	0.0005	0.0005	0.0005
90 %		0.0021	-	-	-	-	-	-	0.0014	0.0010	0.0008	0.0005	-	-	-
none	R4 stream**	0.0053	0.0028	0.0021	0.0021	-	-	-	0.0053	0.0028	0.0019	0.0015	0.0010	0.0005	0.0005
50 %		0.0027	0.0021	0.0021	0.0021	-	-	-	0.0027	0.0014	0.0010	0.0007	0.0005	0.0005	-
75 %		0.0021	0.0021	-	-	-	-	-	0.0014	0.0010	0.0008	0.0005	0.0005	-	-
90 %		0.0021	-	-	-	-	-	-	0.0014	0.0010	0.0008	0.0005	-	-	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*vegetables leafy 1st
**vegetables leafy 2nd
***0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
****0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).

a) The PECsw units are in ng/L instead of µg/L

Table 9.5-9-1: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for fish (acute) based on FOCUS Step 4 calculations with mitigation of spray drift and run-off for the use of LABAMBA in tomato

Intended use Active substance Application rate (g/ha)		Tomato Lambda-cyhalothrin 1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5**	10	15***	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D3 ditch*	0.0125	0.0162	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond*	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0001	-	-	-	-	-	-	-
None	D4 stream*	0.0120	0.0064	0.0044	0.0033	-	-	-	-
50 %		0.0060	0.0032	0.0022	0.0017	-	-	-	-
75 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
90 %		0.0012	0.0006	0.0004	0.0003	-	-	-	-
None	D6 ditch	0.0232	0.0123	0.0045	0.0034	-	-	-	-
50 %		0.0116	0.0033	0.0023	0.0032	-	-	-	-
75 %		0.0058	0.0016	0.0011	0.0016	-	-	-	-
90 %		0.0023	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond*	0.0016	0.0014	0.0014	0.0014	0.0015	0.0011	0.0008	0.0007
50 %		0.0014	0.0014	0.0014	0.0014	0.0009	0.0006	0.0005	0.0004
75 %		0.0014	0.0014	-	-	0.0009	0.0006	0.0004	0.0003

90 %		-	-	-	-	0.0009	0.0006	0.0004	-
None	R1 stream*	0.0112	0.0059	0.0040	0.0034	0.0112	0.0059	0.0040	0.0031
50 %		0.0056	0.0034	0.0034	0.0034	0.0056	0.0030	0.0020	0.0015
75 %		0.0034	0.0034	0.0034	-	0.0028	0.0016	0.0012	0.0008
90 %		0.0034	-	-	-	0.0022	0.0016	0.0012	0.0008
None	R2 stream	0.0149	0.0079	0.0054	0.0041	0.0149	0.0079	0.0054	0.0041
50 %		0.0075	0.0040	0.0027	0.0021	0.0109	0.0040	0.0027	0.0021
75 %		0.0037	0.0020	0.0014	0.0010	0.0037	0.0020	0.0014	0.0010
90 %		0.0015	0.0008	0.0008	0.0008	0.0015	0.0008	0.0005	0.0004
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0079	0.0042	0.0028	0.0022	0.0079	0.0042	0.0028	0.0022
75 %		0.0039	0.0021	0.0017	0.0017	0.0039	0.0021	0.0014	0.0011
90 %		0.0017	0.0017	0.0017	0.0017	0.0016	0.0008	0.0006	0.0004
None	R4 stream	0.0109	0.0058	0.0045	0.0045	0.0109	0.0058	0.0039	0.0030
50 %		0.0054	0.0045	0.0045	0.0045	0.0054	0.0029	0.0048	0.0015
75 %		0.0045	0.0045	-	-	0.0029	0.0020	0.0012	0.0011
90 %		0.0045	-	-	-	0.0029	0.0020	0.0011	0.0011
RAC (ng/L) 7.27		**PEC/RAC**							
None	D3 ditch*	0.0017	0.0022	0.0006	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D4 pond*	0.0002	0.0001	0.0001	0.0001	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
75 %		0.0000	0.0000	0.0000	0.0000	-	-	-	-
90 %		0.0000	-	-	-	-	-	-	-
None	D4 stream*	0.0017	0.0009	0.0006	0.0005	-	-	-	-
50 %		0.0008	0.0004	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-

90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D6 ditch	0.0032	0.0017	0.0006	0.0005	-	-	-	-
50 %		0.0016	0.0005	0.0003	0.0004	-	-	-	-
75 %		0.0008	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0003	0.0001	0.0001	0.0000	-	-	-	-
None	R1 pond*	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001
50 %		0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001
75 %		0.0002	0.0002	-	-	0.0001	0.0001	0.0001	0.0000
90 %		-	-	-	-	0.0001	0.0001	0.0001	
None	R1 stream*	0.0015	0.0008	0.0006	0.0005	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0005	0.0005	0.0005	0.0008	0.0004	0.0003	0.0002
75 %		0.0005	0.0005	0.0005		0.0004	0.0002	0.0002	0.0001
90 %		0.0005	-	-	-	0.0003	0.0002	0.0002	0.0001
None	R2 stream	0.0020	0.0011	0.0007	0.0006	0.0020	0.0011	0.0007	0.0006
50 %		0.0010	0.0006	0.0004	0.0003	0.0015	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0002	0.0001	0.0005	0.0003	0.0002	0.0001
90 %		0.0002	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001
None	R3 stream	0.0022	0.0011	0.0008	0.0006	0.0022	0.0011	0.0008	0.0006
50 %		0.0011	0.0006	0.0004	0.0003	0.0011	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0002	0.0002	0.0005	0.0003	0.0002	0.0002
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001
None	R4 stream	0.0015	0.0008	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004
50 %		0.0007	0.0006	0.0006	0.0006	0.0007	0.0004	0.0007	0.0002
75 %		0.0006	0.0006	-	-	0.0004	0.0003	0.0002	0.0002
90 %		0.0006	-	-	-	0.0004	0.0003	0.0002	0.0002
RAC (ng/L) 2.1		**PEC/RAC**							
None	D3 ditch*	0.0017	0.0022	0.0006	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-

90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D4 pond*	0.0002	0.0001	0.0001	0.0001	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
75 %		0.0000	0.0000	0.0000	0.0000	-	-	-	-
90 %		0.0000	-	-	-	-	-	-	-
None	D4 stream*	0.0017	0.0009	0.0006	0.0005	-	-	-	-
50 %		0.0008	0.0004	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D6 ditch	0.0032	0.0017	0.0006	0.0005	-	-	-	-
50 %		0.0016	0.0005	0.0003	0.0004	-	-	-	-
75 %		0.0008	0.0002	0.0002	0.0002	-	-	-	-
90 %		0.0003	0.0001	0.0001	0.0000	-	-	-	-
None	R1 pond*	0.0002	0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001
50 %		0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001	0.0001
75 %		0.0002	0.0002	-	-	0.0001	0.0001	0.0001	0.0000
90 %		-	-	-	-	0.0001	0.0001	0.0001	
None	R1 stream*	0.0015	0.0008	0.0006	0.0005	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0005	0.0005	0.0005	0.0008	0.0004	0.0003	0.0002
75 %		0.0005	0.0005	0.0005	-	0.0004	0.0002	0.0002	0.0001
90 %		0.0005	-	-	-	0.0003	0.0002	0.0002	0.0001
None	R2 stream	0.0020	0.0011	0.0007	0.0006	0.0020	0.0011	0.0007	0.0006
50 %		0.0010	0.0006	0.0004	0.0003	0.0015	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0002	0.0001	0.0005	0.0003	0.0002	0.0001
90 %		0.0002	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001
None	R3 stream	0.0022	0.0011	0.0008	0.0006	0.0022	0.0011	0.0008	0.0006
50 %		0.0011	0.0006	0.0004	0.0003	0.0011	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0002	0.0002	0.0005	0.0003	0.0002	0.0002
90 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	0.0001

None	R4 stream	0.0015	0.0008	0.0006	0.0006	0.0015	0.0008	0.0005	0.0004
50 %		0.0007	0.0006	0.0006	0.0006	0.0007	0.0004	0.0007	0.0002
75 %		0.0006	0.0006	-	-	0.0004	0.0003	0.0002	0.0002
90 %		0.0006	-	-	-	0.0004	0.0003	0.0002	0.0002

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*National scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculatio was done for vegetables leafy 1st, for scenarios D3, D4 and R1 considering all input data as for leafy vegetables 1st.
**0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
***0.7 and 0.9 was used for used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).a) The PECsw units are in ng/L instead of µg/L

Table 9.5-10-1: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC< 1) for lambda-cyhalothtin for fish (acute) based on FOCUS Step 4 calculations with mitigation of spray drift and run-off for the use of LABAMBA in winter cereals.

PEC_{sw} (ng/L)[a)]	Scenario	STEP 4 Lambda-cyhalothrin							
Nozzle reduction	Vegetative strip (m)	None				5*	10	15**	20
	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D1 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0032	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D1 stream	0.0148	0.0078	0.0053	0.0041	-	-	-	-
50 %		0.0074	0.0039	0.0027	0.0020	-	-	-	-
75 %		0.0037	0.0020	0.0013	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0005	0.0004	-	-	-	-
None	D2 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-

50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0032	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D2 stream	0.0151	0.0080	0.0055	0.0042	-	-	-	-
50 %		0.0075	0.0040	0.0027	0.0021	-	-	-	-
75 %		0.0038	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0005	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0133	0.0070	0.0048	0.0037	-	-	-	-
50 %		0.0066	0.0035	0.0024	0.0018	-	-	-	-
75 %		0.0033	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-

75 %		0.0003	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0135	0.0071	0.0049	0.0037	-	-	-	-
50 %		0.0067	0.0036	0.0024	0.0019	-	-	-	-
75 %		0.0034	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D6 ditch	0.0125	0.0066	0.0045	0.0034	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0031	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0005	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.0003	0.0003	-
90 %		0.0005	0.0005	0.0004	0.0004	0.0003	-	-	-
None	R1 stream	0.0111	0.0059	0.0040	0.0032	0.0111	0.0059	0.0040	0.0031
50 %		0.0055	0.0032	0.0032	0.0032	0.0055	0.0029	0.0020	0.0015
75 %		0.0032	0.0032	0.0032	0.0032	0.0028	0.0015	0.0011	0.0008
90 %		0.0032	0.0032	0.0032	0.0032	0.0021	0.0015	0.0011	0.0008
None	R3 stream	0.0157	0.0083	0.0057	0.0043	0.0157	0.0083	0.0057	0.0043
50 %		0.0078	0.0042	0.0028	0.0024	0.0078	0.0042	0.0028	0.0022
75 %		0.0039	0.0024	0.0024	0.0024	0.0039	0.0021	0.0014	0.0011

90 %		0.0024	0.0024	0.0024	0.0024	0.0016	0.0011	0.0008	0.0006	
None	R4 stream	0.0111	0.0059	0.0041	0.0041	0.0111	0.0059	0.0040	0.0031	
50 %		0.0056	0.0041	0.0041	0.0041	0.0056	0.0029	0.0020	0.0015	
75 %		0.0041	0.0041	0.0041	0.0041	0.0028	0.0019	0.0014	0.0010	
90 %		0.0041	0.0041	0.0041	0.0041	0.0027	0.0019	0.0014	0.0010	
RAC = 7.27 ng/L		**PEC/RAC**								
None	D1 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-	
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-	
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-	
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-	
None	D1 stream	0.0020	0.0011	0.0007	0.0006	-	-	-	-	
50 %		0.0010	0.0005	0.0004	0.0003	-	-	-	-	
75 %		0.0005	0.0003	0.0002	0.0001	-	-	-	-	
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-	
None	D2 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-	
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-	
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-	
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-	
None	D2 stream	0.0021	0.0011	0.0008	0.0006	-	-	-	-	
50 %		0.0010	0.0006	0.0004	0.0003	-	-	-	-	
75 %		0.0005	0.0003	0.0002	0.0001	-	-	-	-	
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-	

	None	D3 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-
	50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
	75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
	None	D4 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
	50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
	75 %		0.0000	0.0000	0.0000	-	-	-	-	-
	90 %		-	-	-	-	-	-	-	-
	None	D4 stream	0.0018	0.0010	-0.0007	0.0005	-	-	-	-
	50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
	75 %		0.0005	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
	None	D5 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
	50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
	75 %		0.0000	0.0000	0.0000	-	-	-	-	-
	90 %		-	-	-	-	-	-	-	-
	None	D5 stream	0.0019	0.0010	0.0007	0.0005	-	-	-	-
	50 %		0.0009	0.0005	0.0003	0.0003	-	-	-	-
	75 %		0.0005	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
	None	D6 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-

50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	R1 pond	0.0002	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001
50 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0000
75 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0000	0.0000	-
90 %		0.0001	0.0001	0.0001	0.0001	0.0000	-	-	-
None	R1 stream	0.0015	0.0008	0.0006	0.0004	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0004	0.0004	0.0004	0.0008	0.0004	0.0003	0.0002
75 %		0.0004	0.0004	0.0004	0.0004	0.0004	0.0002	0.0002	0.0001
90 %		0.0004	0.0004	0.0004	0.0004	0.0003	0.0002	0.0002	0.0001
None	R3 stream	0.0022	0.0011	0.0008	0.0006	0.0022	0.0011	0.0008	0.0006
50 %		0.0011	0.0006	0.0004	0.0003	0.0011	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0003	0.0003	0.0005	0.0003	0.0002	0.0002
90 %		0.0003	0.0003	0.0003	0.0003	0.0002	0.0002	0.0001	0.0001
None	R4 stream	0.0015	0.0008	0.0006	0.0006	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0006	0.0006	0.0006	0.0008	0.0004	0.0003	0.0002
75 %		0.0006	0.0006	0.0006	0.0006	0.0004	0.0003	0.0002	0.0001
90 %		0.0006	0.0006	0.0006	0.0006	0.0004	0.0003	0.0002	0.0001
RAC = 2.1 ng/L		PEC/RAC							
None	D1 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-

	50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
	75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
	None	D1 stream	0.0020	0.0011	0.0007	0.0006	-	-	-	-
	50 %		0.0010	0.0005	0.0004	0.0003	-	-	-	-
	75 %		0.0005	0.0003	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
	None	D2 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-
	50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
	75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
	None	D2 stream	0.0021	0.0011	0.0008	0.0006	-	-	-	-
	50 %		0.0010	0.0006	0.0004	0.0003	-	-	-	-
	75 %		0.0005	0.0003	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
	None	D3 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-
	50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
	75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
	90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
	None	D4 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
	50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-

75 %		0.0000	0.0000	0.0000	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0018	0.0010	0.0007	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0005	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
None	D5 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
75 %		0.0000	0.0000	0.0000	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0019	0.0010	0.0007	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0003	-	-	-	-
75 %		0.0005	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
None	D6 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0004	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	R1 pond	0.0002	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001
50 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0000
75 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0000	0.0000	-

90 %		0.0001	0.0001	0.0001	0.0001	0.0000	-	-	-
None	R1 stream	0.0015	0.0008	0.0006	0.0004	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0004	0.0004	0.0004	0.0008	0.0004	0.0003	0.0002
75 %		0.0004	0.0004	0.0004	0.0004	0.0004	0.0002	0.0002	0.0001
90 %		0.0004	0.0004	0.0004	0.0004	0.0003	0.0002	0.0002	0.0001
None	R3 stream	0.0022	0.0011	0.0008	0.0006	0.0022	0.0011	0.0008	0.0006
50 %		0.0011	0.0006	0.0004	0.0003	0.0011	0.0006	0.0004	0.0003
75 %		0.0005	0.0003	0.0003	0.0003	0.0005	0.0003	0.0002	0.0002
90 %		0.0003	0.0003	0.0003	0.0003	0.0002	0.0002	0.0001	0.0001
None	R4 stream	0.0015	0.0008	0.0006	0.0006	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0006	0.0006	0.0006	0.0008	0.0004	0.0003	0.0002
75 %		0.0006	0.0006	0.0006	0.0006	0.0004	0.0003	0.0002	0.0001
90 %		0.0006	0.0006	0.0006	0.0006	0.0004	0.0003	0.0002	0.0001

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

Table 9.5-11-1: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for lambda-cyhalothrin for fish (acute) based on FOCUS Step 4 calculations with mitigation of spray drift and run-off for the use of LABAMBA in winter oilseed rape

Intended use		Winter oilseed rape							
Active substance		Lambda-cyhalothrin							
Application rate (g/ha)		1 × 7.5							
Nozzle reduction	Vegetative strip (m)	None	None	None	None	5*	10	15**	20

	No spray buffer (m)	5	10	15	20	5	10	15	20
None	D2 ditch	0.0127	0.0067	0.0046	0.0035	-	-	-	-
50 %		0.0063	0.0034	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0076	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D2 stream	0.0152	0.0081	0.0055	0.0042	-	-	-	-
50 %		0.0076	0.0040	0.0028	0.0021	-	-	-	-
75 %		0.0020	0.0020	0.0014	0.0010	-	-	-	-
90 %		0.0015	0.0008	0.0006	0.0004	-	-	-	-
None	D3 ditch	0.0125	0.0066	0.0045	0.0035	-	-	-	-
50 %		0.0063	0.0033	0.0023	0.0017	-	-	-	-
75 %		0.0017	0.0017	0.0011	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0003	-	-	-	-
None	D4 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0130	0.0069	0.0047	0.0036	-	-	-	-
50 %		0.0065	0.0034	0.0023	0.0018	-	-	-	-
75 %		0.0017	0.0017	0.0012	0.0009	-	-	-	-
90 %		0.0013	0.0007	0.0005	0.0004	-	-	-	-
None	D5 pond	0.0014	0.0010	0.0008	0.0007	-	-	-	-
50 %		0.0007	0.0005	0.0004	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-

None	D5 stream	0.0137	0.0073	0.0050	0.0038	-	-	-	-
50 %		0.0068	0.0036	0.0025	0.0019	-	-	-	-
75 %		0.0018	0.0018	0.0012	0.0009	-	-	-	-
90 %		0.0014	0.0007	0.0005	0.0004	-	-	-	-
None	R1 pond	0.0014	0.0010	0.0008	0.0007	0.0014	0.0010	0.0008	0.0007
50 %		0.0007	0.0006	0.0006	0.0005	0.0007	0.0005	0.0004	0.0003
75 %		0.0005	0.0005	0.0005	0.0005	0.0004	0.0003	0.0002	-
90 %		0.0005	0.0005	0.0005	-	0.0004	-	-	-
None	R1 stream	0.0110	0.0058	0.0040	0.0033	0.0110	0.0058	0.0040	0.0030
50 %		0.0055	0.0033	0.0033	0.0033	0.0055	0.0029	0.0020	0.0015
75 %		0.0033	0.0033	0.0033	-	0.0028	0.0015	0.0011	0.0008
90 %		0.0033	-	-	-	0.0028	0.0015	0.0011	0.0008
None	R3 stream	0.0156	0.0083	0.0056	0.0043	0.0156	0.0083	0.0056	0.0043
50 %		0.0078	0.0041	0.0028	0.0020	0.0078	0.0041	0.0028	0.0021
75 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0021	0.0014	0.0011
90 %		0.0023	0.0023	0.0023	0.0023	0.0039	0.0010	0.0008	0.0005
RAC = 7.27 ng/L		**PEC/RAC**							
None	D2 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0002	0.0010	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D2 stream	0.0021	0.0011	0.0008	0.0006	-	-	-	-
50 %		0.0010	0.0006	0.0004	0.0003	-	-	-	-
75 %		0.0003	0.0003	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
None	D3 ditch	0.0017	0.0009	0.0006	0.0005	-	-	-	-

50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0002	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0000	-	-	-	-
None	D4 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
75 %		0.0000	0.0000	0.0000	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D4 stream	0.0018	0.0009	0.0006	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0002	-	-	-	-
75 %		0.0002	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
None	D5 pond	0.0002	0.0001	0.0001	0.0001	-	-	-	-
50 %		0.0001	0.0001	0.0001	0.0000	-	-	-	-
75 %		0.0000	0.0000	0.0000	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0019	0.0010	0.0007	0.0005	-	-	-	-
50 %		0.0009	0.0005	0.0003	0.0003	-	-	-	-
75 %		0.0002	0.0002	0.0002	0.0001	-	-	-	-
90 %		0.0002	0.0001	0.0001	0.0001	-	-	-	-
None	R1 pond	0.0002	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	0.0001
50 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001	0.0000
75 %		0.0001	0.0001	0.0001	0.0001	0.0001	0.0000	0.0000	-
90 %		0.0001	0.0001	0.0001	-	-	-	--	-
None	R1 stream	0.0015	0.0008	0.0006	0.0005	0.0015	0.0008	0.0006	0.0004
50 %		0.0008	0.0005	0.0005	0.0005	0.0008	0.0004	0.0003	0.0002
75 %		0.0005	0.0005	0.0005	-	0.0004	0.0002	0.0002	0.0001

