

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 3600 B

Product name(s): LABAMBA

Chemical active substance:

Lambda cyhalothrin, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L

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When	What
March 2022	Assessment by expert
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6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 3600 B / LABAMBS A

Product name and code	SHA 3600 B / LABAMBSA
Formulation type	Capsule Suspension (CS)
Active substance(s) (incl. content)	Lambda cyhalothrin 100 g/L
Function	insecticide
Product already evaluated as the 'representative formulation' during the approval of the active substance(s)	No
Product previously evaluated in another MS according to Uniform Principles	No

* Information on the detailed composition of LABAMBS can be found in the confidential dRR Part C.

Justified proposals for classification and labelling

According to the criteria given in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008, the following classification and labelling with regard to toxicological data is proposed for the preparation:

Table 6.1-2: Justified proposals for classification and labelling SHA 3600 B / LABAMBS according to Regulation (EC) No 1272/2008

Hazard class(es), categories:	Acute Tox., 4, Skin Sens. 1
Hazard pictograms or Code(s) for hazard pictogram(s):	GHS07
Signal word:	Warning
Hazard statement(s):	H302, H317
Precautionary statement(s):	P261, P270, P280, P333+P313, P362+P364, P501
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]

Table 6.1-3: Summary of risk assessment for operators, workers, bystanders and residents for SHA 3600 B / LABAMBS

	Result	PPE / Risk mitigation measures
Operators	Acceptable	Work wear (arms, body and legs covered) + gloves M/L
Workers	Acceptable	None: for Cereals and Oilseed Gloves: for Brassicas, Tomato
Residents	Acceptable	Buffer zone 2-3 m – Brassicas, Tomato, Cereals and Oilseed

No unacceptable risk for operators, workers and resident was identified when the product is used as intended and provided that the PPE stated in Table 6.1-3 are applied.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and bystanders/residents is presented in the following table.

Table 6.1-4 Critical uses and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn, G, Gn, Gpn or I**	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, bystander or resident exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique ***)	Max. number (min. interval between applications) a) per use b) per crop/season	Max. application rate kg as/ha	Water L/ha min / max			Operator	Worker	Bystander	Residents
1, 2	Brassicas (cabbage, Brussels sprouts, cauliflower) BBCH 11-43	F	LC TM	a) 1 b) 1	a) 0.0075 b) 0.0075	200-600	3 (cabbage), 7 (Brussels sprouts, cauliflower)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
3,4	Tomato BBCH 51-85	F,G	LC TM	a) 1 b) 1	a) 0.0075 b) 0.0075	300-1000	3					
5	Winter cereals (wheat, barley, rye, oats, triticale) BBCH 41-75	F	LC TM	a) 1	a) 0.0075 b) 0.0075	200-400	28					
6,7,8,9	Winter Oilseed rape BBCH 50-59	F	LC TM	a) 1	a) 0.0075 b) 0.0075	200-600	35					

* 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

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable/ Evaluation not possible

6.2 Toxicological Information on Active Substance(s)

Information regarding classification of the active substances and on EU endpoints and critical areas of concern identified during the EU review are given in Table 6.2-1.

Table 6.2-1: Information on active substance(s)

lambda-cyhalothrin	
Common Name	lambda-cyhalothrin
CAS-No.	91465-08-6
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	Hazard classes (s), categories: Acute Tox. 3, Acute Tox. 4, Acute Tox. 2 Code(s) for hazard pictogram(s): GHS06, GHS07 Signal word: Danger Hazard statement(s): H301, H312, H330

	lambda-cyhalothrin
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.00063 mg/kg bw/d
Reference	EFSA Journal 2014;12(5):3677 SANCO/12282/2014 Rev 4 11 December 2015
Conditions to take into account/critical areas of concern with regard to toxicology	
Review Report/EFSA Conclusion for active substance	Personal protective equipment (PPE) during mixing and loading (and during application) have to be considered to ensure that operator exposure does not exceed the AOEL.