90 %		0.0005	-	-	-	0.0004	0.0002	0.0002	0.0001
None	R3 stream	0.0021	0.0011	0.0008	0.0006	0.0021	0.0011	0.0008	0.0006
50 %		0.0011	0.0006	0.0004	0.0003	0.0011	0.0006	0.0004	0.0003
75 %		0.0003	0.0003	0.0003	0.0003	0.0005	0.0003	0.0002	0.0002
90 %		0.0003	0.0003	0.0003	0.0003	0.0005	0.0001	0.0001	0.0001
RAC = 2.1 ng/L		**PEC/RAC**							
None	D2 ditch	0.0060	0.0032	0.0022	0.0017	-	-	-	-
50 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
75 %		0.0008	0.0036	0.0005	0.0004	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	-	-	-	-
None	D2 stream	0.0072	0.0039	0.0026	0.0020	-	-	-	-
50 %		0.0036	0.0019	0.0013	0.0010	-	-	-	-
75 %		0.0010	0.0010	0.0007	0.0005	-	-	-	-
90 %		0.0007	0.0004	0.0003	0.0002	-	-	-	-
None	D3 ditch	0.0060	0.0031	0.0021	0.0017	-	-	-	-
50 %		0.0030	0.0016	0.0011	0.0008	-	-	-	-
75 %		0.0008	0.0008	0.0005	0.0004	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0001	-	-	-	-
None	D4 pond	0.0007	0.0005	0.0004	0.0003	-	-	-	-
50 %		0.0003	0.0002	0.0002	0.0001	-	-	-	-
75 %		0.0001	0.0001	0.0001		-	-	-	-
90 %		-	-	-	--	-	-	-	-
None	D4 stream	0.0062	0.0033	0.0022	0.0017	-	-	-	-
50 %		0.0031	0.0016	0.0011	0.0009	-	-	-	-
75 %		0.0008	0.0008	0.0006	0.0004	-	-	-	-
90 %		0.0006	0.0003	0.0002	0.0002	-	-	-	-

None	D5 pond	0.0007	0.0005	0.0004	0.0003	-	-	-	-
50 %		0.0003	0.0002	0.0002	0.0001	-	-	-	-
75 %		0.0001	0.0001	0.0001	-	-	-	-	-
90 %		-	-	-	-	-	-	-	-
None	D5 stream	0.0065	0.0035	0.0024	0.0018	-	-	-	-
50 %		0.0032	0.0017	0.0012	0.0009	-	-	-	-
75 %		0.0009	0.0009	0.0006	0.0004	-	-	-	-
90 %		0.0007	0.0003	0.0002	0.0002	-	-	-	-
None	R1 pond	0.0007	0.0005	0.0004	0.0003	0.0007	0.0005	0.0004	0.0003
50 %		0.0003	0.0003	0.0003	0.0002	0.0003	0.0002	0.0002	0.0001
75 %		0.0002	0.0002	0.0002	0.0002	0.0002	0.0001	0.0001	
90 %		0.0002	0.0002	0.0002	-	0.0002			
None	R1 stream	0.0052	0.0028	0.0019	0.0016	0.0052	0.0028	0.0019	0.0014
50 %		0.0026	0.0016	0.0016	0.0016	0.0026	0.0014	0.0010	0.0007
75 %		0.0016	0.0016	0.0016	-	0.0013	0.0007	0.0005	0.0004
90 %		0.0016	-	-	-	0.0013	0.0007	0.0005	0.0004
None	R3 stream	0.0074	0.0040	0.0027	0.0020	0.0074	0.0040	0.0027	0.0020
50 %		0.0037	0.0020	0.0013	0.0010	0.0037	0.0020	0.0013	0.0010
75 %		0.0011	0.0011	0.0011	0.0011	0.0019	0.0010	0.0007	0.0005
90 %		0.0011	0.0011	0.0011	0.0011	0.0019	0.0005	0.0004	0.0002

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
a) The PECsw units are in ng/L instead of µg/L
*0.4 was used for run off reduction and erosion in water and sediment according to the Austrian Environmental Agency (AGES).
*0.7 and 0.9 was used for run off reduction and erosion respectively in water and sediment according to the Austrian Environmental Agency (AGES).

Therefore, for

The fish chronic risk assessment with $RAC_{chronic}$ = 0.0031 microgram/L is covered by risk mitigation for acute risk assessment with RAC = 0.0021 microgram/L.

Based on the acute risk assessment for all intended uses the following risk mitigation measures is required:

~~**To protect aquatic organisms respect an unsprayed buffer zone of 5 m to non-agricultural land/surface water bodies for Brassicas, Tomato field, Winter cereals, Winter oilseed rape**~~

~~**Risk for aquatic invertebrates:**~~

~~For the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several/all FOCUS Steps 3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} and higher RAC of 0.0003 µg a .s./L for aquatic invertebrates. RAC value is based on available laboratory data on lambda-cyhalothrin and gamma-cyhalothrin as well as field data on gamma-cyhalothrin. It should be noted that this RAC is only applicable for CS formulations and when exposure to the aquatic environment is predominantly via spray drift. As demonstrated in Section B.8 the highest PEC_{sw} in FOCUS STEP 3 is related to a drift event for all scenarios with the highest PEC_{sw} from exposure via drift calculated for single application. Higher RAC of 0.0003 µg a.s./L is therefore considered applicable for the CS formulation SHA 3600 B / LABAMBA.~~

~~Based on RAC= 0.0003 µg a.s./L for aquatic invertebrates the following risk mitigation measures should be applied:~~

~~***: to protect aquatic organisms respect an unsprayed buffer zone of 5 m to non-agricultural land/surface water bodies for Brassicas, Tomato field, Winter cereals, Winter oilseed rape***~~

~~**It should be noted the risk mitigation measures based on RAC=0.0003 µg a.s./L for aquatic invertebrates covers the risk mitigation measures for all aquatic species.**~~

Metabolites of Lambda-cyhalothrin

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite Ia for each organism group based on FOCUS Step 1 calculation for the use of LABAMBA

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. pulex***		***C. riparius***
Endpoint		LC_{50}	EC_{50}		NOEC
(µg/L)		10800	105 000		20800 (µg/L)
AF		100	100		10
RAC (µg/L)		108	1050		2080
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			**PEC $_{gl\text{-}max}$ (µg/L)**	
Step 1					
Brasicas	0.70	0.0065	0.0007	0.09	0.0003
Tomato	0.70	0.0065	0.0007	0.09	0.0003
Winter cereals	0.70	0.0065	0.0007	0.09	0.0003
Winter oilseed rape	0.70	0.0065	0.0007	0.09	0.0003

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 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite V (PBA) for each organism group based on FOCUS Step 1 calculation for the use of LABAMBA

Group		**Fish acute**	**Inverteb. acute**
Test species		***O. mykiss***	***D. magna***
Endpoint		LC_{50}	EC_{50}
(µg/L)		13300	85000
AF		100	100
RAC (µg/L)		133	850
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**		
Step 1			

Group		Fish acute	Inverteb. acute
Brasicas	0.57	0.0043	0.0007
Tomatto	0.57	0.0043	0.0007
Winter cereals	0.57	0.0043	0.0007
Winter oilseed rape	0.57	0.0043	0.0007

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 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite XV for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in brasicas

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***		***C. riparius***
Endpoint		LC_{50}	EC_{50}		NOEC
(µg/L)		0.84	0.16		580 µg/kg
AF		100	100		10
RAC (µg/L)		0.0084	0.0016		58
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 1					
	0.01	**1.19**	**6.25**	2.26	0.039
Step 2					
Northern Europe March-May	0.01	**1 .19**	**6.25**	-/-	-/-
Southern Europe March-May	0.01	**1.19**	**6.25**	-/-	-/-
Step 3					
D3*/ditch	0.000001	0.0001	0.0006	-/-	-/-
D3**/ditch	< 1e-6	0.0001	0.0006	-/-	-/-
D4*/pond	< 1e-6	0.0002	0.0013	-/-	-/-
D4*/stream	0.000002	0.0001	0.0006	-/-	-/-
D6*/ditch	< 1e-6	0.0002	0.0013	-/-	-/-
R1*/pond	0.000002	0.0002	0.0013	-/-	-/-
R1**/pond	0.000002	0.0001	0.0006	-/-	-/-
R1*/stream	< 1e-6	0.0001	0.0006	-/-	-/-
R1**/stream	< 1e-6	0.0001	0.0006	-/-	-/-
R2*/stream	0.000001	0.0001	0.0006	-/-	-/-
R2**/stream	0.000001	0.0005	0.0025	-/-	-/-
R3*/stream	0.000004	0.0005	0.0025	-/-	-/-
R3**/stream	0.000004	0.0002	0.0013	-/-	-/-
R4*/stream	0.000002	0.0002	0.0013	-/-	-/-
R4**/stream	0.000002	0.0001	0.0006	-/-	-/-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*vegetables leafy 1st
**vegetables leafy 2nd

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite XV for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in tomato

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***		***C. riparius***
Endpoint		LC_{50}	EC_{50}		NOEC
(µg/L)		0.84	0.16		580 µg/kg
AF		100	100		10
RAC (µg/L)		0.0084	0.0016		58
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 1					
	0.01	**1.19**	**6.25**	2.26	0.039
Step 2					
Northern Europe March-May	0.01	**1.19**	**6.25**	-/-	-/-
Southern Europe March-May	0.01	**1.19**	**6.25**	-/-	-/-
Step 3					
D3*/ditch	0.000001	0.0001	0.0006	-/-	-/-
D4*/pond	0.000002	0.0002	0.0013	-/-	-/-
D4*/stream	0.000002	0.0002	0.0013	-/-	-/-
D6/ditch	< 1e-6	0.0001	0.0006	-/-	-/-
R1*/stream	< 1e-6	0.0001	0.0006	-/-	-/-
R2/stream	0.000001	0.0001	0.0006	-/-	-/-
R3/stream	0.000004	0.0005	0.0025	-/-	-/-
R4/stream	0.000002	0.0002	0.0013	-/-	-/-

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold
*National scenarios relevant for Poland are D3, D4 and R1. Due to fact that scenarios (D3, D4 and R1) are not available for tomato in programs used for modelling, the surrogate crop was proposed. Presented calculation was done for vegeta-bles leafy 1st, for scenarios D3, D4 and R1 considering all input data as for vegetables leafy 1st.

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite XV for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in winter cereals

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***		***C. riparius***
Endpoint		LC_{50}	EC_{50}		NOEC

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
(µg/L)		0.84	0.16		580 µg/kg
AF		100	100		10
RAC (µg/L)		0.0084	0.0016		58
FOCUS Scenario	**PEC $_{gl-max}$ (µg/L)**			**PEC $_{gl-max}$ (µg/kg)**	
Step 1					
	0.01	**1.19**	**6.25**	2.26	0.039
Step 2					
Northern Europe Mar-May	0.01	**1.19**	**6.25**	-/-	-/-
Southern Europe Mar-May	0.01	**1.19**	**6.25**	-/-	-/-
Step 3					
D1/ditch	0.000003	0.0004	0.0019	-/-	-/-
D1/stream	0.000005	0.0006	0.0031	-/-	-/-
D2/ditch	0.000003	0.0004	0.0019	-/-	-/-
D2/stream	0.000023	0.0027	0.0144	-/-	-/-
D3/ditch	0.000001	0.0001	0.0006	-/-	-/-
D4/pond	< 1e-6	0.0001	0.0006	-/-	-/-
D4/stream	0.000002	0.0002	0.0013	-/-	-/-
D5/pond	< 1e-6	0.0001	0.0006	-/-	-/-
D5/stream	0.000003	0.0004	0.0019	-/-	-/-
D6/ditch	< 1e-6	0.0001	0.0006	-/-	-/-
R1/pond	0.000001	0.0001	0.0006	-/-	-/-
R1/stream	< 1e-6	0.0001	0.0006	-/-	-/-
R3/stream	0.000004	0.0005	0.0025	-/-	-/-
R4/stream	0.000002	0.0002	0.0013	-/-	-/-

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 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for metabolite XV for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of LABAMBA in winter oilseed rape use no. 8, 9, 11

Group		**Fish acute**	**Inverteb. acute**		**Sed. dwell. prolonged**
Test species		***O. mykiss***	***D. magna***		***C. riparius***
Endpoint		LC_{50}	EC_{50}		NOEC
(µg/L)		0.84	0.16		580 µg/kg
AF		100	100		10
RAC (µg/L)		0.0084	0.0016		58
FOCUS Scenario	**PEC $_{gl\text{-}max}$ (µg/L)**			**PEC $_{gl\text{-}max}$ (µg/kg)**	
Step 1					
	0.01	**1.19**	**6.25**	2.26	0.039
Step 2					
Northern Europe Mar-May	0.01	**1.19**	**6.25**	-/-	-/-
Southern Europe Mar-May	0.01	**1.19**	**6.25**	-/-	-/-
Step 3					
D2/ditch	0.000003	0.0004	0.0019	-/-	-/-
D2/stream	0.000023	0.0027	0.0144	-/-	-/-
D3/ditch	< 1e-6	0.0001	0.0006	-/-	-/-
D4/pond	< 1e-6	0.0001	0.0006	-/-	-/-
D4/stream	0.000002	0.0002	0.0013	-/-	-/-
D5/pond	< 1e-6	0.0001	0.0006	-/-	-/-
D5/stream	0.000003	0.0004	0.0019	-/-	-/-
R1/pond	0.000001	0.0001	0.0006	-/-	-/-
R1/stream	< 1e-6	0.0001	0.0006	-/-	-/-
R3/stream	0.000004	0.0005	0.0025	-/-	-/-

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

zRMS comment:

For the intended uses, calculated PEC/RAC ratios indicated an acceptable risk for all metabolites for aquatic organism.

9.5.3 Overall conclusions

After Step1/2 calculations a risk for all aquatic organisms except algae was determined for lambda cyhalothrin and for metabolite XV in all crops (except sediment organisms).
After Step 3 calculations, metabolite XV was shown to present no unacceptable risk to aquatic and sediment dwelling organisms, whereas lambda-cyhalothrin still presented a risk for aquatic organisms.
~~After application of mitigation and step 4 calculations it has been shown to present no unacceptable acute and chronic risk to sediment dwelling organisms and for aquatic organisms.~~
~~The risk is acceptable when the following risk mitigation measures are considered for:~~

~~Brassicas, Tomato field, Winter cereals, Winter oilseed rape:~~
~~*Spe3: to protect aquatic organisms respect an unsprayed buffer zone of 5 m to non-agricultural land/surface water bodies*~~

For all the intended uses, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{SW} considering reduced exposure of surface water bodies. After Step 4 calculations, an acceptable risk was obtained with the following mitigation measures:

Brassicas:
For D3 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 5 m no spray buffer zone + nozzle reduction of 90% or 10 m no spray buffer zone + nozzle reduction of 75% or 20 m no spray buffer zone + nozzle reduction of 50% should be considered.
For D4 stream 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D6 ditch 30 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 30 m no spray buffer zone + nozzle reduction of 50% should be considered.

For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% or 50 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 75% is needed.
For R2 stream, 40 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.

> ***Spe3*** *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction OR respect an unsprayed buffer zone of 50 m to surface water bodies with 20 m vegetated filter strip with 75% of nozzle reduction.*

Tomato:
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D4 stream 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 pond 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed

Although scenarios D6, R2 and R4 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.

> ***Spe3*** *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction.*

Winter cereals
For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream, 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% should be considered.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D1, D2, D6, R3 and R4 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.

Spe3 *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

Winter oilseed rape
For D4 pond 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D5 pond 10 m no spray buffer zone + nozzle reduction of 75% should be considered.
For R1 pond, 20 m no spray buffer zone + nozzle reduction of 50% or 10 m no spray buffer zone + nozzle reduction of 75% or 5 m no spray buffer zone + nozzle reduction of 90% should be considered.
For D3 ditch 20 m no spray buffer zone + nozzle reduction of 90% should be considered.
For R1 stream 20 m no spray buffer zone together with 20 m vegetated filter strip + nozzle reduction of 90% is needed.
For D4 stream, 20 m no spray buffer zone + nozzle reduction of 90% should be considered

Although scenarios D2, D5 and R3 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.

Spe3 *– To protect aquatic organisms, respect an unsprayed buffer zone of 20 m to surface water bodies with 20 m vegetated filter strip with 90% of nozzle reduction*

9.6 Effects on (KCP 10.3.1)

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with lambda-cyhalothrin and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).
Effects on bees of formulation SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin.
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
Apis mellifera	lambda-cyhalothrin	Oral	LD_{50} = 0.91 µg/bee	EFSA Journal 2014;12(5):3677
Apis mellifera	lambda-cyhalothrin	Contact	LD_{50} = 0.038 µg/bee	EFSA Journal 2014;12(5):3677
Apis mellifera	Metabolite Ia	Oral	LD50> 165 µg/bee	EFSA Journal 2014;12(5):3677
Apis mellifera	Metabolite Ia	Contact	LD50>200 µg/bee	EFSA Journal 2014;12(5):3677
Apis mellifera	SHA 3600 B/LABAMBA	Oral	LD_{50} = 5.3 µg/bee	KCP 10.3.1.1.1 Deepika S. G13384, 2018
Apis mellifera	SHA 3600 B/LABAMBA	Contact	LD_{50} = 4.84 µg/bee	KCP 10.3.1.1.2 Deepika S. G13385, 2018

Higher-tier studies (tunnel test, field studies)

KCP 10.3.1.5
"Lambda cyhalothrin 2.5 WG: A semi-field study to evaluate side effects on honeybees (Apis mellifera L.) in Phacelia tanacetifolia in Germany 2017". Portail B., S17-02719, 2018. Eurofins Agroscience Services Ecotox GmbH.
Adverse effects on adult bee mortality were found for both test item treatments T1 and T2 on 1DAA3 and no permanent adverse effects during the monitoring phase after exposure were observed. No adverse effects on larvae and pupae mortality were found for test item treatment T1, a slightly adverse effect during exposure between 5DBA3 to 0DBA3 was observed in test item treatment T2.
A short repellent effect on flight intensity on 0DAA3 was found for test item treatment T1 and T2.
No test item related adverse effects were observed in behavior of honeybees.
The quantitative assessments of brood development in individually marked cells revealed no test item treatment related adverse effect on honeybee brood development.
No test item related adverse effects on colony strength were observed.
No test item related adverse effects on neither development of brood nor amount of food were observed.

Higher-tier studies (tunnel test, field studies), EFSA 2014

Test	Test Material	Dose Range/evidence of exposure	Results
Hecht-Rost 2012: Semi-field brood test (*Phacelia*) in Switzerland	'Lambda-cyhalothrin 100 CS' (not identical to the representative formulation)	T1: 7.5 g a.s./ha T2: 15 g as/ha T3: 22.5 g as/ha 400 L water/ha, single application. Two toxic references (Insegar 25 WG and Perfekthion). Statistical analysis performed. Foraging activity assessments	T1: 7.5 g a.s./ha Noticeable increase in mortality on the day of application. Increased mortality persisted or 6 days (ignoring 3 DAA). Comparable to control 7 DAA. Foraging activity was very slightly reduced compared to the control and the pre-application activity. No foraging activity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. No differences between the treatment and the control were observed in the brood

Species	Substance	Exposure System	Results	Reference
		performed. Tunnel study and no alternative foraging areas.	assessments.	
			T2: 15 g a.s./ha Noticeable increase in mortality on the day of application. Increased mortality persisted or 2 days. Comparable to control 4 DAA on-wards. Foraging activity was reduced compared to the control and pre-application activity (to a greater extent than for T1 and T3). No forag-ing activity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. Brood termination rate increased for the duration of the assessment. This is not consi-stent with T1 and T3.	
			T3: 22.5 g a.s./ha Noticeable increase in mortality on the day of application. Increased mortality persisted for 6 days (ignoring 3 DAA). Comparable to control 7 DAA. Foraging activity was reduced compared to the control and pre-application activity (to a greater extent than for T1). No foraging ac-tivity 3 DAA for any treatment and control tunnel. Nervous bees and abnormal behaviour noted in the behaviour assessments. No differences between the treatment and the control were observed in the brood assess-ments (in fact lower brood termination rate compared to the control and T1).	
Balluff, 2000: Field study (flowering oilseed rape) in Spain	50 g/kg WG formu-lation (not identical to the representative formulation)	20 or 25 g a.s./ha, single application Pollen source identification; bees were collecting mainly on treated fields	Increase in mortality immediately after appli-cation. The number of paralysed bees reached a maximum 60 minutes after application. On DAA 1 – DAA 7 no abnormal behavior of the bees was observed. No differences between the treatment and the control were observed in the brood assess-ments.	
Schur, 2000: Field study (flowering	'Karate 10CS'	7.5 g a.s./ha, single application.	Increase in mortality immediately after appli-cation (0 DAA). In 1 replicate the increase in	

Species	Substance	Exposure System	Results	Reference
Phacelia tanaceti-folia) in Germany		Pollen source identification; lower amounts of *phacelia* noted in treated than in control at 2 sites. Field location was stated to be away from other flowering crops.	mortality was also apparent 1 DAA. Foraging numbers were considered reasonable prior to application. In all treatment replicates the foraging activity was decreased for 1 day. In one replicate lower numbers were observed on the treated plots for 2 days after application. Symptoms of intoxication were noted shortly after application (0 DAA).	
Nengel 1998: Field study (flowering *Phacelia tanaceti-folia*) in Germany.	'Karate 10 CS'	15 g a.s./ha, single application during bee flight. 2 trials. Pollen source identification. Field location was stated to be away from other flowering crops. The RMS noted heavy precipitation 5 DAA.	Increased mortality for 1 day after treatment in both trials. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments. A large proportion of the pollen was stated to have been *Phacelia*.	
Nengel 1999b: Field study (flowering *Phacelia tanaceti-folia*) in Germany	'Karate 10CS'	T1: 7.5 g a.s./ha T2: 15 g a.s./ha. single application during bee flight. Pollen source identification. Field location was stated to be away from other flowering crops.	Increased mortality for 1-2 days in T1. Increased (higher level) was observed in T2 and persisted for 3 days. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments.	
Nengel 1999c: Field study (flowering *Phacelia tanaceti-folia*) in Germany	Karate 10CS	T1: 7.5 g a.s./ha T2: 15 g a.s./ha. single application during bee flight. Pollen source identification	Increased mortality for 1 day in T1. Increased (higher level) was observed in T2 and persisted for 2 days. Signs of intoxication were also observed after application. Normal bee behaviour was reported for days 1 – 7 DAA. Foraging numbers were considered reasonable prior to application. Reduced flight intensity on 0 DAA in both treatments.	

9.6.1.1 Justification for new endpoints

Not relevant. The endpoints used were the EU agreed ones.

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 Brassicas also covers the risk for birds from all other intended uses in groups (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 SHA 3600 B/LABAMBA in brassicas

Intended use	**Brassicas**		
Active substance	lambda-cyhalothrin		
Application rate (g/ha)	1 × 7.5		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	0.91	7.5	8.24
Contact toxicity	0.038		**197.37**
Product	SHA 3600 B/LABAMBA		
Application rate (L/ha)	1 ×0.075		
Test design	**LD_{50} (lab.) (µg/bee)**	**Single application rate (g/ha)**	**Q_{HO}, Q_{HC} criterion: $Q_H \leq 50$**
Oral toxicity	5.3	79.28*	14.96
Contact toxicity	4.84		16.38

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.
*Based on the density of the formulation = 1.057 g/mL and dose of 0.075 L/ha

The calculated HQcontact values indicated a high risk from the active substance for all representative field uses of SHA 3600 B/LABAMBA.
Data from DAR EU shows that the different formulations of Lambda-cyhalothrin have similar toxicity for honey bees, irrespective of the formulation type. This demonstrates that the toxicity is because of the active substance lambda-cyhalothrin and is not influenced by the formulation components.
The test of Lambda-cyhalothrin and the formulations introduces that contact route is more toxic to honey bees compared to oral route.

zRMS comment:

Peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin in EFSA Jo urnal 2014;12(5):367717in 5/9 FOCUS scenarios for the use on honey bees, oral and contact hazard quotients (HQ_{oral} and $HQ_{contact}$) were calculated using the available toxicity data with the active substance and three of the four representative formulations ('Lambda-Cyhalothrin 100 CS', 'Karate 10CS' and 'Lambda 50 EC').

The calculated $HQ_{contact}$ values indicated a high risk from the active substance for all representative field uses, whilst the HQ_{oral} values for the active substance were all less than the trigger value indicating a low

risk.

Honey bee semi-field (tunnel study) and field studies were available with two of the four representative formulations ('Karate 10CS' (or similar formulation) and 'Lambda-Cyhalothrin 100 CS') on flowering Phacelia tanacetifoliaor oilseed rape. Adult honey bee mortality was observed in the tunnel study performed with 'Lambda-Cyhalothrin 100 CS' but the magnitude and the duration of this effect was considered not relevant. The study included detailed bee brood assessments and no clear adverse effect was observed. Some effects on mortality were also observed in the field studies performed with the representative formulation 'Karate 10CS' (and similar formulation). On the basis of these studies, overall, a low risk to honey bees was concluded for the representative uses in spring and winter cereals (Northern and Southern Europe), potatoes and seed potatoes (Northern and Southern Europe) and field tomatoes (Northern and Southern Europe).

It should be noted that, due to the variation in toxicity observed in the available acute studies, the experts at the Pesticides Peer Review Experts' Meeting 107 did not consider appropriate to read-across the available higher tier data between the different formulations. Therefore, whist a low risk to bees was concluded for the representative field uses of lambda-cyhalothrin, further consideration of the risk posed by the plant protection products is required. In addition, it was not considered appropriate to extrapolate the studies performed on flowering Phacelia tanacetifolia and oilseed rape to crops other than field crops.

A low risk to honey bees was concluded for the representative uses in glasshouse tomatoes. No assessment of the risk to pollinators which may be used in glasshouses was available.

For formulation SHA 3600 B/LABAMBA, HQ values were below 50, indicating acceptable risk for bees. The acute risk for bees for the a.s.- lambda-cyhalotrin is unacceptable but several semi-field studies are available and they are considered sufficient to conclude to an acceptable risk for bees with the following mitigations measure:

- **SPe8: Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present.**

The final risk mitigation measures to bees should be considered at MSs level.

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

Accordingly, field studies were conducted to obtain more information about the risk of lambda-cyhalothrin formulations to honey bees. In all semi-field and field tests conducted, any acute effects were of short-term duration only. Observed effects on mortality and/or foraging lasted for a few days. In any studies, there were no effects in the bee brood provided irrespective of dose or formulation type.

Additionally own higher tier studies were conducted on lambda cyhalothrin with *Apis mellifera* in *Phacelia tanacetifolia*. Adverse effects on adult bee mortality were found for both test item treatments T1 and T2 on 1DAA3 and no permanent adverse effects during the monitoring phase after exposure were observed. No adverse effects on larvae and pupae mortality were found for test item treatment T1, a slightly adverse effect during exposure between 5DBA3 to 0DBA3 was observed in test item treatment T2. A short repellent effect on flight intensity on 0DAA3 was found for test item treatment T1 and T2. No test

item related adverse effects were observed in behaviour of honeybees. The quantitative assessments of brood development in individually marked cells revealed no test item treatment related adverse effect on honeybee brood development. No test item related adverse effects on colony strength were observed. No test item related adverse effects on neither development of brood nor amount of food were observed.

zRMS comment:

The study is provided for formulation WG and was not used in the risk assessment for formulation CS.

No comparison of composition of both formulations and their toxicity was provided by the applicant.

The study was not used in the risk assessment.

9.6.3 Effects on bumble bees

Not relevant.

9.6.4 Effects on solitary bees

Not relevant.

9.6.5 Overall conclusions

Hazard quotients showed that no acute oral risk to bees is expected, whereas acute contact risk to bees is expected after the application of Lambda cyhalothrin 10CS.
Higher tier studies (tunnel and field test) are available in the monograph as well as own studies to address the risk to bees.
In conclusion, although an acute contact risk on bees is expected after the application of Lamba cyhalothrin 10% CS, the results of the semi-field and field-studies showed that at the application rate supported in the GAP, the noted effects were principally observed on the day of application. Therefore, the risk for bees after the application of Lambda cyhalothrin 10%CS at the proposed rate supported in the GAP could be considered as acceptable.

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 have been carried out with lambda-cyhalothrin. Full details of these studies are provided in the respective EU DAR.

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

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	Lambda-cyhalothrin 50 EC	Laboratory test glass plates (2D)	**LR_{50} = 0.0037 g a.s./ha**	EFSA 2014; 12 (5): 3677
Aphidius rhopalosiphi (adults)	Lambda-cyhalothrin 100 g/L CS (WF2639)	Laboratory test glass plates (2D)	**LR_{50} = 1.06 g a.s./ha**	EFSA 2014; 12 (5): 3677
Aphidius rhopalosiphi (adults)	Lamba-cyhalothrin 50g/kg WG (YF8048A)	Laboratory test glass plates (2)	LR_{50} = 0.59 g a.s./ha	EFSA 2014; 12 (5): 3677
Typhlodromus pyri (protonymphs)	Lambda-cyhalothrin 50 EC	Extended laboratory test (2D)	LR_{50} = 0.0017 g a.s./ha Red. of reproduction: <50% at 0.0009 g a.s./ha	EFSA 2014; 12 (5): 3677
Typhlodromus pyri (protonymphs)	Karate 10 CS (A12690B)	Extended laboratory test Leaf disc (2D)	LR_{50} = 0.0243 g a.s./ha Red. of reproduction: <50% at 0.009 g a.s./ha	EFSA 2014; 12 (5): 3677
Aphidius rhopalosiphi (adults)	Karate 10 CS (A12690B)	Extended laboratory test Bean leaves (2D)	LR_{50} = 0.35 g a.s./ha Red. of reproduction: No sublethal effects at treatment rates of up to and including 0.5 g a.s./ha	EFSA 2014; 12 (5): 3677
Orius insidiosus (nymphs)	Karate 10 CS (A12690B)	Extended laboratory test bean leaves (2D)	LR_{50} = 0.018 g a.s./ha Red. of reproduction: <50% at 0.020 g a.s./ha	EFSA 2014; 12 (5): 3677
Chrysoperla carnea (larvae)	Karate 10 CS (A12690B)	Extended laboratory test Bean leaf disc (sprayed as whole plants before cutting) (3D)	LR_{50} = 4.3 g a.s./ha The NOAEL on reproduction could be establish on the emergent adults at treatment rates of up to and including 2.0 g a.s./ha	EFSA 2014; 12 (5): 3677
Aleochara bilineata (adult)	Karate 10 CS (A12690B)	Extended laboratory test Sandy soil (2D)	LR_{50} = 5.5 g a.s./ha Red. of reproduction: 60% at 7.5 g a.s./ha <50% at 1 g a.s./ha	EFSA 2014; 12 (5): 3677

Chrysoperla carnea (larvae)	Lambda-cyhalothrin 100 CS	Extended laboratory test Leaf discs (2D)	LR_{50}> 7.5 g a.s./ha ER_{50}> 7.5 g a.s./ha	EFSA 2014; 12 (5): 3677
Typhlodromus pyri (protonymphs)	Lambda-cyhalothrin 100 CS	Extended laboratory test Leaf discs (2D)	LR_{50} = 0.06 g a.s./ha Red. of reproduction: <50% at 0.00148 g a.s./ha	EFSA 2014; 12 (5): 3677
Aphidius rhopalosiphi (adults)	Lambda-cyhalothrin (WG 50 g/kg)	Extended laboratory test Apple leaves (2D)	LR_{50} = 2.2 g a.s./ha ER_{50} = 1.3 g a.s./ha Red. of reproduction: <50%% at 0.020 g a.s./ha	EFSA 2014; 12 (5): 3677
Typhlodromus pyri (protonymphs)	Lambda-cyhalothrin (WG 50 g/kg)	Extended laboratory test apple leaves (2D)	LR_{50} = 0.026 g a.s./ha	EFSA 2014; 12 (5): 3677
Typhlodromus pyri	Lambda Cyhalothrin 10% CS	An extended laboratory test Bean leaves (2D)	**LR50: 0.44 mL/ha** **0.044 g a.i./ha** NOERmortality >0.15625 mL/ha a.i./ha ER50reproduction: >0.625 mL/ha >0.0625 g a.i./ha NOER reproduction: 0.625 mL/ha 0.0625 g a.i./ha	KCP 10.3.2-01
Chrysoperla carnea	Lambda Cyhalothrin 10% CS	An extended laboratory test Bean leaves (2D)	**LR50: 0.0509 L/ha** **5.09 g a.i./ha** NOERmortality 0.0039L/ha 0.39 g a.i./ha ER50fecundity: 0.0629 L/ha 6.29 g a.i./ha NOERfecundity: 0.0156L/ha 1.56 g a.i./ha	KCP 10.3.2-02
Aphidius rhopalosiphi	Lambda Cyhalothrin 10% CS	An extended laboratory test Bean plants (3D)	**LR50: 0.02 L/ha** **2 g a.i./ha** NOERmortality 0.0039L/ha 0.39 g a.i./ha ER50fecundity:0.02 L/ha 2 g a.i./ha NOERfecundity: <0.0039L/ha	KCP 10.3.2-03

			<0.39 g a.i./ha	
Aleochara bilineala	Lambda Cyhalothrin 10% CS	An extended laboratory test (2D)	**LR50: 0.11 L/ha** **11 g a.i./ha** NOERmortality 0.0313 L/ha 3.13 g a.i./ha ER50fecundity:>0.0625 L/ha >6.25 g a.i./ha NOERfecundity: <0.0156/L ha <l.56 g a.i./ha	KCP 10.3.2-04
Typhlodromus pyri (protonymphs)	Lambda-cyhalothrin (WG 50 g/kg)	Aged residue test apple leaves (2D)	Mortality at 7.5 g a.s./ha: 4.3 % at 27 DA(L)T Red. of reproduction at 7.5 g a.s./ha: 2.3 % at 27 DA(L)T	EFSA 2014; 12 (5): 3677
Chrysoperla carnea (larvae)	Lambda-cyhalothrin 100 CS	Aged residue test Dwarf bean leaves (2D)	Mortality at 4.6-46 g a.s./ha: > 80 % at 7 DA(L)T <10 % at 21 DA(L)T Red. of reproduction at 4.6-46 g a.s./ha: <50 % at 21 DA(L)T	EFSA 2014; 12 (5): 3677
Aphidius rhopalosiphi (adults)	Lambda-cyhalothrin 100 CS	Aged residue test Dwarf bean leaves and barley seedlings (2D)	Mortality at 4.6-46 g a.s./ha: > 89 % at 7 DA(L)T <10 % at 21 DA(L)T Red. of reproduction at 4.6-46 g a.s./ha: <50 % at 21 DA(L)T	EFSA 2014; 12 (5): 3677
Typhlodromus pyri	Lambda cyhalothrin 2.5 WG	Aged residue test Apple leaves (3D)	Mortality at 2.25 - 17 g as/ha <50% at 42 DA(L)T Red. of reproduction at at 2.25 - 17 g as/ha <50% at 42 DA(L)T	KCP 10.3.2.4 Serrano C., TRC07-21BA*
Typhlodromus pyri	Labamba	Aged residue test	At the rate of 13 g a.s./ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 56 days after the test item application (exposure 56 DAA1).	Sara Varela., 2021

			The test item at the rate of 26 g active ingredient (a.s.)/ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 70 days after the test item application (exposure 70 DAA1).	
Field or semi-field test				
For the representative uses in cereals in northern Europe (Denmark), central Europe (Germany) and southern Europe (Italy), the effects on non-target arthropods of a multiple application regime of 3 x 10 g a.s./ha has been investigated in three studies. No acceptable field studies are available to assess the risk to NTA from the representative uses in tomatoes, potatoes and orchards (plums and peaches). Recovery was not demonstrated within 1 year in the available field data from Denmark and Germany for sensitive species such as Linyphid spiders. Hence, from the field data potential for recovery/re-colonisation is not demonstrated within 1 year after the first treatment for in-field habitats and within an ecologically relevant time for off-field habitats at the proposed use in cereal in central and northern EU. From the study in Italy, a potential recovery was indicated one year after the first treatment. There is no acceptable field data to cover the representative use in tomatoes, potatoes and orchards				

*The study was not considered in the risk assessment for Labamba

9.7.1.1 Justification for new endpoints

Not relevant. The endpoints used were the EU agreed ones.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods 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), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group brassicas also covers the risk for non-target arthropods from all other intended uses in groups (see 9.1.2).

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of SHA 3600 B/LABAMBA ~~in Brassicas~~

Intended use	Brassicas. tomatoes, winter cereals and winter oilseed rape
Active substance/product	Lambda-cyhalotrin
Application rate (g/ha)	1 × 7.5
MAF	1

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	0.0037	7.5	2027.03
Aphidius rhopalosiphi	1.06		7.08
Test species Higher-tier	**Rate with ≤ 50 % effect (g/ha)LR50/ER50**	**PERin field (g/ha)**	**PERin-field below rate with ≤ 50 % effect?**
Typhlodromus pyri	0.044/0.0625	7.5	**no**
Chrysoperla carnea	5.09/6.29		**no**
Aphidius rhopalosiphi	2/2		**no**
Aleochara bilineala	11/11		yes
Test species Higher-tier	**Rate with ≤ 50 % effect** (g a.s./ha) at DALT	**$PER_{in\text{-}field}$** (g a.s./ha)	$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?
Typhlodromus pyri	26 (70 DALT)	7.5	yes
Aphidius rhopalosiphi	46 (21 DALT)		yes
Chrysoperla carnea	46 (21 DALT)		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.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

Tomato – greenhouse

Exposure to non-target arthropods cannot be fully excluded for permanent greenhouses (i.e. non-target arthropods entering the glasshouse through open vents) especially in areas with extensive glasshouse production. However, overall it was agreed that a risk assessment for non-target arthro-pods was not necessary for uses restricted to permanent greenhouses and no unacceptable risk is expected.

zRMS comment:

High in-field risk was indicated for species: Typhlodromus pyri, Chrysoperla carnea and Aphidius rhopalosiphi based on LR_{50}/ER_{50} values obtained from extended laboratory studies.

Further refinement was required for these species.

9.7.2.2 Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group Brassicas also covers the risk for non-target arthropods from all other intended uses in groups (see 9.1.2).

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of SHA 3600 B/LABAMBA ~~in Brassicas~~

Intended use	Brassicas. tomatoes, winter cereals and winter oilseed rape
Active substance/product	Lambda-cyhalotrin
Application rate (g/ha)	1 × 7.5
MAF	1.0
vdf	10 (Tier 1) / 10 (2D) and 1 (3D)

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate %**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	0.0037	2.77	0.021	10	**56.15**
Aphidius rhopalosiphi	1.06			10	0.20

Test species Higher-tier	**Rate with ≤ 50 % effect (g/ha)-LR_{50}/ER_{50}**	**Drift rate %**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$PER_{off\text{-}field}$ below rate with ≤ 50 % effect?**
Typhlodromus pyri	0.044/0.0625	2.77	0.21	5	**no**
Chrysoperla carnea	5.09/6.29		0.21		**yes**
Aphidius rhopalosiphi	2/2		0.21		**yes**
Aleochara bilineala	11/11		0.21		**yes**

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.

* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

The effects of Lambda cyhalothrin on non-target arthropods were observed in additional aged residues studies.

A semi-field application on potted apple plants were performed. The test product was sprayed at the rates of 2.35 and 17.0 g a.s./ha. As test species protonymphs of the parasitoid the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae) was used. Based on the results of the present study it can be concluded that residues of the lambda-cyhalothrin applied to the rate of 2.35 g a.s./ha causes mortality less than 50 % compared to the control and has less than 50 % reduction on the reproduction of *Typhlodromus pyri* from 14 days after the application. Residues of the test product lambda-cyhalothrin applied to the rate of 17.0 g a.s./ha causes mortality less than 50 % compared to the control and has less than 50 % reduction on the reproduction of *Typhlodromus pyri* after exposure to residues aged for 42 days.

Study of aged residues effects on *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and *Chrysopoerla carnea* (Neuroptera: Chrysopidae) were conducted using bean leaves. The product was applied in the rates 4.623 g a.s/ha, 15.466 g a.s./ha, 25.5 g. as/ha and 46.0 g a.s./ha. For *Aphidius* at 0 DAA and 7 DAA, there were significant differences between mortality in the control and all test item treatments after 48 hours. At 21 DAA, there was no significant difference between mortality in the control and all test item treatments after 48 hours. Fecundity assessment was only evaluated at 21 DAA, where the corrected mean mortality was < 50% in all test item treatments after 48 hours. At 21 DAA, there was no significant dif-

ference between fecundity in the control and all test item.

For *Chrysopoerla* at 0DAA and 7DAA, there were significant differences between cumulative mean mortality in the control and all test item treatments. At 21DAA, there was no significant difference between cumulative mean mortality in the control and all test item treatments. Fecundity (mean number of eggs / female / day) and fertility (mean hatching rate) assessments were only evaluated at 21 DAA, where the corrected cumulative mean mortality was < 50% in all test item treatments. At 21DAA, there was no significant difference between fecundity/fertility in the control and all test item treatments.