6.3 Toxicological Evaluation of Plant Protection Product

A summary of the toxicological evaluation for SHA 3600 B / LABAMBS is given in the following tables. Full summaries of studies on the product that have not been previously considered within an EU peer review process are described in detail in Appendix 2.

Table 6.3-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for SHA 3600 B / LABAMBA S

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (calculation)	994 mg/kg bw	Yes	Acute Tox., 4, H302	Calculated
LD ₅₀ dermal, rat (calculation)	> 2000 mg/kg bw	Yes	None	Calculated
LC ₅₀ inhalation, rat (OECD 403)	>2.42 mg/L air	Yes	None	xxxxxxxxxxxxx., 2019
Skin irritation, rabbits (calculation)	Non-irritant	Yes	None	Calculated
Eye irritation, rabbits (calculation)	Non-irritant	Yes	None	Calculated
Skin sensitisation, guinea pigs (calculation)	Sensitising	Yes	Skin Sens. 1, H317	Calculated
Supplementary studies for combinations of plant protection products	not required		-	-

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 3600 B / LABAMBA S

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
Toxicological properties of active substance(s) (relevant for classification of product)	lambda cyhalothrin (10 % (w/w))	H301, H312, H330	Reg. 1272/2008	H302, H317
Toxicological properties of	-	-	-	-

	Substance (Concentration in product, % w/w)	Classification of the substance (acc. to the criteria in Reg. 1272/2008)	Reference	Classification of product (acc. to the criteria in Reg. 1272/2008)
non-active substance(s) (relevant for classification of product)				
Further toxicological information	No data – not required			

* Please use concentration range or concentration limit (e.g. 1-10 % or > 1 %) as provided in MSDS.

** Material safety data sheet by the applicant

6.4 Toxicological Evaluation of Groundwater Metabolites

All metabolite concentrations are predicted to stay below 0.1µg/L – no groundwater assessment is required.

6.5 Dermal Absorption (KCP 7.3)

A summary of the dermal absorption rates for the active substances in SHA 3600 B / LABAMBS are presented in the following table.

Table 6.5-1: Dermal absorption rates for active substances in SHA 3600 B / LABAMBA S

	Lambda cyhalothrin	
	Value	Reference
Concentrate	25%	EFSA Journal 2014;12(5):3677
Dilution	25%	EFSA Journal 2014;12(5):3677

6.5.1 Justification for proposed values – lambda-cyhalothrin

According to the RAR, in the absence of dermal absorption data of the formulation a default values. However, the Log Pow is 5.5 and the molecular weight is 449.9 g/mol, which is very close to where a dermal absorption of 10% can also be considered according to the guidance for dermal absorption (i.e. for substances with Log Pow >4 and MW > 500). This in addition to the known low absorption for lambda-cyhalothrin suggests that 10% is sufficient as default to be used in the exposure estimations, in absence of product specific data.

However on Pesticides Peer Review Meeting 108 (20-22 November 2013) experts agreed to use the default 25% value for the concentrate as recommended in the guidance, supported by the oral absorption value of 25%.

Considering the value of the oral absorption used to derive the AOEL, it was agreed to reduce the dermal absorption value to 25%. The majority of the experts agreed with a value of 25%, while a minority agreed with a value of 75%.

In conclusion, the agreed dermal absorption values are 25% for both the dilution and the concentrate for all the representative formulations.

Therefore, the percentage absorptions used in the human exposure assessment for lambda cyhalothrin, are taken from the EU Endpoints.

6.6 Exposure Assessment of Plant Protection Product (KCP 7.2)

Table 6.6-1: Product information and toxicological reference values used for exposure assessment

Product name and code	SHA 3600 B / LABAMBA A S
Formulation type	CS
Category	Insecticide
Active substance(s) (incl. content)	Lambda cyhalothrin 100 g/l
AOEL systemic	0.00063 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	25 %
Dermal absorption	Concentrate: 25% Dilution: 25 %

6.6.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 6.1-4. A list of all intended uses within the CEU-zone is given in Part B, Section 0.

Justification

Critical GAPs used are the one with the most conservative values regarding risk assessment for each crops.