Potential of recovery of NTA was also indicated in the study with lambda-cyhalothrin on predatory mites (Acari: Phytoseiidae) under field conditions. Populations had recovered at 43 DAA for the 20 g a.s./ha treatment and at 28 DAA for the 4.21 g a.s./ha treatment. Additionally population recovery was observed after 29 days after second application of 20g s.a./ha.

It can therefore be concluded that two applications of lambda-cyhalothrin, applied at field and drift rates (20 and 4.2 g a.s./ha respectively) are not expected to cause long-term reductions in phytoseiid mite populations.

zRMS comment:

The new field study was submitted by the applicant to refine the risk assessment for NTA.
The short and long-term effects (immediate reduction, persistence of effect, recovery potential) of a Lambda-Cyhalothrin formulation (TF-LC 2.5% WG) on leaf dwelling phytoseiid mite populations were determined under field conditions in a peach (nectarine) orchard. There were two applications of the test and reference items and the water control with a 14-day interval. The test design included 2 application rates for the test item treatment (maximum application rate of 20 g a.s./ha and drift rate of 4.21 g a.s./ha), a reference item treatment (Deltamethrin 25 g/L EC at 12.5 g a.s./ha) and a water control.
It should be noted that the study was provided for formulation WG (2.5 g a.s./L) instead of formulation CS (10 g a.s./L) and it was considered by zRMS not appropriate to use in the risk assessment.
In addition, the study was provided for orchards not for arable crops as is recommended in ESCORT 2 or ESCORT 3.

Table 9.7-4$_{corr}$: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of SHA 3600 B/LABAMBA

Intended use	Brassicas. tomatoes, winter cereals and winter oilseed rape
Active substance/product	Lambda-cyhalotrin
Application rate (g/ha)	1 × 7.5
MAF	1

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**$PER_{in\text{-}field}$ (g/ha)**	**$HQ_{in\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri	0.0037	7.5	**2027.03**
Aphidius rhopalosiphi	1.06		**7.08**
Test species Higher-tier	**Rate with ≤ 50 % effect (g/ha)LR_{50}/ER_{50}**	**PERin field (g/ha)**	**PERin-field below rate with ≤ 50 % effect?**
Typhlodromus pyri	0.044/0.0625	7.5	**no**
Chrysoperla carnea	5.09/6.29		**no**
Aphidius rhopalosiphi	2/2		**no**
Aleochara bilineala	11/11		**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.
* If an LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

In addition, based on the risk assessment provided in the Table 9.7-5 for remained species the risk **in** – field needs further refinement.
The applicant used the age residue studies for representative formulation. According to PART C the composition of Lambda are similar to representative Formulation and the studies can be used for Labamba risk assessment for NTA.
Study of aged residues effects on *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and *Chrysopoerla carnea* (Neuroptera: Chrysopidae) were conducted using bean leaves. The product was applied in the rates 4.623 g a.s/ha, 15.466 g a.s./ha, 25.5 g. as/ha and 46.0 g a.s./ha. For *Aphidius* at 0 DAA and 7 DAA, there were significant differences between mortality in the control and all test item treatments after 48 hours. At 21 DAA, there was no significant difference between mortality in the control and all test item treatments after 48 hours. Fecundity assessment was only evaluated at 21 DAA, where the corrected mean mortality was < 50% in all test item treatments after 48 hours. At 21 DAA, there was no significant difference between fecundity in the control and all test item.
For *Chrysopoerla* at 0DAA and 7DAA, there were significant differences between cumulative mean mortality in the control and all test item treatments. At 21DAA, there was no significant difference between cumulative mean mortality in the control and all test item treatments. Fecundity (mean number of eggs / female / day) and fertility (mean hatching rate) assessments were only evaluated at 21 DAA, where the corrected cumulative mean mortality was < 50% in all test item treatments. At 21DAA, there was no significant difference between fecundity/fertility in the control and all test item treatments.

For T.pyri the new age residue study:,,Lambda cyhalothrin 10% CS: Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions, Sara Varela, 2021" was provided by the applicant.

Based on the results of this study performed on *Typhlodromus pyri*, after the application of Lambda cyhalothrin 10% CS, it can be concluded that this product, at the rate of 13 g a.s./ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 56 days after the test item application (exposure 56 DAA1). The test item at the rate of 26 g active ingredient (a.s.)/ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 70 days after the test item application (exposure 70 DAA1).
In case of off-field risk assessment the applicant provided risk mitigation measures at **Point 9.7.2.4.**

9.7.2.4 Risk mitigation measures

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following tables.

Table 9.7-4: Assessment of the off-field risk for non-target arthropods due to the use of SHA 3600 B/LABAMBA in brassicas, tomatoes, winter cereals and winter oilseed rape considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

Intended use		Brassicas. tomatoes, winter cereals and winter oilseed rape			
Active substance/product		Lambda cyhalotrin			
Application rate (g/ha)		1 × 7.5			
MAF		1.0			
vdf		10			
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)**
1/3	2.77%	0.208	0.104	0.052	0.021
5	0.57%	0.043	0.021	0.011	0.004
10	0.29%	0.022	0.011	0.005	0.002
15	0.20%	0.015	0.008	0.004	0.002
20	0.15%	0.011	0.006	0.003	0.001
30	0.10%	0.0080	0.0040	0.0020	0,0008
40	0.07%	0.0050	0.0026	0.0013	0,0005
Tier 1 toxicity value		**$HQ_{off-field}$**			
LR_{50} = 0.0037 g/ha		**criterion: HQ ≤ 2**			
1/3		**56.15**	**28.07**	**14.04**	**5.61**
5		**11.55**	**5.78**	**2.89**	1.16
10		**5.88**	**2.94**	1.47	0.59
15		**4.05**	**2.03**	1.01	0.41
20		**3.04**	1.52	0.76	0.30
30		**2.03**	1.01	0.51	0.20
40		1.42	0.71	0.35	0.14

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

9.7.3 Overall conclusions

The results of the risk assessment showed unacceptable in-field risk after the application of SHA 3600 B/LABAMBA according to the GAP. The off-field risk is acceptable when the following risk mitigation measures are considered for:

- Brassicas, tomato (field), winter cereals and winter oilseed rape: 5m buffer zone with 90% nozzles reduction or 10m buffer zone with 75% nozzles reduction or 15m buffer zone with 75% nozzles reduction or 20m buffer zone with 50% nozzles reduction or 30m buffer zone with 50% nozzles reduction or 40m buffer zone,

Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles or an unsprayed buffer zone of 10m with 75% drift reducing nozzles or an unsprayed buffer zone of 20m with 50% drift reducing nozzles or an unsprayed buffer zone of 40m

Tomato – greenhouse
According to EFSA Supporting publication 2015:EN-924, it was discussed at the Pesticides Peer Review Expert Meeting 129 (March, 2015) whether vents will be open during applications, however, it was considered that it is standard practice to close the vents during applications. In addition, exposure to non-target arthropods cannot be fully excluded for permanent greenhouses (i.e. non-target arthropods entering the glasshouse through open vents) especially in areas with extensive glasshouse production. However, overall it was agreed that a risk assessment for non-target arthropods was not necessary for uses restricted to permanent greenhouses and no unacceptable risk is expected.

zRMS comment:

Field uses:

The off-field risk is acceptable for NTA when the following risk mitigation measures are considered for:

Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles or an unsprayed buffer zone of 10m with 75% drift reducing nozzles or an unsprayed buffer zone of 20m with 50% drift reducing nozzles or an unsprayed buffer zone of 40m

Tomato – greenhouse uses

The risk for permanent glasshouse is considered as acceptable without risk mitigation measures.

In conclusion: The risk mitigation measures should be considered at MSs level.

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 lambda-cyhalothrin and its relevant metabolites. 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 SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin. A new chronic study with earthworms is currently ongoing and the final report will be presented when it will be available.
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
Eisenia fetida	lambda-cyhalothrin	14 d, acute 10 % peat content	$LC_{50\ corr}$>500 mg/kg*	EFSA 2014; 12 (5): 3677
Eisenia fetida	lambda-cyhalothrin	Mixed into substrate 56 d, chronic 5% peat content	$NOEC_{corr}$ = 3.125 mg/kg*	EFSA 2014; 12 (5): 3677
Eisenia fetida	Metabolite Ia	Mixed into substrate	NOEC = 6.25 mg	EFSA 2014; 12 (5):

Species	Substance	Exposure System	Results	Reference
		56 d, chronic 5% peat content	a.s./kg	3677
Eisenia fetida	Metabolite V	Mixed into substrate 56 d, chronic 5% peat content	$NOEC_{Corr}$ = 3.125 mg/kg*	EFSA 2014; 12 (5): 3677
Eisenia fetida	Metabolite XV	Overspray 14 d, acute 10 % peat content	$LC50_{Corr}$>500 mg/kg*	EFSA 2014; 12 (5): 3677
Eisenia fetida	Metabolite XV	Mixed into substrate 56 d, chronic 5% peat content	$NOEC_{Corr}$ =25 mg a.s./kg*	EFSA 2014; 12 (5): 3677
Folsomia candida	Lambda-cyhalothrin 100 CS	28 d, chronic	$NOEC_{corr}$ = 2.73 mg a.s./kg dw	EFSA 2014; 12 (5): 3677
Hypoaspis aculeifer	Lambda-cyhalothrin 100 CS	14 d, chronic	NOEC = 4.67 mg a.s./kg dw	EFSA 2014; 12 (5): 3677

* 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

Not relevant. The endpoints used were the EU agreed ones.

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 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for lambda-cyhalothrin.
To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group brassicas also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups (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 SHA 3600 B/LABAMBA in brassicas.

Intended use	Brassicas, (Tomatoes, Winter cereals and winter oilseed rape, tomato)		
Acute effects on earthworms			
Product/active substance	**LC_{50} (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_a (criterion TER ≥ 10)**
lambda-cyhalothrin	500	0.003	166666.67

Hydroxylated lambda-cyhalothrin (metabolite XV)	> 500	0.001	> 500000
Chronic effects on earthworms			
Product/active substance	**NOEC (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**TER_{lt} (criterion TER ≥ 5)**
lambda-cyhalothrin	3.125	0.003	1041.67
TFP-acid (metabolite Ia)	6.25	0.001	6250
3-phenoxybenzoic acid (metabolite V)	3.125	0.001	3125
Hydroxylated lambda-cyhalothrin (metabolite XV)	25	0.001	25000
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)**
Lambda-cyhalothrin (Folsomia)	2.73	0.003	910
Lambda-cyhalothrin (Hypoapsis)	4.67	0.003	1556.67

TER values shown in bold fall below the relevant trigger.

Tomato – greenhouse

The Applicant considers that the risk assessment on non-target soil meso- and macrofauna are not needed according to conclusion from dRR B8 where no calculations of PECsoil for active and metabolites for greenhouse were provided since PECsoil is not considered relevant for greenhouse uses. Please, refer to dRR B8 for more details.

zRMS comment:

zRMS agrees with the provided risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) in Table 9.8-2. No chronic studies for Labamba was submitted. However, taking into account that the product has only one active substance the risk can be based on the toxicity of Lambda-cyhalothrin.

Labamba poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use pattern.

9.8.2.2 Higher-tier risk assessment

Not relevant.

9.8.3 Overall conclusions

No acute and chronic risk for earthworms from lambda-cyhalothrin and the metabolites Ia, metabolite V and metabolite XV is expected since the TER values are above the trigger.

No chronic risk is expected for soil macrofauna since the TER values are above the trigger value of 5. Therefore, no risk for earthworms and soil macroorganisms is expected after the application of Lambda-cyhalothrin 10% CS according to the proposed uses.

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 lambda-cyhalothrin and its relevant metabolites.
Effects on soil microorganisms of SHA 3600 B/LABAMBA were not evaluated as part of the EU assessment of lambda-cyhalothrin.
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	Hydroxylated lambda-cyhalothrin (metabolite XV)	28 d, aerobic soil type	Nitrate formation rate 0.025 mg/kg soil dw ± 0 %	EFSA 2014; 12 (5): 3677
N-mineralisation	SHA 3600 B/LABAMBA	28 d, aerobic	No significant effects (<25% effect compared to untreated control) when tested at 3.524 mg test item/kg dry soil (i.e. 0.333 mg of lambda-cyhalothrin / kg dry soil) and: 17.620 mg the test item/kg dry soil (i.e. 1.67 mg of lambda-cyhalothrin / kg dry soil)	KCP 10.5.1 Anand H.S., 2019 G13389
~~C-mineralisation~~	~~SHA 3600 B/LABAMBA~~	~~28 d, aerobic~~	~~No significant effects (<25% effect compared to untreated control) when tested at 3.524 mg test item/kg dry soil (i.e. 0.333 mg of lambda-cyhalothrin / kg dry soil) and: 17.620 mg the test item/kg dry soil (i.e. 1.67 mg of lambda-cyhalothrin / kg dry soil)~~	~~KCP 10.5.2 Anand H.S., 2019 G13388~~

9.9.1.1 Justification for new endpoints

Not relevant. The endpoints used were the EU agreed ones.

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 8.7-3 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 Brassicas also covers the risk for the soil microorganisms from all other intended uses in groups (see 9.1.2).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of SHA 3600 B/LABAMBA in brassicas

Intended use	Brassicas (tomatoes, winter cereals and winter oilseed rape)		
N-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
Hydroxylated lambda-cyhalothrin (metabolite XV)	0.025 (at 28 d)	0.001	yes
SHA 3600 B/LABAMBA	1.67 (at 28 d)	0.003	yes
C-mineralisation			
Product/active substance	**Max. conc. with effects ≤ 25 % (mg/kg dw)**	**PEC_{soil} (mg/kg dw)**	**Risk acceptable?**
SHA 3600 B/LABAMBA	1.67 (at 28 d)	0.003	yes

Tomato – greenhouse

The Applicant considers that the risk assessment on non-target soil microorganisms are not needed according to conclusion from dRR B8 where no calculations of PECsoil for active and metabolites for greenhouse were provided since PECsoil is not considered relevant for greenhouse uses. Please, refer to dRR B8 for more details.

zRMS comment:

Labamba has no significant effect on soil micro-organisms at 1.67 mg a.s./kg dry soil.

Based on it, can be concluded that Labamba under field conditions, use at the proposed rates poses no unacceptable risk to non-target soil micro-organisms.

9.9.3 Overall conclusions

No risk for soil microorganisms is expected from exposure to metabolite XV since the PECsoil is below the max. conc. with effects ≤ 25%.
At 1.67 mg Lambda-cyhalothrin SHA 3600 B/LABAMBA /kg dw soil, the effects on soil microorganisms were ≤ 25%. This concentration is higher than the highest $PEC_{soil\ acc}$ obtained for the formulation SHA 3600 B/LABAMBA.
Therefore, based on these results, no risk for soil microorganisms is expected after the application of SHA 3600 B/LABAMBA according to the proposed GAP.

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

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with lambda cyhalothrin. Full details of these studies are provided in the respective EU DAR and related documents.
However, the provision of further data on the SHA 3600 B/LABAMBA is not considered essential, because EFSA had concluded that no effects on the vegetative vigour on non-target plants were observed in the studies provided on the representative formulations and therefore a low risk to non-target terrestrial plants was concluded. The foliar application of for representative formulation i.e Lambda-Cyhalothrin 100 CS at a rate of 30 g a.s./ha to six terrestrial plant species at the 2 to 4 leaf stage did not produce adverse effects on survival and shoot fresh weight. NOEC 'Lambda-Cyhalothrin 100 CS' was 30 g a.s./ha, which is twice higher than SHA 3600 B/LABAMBA maximum application rate.

9.10.1.1 Justification for new endpoints

Not relevant. The endpoints used were the EU agreed ones.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

zRMS comment:

The risk assessment provided below is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/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.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use with single application rate of 7.5 g a.s./ha and drift factor of 2.77% covers the risk for non-target terrestrial plants from all intended uses.

Table 9.10-1: Assessment of the risk for non-target plants due to the use of Labamba .

Intended use	Brassicas, tomatoes, winter cereals and winter oilseed rape
Active substance/product	Lambda-cyhalotrin

Single application rate		7.5 g a.s./ha		
Drift factor (%drift/100)		0.0277 (at a distance of 3 m)		
Test species	**ER_{50} (g a.s./ha)**	**Drift rate**	**$PER_{off-field}$ (g a.s./ha)**	**TER criterion: TER ≥ 5**
All species	>30	2.77%	0.20	150

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

The risk for non-target plants is considered acceptable.

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

Not relevant.

9.10.2.3 Higher-tier risk assessment

Not relevant.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

No risk for non-target terrestrial plants is expected after the application of Lambda cyhalothrin 10% CS.

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

Effects on biological methods for sewage treatment.

Test type/organism	Respiration activated sludge
End point	NOEC 100 mg/L

The EFSA conclusion on the peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin states that a low risk was concluded for sewage treatment organisms.

9.12 Monitoring data (KCP 10.8)

Not relevant

9.13 Classification and Labelling

	Lambda cyhalothrin 10% CS		
Common Name	LABAMBA		
Classification and proposed labelling			
With regard to ecotoxicological endpoints (according to the	Aquatic Acute 1; Aquatic Chronic 1;	H400 H410	Very toxic to aquatic life. Very toxic to aquatic life with long lasting

	Lambda cyhalothrin 10% CS
criteria in Reg. 1272/2008, as amended)	effects. EUH401: To avoid risks to human health and the environment, comply with the instructions for use
Additional C&L proposal	~~Spe3: To protect aquatic organisms respect an unsprayed vegetated buffer zone of 20 m + 90% drift reduction nozzles to non-agricultural land/surface water bodies~~ ~~Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m~~ Spe3: to protect aquatic organisms respect an unsprayed buffer zone of 5 m surface water bodies Spe 3: To protect non-target arthropods respect an unsprayed buffer zone of 5m with 90% drift reducing nozzles or an unsprayed buffer zone of 10m with 75% drift reducing nozzles or an unsprayed buffer zone of 20m with 50% drift reducing nozzles or an unsprayed buffer zone of 40m SPe8: Dangerous for bees. To protect bees and other pollinating insects, do not apply during the flowering period or during honeydew production period, do not apply when weeds in flower are present

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.3.1.1.1	Deppika Rani S.	2018	"Lambda-cyhalotrin 10% CS: Acute Oral Toxicity Test in Honey Bees" Study No.: G13384 Eurofins Advinus Limited GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.1.2	Deppika Rani S.	2018	"Lambda-cyhalotrin 10% CS: Acute Contact Toxicity Test in Honey Bees" Study No.: G13385 Eurofins Advinus Limited GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.1.5	Portail B.	2018	"Lambda cyhalothrin 2.5 WG: A semi-field study to evaluate side effects on honey-bees (Apis mellifera L.) in Phacelia tanacetifolia in Germany 2017" Study No.: S17-02719, 2018 Eurofins Agroscience Services Ecotox GmbH GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2-01	Bala P.	2020	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the predatory mite, Typhlodromus pyri (Scheuten)" Study No.: 6026/2019. Bioscience Research Foundation GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2-02	Mohanruj M.	2020	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on on larvae of the green lacewing Chrysoperla carnea (L.)" Study No.: 6194/2019 Bioscience Research Foundation GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2-03	Sonali G.	2019	An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the parasitic wasp, Aphidius rhopalosiphi (De StefaniPerez) Study No.: 6024/2019 Bioscience Research Foundation GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2-04	Angayarkanni V.	2019	An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the rove beetle, Aleochara bilineala (Gyllenhal)	N	Sharda Cropchem Limited

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Study No.: 6195/2019 Bioscience Research Foundation GLP, Unpublished		
KCP 10.3.2.4	Serrano C.	2007	"Side-effects of Lambda-cyhalothrin 2.5% WG on predatory mites (Acari: Phytoseiidae) in peach trees under field conditions" Study No.: TRC07-21BA. TrialCamp GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.3.2.4	Varela S.	2021	Lambda cyhalothrin 10% CS: Toxicity to the Predatory Mite, Typhlodromus pyri Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions Study No.: S20-07842 Eurofins Trialcamp S.L.U. GLP, Unpublished	N	Sharda Cropchem Limited.
KCP 10.5.1	Anand H. S	2019	"Soil Microorganisms: Nitrogen Transformation Test od Lambda-cyhalotrin 10% CS" Study No.: G13389 Eurofins Advinus Limited GLP, Unpublished	N	Sharda Cropchem Limited
KCP 10.5.2	Anand H. S	2019	"Soil Microorganisms: Carbon Transformation Test od Lambda-cyhalotrin 10% CS" Study No.: G13388 Eurofins Advinus Limited GLP, Unpublished	N	Sharda Cropchem Limited

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

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:	The study is considered valid. All validity criteria were met. • No mortality in control and is within the specified 10 per cent limit at the end of the test • The LD_{50} of the toxic standard, Dimethoate at 24 hours was 0.13 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.116 to 0.155 µg a.i./bee **Agreed endpoint:** **LD_{50} 48h_{oral} =5.3 µg product/bee**

Reference:	KCP 10.3.1.1.1
Report:	"Lambda Cyhalothrin 10% CS: Acute Oral Toxicity Test in Honeybees". Deepika Rani S., 2018, G13385. Department of Safety Assessment Eurofins Advinus Limited
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 213 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary
The acute oral toxicity of Lambda Cyhalothrin 10% CS was studied on the honeybee Apis mellifera L. Active adult foraging worker honeybees were exposed to Lambda Cyhalothrin 10% CS at the concentrations of of 0.75, 1.65, 3.63, 7.99 and 17.58 µg test item/bee along with sucrose (50% w/v sucrose in Milli-Q water) and three concentrations of the toxic standard Dimethoate at 0.075, 0.15 and 0.30 µg a.i./bee.
There was no mortality and behavioral changes of bees observed in the control group during 4, 24 and 48 h post treatment.
Similarly, no mortalities or behavioral changes observed at test item concentrations of 0.75 µg test item/bee respectively at 4 h after the start of the test and also at 24 h and 48 h post treatment. The per cent mortalities for the concentrations 1.65,3.63,7.99 and 17.58 µg test item/bee at 4 h post treatment were 6.67, 16.67, 43.33 and 50.00% and the percent mortalities for the concentrations 1.65, 3.63, 7.99 and 17.58 µg test item/bee at 24 and 48 h post treatment were 13.33, 43.33, 60.00 and 86.67%
The per cent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 10.00, 36.67 and 73.33% at tested concentrations of 0.075, 0.15 and 0.30 µg a.i/bee respectively. The per cent mortalities at 24 and 48 h post treatment were 13.33, 53.33 and 100% at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i/bee respectively.
The LD_{50} value of the test item, Lambda Cyhalothrin 10% CS at 24 and 48 h is 5.3 µg/bee with fiducial limits at 95 per cent ranging from 3.984 to 7.041 µg/bee.
The LD_{50} value of toxic standard, Dimethoate at 4 h is 0.19 µg/bee with fiducial limits at 95 per cent ranging from 0.155 to 0.241 µg a.i./bee.
The LD_{50} value of toxic standard, Dimethoate at 24 and 48 h was 0.13 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.116 to 0.155 µg a.i./bee.

Material and methods

Test item: Name: Lambda cyhalothrin 10% CS
Batch number: SCL-89123
Content: 100 g/L (9.46%) of Lambda Cyhalothrin
Manufacturing date: 6th April 2017

	Expiry date: 5th April 2017
Reference item	Dimethoate Product number: 45449 Batch number: BCBS9338V Expiry date: August 2021 Purity: 99.8% (CAS number: 60-51-5)
Test organisms:	Adult foraging workers of the honeybee species, Apis mellifera L Source: Ecotoxicology Laboratory Eurofins Advinus Limited
Test design:	Test item: - exposure time: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate Reference item: - exposure time: 48 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test medium:	50% w/v sucrose in Milli-Q water
Endpoints:	- honeybee mortality after 48 hours of exposure - the LD_{50}/4 h, LD_{50}/24 h and LD_{50}/48 h of exposure - the LD_{50}/4 h, LD_{50}/24 h and LD_{50}/48 h of the reference item (dimethoate)
Test conditions:	Temperature: 23 – 25°C Relative air humidity: 60 – 61%
Statistical analysis:	statistical method of Probit analysis using an in-house developed and validated computer program
Validity criteria:	- 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 toxic standard, Dimethoate at 24 hours was 0.13 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.116 to 0.155 µg a.i./bee

Findings

Group	Treatment (µg/bee)	No. of honey-bees tested			Cumulative No. of honeybees observed dead at											
					4 hours				24 hours				48 hours			
		R1	R2	R3	R1	R2	R3	PMM	R1	R2	R3	PMM	R1	R2	R3	PMM
G1	Control	10	10	10	0	0	0	0	0	0	0	0	0	0	0	0
G2	0.75	10	10	10	0	0	0	0	0	0	0	0	0	0	0	0
G3	1.65	10	10	10	1	0	1	6.67	1	1	2	13.3	1	1	2	13.3
G4	3.63	10	10	10	2	2	1	16.67	4	3	6	43.3	4	3	6	43.3
G5	7.99	10	10	10	6	5	2	43.3	7	5	6	60.0	7	5	6	60.0
G6	17.58	10	10	10	6	5	4	50.0	8	9	9	86.67	8	9	9	86.67

Endpoints	
LD_{50} - 48 h	5.3 µg f.p./bee

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

Comments of zRMS:	The study is considered valid. All validity criteria were met. • there was no mortality in control and is within the specified 10 per cent limit at the end of the test • the LD_{50} of the toxic standard, Dimethoate at 24 hours was 0.12 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.097 to 0.139 µg a.i./bee

	Agreed endpoint: **LD_{50}48h = 4.84 µg product/bee**

Reference:	KCP 10.3.1.1.2
Report:	"Lambda Cyhalothrin 10% CS: Acute Contact Toxicity Test in Honeybees". Deepika Rani S., 2018, G13385. Department of Safety Assessment Eurofins Advinus Limited
Guideline(s):	OECD Guideline for the Testing of Chemicals No. 214 (1998)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary
The acute contact toxicity of Lambda Cyhalothrin 10% CS was studied on the honeybee Apis mellifera L. Active adult foraging worker honeybees were exposed to Lambda Cyhalothrin 10% CS at the concentrations of 0.75, 1.65, 3.63, 7.99 and 17.58 µg test item/bee along with Milli-Q water control and three concentrations of the toxic standard, Dimethoate at 0.075, 0.15 and 0.30 µg a.i./bee.
There was no mortality and behavioral changes of bees observed in the control group during 4, 24 and 48 h post treatment.
Similarly, no mortalities or behavioral changes observed at test item concentrations of 0.75 µg test item/bee respectively at 4 h after the start of the test and also at 24 h and 48 h post treatment. The per cent mortalities for the concentrations 1.65, 3.63, 7.99 and 17.58 µg test item/bee at 4 h post treatment were 10.00, 23.33, 46.66 and 53.33% and the per cent mortalities for the concentrations 0.75, 1.65, 3.63, 7.99 and 17.58 µg test item/bee at 24 and 48 h post treatment were 13.33, 46.67, 63.33 and 90.0%
The per cent mortalities for the toxic standard, Dimethoate at 4 h post treatment were 13.33, 40.00 and 76.66% at tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee respectively. The per cent mortalities at 24 and 48 h post treatment were 26.67, 60.00 and 100 % at the tested concentrations of 0.075, 0.15 and 0.30 µg a.i./bee respectively.
The LD_{50} value of the test item, Lambda Cyhalothrin 10% CS at 24 and 48 h is 4.84 µg/bee with fiducial limits at 95 per cent ranging from 3.704 to 6.328 µg/bee.
The LD_{50} value of toxic standard, Dimethoate at 4 h was 0.18 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.143 to 0.222 µg a.i./bee.
The LD_{50} value of toxic standard, Dimethoate at 24 and 48 h was 0.12 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.097 to 0.139 µg a.i./bee

Material and methods

Test item:	Name: Lambda cyhalothrin 10% CS Batch number: SCL-89123 Content: 100 g/L (9.46%) of Lambda Cyhalothrin Manufacturing date: 6th April 2017 Expiry date: 5th April 2017
Reference item	Dimethoate Product number: 45449 Batch number: BCBS9338V Expiry date: August 2021 Purity: 99.8% (CAS number: 60-51-5)
Test organisms:	Young adult foraging workers of the honeybee species, Apis mellifera L. Source: Ecotoxicology Laboratory Eurofins Advinus Limited

Test design:	Test item: - exposure time: 48 hours - number of doses: 5 doses and a control - number of replicates: 3 replicates - number of bees: 10 bees/replicate Reference item: - exposure time: 48 hours - number of doses: 3 doses - number of replicates: 3 replicates - number of bees: 10 bees/replicate
Test medium:	50% w/v sucrose in Milli-Q water
Endpoints:	- honeybee mortality after 48 hours of exposure - the LD_{50}/4 h, LD_{50}/24 h and LD_{50}/48 h of exposure - the LD_{50}/4 h, LD_{50}/24 h and LD_{50}/48 h of the reference item (dimethoate)
Test conditions:	Temperature: 23 – 25°C Relative air humidity: 59 – 61%
Statistical analysis:	statistical method of Probit analysis using an in-house developed and validated computer program
Validity criteria:	- there was no mortality in control and is within the specified 10 per cent limit at the end of the test - the LD_{50} of the toxic standard, Dimethoate at 24 hours was 0.12 µg a.i./bee with fiducial limits at 95 per cent ranging from 0.097 to 0.139 µg a.i./bee

Findings

Group	Treatment (µg/bee)	No. of honey-bees tested			Cumulative No. of honeybees observed dead at											
					4 hours				24 hours				48 hours			
		R1	R2	R3	R1	R2	R3	PMM	R1	R2	R3	PMM	R1	R2	R3	PMM
G1	Control	10	10	10	0	0	0	0	0	0	0	0	0	0	0	0
G2	0.75	10	10	10	0	0	0	0	0	0	0	0	0	0	0	0
G3	1.65	10	10	10	1	1	1	10.00	2	1	1	13.3	2	1	1	13.3
G4	3.63	10	10	10	2	2	3	23.33	4	5	5	46.67	4	5	5	46.67
G5	7.99	10	10	10	5	5	4	46.67	7	7	5	63.33	7	7	5	63.33
G6	17.58	10	10	10	6	6	4	53.33	9	9	9	90.00	9	9	9	90.00

Endpoints	
LD_{50} - 48 h	4.84 µg f.p./bee

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

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

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

Comments of zRMS:	The study is not considered in the risk assessment for Lambda-cyhalotrin 10 CS. The reason for this that WG formulation instead if CS formulation was tested.

Reference:	KCP 10.3.1.5
Report:	"Lambda cyhalothrin 2.5 WG: A semi-field study to evaluate side effects on honeybees (*Apis mellifera* L.) in *Phacelia tanacetifolia* in Germany 2017". Portail B., S17-02719, 2018. Eurofins Agroscience Services Ecotox GmbH
Guideline(s):	OECD guidance document No. 75 (2007) and current recommendations of the AG Bienenschutz (Pistorius, J. et al., 2012), OEPP/EPPO Guideline No. 170(4), 2010, EU Guideline 7029/VI/95 rev.5.
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The aim of the study was to evaluate potential side effects of a spray application of Lambda-cyhalothrin 2.5% WG on the honeybee (*Apis mellifera* L.) under confined semi-field conditions by following the OECD guidance document No. 75 (2007), with methodological improvements by the AG Bienenschutz (PISTORIUS *et al*., 2012). The crop used was full-flowering *P. tanacetifolia*, the study was conducted in the region of Pforzheim, Baden-Württemberg, Germany.
The study consisted of four treatment groups: two test item groups T1 and T2 (lambda-cyhalothrin), a toxic reference item group R (Insegar) and a water-treated control C. T1 and T2 were applied once before flowering of *Phacelia tanacetifolia* (A1) with the active ingredient rate of 10 g/ha. The second application of T1 (A3) and T2 (A2) with the active ingredient rate of 10 g/ha was done during full flowering of crop with bees present, during bee flight (T1) and after bee flight (T2), respectively. The toxic reference item and control were applied during full flowering of crop with bees present, during bee flight (A3). Tap water was applied in the control group and Insegar was applied at a target rate of 1200 g product/ha in the reference item group (corresponding to 300 g fenoxycarb/ha). The spray volume was 400 L/ha in all treatment groups.
The initial mean colony size per treatment group was in the range of 7101 to 7784 bees. The honeybees remained in the tunnels for 13 days and colonies were assessed once before, twice during and four times after the end of the confined phase.

Materials and methods

Product:	Lambda-cyhalothrin 2.5% WG (CAS number: 91465-08-6)
Batch number:	SCL-35901
Test system:	*Apis mellifera* L. (Hymenoptera: Apidae)
Crop:	Semi field conditions with *Phacelia tanacetifolia*.
Location:	The study was conducted in the region of Pforzheim, Baden-Württemberg, Germany.
Experimental layout:	The area covered per tunnel was 100 m^2 (20m length, 5m width and 3.5 m height). Area covered by crop was 82.72 m^2 and area covered by linen sheets was 17.28 m^2. Floor space each and a height approximately 3.5 m. Covering gauze (mesh size: 1.5 mm) Distance between the tunnels at least 4m One bee colony per tunnel and water supply for bees
Treatments:	

Control: water treated
T1: 10 g a.s./ha, applied twice with 14d interval during bee flight
T2: 10 g a.s./ha, applied twice with 14 d interval after bee flight
Reference: Insegar, 1200 g product/ha (300 g fenoxycarb/ha)
400 L/ha spray volumen in all treatment groups
5 replicates for the control C and treatments T1 and T2
4 replicates for the refrence item

Duration:

3 days monitoring phase, set-up in tunnels 2 days after 1st application, 7 days inside the tunnel after 2nd application, + 28 days after treatment (out of the tunnels)

Test conditions:

Temperature:
10.2 – 28.5 ºC (monitoring phase before exposure)
11.8 – 34.3ºC (confinement in tunnels)
10.2 – 29.5ºC (monitoring phase after exposure)
Daily precipitation:
0.0 – 3.5 mm (monitoring phase before exposure)
0.0 – 28 mm (confinement in tunnels). Heavy rainfalls occurred on 1DBA3 (11m), 2DAA3 (6mm) and 3DAA3 (28mm). Short rainfall (1.2 mm) occurred 1.5 h after application A1 and no rainfall occurred at least 2h after application
0.0 – 35 mm (monitoring phase after exposure)

Feeding:

1 kg sugar syrup (Apiinvert®) on 4DAA3 (caused by heavy rainfalls on 1DBA3 and 2DAA3)
5 L sugar syrup (Apiinvert®) on 19DAA3

Water:

Container filled with water in each tunnel. The surface of the water was covered with floatable material to prevent the bees from drowning.

Hive:

Colonies with 10 combs, one queen and 7101 to 7784 bees before the start of the test. Queens originated from one breeding line (sister queens were used, not older than 2 years)
5-6 brood coms containing eggs, larvae and capped cells
5-9 combs containing honey and pollen
Colonies free of Nosema and Varroa disease and all brood stages were present at the start of the test

Residues:

Samples of forager bees (for pollen and nectar). Samples from honey stomachs and pollen from pollen loads were collected on 2DBA3, 1DAA3, 4DAA3 and 6DAA3 from the colonies Cs, T1s and T2s. On each sampling day> 200 forager bees per tunnel were collected for A-sample and> 150 forager bees for R-sample.

Monitoring site:

Located at a distance of 16 km to the field site, without flowering main crops attractive to honeybees within the surrounding.

Assessments

- Total and mean number of dead bees (worker and pupae) on the linen sheets in tunnels, in the dead bee traps and in the dead bee bottoms before as well as after the application in T1, T2, C and R, respectively.
- Flight intensity (mean number of forager bees/m^2 *Phacelia tanacetifolia)* before as well as after the start of exposure in T1, T2, C and R, respectively.

- Behaviour of the bees in the crop and around the hive.
- Condition of the colonies (colony strength and area of the different brood stages and food storage per colony and assessment date).
- Development of the bee brood assessed in individual brood cells. For this particular assessment, between 209 and 243 individually marked cells per colony were selected.
- Residues in nectar, pollen (from forager bees).

Statistics

The data of mortality, flight intensity and brood index, compensation index and termination rates of the test item groups and the reference item group were compared to the control. The data from all treatment groups were tested for normality using the Shapiro-Wilk test ($p > 0.05$) and for homoscedasticity using F-test ($p > 0.05$). In case of non-homoscedasticity but proven normality, t-test with method Satterthwaite was performed (one-sided, $p \leq 0.05$). In case of non-normality and non-homoscedasticity Mann-Whitney exact test one-sided, $p \leq 0.05$ was used. Log-transformations were conducted if necessary to achieve better fit to normality and homoscedasticity of data.
If data were normal and homogeny, data were statistically compared using t-test pooled (one-sided, $p \leq 0.05$).
For pre-exposure phase data were compared with two-sided approach.
During the exposure phase: Right-sided tests were used for mortality and left-sided tests were used for flight intensity. For brood and compensation indices, left-sided tests were used, for the termination rates right-sided tests were used.
Mortality of worker bees was evaluated separately from mortality of larvae/pupae.
All statistical analysis was conducted using SAS release Version 9.3

Results

Mortality

Treatment group		**Control (C) adapted for T1 and R**	**Control (C) adapted for T2**	**Test item (T1)**	**Test item (T2)**	**Reference item (R)**
Daily mean mortality (dead worker bees/colony) ± STD	8DBA3 to 6DBA3	16.5 ± 1.4	16.5 ± 1.4	30.9 ± 19.1	15.3 ± 1.6	18.3 ± 6.5
	5DBA3 to 0DBA3	62.6 ± 24.1	59.2 ± 24.2	49.0 ± 40.1	53.4 ± 18.3	52.4 ± 21.4
	0DAA3	51.7 ± 3.5	72.0 ± 3.5	98.8 ± 42.6	70.8 ± 23.7	38.5 ± 13.5
	1DAA to 7DAA3	83.1 ± 20.2	85.7 ± 20.3	63.4 ± 30.5	62.8 ± 9.9	60.2 ± 21.2
	0DAA to 27DAA3	79.5 ± 19.9	79.8 ± 23.6	89.7 ± 26.7	100.2 ± 23.9	80.5 ± 29.4
Daily mean mortality (dead larvae +pupae/colony) ± STD	8DBA3 to 6DBA3	0.1 ± 0.2	0.1 ± 0.2	0.6 ± 0.5	0.0 ± 0.0	0.1 ± 0.2
	5DBA3 to 0DBA3	0.1 ± 0.2	0.1 ± 0.1	0.4 ± 0.4	0.4* ± 0.2	0.5* ± 0.2
	0DAA3	0.0 ± 0.0	0.3 ± 0.6	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
	1DAA to 7DAA3	0.3 ± 0.3	0.4 ± 0.4	0.3 ± 0.3	0.5 ± 0.6	0.9* ± 0.4

	0DAA to 27DAA3	0.1 ± 0.2	0.2 ± 0.2	0.1 ± 0.1	0.2 ± 0.2	5.0* ± 5.2

During the pre-exposure period before set-up of the colonies in the tunnels (8DBA3 to 6DBA3), the mean daily mortality of adult bees was not statistically significant different between the treatment groups.
During the first exposure phase in the tunnels (5DBA3 to 0DBA3, before application A2 and A3), the mean daily mortality, was 62.6 in C adapted for T1 and R, and 59.2 in C adapted for T2, 49.0 in T1, 53.4 in T2 and 52.4 in R dead bees/colony/day, respectively. There were no statistically significant differences between the treatment groups concerning mortality during this period.
On the day of application (0DAA3) the mean numbers of dead bees in the treatment groups C adapted for T1 and R, in C adapted for T2, in T1, T2 and R were: 51.7, 72.0, 98.8, 54.8 and 38.5 dead bees/colony/day, respectively.

In the following period of confinement from 1DAA3 to 7DAA3, the mean daily mortality values were 83.1, 85.7, 63.4, 62.8 and 60.2 dead bees/colony/day, respectively and not statistically significant higher than in the control (t-test pooled, one sided, α=0.05). On the day 1DAA3 in treatment T1 and T2 statistically significant higher values than in the control (t-test pooled, one sided, α=0.05) were observed.
During the monitoring phase (8DAA3 to 27DAA3) levels of mortality statistically significantly higher in comparison to the control were observed on 15DAA3, 19DAA3 and 27DAA3 in T1, on 15DAA3, 16DAA3, 19DAA3, 21DAA3, 22DAA3 and 27DAA3 in T2, and on 16DAA3 in R (t-test pooled, one sided, α=0.05).
During the entire period after the application A3 (0DAA3 to 27DAA3), the mean daily mortality was similar in all treatments groups, with no statistically significant differences to the control.
Overall, adverse effects on adult bee mortality were found for both test item treatments T1 and T2 on 1DAA3, and not permanent adverse effects during the monitoring phase after exposure were observed.
During the pre-exposure period before set-up of the colonies in the tunnels (8DBA3 to 6DBA3), the mean daily mortality of larvae and pupae was similar in all treatments groups.
During the first exposure phase in the tunnels (5DBA3 to 0DBA3, before application A2 and A3), the mean daily mortality, was 0.1 in C adapted for T1 and R, and 0.1 in C adapted for T2, 0.4 in T1, 0.4 in T2 and 0.5 in R larvae/pupae/colony/day, respectively. Statistically significant differences between the treatment group T2 and control, and reference item R and control were observed concerning mortality during this period. On 2DBA3 a statistically significant difference was observed between the treatment group R and control, respectively.
On the day of application (0DAA3) the mean numbers of dead larvae and pupae were very low and similar in all treatment groups.