6.6.2 Operator exposure (KCP 7.2.1)

6.6.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substances during application of SHA 3600 B / LABAMBS according to the critical use(s) is presented in Table 6.6-2. Outcome of the estimation is presented in

Table 6.6-3. Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Brassicas, Tomato, Oilseed rape, Cereals (max. 0.075/kg product/ha)
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015 ECPA Greenhouse model

Table 6.6-3: Estimated operator exposure

Model data		Level of PPE	lambda-cyhalothrin	
			Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to low crops (Brassicas, Tomato, Oilseed rape, Cereals)				
Application rate		0.0075 kg a.s./ha		
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered)	0.0174754	2774	
	Work wear (arms, body and legs covered) + gloves M/L	0.0004964	79	
Greenhouse application outdoors to tomato				
Application rate		0.0075 kg a.s./ha		
Greenhouse (ECPA; 75 th percentile) Body weight: 60 kg	None PPE during mix/loading and application	0.00026	42	

According to the AOEM model, calculations, it can be concluded that the risk for the operator using LABAMBA is acceptable for Brassicas, Tomato, Oilseed rape, Cereals with the use of gloves and work wear during mixing/loading using tractor mounted boom spray application outdoors

Implication for labelling: P280: Wear protective gloves/protective clothing.

6.6.3 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.4 Worker exposure (KCP 7.2.3)

6.6.4.1 Estimation of worker exposure

Table 6.6-4 shows the exposure model(s) used for estimation of worker exposure after entry into a previously treated area or handling a crop treated with SHA 3600 B / LABAMBS according to the critical use(s). Outcome of the estimation is presented in Table 6.6-5. Detailed calculations are in Appendix 3.

Table 6.6-4: Exposure models for intended uses

Critical use(s)	Brassicas, Tomato, Oilseed rape, Cereals (max. 0.075/kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015

Table 6.6-5: Estimated worker exposure

		lambda-cyhalothrin	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Cereals, Oilseed rape			
Inspection, irrigation/Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.0075 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.0023438	372
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0002625	42
Brassicas, Tomato			
Reaching, picking/ Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.0075 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0043500	690
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0018750	298
	Work wear (arms, body and legs covered) + gloves TC: 580 cm ² /person/h	0.0004350	69
Tomato			
Reaching, picking/ Indoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.0075 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0043500	690
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0018750	298

	Work wear (arms, body and legs covered) + gloves TC: 580 cm ² /person/h	0.0004350	69
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It is concluded that there is no unacceptable risk anticipated for the worker wearing with Work wear (arms, body and legs covered) + gloves for maintenance activities when for re-entering stone lambda cyhalothrin 10% CS.

Workers working in cereals and oilseed rape must wear work wear only, while workers working in brassica vegetables and fruiting vegetables have to wear work wear and gloves

6.6.4.2 Refinement of generic DFR value (KCP 7.2)

If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² (30 mg a.s./m²).

6.6.4.3 Measurement of worker exposure

Since the worker exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) will not be exceeded under conditions of intended uses and considering above mention PPE, a study to provide measurements of worker exposure was not necessary and was therefore not performed.

6.6.5 Bystander and resident exposure (KCP 7.2.2)

6.6.5.1 Estimation of bystander and resident exposure

Table 6.6-6 shows the exposure model(s) used for estimation of bystander and resident exposure to lambda-cyhalothrin. Outcome of the estimation is presented in Table 6.6-7. Detailed calculations are in Appendix 3.

Table 6.6-6: Exposure models for intended uses

Critical use(s)	Brassicac, Tomato, Oilseed rape, Cereals (max. 0.075/kg product/ha)
Model	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874 calculator version: 30/03/2015.