In the following period of confinement from 1DAA3 to 7DAA3, the mean daily mortality in the test item treatment groups T1 and T2 was not statistically significant higher than in the control. The mean daily mortality in the test reference group R on 7DAA3 and for the period 1DAA3 to 7DAA3 was statistically significant higher than in the control (t-test pooled, one sided, α=0.05).
During the monitoring phase (8DAA3 to 27DAA3) levels of mortality statistically significantly higher in comparison to the control were observed on 10DAA3, 11DAA3, 12DAA3, 13DAA3 and 14DAA3, for the period 8DAA3 to 27DAA3 and 0DAA3 to 27DAA3 in R (t-test pooled, t-test Satterthwaite, Mann Whitney Exact Test, one sided, α=0.05) showing sensitivity of the test organism.
During the entire period after the application A3 (0DAA3 to 27DAA3), the mean daily mortality was in C adapted for T1 and R 0.2, in C adapted for T2 0.2, in T1 0.1, in T2 0.2 and 5.0 in R dead larvae/pupae/colony/day, respectively with no statistically significant differences to the control in T1 and T2.
Overall, no adverse effects on larvae and pupae bee mortality were found for test item treatment T1, an adverse effect during exposure between 5DBA3 to 0DBA3 was observed in test item treatment T2.

Flight intensity

Treatment group		Control (C) adapted for T1 and R	Control (C) adapted for T2	Test item (T1)	Test item (T2)	Reference item (R)
Daily mean flight intensity (bees/m²) ± STD	5DBA3 to 0DBA3	13.8 ± 1.7	14.1 ± 1.8	13.5 ± 1.3	14.6 ± 1.6	12.9 ± 1.3
	0DAA3	18.1 ± 2.8	17.4 ± 2.7	8.2* ± 1.3	11.3* ± 3.0	12.9* ± 1.9
	1DAA3	6.0 ± 5.7	6.0 ± 5.7	9.2 ± 4.9	10.4 ± 2.4	9.2 ± 5.6
	0DAA3 to 7DAA3	11.4 ± 2.7	11.3 ± 2.6	11.1 ± 1.8	12.3 ± 1.4	11.1 ± 1.5

DAA: days after application; DBA: days before application; STD: standard deviation
* Statistically significantly lower than control group

After set-up of the colonies inside the tunnels until the day of the application A3 (5DBA3 to 0DBA3), the mean daily flight intensity was not statistically significant reduced in the test item treatment T1 and T2 when compared to the control during this period.
The mean daily flight intensity after the application (0DAA3) was accounted to 18.1, 17.4, 8.2, 11.3, 12.9 forager bees/m^2, for C adapted to T1 and R, C adapted for T2, T1, T2 and R, respectively. Flight intensity was statistically significant reduced in the treatments T1, T2 and R when compared to the control (t-test pooled, one-sided, $\alpha = 0.05$).

One day after the application (1DAA3), the mean flight intensity assessed on three occasions during the day was not statistically significant reduced in any of the treatments when compared to the control on that day.

On days 2DAA3 and 3DAA3 heavy rainfalls occurred, which reduced significantly flight activity in all tunnels.

Mean post-application flight intensity (0DAA3 to 7DAA3) was not statistically significant reduced in any of the test item treatment when compared to the control.

Overall, a short repellent effect on flight intensity on 0DAA3 was found for test item treatment T1 and T2.

Behavior of bees
Before the exposure phase in the tunnels behaviour abnormalities were observed in all treatments groups on a similar level.

On the day of application A3 no behaviour abnormalities were observed in the control. In the test item treatment T1 36 bees with locomotion problems, 12 cramping bees, 4 inactive bees, 6 hanging bees and one intensive cleaning bee were observed on that day. In the test item treatment T2 9 bees with locomotion problems, 13 inactive bees, 17 hanging bees, one intensive cleaning bee and one trembling bee were observed. On the day of application A3 also in the reference item treatment R behaviour abnormalities were observed: 4 bees with locomotion problems, 57 inactive bees, 2 hanging bees and 3 intensive cleaning bees.

From 1DAA3 to 7DAA3 locomotion problems, trembling, inactive, clustering and cramping bees were observed in all treatments groups including the control, on a similar, low level.

Number of bees behaving abnormal increased slightly during the monitoring phase in comparison to previous phases.

From day 0DAA3 to 27DAA3 304 bees with locomotion problems, 33 cramping and 18 trembling and 60 clustering bees were observed in the control. In the test item groups T1 and T2 the numbers were similar: 192 bees with locomotion problems, 39 cramping and 66 trembling, 4 inactive bees, 6 hanging bees; 80 clustering bees were observed in T1, and 313 bees showing locomotion problems, 70 cramping, 14 inac-

tive, 17 hanging, 6 intensive cleaning, 46 trembling and 69 clustering bees were observed in T2, respectively. In the reference item group 209 bees showing locomotion problems, 32 cramping, 6 inactive, 2 hanging and 7 trembling bees and 4 intensive cleaning bees were observed during this period.

Thereafter, at the end of the study, behaviour was almost comparable to the control.

Development of honeybee brood in individual cells

Summary of the brood and compensation indices and termination rates

Treatment	Brood index / Compensation index at x days after brood area fixing day (BFD)					Termination rate (BFD+21)
	0	+5	+10	+16	+21	[%]
Control	**1.00 / 1.00**	**2.23 / 2.25**	**2.74 / 2.85**	**2.73 / 3.08**	**3.40 / 4.17**	**32.05**
STD	0.00 / 0.00	0.64 / 0.63	1.04 / 0.92	1.05 / 0.59	1.34 / 0.52	26.87
Test item T1	**1.00 / 1.00**	**1.86 / 1.86**	**2.34 / 2.37**	**2.32 / 2.81**	**2.90 / 3.87**	**41.98**
STD	0.00 / 0.00	0.77 / 0.77	1.22 / 1.18	1.24 / 0.68	1.55 / 0.53	30.92
Test item T2	**1.00 / 1.00**	**1.52 / 1.52**	**2.05 / 2.11**	**2.05 / 2.90**	**2.57 / 3.92**	**48.72**
STD	0.00 / 0.00	1.20 / 1.20	1.63 / 1.60	1.63 / 0.83	2.05 / 0.95	40.91
Reference item R	**1.00 / 1.00**	**1.36 / 1.37**	**1.62 / 1.68**	**1.43 / 1.86***	**1.78 / 2.36***	**64.52**
STD	0.00 / 0.00	0.95 / 0.95	1.29 / 1.29	1.14 / 0.72	1.42 / 1.02	28.38

BFD: Brood area fixing day; STD: Standard deviation
*: Statistically significantly lower (compensation indices) compared to the control

In the control group C, successful development was observed in the majority of the marked brood cells. The exception was the colony Cb, which development was impaired probably due to lack of sufficient amount of food at the beginning of the study and cold and rainy weather period, which further affected the flight intensity and amount of stored food. This colony collapsed at the end of the study and from this reason was excluded from the evaluation of brood data. Brood indices and compensation indices in C increased throughout the entire assessment period. At the last assessment (BFD+21), the mean values of the indices in treatment group C were 3.40 (brood index) and 4.17 (compensation index) and the mean termination rate was 32.05 %.

In the test item treatment group T1 the brood and compensation indices increased from 1.00 to 2.90 and 3.87, respectively, on BFD+21. The mean termination rate at the end of the observation period (BFD+21) was at 41.98 %.
In the test item treatment group T2 the brood and compensation indices increased from 1.00 to 2.57 and 3.92, respectively, on BFD+21. The mean termination rate at the end of the observation period (BFD+21) was at 48.72 %.
No statistically significant differences of the brood index, compensation index and termination rate were observed in any of the test item treatments compared to the control at any time (t-test pooled, one-sided, $\alpha = 0.05$).
In the reference item treatment group R, the mean value of the brood index increased from 1.00 to only 1.78, the mean compensation index increased to only 2.36 and the mean termination rate was 64.52 % at the last assessment (BFD+21). The mean compensation indices on assessment days BFD+16 and BFD+21 in treatment group R were statistically significant different from the respective values in the control (t-test pooled, one-sided, $\alpha = 0.05$), which shows sensitivity of the test organisms.

Overall, the quantitative assessments of brood development in individually marked cells revealed no test item treatment-related adverse effect on honeybee brood development.

Strength of colonies
The overall development of colony strength of all treatment groups showed minor fluctuations in a typical and normal range. The colony strength values of the test item group were on approximately the same or higher level than the corresponding values of the control group during the entire study.
Therefore, no test item related adverse effects on colony strength were observed.

Development of the Brood Area
The mean amount of brood in the colonies (sum of cells containing eggs, larvae, and pupae) was assessed. All brood stages were observed in the colonies of all treatment groups.
The mean values of cells containing brood per colony of the test item groups were on approximately the same or higher level than the corresponding values of the control group during the entire study. The number of cells containing brood in the reference item treatment decreased continuously during the entire study indicating an effect on the colony and sensitivity of the test organism.
Therefore, no test item related adverse effects on development of brood were observed.

Development of the food storage area
The mean amount of food stores in the colonies (sum of cells containing nectar and pollen) was assessed. During the exposure phase in the tunnels the amount of food in most of the colonies decreased due to reduced foraging activity caused by heavy rainfalls (on 1DBA3 and 2DAA3). To compensate the lack of food a supplement feeding was conducted on 4DAA3, when each colony was fed with 1 kg sugar syrup (Apiinvert®).
On the following colony assessment, on 8DAA3 (first assessment on the monitoring site), the amount of food increased in all colonies.
A decrease of nectar stores was observed in all colonies on the next colony assessments: 14DAA3 and 19DAA3. To compensate the lack of food and enable further development of the colonies, on 19DAA3, all colonies were fed with 5 L sugar syrup (Apiinvert®).
On the last colony assessment on 29DAA3 the food stores were on similar level in all treatments groups.

Residue analysis
No residues of Lambda-Cyhalothrin were detected at or above the limit of quantification of 0.01 mg/kg in any of the nectar samples from the untreated plot C and the treated plots T1s and T2s.
No residues of Lambda-Cyhalothrin were detected at or above the limit of quantification of 0.01 mg/kg in any of the pollen samples from the untreated group C.
On 2DBA3 no residues of Lambda-Cyhalothrin in pollen from forager bees were detected in T1s (<LOQ). They were on a low level in T2s (0.01 mg/kg). On 1DAA3 (one day after application during bee flight) the highest level of residues was detected in both treated plots T1s and T2s with 0.23 mg/kg in T1s and 0.44 mg/kg in T2s. Within the next three days, the residues strongly decreased and remained on a low level. At the following assessments the residues of Lambda-Cyhalothrin were 0.01 (4DAA3) and 0.02 mg/kg (6DAA3) in T1s and 0.02 (4DAA3) and 0.01 mg/kg (6DAA3) in T2s.

Conclusion

Adverse effects on adult bee mortality were found for both test item treatments T1 and T2 on 1DAA3 and no permanent adverse effects during the monitoring phase after exposure were observed. No adverse effects on larvae and pupae mortality were found for test item treatment T1, a slightly adverse effect during exposure between 5DBA3 to 0DBA3 was observed in test item treatment T2.
A short repellent effect on flight intensity on 0DAA3 was found for test item treatment T1 and T2.
No test item related adverse effects were observed in behaviour of honeybees.
The quantitative assessments of brood development in individually marked cells revealed no test item treatment related adverse effect on honeybee brood development.
No test item related adverse effects on colony strength were observed.
No test item related adverse effects on neither development of brood nor amount of food were observed.
Statistically significant adverse effects of the reference item R on honey bee brood development in individual cells were observed on BFD16 and BFD21 (compensation index). Additionally pupal mortality

was statistically significant higher than in the control on days: 10DAA3, 11DAA3, 12DAA3, 13DAA3 and 14DAA3. Therefore, the performance of the reference item treatment R was considered sufficient for validity of the test. Also the mean brood termination rate for eggs over all replicates in the control group was ≤ 40% (32.05%) at the end of the study.
No residues of Lambda-Cyhalothrin were detected at or above the limit of quantification of 0.01 mg/kg in any of the nectar samples from the untreated plot C and the treated plots T1s and T2s. No residues of Lambda-Cyhalothrin were detected at or above the limit of quantification of 0.01 mg/kg in any of the pollen samples from the untreated plot C. Overall, low residues were detected in T1s and T2s reaching the highest level on 1DAA3 (0.23 mg/kg in T1s and 0.44 mg/kg in T2s). Afterwards the residues strongly decreased and remained on a low level. At the following assessments the residues of Lambda-Cyhalothrin were 0.01 mg/kg (4DAA3) and 0.02 mg/kg (6DAA3) in T1s and 0.02 mg/kg (4DAA3) and 0.03 mg/kg (6DAA3) in T2s.

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

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.

- Mortality of the control group was 0% on day 7 of exposure (criterion: a maximum of 20%),
- Corrected mortality of the mites exposed to the reference item at the rate of 5.0 mL/ha was 100% on day 7 of exposure (criterion: from 50 to 100%),
- The mean number of eggs per female in the control group was 4.23 (required: ≥ 4 eggs per female).

Agreed endpoints:

Study group [application rate]	**Parameter (endpoint)**					
	Mortality			**Reproduction**		
***Test item* [mL/ha]**	**Total [%]**	**LR50**		**Mean no. of mummies/ Female (Rr) [no.]**	**Fecundity reduction Pr [%]**	
	[%]	**Test item [mL/ha]**	**Active ingredient [g/ha]**			**Test item [mL/ha]**
Control (0.0)	**0.0**	**-**		**4.23**	**-**	
	Lambda Cyhalothrin 10% CS					
0.15625	13.33	**0.44**	**0.044**	**4.21**	**0.37**	**>0.625**
0.3125	26.67			**3.69**	**12.70**	
0.625	58.33			**3.54**	**16.29**	
1.25	100					
2.5	100					
5.0	100					
NOER $_{mortality}$		**>0.15625**	**>0.0165265**	**NOER $_{fecundity}$**		**0.625**

Reference:	KCP 10.3.2-01
Report:	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the predatory mite, Typhlodromus pyri (Scheuten)" P. Bala, 2020, 6026/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994), ESCORT 2 (Candolfi M.P. et al., 2001), IOBC, BART, and EPPO Joint Initiative (Blümel S. et al., 2000)
Deviations:	The study finished in November 2019, not in January 2020 as it had been planned. This deviation did not affect the study result.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study was carried out based on the Sponsor recommended rates for the test item as the definite test. There were 0.15625, 0.3125, 0.625, 1.25, 2.5 and 5 mL of the test item/ha. A 24 hours old (protonymphal stage) of predatory mites T. pyri were exposed to the test item applied to discs and fed with pine pollen (Pinussp.) 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, 1 1 and 14 days post treatement of the test item. Mortality of T.pyri after 7 days of the treatment and the reproduction reduction (Pr) after 14 days of the treatment were test endpoints.
To verify the sensitivity of the mites and the precision of the test procedure, the insecticide,
ROGOHIT (30% dimethoate) was used as a reference item. The rate of the reference item was 5.0 mL/ha (1.5 g a.i./ha)

Material and methods

Test item:	Lambda Cyhalothrin 10% CS Batch number: SCL-58261 Content: 9.46% (w/w) Manufacturing date: 06th June, 2019 Expiry date: 05 th June, 2021
Reference item	ROGOHIT, Dimethoate 30% EC, w/w HPM Chemicals & Fertilizer Ltd Production date: 22.06.2018 Expiry date: 21.06.2020
Test organisms:	The predatory mite, Typhlodromus pyri (Sch.) (Acari: Phytoseiidae) Age: 24-hour-old protonymphs
Test design:	- 7 study groups: 5 concentration of test item, control group and reference item - 3 replicates, 20 mites in each replicate
Endpoints:	- mite mortality after 7 days of the treatment - LR50 and $NOER_{mortality}$ - reproduction reduction (Pr) after 14 days of the treatment - ER50 and $NOER_{reproduction}$
Test conditions:	Temperature: 23.0 ± 24.5 0C Relative air humidity: 60 80 %. Photoperiod: 16 h light : 8 h dark, 5400 5890 lux
Statistical analysis:	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

Validity criteria: - mortality of the control group was 0% on day 7 of exposure (criterion: a maximum of 20%),
- corrected mortality of the mites exposed to the reference item at the rate of 5.0 mL/ha was 100% on day 7 of exposure (criterion: from 50 to 100%),
- the mean number of eggs per female in the control group was 4.23 (required: ≥ 4 eggs per female).

Findings

Study group [application rate]	**Parameter (endpoint)**						
	Mortality			**Reproduction**			
***Test item* [mL/ha]**	**Total [%]**	**LR50**		**Mean no. of mummies/ Female (Rr) [no.]**	**Fecundity reduction Pr [%]**	**ER50**	
	[%]	**Test item [mL/ha]**	**Active ingredient [g/ha]**			**Test item [mL/ha]**	**Active ingredient [g/ha]**
Control (0.0)	**0.0**	**-**		**4.23**	**-**	**-**	
Lambda Cyhalothrin 10% CS							
0.15625	13.33	**0.44**	**0.044**	**4.21**	**0.37**	**>0.625**	**>0.0625**
0.3125	26.67			**3.69**	**12.70**		
0.625	58.33			**3.54**	**16.29**		
1.25	100						
2.5	100						
5.0	100						
NOER $_{mortality}$		**>0.15625**	**>0.0165265**	**NOER $_{fecundity}$**		**0.625**	**0.0625**

Comments of zRMS:

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

- mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted) in the control: 6.67% (a criterion: <20 %),
- fecundity (mean number of eggs per female per day) in the control 37.20 (criterion: >15%)
- fertility (mean hatching rate) in the control: 98.67% (criterion: >70%).
- mortality in the reference item treatment was 100% (criterion: >50%).

Agreed endpoints:

Study group [application rate]	Parameter (endpoint)						
	Mortality			Reproduction			
Test item [L/ha]	Total (Corrected) [%]	LR50		Fecundity [no.]	Fecundity reduction [%]	ER50	
	[%]	Test item [L/ha]	Active ingredient [g/ha]			Test item [L/ha]	Active ingredient [g/ha]
Control (0.0)	**6.67 (0)**	-		**37.20**	-	-	
Lambda Cyhalothrin 10% CS							
0.0156	20 (14.29)	**0.0509**	**5.09**	29.80	19.89	**0.0629**	**6.29**
0.0313	36.67 (32.14)			23.30	37.63		
0.0625	60 (57.14)			20.20	45.70		
0.125	80 (78.57)			13.67	63.25		
0.25	93.33 (92.86)			10	73.12		
0.5	100 (100)			0	100		
NOER $_{mortality}$		**0.0156**	**1.56**	**NOER $_{fecundity}$**		**0.0156**	**1.56**

Reference:	KCP 10.3.2-02
Report:	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on on larvae of the green lacewing Chrysoperla carnea (L.)" M. Mohanruj, 2020, 6194/2019/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994), ESCORT 2 (Candolfi M.P. et al., 2001), IOBC, BART, Candolfi M. P. et al., 2001
Deviations:	The study finished in December 2019, not in November 2019 as it had been planned. This deviation did not affect the study result.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study was carried out based on Sponsor recommended rates for the test item as thedefinitivetest, i.e.0.0156, 0.0313, 0.0625, 0.125, 0.25 and 0.5L/ha. Each group was divided into 30 replicates with one larva for mortality assessment and into 10 replicates with one female for fecundity assessment. The 2-3 days oldlarvae were continuously exposed to the test item on the leafs until at least, 5 days after formation of pupae. Direct treatment effects (mortality) and any change in behaviour, with respect to the control, were assessed until the adults emerged. Mortality assessments were carried out just after exposure (ap-

proximately 2 hours) and then, at least three times per week until all have pupated. Pupation and hatching of the adults were recorded. The number of escaped/dead larvae and the number of pupae that fail to develop into adults were combined and the value used to calculate the total juvenile mortality. Reproduction was evaluated with 2 synchronisations of egg laying (24-h periods) in a week to calculate the eggs per female and day (fecundity rate) and the larvae emerging from eggs to calculate the percentage of viable eggs (fertility rate).

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 0.65 L/ha. The control group was treated with distilled water.

Material and methods

Test item:	Lambda Cyhalothrin 10% CS Batch number: SCL-58261 Content: 9.46% (w/w) Manufacturing date: 06th June, 2019 Expiry date: 05 th June, 2021
Reference item	ROGOHIT, Dimethoate 30% EC, w/w HPM Chemicals & Fertilizer Ltd, Batch No.T0023356 Production date: 22.06.2018 Expiry date: 21.06.2020
Test organisms:	Chrysoperla carnea (L.), Neuroptera, Chrysopidae First instar larvae (2-3 days old)
Test design:	- 7 study groups: 5 concentration of test item, control group and reference item - 3 replicates, 20 mites in each replicate
Test conditions:	Temperature: 23.0 - 26.0 0C Relative air humidity: 63-80 %. Photoperiod: 16 h light : 8 h dark, 1250 - 1850 lux
Statistical analysis:	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. The corrected mortality was obtained by comparing the value observed in the treated group with that in the control group, according to the formula of Abbott (1925), modified by Schneider-Orelli (1947).
Validity criteria:	- mortality (dead larvae and pupae and adults dying during emergence or not successfully moulted) in the control: 6.67% (a criterion: <20 %),

- - fecundity (mean number of eggs per female per day) in the control 37.20 (criterion: >15%)
- - fertility (mean hatching rate) in the control: 98.67% (criterion: >70%).
- - mortality in the reference item treatment was 100% (criterion: >50%).

Findings

Study group [application rate]	**Parameter (endpoint)**						
	Mortality			**Reproduction**			
Test item **[L/ha]**	**Total (Corrected) [%]**	**LR50**		**Fecundity [no.]**	**Fecundity reduction [%]**	**ER50**	
	[%]	**Test item [L/ha]**	**Active ingredient [g/ha]**			**Test item [L/ha]**	**Active ingredient [g/ha]**
Control (0.0)	**6.67 (0)**	-		**37.20**	-	-	
Lambda Cyhalothrin 10% CS							
0.0156	20	**0.0509**	**5.09**	29.80	19.89	**0.0629**	**6.29**

	(14.29)						
0.0313	36.67 (32.14)			23.30	37.63		
0.0625	60 (57.14)			20.20	45.70		
0.125	80 (78.57)			13.67	63.25		
0.25	93.33 (92.86)			10	73.12		
0.5	100 (100)			0	100		
NOER $_{mortality}$		**0.0156**	**1.56**	**NOER $_{fecundity}$**		**0.0156**	**1.56**

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

- 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 93.3% (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 27.5 (criterion: a minimum of 5.0 mummies/female)

Agreed endpoints

Study group [application rate]	**Parameter (endpoint)**					
	Mortality			**Reproducti**		
***Test item* [L/ha]**	**Total [%]**	**LR50**		**Mean no of mummies/female [no.]**	**Fecundity reduction [%]**	
	[%]	**Test item [L/ha]**	**Active ingredient [g/ha]**			
Control (0.0)	0	-		27.5	-	
	Lambda Cyhalothrin 10% CS					
0.0039	0	**0.02**	**2**	20.6	25.1	
0,0078	26.7			16.5	40	
0.0156	50			13.8	49.8	
0.0313	80			11.7	57.5	
0.0625	90			6.5	76.4	
0.125	100			3.8	86.2	
NOER $_{mortality}$		**0.0039**	**0.39**	**NOER $_{fecundity}$**		

Reference:	KCP 10.3.2-03
Report:	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the parasitic wasp, Aphidius rhopalosiphi (De StefaniPerez)" G. Sonali, 2019, 6024/2019. Bioscience Research Foundation
Guideline(s):	ESCORT I (Barrett et al., 1994) and the ESCORT 2 (Candolfi M.P. el al., 2001) guid-

	ance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Mead-Briggs M.A. el al., 2000; Mead-Briggs M.A. el al., 2010)
Deviations:	The study finished in September 2019, not in July 2019 as it had been planned. This deviation did not affect the study results
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study was carried out based on Sponsor recommended rates for the test item as the definite test. There were 0.0039, 0.0078, 0.0156, 0.0313, 0.0625 and 0.125 L/ha. Adult female wasps were exposed to the test item applied to bean leaf. Observations of settling behavior were made during the initial 3 hours of exposure. The aims were to determine repellent effects of Lambda Cyhalothrin 10% CS and to check if the test insects had contact with barley plants sprayed with the test item. Settling behavior of females from each replicates was observed five times. Mortality was determined 2, 24 and 48 hours after the release of wasps to the test arenas.

Females, which survived 48-hour exposure to test the 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 Lambda Cyhalothrin 10% 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 hours 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, ROGOHIT (30% dimethoate EC) was used as a reference item.

Material and methods

Test item:	Lambda Cyhalothrin 10% CS Batch number: SCL-58261 Content: 9.46% (w/w) Manufacturing date: 06th June, 2019 Expiry date: 05 th June, 2021
Reference item	ROGOHIT, Dimethoate 30% EC, w/w HPM Chemicals & Fertilizer Ltd, Batch No.T0023356 Production date: 22.06.2018 Expiry date: 21.06.2020
Test organisms:	Aphidius rhopalosiphi (De Stefani-Perez) Age: Larvae (24 - 48 hours after emerging from mummies) Source: BRF Insectary
Test design:	7 study groups: 5 concentration of test item, control group and reference item Duration: 14 days
Test conditions:	Temperature: 18.2–21.3°C Relative air humidity: 62–79% Photoperiod: 16 hours light (5200-5780 lux): 8 hours dark

Statistical analysis: Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviationswere calculated using validated Excel sheets

Validity criteria:
- 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 93.3% (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 27.5 (criterion: a minimum of 5.0 mummies/female)

Findings

Study group [application rate]	**Parameter (endpoint)**						
	Mortality			**Reproduction**			
***Test item* [L/ha]**	**Total [%]**	**LR50**		**Mean no of mummies/female [no.]**	**Fecundity reduction [%]**	**ER50**	
	[%]	**Test item [L/ha]**	**Active ingredient [g/ha]**			**Test item [L/ha]**	**Active ingredient [g/ha]**
Control (0.0)	0	-		27.5	-	-	
Lambda Cyhalothrin 10% CS							
0.0039	0	**0.02**	**2**	20.6	25.1	**0.02**	**2**
0,0078	26.7			16.5	40		
0.0156	50			13.8	49.8		
0.0313	80			11.7	57.5		
0.0625	90			6.5	76.4		
0.125	100			3.8	86.2		
NOER $_{mortality}$		**0.0039**	**0.39**	**NOER $_{fecundity}$**		**<0.0039**	**<0.39**

Comments of zRMS: The study is considered acceptable. All validity criteria were met.
- The mean number of beetles emerging from the fly pupae in the control was 800.00 (a criterion: >400)
- Reduction in reproduction of beetles in the reference group was 91.25 (a criterion: >50%)

Agreed endpoints:

Study group [application rate]	**Parameter (endpoint)**						
	Mortality			**Reproduction**			
***Test item* [L/ha]**	**Total (Corrected) [%]**	**LR50**		**Offspring production [no.]**	**Fecundity reduction [%]**	**ER50**	
	[%]	**Test item [L/ha]**	**Active ingredient [g/ha]**			**Test item [L/ha]**	**Active ingredient [g/ha]**
Control (0.0)	**2.5 (0)**	-		**800**	-	-	

	Lambda Cyhalothrin 10% CS							
	0.0156	3.75 (1.28)	**0.11**	**11**	710	11.25	**>0.0625**	**>6.25**
	0.0313	8.75 (6.41)			600	25.00		
	0.0625	28.75 (26.92)			450	43.75		
	0.125	55 (53.58)			-	-		
	0.25	88.75 (88.46)			-	-		
	0.5	93.75 (93.59)			-	-		
	NOER $_{mortality}$		**0.0313**	**3.13**	**NOER $_{fecundity}$**		**<0.0156**	**<1.56**

Reference:	KCP 10.3.2-04
Report:	"An extended laboratory test for evaluating the effects of Lambda Cyhalothrin 10% CS on the rove beetle, Aleochara bilineala (Gyllenhal)" V. Angayarkanni, 2019, 6195/2019. Bioscience Research Foundation
Guideline(s):	ESCORT 1 (Barrett K.L. et al., 1994) and the ESCORT 2 (Candolfi M.P. et al., 2000) guidance documents and the guidelines developed by the IOBC, BART, and EPPO Joint Initiative (Grimm C. et al., 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary

The study was carried out based on Sponsor recommended rates for the test item as the definitive test, i.e.0.0156, 0.0313, 0.0625, 0.125, 0.25 and 0.5 L/ha. Natural standard soil (type LUFA 2.1) was used as test substrate, whereas raw beetles, Aleochara bilinea/a (Gyllenhal)were used as test organisms. Each group was divided into four replicates. There were20 adult beetles (10 females and 10 males) in each replicate. The duration of the study was 77 days and included the following phases: exposure phase (mortality assessment) — 4 weeks (28 days), drying substrate phase 1 week (7 days) and hatching (production of offspring's) phase (fecundity assessment) — 6 weeks (42 days).After 7,
14 and 21 days post-application, approximately 500 unparasitised onion fly (Deliaantiqua) pupae were added to each test vessel. After 28 days post-application, the remaining parental generation of adults were removed and counted and the soil was left to dry for a further 7 days, after which the soil was sieved to separate the host puparia. Fecundity was assessed daily by counting the number of offspring produced over 42 days. Mortality of the beetles after 28 days of exposure and fecundity after the 6-week period were the 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 1.1 L/ha (330 g dimethoate/ha). The control group was treated with distilled water..

Material and methods

Test item: Lambda Cyhalothrin 10% CS
Batch number: SCL-58261
Content: 9.46% (w/w)
Manufacturing date: 06th June, 2019

	Expiry date: 05 th June, 2021
Reference item	ROGOHIT, Dimethoate 30% EC, w/w HPM Chemicals & Fertilizer Ltd, Batch No.T0023356 Production date: 22.06.2018 Expiry date: 21.06.2020
Test organisms:	Rove beetle, Aleochara bilineala (Gyll) Age: Adult beetles (between 1 to 7 days) Source: BRF Insectary
Test design:	- 7 study groups: 5 concentration of test item, control group and reference item - Number of beetles per replicate/treatment 20 (10 female and 10 male beetles) / 80 (40 female and 40 male beetles) - Feeding: Minced beef ad libitum (supplied every 3 days)
Test conditions:	Temperature: 19.4–20.5°C Relative air humidity: 63–72% Photoperiod: 16 hours light (1550 – 1590 lux): 8 hours dark Test substrate: Natural standard soil (type LUFA 2.1)
Statistical analysis:	Probit analysis in NCSS (Number Cruncher Statistical System) and one-way ANOVA using Graphpad Prism 8.0. The means and standard deviationswere calculated using validated Excel sheets
Validity criteria:	- The mean number of beetles emerging from the fly pupae in the control was 800.00 (a criterion: >400)

- Reduction in reproduction of beetles in the reference group was 91.25 (a criterion: >50%)

Findings

Study group [application rate]	**Parameter (endpoint)**						
	Mortality			**Reproduction**			
Test item **[L/ha]**	**Total (Corrected) [%]**	**LR50**		**Offspring production [no.]**	**Fecundity reduction [%]**	**ER50**	
	[%]	**Test item [L/ha]**	**Active ingredient [g/ha]**			**Test item [L/ha]**	**Active ingredient [g/ha]**
Control (0.0)	**2.5 (0)**	-		**800**	-	-	
Lambda Cyhalothrin 10% CS							
0.0156	3.75 (1.28)	**0.11**	**11**	710	11.25	**>0.0625**	**>6.25**
0.0313	8.75 (6.41)			600	25.00		
0.0625	28.75 (26.92)			450	43.75		
0.125	55 (53.58)			-	-		
0.25	88.75 (88.46)			-	-		
0.5	93.75 (93.59)			-	-		
NOER $_{mortality}$		**0.0313**	**3.13**	**NOER $_{fecundity}$**		**<0.0156**	**<1.56**

Comments of zRMS: The study is considered acceptable. All validity criteria were met.

- Maximum mortality in the control group was 18.0 % (exposure of 56 DAA1).
- Minimum mortality (corrected to control) in the toxic reference was 100.00 % (every exposures).
- Actual minimum value was 6.34 eggs per female (exposure 70 DAA1).

Agreed endpoint:

Lambda cyhalothrin 10% CS Aging residue periods studied: 0, 28, 56, 70 and 84 DAA1 (days after the test item application)		
Rates	13 g lambda cyhalothrin/ha] [0.13 L FP/ha [Lambda cyhalothrin 10% CS]	26 g lambda cyhalothrin/ha] [0.26 L FP/ha [Lambda cyhalothrin 10% CS]
Effects less than 50 % (compared to the control)		
7-d Mortality < 50%	From 56 DAA1 (aged residue for 56 days)	From 70 DAA1 (aged residue for 70 days)
7-14 d Reduction Fecundity < 50%	From 56 DAA1 (aged residue for 56 days)	From 70 DAA1 (aged residue for 70 days)
No significant effects (compared to the control)		
Mortality	From 56 DAA1 (aged residue for 56 days)	Not determined
Fecundity	From 56 DAA1 (aged residue for 56 days)	Not determined

Reference:	KCP 10.3.2-05
Report:	Lambda cyhalothrin 10% CS.Toxicity to the Predatory Mite, *Typhlodromus pyri* Scheuten (Acari, Phytoseiidae) after Exposure to Freshly Applied and Aged Spray Deposits under Extended Laboratory Conditions.
Guideline(s):	IOBC (Blumel *et al.*, 2000) modified, Grimm C. *et al*. (2001), Oomen P.A. (1988) and Pia Ternes *et al*. (2001), Sara Varela., Eurofins Trialcamp S.L.U. Poligon Industrial L'Alter Avda. Antic Regne de Valencia,25 46290 Alcasser (Valencia), Spain
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Test design: Apple trees (*Malus domestica* (Borkh), Rosaceae) were used for trial purposes. Four plots were used with 6 potted trees per plot: one plot for water treated control, one plot for each rate of the test item and one plot for the toxic reference. The treated plot size was 20 m² (10 m x 2 m) for the treatments and the pots were arranged in one crop row (0.5 m between plants).

Application was performed using a compressed air knapsack sprayer and one nozzle "Albuz Hollow Cone Yellow ATR-80" simulating an application in field (volume 800 L/ha), working at pressure of 4 bars and applying the trees outdoors. After application, plants were maintained under outdoor conditions with the use of a translucent roof to cover the crop when it rains to provide natural ageing conditions and to avoid the washing-off by rain. The reference item was applied at the same time as the test item. Moreover, the reference item was applied at each ageing period using a similar method, a compressed air knapsack sprayer; the same 6 pots with apple trees on day 0 were applied with the reference item in 28, 56, 70 and 84 DAA1.

At each ageing period, 5 fragments of leaves from different trees per treatment group were sampled in order to assemble the test units. Then, twenty protonymphs of *Typhlodromus pyri* were introduced into each test unit (5 replicates per treatment). Direct treatment effects (mortality) and any change in behaviour, with respect to the control, were assessed after 1, 3 and 7 days at each exposure. Reproduction was assessed on days 9, 11 and 14 for the control group and for test item groups at each exposure when mortality was below 50 % (corrected to control).

Endpoints: To study the mortality at 7 days after exposure (lethal effect) to residues on leaves for the following periods: 0 (fresh and dry residue) and 28, 56, 70 and 84 days after the test item application (DAA1); actual periods were 0, 28, 56, 70 and 84 DAA1.

To study the fecundity of the survivor females during 7 days following exposure to residues on leaves for the aforementioned ageing periods.

The ageing period of the residue at the tested rates with effects below 50%, relative to the control, was determined.

Test conditions: During the exposures (bioclimatic room):

Temperature:	24.4 – 27.0 ° C
Relative humidity:	73.2 – 94.6 * %
Light regime:	16h light / 8h darkness
Light intensity:	1125 - 1953 lux

*** Relative humidity was registered above 90 % < 2 hours continuously without negative effects in the study. Short-term deviation, not considered as deviation.**

Statistics: Chi²-2x2 Test (0, 28, 56, 70 and 84 DAA1) with mortality (dead + escaped individuals) at 7 d (one-sided greater, $\alpha = 0.05$) were used to detect significant differences between mortality data of the test item and the control groups in the exposures (bioassays) of 0, 28,

56, 70 and 84 DAA1.

At the rate of 13 g a.i./ha mortality was above 50 % in comparison with the control group with fresh and dry residue and at 28 DAA1, therefore reproduction was not performed at 0 and 28 DAA1. At the rate of 26 g a.i./ha mortality was above 50 % in comparison with the control group with fresh and dry residue, at 28 and 56 DAA1, therefore reproduction was not performed at 0, 28 and 56 DAA1. Reproduction was statistically studied in the exposures of 56 and 70 DAA1 with the test item at the rate of 13 g a.i./ha, while it was studied in the exposures of 70 and 84 DAA1 with the test item at the rate of 26 g a.i./ha. At the exposures studied, reproduction data met normality (Shapiro-Wilk's Test) and homoscedasticity (Levene's Test). Therefore, STUDENT-t-test for Homogeneous Variances with cumulative offspring/female at 14 d (one-sided smaller, α = 0.05) was used to detect significant differences between fecundity data of the test item and the control groups.

Dates of work: [Experimental Phase]: 05 Jul 2021 – 11 Oct 2021

Findings:

Exposure of **0 DAA1** (days after the test item application)					
Treatment group	**Rate [g a.i./ha] [a]**	**Mean mortality [b] [%]**	**Corrected mortality [%]**	**Reproduction [eggs/female]**	**Reduction in reproduction rate [%]**
Control (tap water)	---	13.75	--	Not studied	--
Lambda cyhalothrin 10% CS	13	100.00 sd	100.00	Not studied	--
Lambda cyhalothrin 10% CS	26	100.00 sd	100.00	Not studied	--
Dimethoate 40 % w/v EC	184.05	100.00	100.00	Not studied	--

Exposure of **28 DAA1** (days after the test item application)					
Treatment group	**Rate [g a.i./ha] [a]**	**Mean mortality [b] [%]**	**Corrected mortality [%]**	**Reproduction [eggs/female]**	**Reduction in reproduction rate [%]**
Control (tap water)	---	17.00	--	Not studied	--
Lambda cyhalothrin 10% CS	13	100.00 sd	100.00	Not studied	--
Lambda cyhalothrin 10% CS	26	100.00 sd	100.00	Not studied	--
Dimethoate 40 % w/v EC	184.05	100.00	100.00	Not studied	--

[a] Rate in g of active ingredient /ha

[b] "sd": statistically significant increase compared to the control (Chi²-2x2 Test at 0, 28 DAA1, one-sided greater, α = 0.05)

Exposure of **56 DAA1** (days after the test item application)					
Treatment group	**Rate [g a.i./ha] [a]**	**Mean mortality [b] [%]**	**Corrected mortality [%]**	**Reproduction [egga/female]**	**Reduction in reproduction rate [%]**
Control (tap water)	---	18.00	--	6.89	--
Lambda cyhalothrin 10% CS	13	21.00	3.66	5.94	13.75
Lambda cyhalothrin 10% CS	26	69.00 sd	62.20	Not studied	--
Dimethoate 40 % w/v EC	184.05	100.00	100.00	--	--

Exposure of **70 DAA1** (days after the test item application)					
Treatment group	**Rate [g a.i./ha] [a]**	**Mean mortality [b] [%]**	**Corrected mortality [%]**	**Reproduction [c] [egga/female]**	**Reduction in reproduction rate [%]**
Control (tap water)	---	16.00	--	6.34	--
Lambda cyhalothrin 10% CS	13	20.00	4.76	5.56	12.29
Lambda cyhalothrin 10% CS	26	45.00 sd	34.52	3.81 sd	39.87
Dimethoate 40 % w/v EC	184.05	100.00	100.00	--	--

Exposure of **84 DAA1** (days after the test item application)					
Treatment group	**Rate [g a.i./ha] [a]**	**Mean mortality [b] [%]**	**Corrected mortality [%]**	**Reproduction [c] [egga/female]**	**Reduction in reproduction rate [%]**
Control (tap water)	---	9.00	--	6.95	--
Lambda cyhalothrin 10% CS	13	Not studied	--	Not studied	--
Lambda cyhalothrin 10% CS	26	36.00 sd	29.67	4.66 sd	32.97
Dimethoate 40 % w/v EC	184.05	100.00	100.00	--	--

[a] Rate in g of active ingredient /ha

[b] "sd": statistically significant increase compared to the control (Chi²-2x2 Test at 56, 70 and 84 DAA1, one-sided greater, $\alpha = 0.05$)

[c] Negative value means increase in reproduction rate in comparison to the control group

[c] "sd": statistically significant decrease compared to the control (Student-test at 70 and 84 DAA1, one-sided smaller, $\alpha = 0.05$)

In the control group, mortality below 20 % was achieved at every exposure (actual maximum 18.00 % at 56 DAA1) and an acceptable reproductive capacity ≥ 4.0 eggs/female (minimum: 6.34 eggs/female at 70 DAA1) was assessed over a further 7 days of each

Conclusions: All validity criteria were met, and the sensitivity of the test organisms and the test conditions were confirmed: mean mortality below 20% (maximum 18.00 % at 56 DAA1) was achieved 7 days after exposure of the organisms and an acceptable reproductive capacity ≥ 4.00 eggs/female (minimum 6.34 eggs/female at 70 DAA1) was assessed over a further 7 days of each exposure, when performed, in the control groups. The reference item caused above 50 % mortality (corrected relative to control) in the performed exposures of 0, 28, 56, 70 and 84 DAA1 (actual 100 % at every exposures). Accordingly, the study was deemed valid.