Table 6.6-7: Estimated resident exposure

		lambda-cyhalothrin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to Brassicac, Tomato, Oilseed rape, Cereals Buffer zone: 5 m Drift reduction technology: yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha			

Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.0075 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0000839	13.32
	Vapour (75 th perc.)	0.0010700	169.84
	Deposits (75 th perc.)	0.0000059	0.94
	Re-entry (75 th perc.)	0.0003164	50.22
	Sum (mean)	0.0013730	217.94
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0000153	2.42
	Vapour (75 th perc.)	0.0002300	36.51
	Deposits (75 th perc.)	0.0000026	0.42
	Re-entry (75 th perc.)	0.0001758	27.90
	Sum (mean)	0.0003801	60.33

Refinement

The Applicant propose refinement for volatilization:

It is assumed that the human is exposed to air containing the active substance at its saturated vapour concentration (SVC). This represents a worst-case as the active substance cannot achieve a higher concentration in the air ¹².

$$SVC = \frac{mw[g/mol] * [Pa]}{R[Jmol^{-1} K^{-1}] * T[K]} = 0.41 * mw * vp$$

Where:

- SVC Saturated vapour concentration (mg as/m³)
- vp Vapour pressure of active substance (Pa)
- mw Molecular weight (g/mol)
- R Gas constant (J/K*mol)
- T Ambient temperature (K)

Saturated vapour concentration is calculated as:

$$SVC = 0.41 * \text{Molecular weight (g/mol)} * \text{Vapour pressure (Pa)}$$

$$SVC = 0.41 * 449.9 \text{ g/mol} * 2 * 10^{-7} \text{ Pa}$$

$$SVC = 0.00004 \text{ mg/m}$$

1-3 year old children:

$$\text{Vapour exposure} = d_AirCon * d_BreathRCh * d_BwChild ***$$

¹ Assessment of Inhalation Exposure of Volatilised Biocide Active Substance

² Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C)

*** According EFSA Journal 2022;20(1):7032 (Guidance on the assessment of exposure of operators, workers, residents and bystanders)

Where:

d_AirCon - 0.00004 mg/m³ (vapour concentration)
 d_BreathRCh - 1.07 m³/day/kg (breathing rate child)
 d_BwChild - 10 kg (body weight)

Vapour exposure: $0.00004 \times 1.07 \times 10 = 0.00428$ mg a.s./day
 $= 0.0000428$ mg a.s./kg bw/day = 6.79 %AOEL

Table 7.4.1-4: Refined estimated child resident exposure (longer term exposure)

Tractor mounted boom spray application outdoors to Brassicas, Tomato, Oilseed rape, Cereals Buffer zone: 2-3m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 365 days			
Number of applications and application rate		1 x 0.0075 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0002522	40.03
	Vapour (75 th perc.)	0.0000428	6.79
	Deposits (75 th perc.)	0.0000288	4.58
	Re-entry (75 th perc.)	0.0003164	50.22
	Sum (mean)	0.0004546	72.15

It can be concluded that there is no undue risk to any resident/bystander (child & adult) after accidental short-term exposure nor to any resident exposure to LABAMBA (Lambda-cyhalothrin 10% CS). Buffer zone 2-3m.

6.6.5.2 Measurement of bystander and/or resident exposure

Since the bystander and/or resident exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) for lambda cyhalothrin will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of bystander/resident exposure was not necessary and was therefore not performed.

6.6.6 Combined exposure

Not relevant. The product contains only one active substance.

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 7.1.3	xxxxxxxxxxxxxxxx	2019	“Acute inhalation toxicity study of lambda cyhalothrin 10% CS in rats” xxxxxxxxxxxxxxxx, n° G13185 GLP, Unpublished	Y	SHARDA Cropchem Ltd.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the studies relied upon

A 2.1 Statement on bridging possibilities

Comments of zRMS:	Comment on statement; acceptable or not
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A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	The acute oral toxicity of Lambda-cyhalothrin 10% CS was estimated to be 994 mg/kg (Considering the worst case with the harmonized classification of Lambda-cyhalothrin). According to the Regulation EC No. 1272/2008, Lambda cyhalothrin 10% CS is classified Acute Tox.4/H302
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The classification of LABAMBS (Lambda cyhalothrin 10% CS) was performed by calculation. The assessment of all acute toxicological properties of Lambda cyhalothrin 10% CS are derived from the classification of the active compound and co-formulants. For obvious confidentiality reasons, the names and percentages of co-formulants are dis-closed in Part C.