Based on the results of this study performed on *Typhlodromus pyri,* after the application of Lambda cyhalothrin 10% CS, it can be concluded that this product, at the rate of 13 g active ingredient (a.i.)/ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 56 days after the test item application (exposure 56 DAA1). The test item at the rate of 26 g active ingredient (a.i.)/ha will not cause mortality greater than 50 % and reduction on reproduction will be less than 50 % from 70 days after the test item application (exposure 70 DAA1).

Lambda cyhalothrin 10% CS Aging residue periods studied: 0, 28, 56, 70 and 84 DAA1 (days after the test item application)		
Rates	13 g lambda cyhalothrin/ha] [0.13 L FP/ha [Lambda cyhalothrin 10% CS]	26 g lambda cyhalothrin/ha] [0.26 L FP/ha [Lambda cyhalothrin 10% CS]
Effects less than 50 % (compared to the control)		
7-d Mortality < 50%	From 56 DAA1 (aged residue for 56 days)	From 70 DAA1 (aged residue for 70 days)
7-14 d Reduction Fecundity < 50%	From 56 DAA1 (aged residue for 56 days)	From 70 DAA1 (aged residue for 70 days)
No significant effects (compared to the control)		
Mortality	From 56 DAA1 (aged residue for 56 days)	Not determined
Fecundity	From 56 DAA1 (aged residue for 56 days)	Not determined

A 2.3.2.3 KCP 10.3.2.3 Semi-field studies with non-target arthropod

A 2.3.2.4 KCP 10.3.2.4 Field studies with non-target arthropods

Comments of zRMS:	The study is not relevant to assess the effect for arable crops.

Reference:	KCP 10.3.2.4
Report	Side-effects of Lambda-cyhalothrin 2.5% WG on predatory mites (Acari: Phytoseiidae) in peach trees under field conditions. Serrano C., 2007, TRC07-21BA.
Guideline(s):	Yes (Blümel *et al*. 2000)
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test item:

Description: lambda cyhalothrin 2.5% WG (code: TF-LC 2.5WG)
Production batch: L0720
Active ingredients content: lambda cyhalothrin 22 g/kg (analysed)

Vehicle and/or positive control: water / Decis (deltamethrin 25 g/L)

Test system:

Species:	Phytoseiid mites, identified as *Euseilus stipulatus* (Athias-Henriot) and *Typhlodromus phialatus* (Athias-Henriot), and prey species *Tetranychus* sp. and *Panonychus ulmi*
Age:	All mobile stages of phytoseiid mites were counted
Number:	The mean number of mites counted was less than 30 per control plot on each sampling occasion although the number of leaves collected for sampling was increased to 75 per sample. Phytoseiid mite density is not high in peach orchards and there is high heterogeneity of distribution.
Location:	A peach (nectarine) orchard in a representative peach growing area near Llombay in Valencia, Spain.
Test conditions:	The field phase took place from 10 July 2007 to 22 August 2007; weather conditions were considered typical for the season in the area. Temperature and precipitation were recorded daily from the nearest meteorological station.

Test conditions:

Treatments:	2 applications with a 14-day interval: 20 g a.s./ha (field rate) and 4.21 g a.s./ha (drift rate)
Control:	water: untreated control
Reference item:	Decis (deltamethrin 25 g/L EC)
Replicates:	5 replicates per treatment in a randomized block design. The plot size was about 63 m^2 (3 trees in the same row) and all were situated in a homogenous single orchard.

Test design:

The short and long-term effects (immediate reduction, persistence of effect, recovery potential) of a Lambda-Cyhalothrin formulation (TF-LC 2.5% WG) on leaf dwelling phytoseiid mite populations were determined under field conditions in a peach (nectarine) orchard. There were two applications of the test and reference items and the water control with a 14-day interval. The test design included 2 application rates for the test item treatment (maximum application rate of 20 g as/ha and drift rate of 4.21 g as/ha), a reference item treatment (Deltamethrin 25 g/L EC at 12.5 g as/ha) and a water control. There were 5 replicate plots per treatment, with three trees arranged in the same row per plot. Leaves were sampled randomly and the number of phytoseiid mites and prey were directly counted using a magnifying glass. The assessments were performed before treatment and 0, 7 and 14 days after the first application (DAA) and 7, 14, 22 and 29 days after the second application (DAB). The reduction of phytoseiid mite population was evaluated and compared to the control.
75 leaves were collected randomly from each plot, selected from all over the tree and in the middle zone of the shoots for each plot. Phytoseiid and prey mites were counted directly usin a magnifying glass.

Statistics:

For each treatment, a statistical analysis of the homogeneity and normality of replicate results was made using Bartlett's and Kolmogoroff-Smirnov's test procedures. Normality of replicate results was obtained for both variables in all the assessments. In some assessments, homogeneity was not obtained and data were transformed.
In the cases of normally distributed and homogenous data, an ANOVA was performed for each assessment and Dunnett's multiple *t*-test was applied (α =0.05, one-sided) to attribute significant differences to treatment. To obtain differences between two treatments, a Student-Newman-Keuls test was used. In other cases, the nonparametric Friedman χ^2 test was performed (ARM 7.3 © Gylling Data Management, Inc (1982-2007).

Results

The density of phytoseiid mites in the control treatment was consistent throughout the study. Mean numbers ranged from 15 to 21 mites per treatment on 75 leaves.
The 20 g as/ha test item treatment rate showed a significant and consistent reduction of phytoseiid mite numbers compared to the control, from 7 DAA to 36 DAA/22 DAB. The reduction was about 50-60%. Population recovery was observed 29 days after the second application (29 DAB) when there were no significant differences between field-rate treated and control plots.
The drift rate test item treatment, 4.21 g as/ha, showed a significant reduction in phytoseiid numbers (less than 45% of control numbers) until 7 DAB but the population showed a recovery 14 days after the second application when there were no significant differences between treated and control plots.
In the reference item treatment, numbers of phytoseiid mites were found to be more than 50% lower than the controls from the 7 DAA sampling occasion until 36DAA. This confirms that the test system and the study site were adequate for the study requirements. Populations in the reference item treatment had recovered on the final sampling occasion of the study, 43 DAA. The results as reduction percentage compared to the water control are shown in Table 1 below.

Table 1: Number of individuals per sample (27 leaves) on each sampling occasion

Sampling Date				**11Jul07**		**18Jul07**		**25Jul07**		**1Aug07**		**8Aug07**		**16Aug07**		**23Aug07**	
Days After First/Last Application				**0 0**		**7 7**		**14 0**		**21 7**		**28 14**		**36 22**		**43 29**	
Trt	Treatment		Rate														
No.	Name	Rate	Unit	△		△		△		△		▲		△		△	
1	Untreated control			20.8	a	21.4	a	21.2	a	14.8	a	17.2		19.6	a	20.6	a
2	Lambda-Cyhalothrin	20	g as/ha	17.6	a	11.0	b	10.0	b	7.6	b	6.0		8.2	b	13.6	a
						(49%)		(53%)		(49%)		(65%)		(58%)		(34%)	
3	Lambda-Cyhalothrin	4.21	g as/ha	20.0	a	16.0	a	12.2	b	9.6	b	11.0		16.0	a	22.6	a
						(25%)		(42%)		(35%)		(36%)		(18%)		(-10%)	
4	Deltamethrin	12.5	g as/ha	22.4	a	8.4	b	8.2	b	7.0	b	7.4		9.2	b	22.0	a
						(61%)		(61%)		(53%)		(57%)		(53%)		(-7%)	

Means followed by same letter do not significantly differ:
△: Mean comparisons performed only when ANOVA Treatment P (F) is significant at mean comparison OSL (P=.05, Dunnett's vs. Control).
▲ Data did not show homogeneity of variance before and after transformation. Mean comparisons were performed with Friedman χ^2 showing a significant difference between at least one of the treatments compared with the others.

Conclusion

The test item, lambda-cyhalothrin 2.5% WG, applied at a field rate of 20 g a.s./ha and a drift rate of 4.2 g a.s./ha caused reductions in populations of phytoseiid mites when compared to the control after the first and second applications. Recovery was observed in the drift rate 14 days after the second application and in the field rate, 29 days after the second application.

It can therefore be concluded that two applications of lambda-cyhalothrin 2.5% WG, applied at field and drift rates (20 and 4.2 g a.s./ha respectively) are not expected to cause long-term reductions in phytoseiid mite populations.

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

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

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:	The study is considered acceptable. All validity criteria were met. • The test results were evaluated based on the difference between treated and control samples and the difference should be within ± 25% (average value) on each interval of analysis. The variation between results of replicate control samples should be within ± 15%9 ranged from 2.97-3.16%). **Agreed endpoints:** After 28 days of incubation, the lowest treatment group deviated by 1.22% and highest treatment group deviated by 3.35% from the control with respect to the nitrate content. Based on the experiment results, it can be concluded that the test item, Lambda Cyhalothrin 10% CS does not have long-term influence on nitrogen transformation in the soil microorganisms

Reference:	KCP 10.5.1
Report:	"Soil Microorganisms: Nitrogen Transformation Test of Lambda Cyhalothrin 10%CS". Anand H.S., 2019, G13389. Analytical R & D Department Eurofins Advinus Limited
Guideline(s):	OECD Guideline No. 216 (2000)
Deviations:	Exception: As per the sponsor's requirement, the predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the active substances with the mobility in soil Kfoc> 500 mL/g, instead of 5 cm soil depth.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary
The study on "Soil Microorganisms: Nitrogen Transformation Test of Lambda Cyhalothrin 10% CS" was Sponsored by Sharda Cropchem Limited, 2nd Floor, Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West) Mumbai - 400056, India. The test item, Lambda Cyhalothrin 10% CS was supplied by the Sponsor. 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 ± 2 0 C for 28 days and the average recorded maximum and minimum temperatures were 20.2 0 C and 19.9 0 C, respectively. The application rates of test item were control (only Milli-Q water), low concentration level of 3.524 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 0.333 mg a.s./kg dry weight of soil and high concentration level of 17.620 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 1.67 mg a.s./kg dry weight of soil. The soil treated with test item and untreated (control) were incubated and sampled for analysis after 0, 7, 14 and 28 days of incubation. The test was carried out in the dark at temperature of 20 ± 2°C.
The variations between results of replicate control samples were within ± 15%. After 28 days of incubation, the lowest treatment group deviated by 1.22% and highest treatment group deviated by 3.35% from control with respect to nitrate formation rates which was below the threshold value of < 25%. Hence, the experiment was concluded after 28 days incubation.
Based on the experimental results, it can be concluded that the test item, Lambda Cyhalothrin 10% CS does not have long-term influence on nitrogen transformation in soil microorganisms.
Material and methods

Test item:	Name: Lambda Cyhalothrin 10% CS Batch number: SCL-89123 Content: 100 g/L (9.46 % (w/w)) Production date: April, 6th, 2017 Expiry date: April, 5th,, 2019
Test design:	Sieved soil was amended with powdered Lucerne plant meal and treated with the test item and untreated (control) are incubated and sampled for analysis on 0, 7, 14 and 28 days of incubation. The samples of treated and control soils were extracted with an extractant and the quantities of nitrate in the extracts were determined. The rate of nitrate formation in the treated soil samples was compared with rate in control and the percent deviation of the treated from the control was calculated.
Test medium:	Soil collected on 26th of November 2018 from Agro-Forestry Division, Dry Land Research Centre, GKVK, Bengaluru, Karnataka state. Soil Samples were collected from a depth of about 20 cm from the site where no organic fertilizer was used for the past 6 months before collection. The soil was pre-incubated in the dark in BOD incubator for 4 days at the test temperature of 20 ± 2ºC and the moisture content of the soil was maintained at about 40% of the maximum water holding capacity by adding the Milli-Q water. The soil was amended with a suitable organic substrate, e.g., powdered Lucerne grass meal (alfa-alfa) with a C / N ratio 13/1. Lucerne-soil ratio was 5 g of powdered Lucerne-grass meal per kilogram of soil (dry weight).
Endpoints:	The mean nitrate formation 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.
Test concentration:	Two concentrations of test item were used for the study – lower: 3.524 mg f.p./kg dw (corresponding to 0.333 mg a.s./kg dw) and higher: 17.620 mg f.p./kg dw (corresponding to 1.67 mg a.s./kg dw).
Test conditions:	Temperature: 20.0 ± 2.0°C, soil moisture: about 50% of the maximum water holding capacity of the soil with a range of ± 5 % Ilumination: incubation in darkness
Statistical analysis:	The statistical analysis of the experimental data of day 28 was carried out using licensed copies of SYSTAT Statistical Package Ver. 12.0. The variable (CO2, mg/kg dry weight of soil/h) was tested using ANOVA. Comparison of means between treatment groups and control group was done using F-test.
Validity criteria:	The test results were evaluated based on the difference between treated and control samples and the difference should be within ± 25% (average value) on each interval of analysis. The variation between results of replicate control samples should be within ± 15%

Findings

After 28 days of incubation, the lowest treatment group deviated by 1.22% and highest treatment group deviated by 3.35% from the control with respect to the nitrate content.

Sampling interval (Day)	Sample	Mean nitrate content [mg/kg/day]	% deviation from the control
0	Control	90.13	-
	Lower concentration	92.98	3.16
	Higher concentration	92.81	2.97
7	Control	13.41	-
	Lower concentration	13.67	1.94
	Higher concentration	13.84	3.21
14	Control	6.33	-
	Lower concentration	6.64	4.90

	Higher concentration	6.53	3.16
28	Control	3.28	-
	Lower concentration	3.32	1.22
	Higher concentration	3.39	3.35

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 ± 2 0 C for 28 days and the average recorded maximum and minimum temperatures were 20.2 0C and 19.9 0 C, respectively. The results of the measurement of nitrate content for control (soil treated with Milli-Q water), low concentration level of 3.524 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 0.333 mg a.s./kg dry weight of soil and high concentration level of 17.620 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 1.67 mg a.s./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 1.22% and highest treatment group deviated by 3.35% from the control with respect to the nitrate content.
Based on the experiment results, it can be concluded that the test item, Lambda Cyhalothrin 10% CS does not have long-term influence on nitrogen transformation in the soil microorganisms.

Comments of zRMS:	The study is not used in the risk assessment.

Reference:	KCP 10.5.2
Report:	"Soil Microorganisms: Carbon Transformation Test of Lambda Cyhalothrin 10% Cs". Anand H.S, 2019, G13388. Analytical R & D Department Eurofins Advinus Limited
Guideline(s):	OECD Guideline No. 217 (2000)
Deviations:	Exception: As per the sponsor's requirement, the predicted environmental concentration (PEC) was calculated assuming 1 cm of the soil depth according to the German conditions for the active substances with the mobility in soil Kfoc> 500 mL/g, instead of 5 cm soil depth.
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study):	No

Summary
The study on "Soil Microorganisms: Carbon Transformation Test of Lambda Cyhalothrin 10% CS" was Sponsored by Sharda Cropchem Limited, 2nd Floor, Prime Business Park, Dashrathlal Joshi Road, Vile Parle (West)Mumbai - 400056, India. The test item, Lambda Cyhalothrin 10% CS was supplied by the Sponsor. 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 ±2 0 C for 28 days and the average recorded maximum and minimum temperatures were 20.2 0 C and 19.9 0 C, respectively. The application rates of test item were control (only Milli-Q water), low concentration level of 3.524 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 0.333 mg a.s./kg dry weight of soil and high concentration level of 17.620 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 1.67 mg a.s./kg dry weight of soil. The soil treated with test item and untreated (control) were incubated and sampled for analysis after 0, 7, 14 and 28 days of incubation. The test was carried out in the dark at temperature of 20 ± 2°C.
The variations between results of replicate control samples were within ± 15%. After 28 days of incubation, the lowest treatment group deviated by 4.24% and highest treatment group deviated by 9.42% 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 incubation.

Based on the experiment results, it can be concluded that the test item, Lambda Cyhalothrin 10% CS was not having long-term influence on carbon transformation in soil microorganisms.

Material and methods

Test item: Name: Lambda Cyhalothrin 10% CS
Batch number: SCL-89123
Content: 100 g/L (9.46 % (w/w))
Production date: April, 6th, 2017
Expiry date: April, 5th,, 2019

Test design: Sieved treated and untreated (control) soil samples were incubated and sampled for analysis, on 0, 7, 14 and 28 days of incubation. The samples of treated and control soils were mixed with glucose and glucose induced respiration rates were measured. Three replicates for each of the both treated and untreated soils were taken (each containing 25 g, dry weight). The soil samples were incubated as a series of individual (for each sampling interval) flasks (each containing 25 g (dry weight) for samplings up to 28 days and for samples beyond 28 days, soil samples were incubated in bulk. The test item was applied using Milli-Q water as carrier. The mean respiration rate in the treated soil samples was compared with that in control and the percent deviation of the treated from the control was calculated. All tests run for 28 days and differences between treated and untreated soils were less than 25 % measurements and hence, experiment was concluded after 28 days of incubation.

Test medium: Soil collected on 26th of November 2018 from Agro-Forestry Division, Dry Land Research Centre, GKVK, Bengaluru, Karnataka state. Soil Samples were collected from a depth of about 20 cm from the site where no organic fertilizer was used for the past 6 months before collection. The soil was pre-incubated in the dark in BOD incubator for 3 days at the test temperature of 20 ± 2^{o}C and the moisture content of the soil was maintained at about 40% of the maximum water holding capacity by adding the Milli-Q water.

Endpoints: The mean 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.

Test concentration: Two concentrations of test item were used for the study – lower: 3.524 mg f.p./kg dw (corresponding to 0.333 mg a.s./kg dw) and higher: 17.620 mg f.p./kg dw (corresponding to 1.67 mg a.s./kg dw).

Test conditions: Temperature: 20.0 ± 2.0°C,
soil moisture: about 50% of the maximum water holding capacity of the soil with a range of ± 5 %
Ilumination: incubation in darkness

Statistical analysis: The statistical analysis of the experimental data of day 28 was carried out using licensed copies of SYSTAT Statistical Package Ver. 12.0. The variable (CO2, mg/kg dry weight of soil/h) was tested using ANOVA. Comparison of means between treatment groups and control group was done using F-test.

Validity criteria: The test results were evaluated based on the difference between treated and control samples and the difference should be within ± 25% (average value) on each interval of analysis. The variation between results of replicate control samples should be within ± 15%

Findings

The calculated % deviations in the glucose induced respiration rates (i.e., carbon dioxide released rates) between treated and control are summarized in Table 15 and which was < 25%.

After 28 days of incubation, the lowest treatment group deviated by 4.24% and highest treatment group deviated by 9.42% from control with respect to the glucose induced respiration rates (carbon dioxide released rates).

Sampling interval (Day)	Sample	Mean glucose induced respiration rate	% deviation from the control

		[mg/kg/h]	
0	Control	75.76	-
	Lower concentration	85.28	12.56
	Higher concentration	89.33	17.91
7	Control	74.20	-
	Lower concentration	81.16	9.39
	Higher concentration	84.39	13.73
14	Control	88.19	-
	Lower concentration	87.81	-0.43
	Higher concentration	89.24	1.19
28	Control	75.37	-
	Lower concentration	78.57	4.24
	Higher concentration	82.48	9.42

Conclusions

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 ±2 0C for 28 days and the average recorded maximum and minimum temperatures were 20.2 0 C and 19.9 0 C, respectively. The application rates of test item were control (only Milli-Q water), low concentration level of 3.524 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 0.333 mg a.s./kg dry weight of soil and high concentration level of 17.620 mg test item/kg dry weight of soil and as Lambda Cyhalothrin: 1.67 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 4.24% and highest treatment group deviated by 9.42% 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 incubation.

Based on the experiment results, it can be concluded that the test item, Lambda Cyhalothrin 10% CS was not having long-term influence on carbon 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

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data