The acute oral toxicity classification for Lambda cyhalothrin 10% CS was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{10.00\%}{100} + \frac{XXX\%}{500} + \frac{XXX\%}{500} + \frac{XXX\%}{670}} = 994 \frac{mg}{kg}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Lambda cyhalothrin 10% CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

The acute oral toxicity of Lambda-cyhalothrin 10% CS was estimated to be 994 mg/kg (Considering the worst case with the harmonized classification of Lambda-cyhalothrin). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is classified as acute oral toxicity, therefore **H302** with pictogram GHS07 and signal word “Warning” is proposed.

A 2.3 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

Comments of zRMS:	<p>The acute oral toxicity of Lambda-cyhalothrin 10% CS was estimated to be 11001 mg/kg and therefore > 2000 mg/kg .</p> <p>Under the GHS classification system this component does not get the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.</p> <p>According to the Regulation EC No. 1272/2008 Lambda-cyhalothrin 10% CS is not classified</p>
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The acute dermal toxicity classification for Lambda cyhalothrin 10% CS was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{10.00\%}{1100}} = 11001 \frac{mg}{kg}$$

The acute oral toxicity of Lambda-cyhalothrin 10% CS was estimated to be > 2000 mg/kg (Considering the worst case with the harmonized classification of Lambda-cyhalothrin). Under the GHS classification system this component does not get the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p>Under the experimental conditions, the inhalation LC₅₀ of LABAMBA (Lambda cyhalothrin 10% CS) is higher than 2.42 mg/L air in rats.</p> <p>According to the Regulation (EC) No. 1272/2008, LABAMBA (Lambda cyhalothrin 10% CS) is not classified. No signal word or hazard statement is required</p>
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The acute inhalation toxicity classification for Lambda cyhalothrin 10% CS was calculated:

$$ATE_{mix} = \frac{100}{\sum_r \frac{C_i}{ATE_i}}$$

$$ATE_{mix} = \frac{100\%}{\frac{10.00\%}{0.05}} = 0.5 \frac{mg}{l}$$

The acute inhalation toxicity of Lambda-cyhalothrin 10% CS was estimated to be 0.5 mg/l (Considering the worst case with the harmonized classification of Lambda-cyhalothrin). Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC)

no. 1272/2008.

Based on the composition and in accordance with the provisions of the Regulation EC 1272/2008, the formulation LABAMBS (Lambda cyhalothrin 10% CS) requires classification in regards to eye irritation harmful if inhaled (H330). However, since the results of inhalation study on rats were available the applicant decided to compare the findings of in vivo testing with calculated result. According to acute inhalation toxicity Study (K.VENUGOPALA RAO, M.V.Sc., PhD, DABT., 2019) which was carried out in compliance with OECD Guideline No 403, LABAMBS (Lambda cyhalothrin 10% CS) is not harmful by inhalation in rats.

Therefore, LABAMBS (Lambda cyhalothrin 10% CS) is not classified. No signal word or hazard statement is required for this hazard.

A 2.4.1 Acute inhalation toxicity

Reference:	KCP 7.1.3
Report	“Acute inhalation toxicity study of Acute inhalation toxicity study of lambda cyhalothrin 10% CS in rats in rats” xxxxxxxxxxxxxxxxxxxx., 20019, n° G13185.
Guideline(s):	Yes (OECD 403)
Deviations:	Yes
GLP:	Yes
Acceptability:	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	LABAMBS (Lambda cyhalothrin 10% CS) (Batch No. SCL-89123)
Species	Rat, Wistar
No. of animals (group size)	6 rats/sex/dose
Concentration(s)	2.42 mg/L air
Exposure	4 hours
Vehicle/Dilution	Milli-Q water,
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Concentration(s) and exposure conditions

Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
12	2.42	2.79	1.99

* MMAD = Mass Median Aerodynamic Diameter

** GSD = Geometric Standard Deviation

Table A 2: Results of acute inhalation toxicity study in rats of LABAMBS (Lambda cyhalothrin 10% CS)

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC ₅₀ (mg/L air) (14 days)
Male rats				
2.42	0/0/6	-	-	> 2.42
Female rats				
2.42	0/0/6	-	-	> 2.42

* Nu.mber of animals which died/number of animals with clinical signs/number of animals used

Table A 3: Summary of findings of acute inhalation toxicity study in rats of LABAMBS (Lambda cyhalothrin 10% CS)

Mortality:	No mortality occurred.
Clinical signs:	Clear nasal discharge and lethargy was observed on day 1. All animals were normal from day 2 onwards.
Body weight:	Body weight gain was considered to be normal.
Macroscopic examination:	The only apparent abnormality found was a slightly distended uterus in one animal in control and in test.

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of LABAMBS (Lambda cyhalothrin 10% CS) is higher than 2.42 mg/L air in rats. According to the Regulation (EC) No. 1272/2008, LABAMBS (Lambda cyhalothrin 10% CS) is not classified. No signal word or hazard statement is required

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008. According to the Regulation EC No. 1272/2008, Lambda cyhalothrin 10% CS is not classified.
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The product contains < 1% of co-formulants considered as skin corrosive (classified as: Skin Corr. 1; H314) and < 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008. According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is not classified.
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The product contains < 1% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318) and < 10% of co-formulants considered as eye irritant (classified as: Eye Irrit. 2; H319). Under the GHS classification system this component is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008. According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is classified as Skin Sens.1/H317 with pictogram GHS07
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The product contains > 1% of co-formulants considered as skin sensitiser (classified as: Skin Sens. 1; H317).. Under the GHS classification system this component gets the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

According to the Regulation EC No. 1272/2008, Lambda-cyhalothrin 10% CS is classified as skin sensitiser, therefore **H317** with pictogram GHS07 and signal word “Warning” is proposed.

A 2.8 Supplementary studies for combinations of plant protection products (KCP 7.1.7)

No supplementary studies are necessary.

A 2.9 Data on co-formulants (KCP 7.4)

A 2.9.1 Material safety data sheet for each co- formulant

Information regarding material safety data sheets of the co-formulants can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.9.2 Available toxicological data for each co-formulant

Available toxicological data for each co-formulant can be found in the confidential dossier of this submission (Registration Report - Part C).

A 2.10 Studies on dermal absorption (KCP 7.3)

Comments of zRMS:	Acceptable
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According to the RAR, in the absence of dermal absorption data of the formulation a default values. However, the Log Pow is 5.5 and the molecular weight is 449.9 g/mol, which is very close to where a dermal absorption of 10% can also be considered according to the guidance for dermal absorption (i.e. for substances with Log Pow >4 and MW > 500). This in addition to the known low absorption for lambda-cyhalothrin suggests that 10% is sufficient as default to be used in the exposure estimations, in absence of product specific data.

However on Pesticides Peer Review Meeting 108 (20-22 November 2013) experts agreed to use the default 25% value for the concentrate as recommended in the guidance, supported by the oral absorption value of 25%.

Considering the value of the oral absorption used to derive the AOEL, it was agreed to reduce the dermal absorption value to 25%. The majority of the experts agreed with a value of 25%, while a minority agreed with a value of 75%.

In conclusion, the agreed dermal absorption values are 25% for both the dilution and the concentrate for all the representative formulations.

Therefore, the percentage absorptions used in the human exposure assessment for lambda cyhalothrin, are taken from the EU Endpoints.

A 2.11 Other/Special Studies

Not relevant. No other special studies were required.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for lambda-cyhalothrin

Table A 4: Input parameters considered for the estimation of operator exposure

Substance	lambda cyhalothrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate -0,0075 kg a.s. /ha	Spray dilution = 0,0375 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of 5×10^{-3}Pa
Scenario	Brassica vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 1, Application interval = 365 days
Percentage Absorption	Dermal for product = 25	Dermal for in use dilution = 25	Oral = 25	Inhalation = 100	
RVNAS	0,00063 mg/kg bw/day		RVAAS	0,00063 mg/kg bw/day	
DFR	3 µg a.s./cm ² per kg a.s./ha		DT50	30 days	
Operator Model	Mixing, loading and application AOEM				
Potential exposure	Longer term systemic exposure mg/kg bw/day		0,0175	% of RVNAS	2773,87%
	Acute systemic exposure mg/kg bw/day		0,2739	% of RVAAS	43480,38%
Mixing and Loading	Gloves = Yes		Clothing = Work wear - arms, body and legs covered	RPE = None	Soluble bags = No
Application	Gloves = No		Clothing = Work wear - arms, body and legs covered	RPE = None	Closed cabin = No

Table A 5: Estimation of operator exposure towards lambda-cyhalothrin according to EFSA guidance

1. Total			
	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	1,0485210	0,0297852	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0174754	0,0004964	
% of RVNAS	2773,87%	78,80%	

Table A 6: Estimation of operator exposure towards lambda-cyhalothrin according to ECPA Grenhouse model

<u>Data entry screen & summary calculation sheet</u>		GREENHOUSE MODEL v_2.1			
Product:	LABAMBS	75th percentile			
Formulation:	Liquid				
Body weight [kg]:	60				
Active substance(s):	lambda	Substance 2	Substance 3	Substance 4	
Concentration [g/l or kg]:	100	0	0	0	
Inhalation absorption [%]	100	0	0	0	
Dermal absorption [%]					
Concentrate:	25,0	0,0	0,0	0,0	
Dilution:	25,0	0,0	0,0	0,0	
AOEL [mg/kg bw/day]	0,0006	0,0	0,0	0,0	
Scenario 1:	Low crop, standard				
Application rate [l or kg product/ha]:	0,075				
Dose [kg a.s./ha]:	0,0075	0,0	0,0	0,0	
Work rate [ha/day]:	1,00				
PPE during application:					
PPE during mix/loading:		Respiration:	None		
Respiration:	None	Hands:	None		
Hands:	None	Head:	None		
		Body:	Coverall		

<u>Summary</u>				
Predicted systemic exposure as a percentage of the AOEL: Greenhouse Model				
75th percentile				
Active substance	Protection	Systemic exposure [mg/kg bw/day]	AOEL [mg/kg bw/day]	% of AOEL
Low crop, standard				
lambda	None	0,00026	0,0006	42,0
	With			

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for lambda-cyhalothrin

Table A 7: Input parameters considered for the estimation of worker exposure for Cereals and Oilseeds

Worker exposure from residues on foliage for	
Crop type	Cereals
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Inspection, irrigation
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,0075 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1,0
Dermal absorption of the product	25,00%
Dermal absorption of the in-use dilution	25,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0225 µg a.s./cm ²
Working hours	2 hr
Dermal transfer coefficient - Total potential exposure	12500 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	1400 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	no TC available for this assessment cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³

Table A 8: Estimation of worker exposure towards lambda-cyhalothrin according to EFSA guidance

1. Total	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,1406250	0,0157500	no TC available for this assessment
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0023438	0,0002625	
% of RVNAS	372,02%	41,67%	

Table A 9: Input parameters considered for the estimation of worker exposure for brassica and tomato

Worker exposure from residues on foliage for	
Crop type	Brassica vegetables
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,0075 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1,0
Dermal absorption of the product	25,00%
Dermal absorption of the in-use dilution	25,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0225 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ⁻³
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ⁻³
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ⁻³

Table A 10: Estimation of worker exposure towards lambda-cyhalothrin according to EF-SA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,2610000	0,1125000	0,0261000
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0043500	0,0018750	0,0004350
% of RVNAS	690,48%	297,62%	69,05%

Table A 11: Input parameters considered for the estimation of worker exposure for tomato indoor

Worker exposure from residues on foliage for	
Crop type	Fruiting vegetables
Indoor or outdoor	Indoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Reaching, picking
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,0075 kg a.s./ha
Number of applications	1
Interval between multiple applications	365 days
Half-life of active substance	30 days
Multiple application factor	1,0
Dermal absorption of the product	25,00%
Dermal absorption of the in-use dilution	25,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0225 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	5800 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	2500 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	580 cm ² /hr
Inhalation transfer coefficient for automated applications	NA ha/hr*10 ^{^-3}
Inhalation transfer coefficient for cutting ornamentals	NA ha/hr*10 ^{^-3}
Inhalation transfer coefficient for sorting / bundling ornamentals	NA ha/hr*10 ^{^-3}

Table A 12: Estimation of worker exposure towards lambda-cyhalothrin according to EF-SA guidance

1. Total			
	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,2610000	0,1125000	0,0261000
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0043500	0,0018750	0,0004350
% of RVNAS	690,48%	297,62%	69,05%

A 3.3 Bystander and resident exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for lambda-cyhalothrin

Table A 13: Input parameters considered for the estimation of longer term resident exposure

Resident exposure for	
Croptype	Fruiting vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted-Drift Reduction
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	5 m
Application rate of the product	0,0075 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,0375 g a.s./l
Dermal absorption of product	25,00%
Dermal absorption of in-use dilution	25,00%
Oral absorption	25,00%
Dislodgeable foliar residue (i_AppRate*_i_DFR)	0,0225 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa Pa
Concentration in air	0,001 mg/m ³
Resident dermal spray drift exposure 75th percentile - adult	0,23798 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,2175 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00009 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00017 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,12278 ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,12 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00008 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00014 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0,25 hours
Light clothing adjustment factor	18,0%
Breathing rate adult	0,23 m ³ /day/kg
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg
Drift percentage on surface (75th percentile)	2,30%
Drift percentage on surface (mean)	1,80%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Table A 14: Estimation of longer term resident exposure towards lambda-cyhalothrin according to EFSA guidance

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0008392	0,0107000	0,0000592	0,0031641	0,0137304
Total systemic exposure per kg body weight (mg/kg/day)	0,0000839	0,0010700	0,0000059	0,0003164	0,0013730
% of RVNAS	13,32%	169,84%	0,94%	50,22%	217,94%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0009164	0,0138000	0,0001574	0,0105469	0,0228060
Total systemic exposure per kg body weight (mg/kg/day)	0,0000153	0,0002300	0,0000026	0,0001758	0,0003801
% of RVNAS	2,42%	36,51%	0,42%	27,90%	60,33%

Table A 15: Input parameters considered for the refined estimation of longer term resident exposure

Resident exposure for	
Croptype	Fruiting vegetables
Application method	Downward spraying
Application equipment	Vehicle-mounted
Formulation type	Soluble concentrates, emulsifiable concentrate, etc.
Buffer strip	2-3 m
Application rate of the product	0,0075 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,0375 g a.s./l
Dermal absorption of product	25,00%
Dermal absorption of in-use dilution	25,00%
Oral absorption	25,00%
Dislodgeable foliar residue (L_AppRate*_L_DFR)	0,0225 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa Pa
Concentration in air	0,001 mg/m ³ - 0.00004 mg/m ³
Resident dermal spray drift exposure 75th percentile - adult	0,47 ml spray dilution/person
Resident dermal spray drift exposure 75th percentile - child	0,327 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - adult	0,00010 ml spray dilution/person
Resident inhal. spray drift exposure 75th percentile - child	0,00022 ml spray dilution/person
Resident dermal spray drift exposure mean - adult	0,22318 ml spray dilution/person
Resident dermal spray drift exposure mean - child	0,18 ml spray dilution/person
Resident inhal. spray drift exposure mean - adult	0,00009 ml spray dilution/person
Resident inhal. spray drift exposure mean - child	0,00017 ml spray dilution/person
Exposure duration dermal	2 hours
Exposure duration inhalation	24 hours
Exposure duration entry into treated crops	0,25 hours
Light clothing adjustment factor	18,0%
Breathing rate adult	0,23 m ³ /day/kg
Breathing rate child (1-3 year old)	1,07 m ³ /day/kg
Drift percentage on surface (75th percentile)	5,60%
Drift percentage on surface (mean)	4,10%
Turf transferable residues percentage	5,00%
Transfer coeff. of surface deposits-adult	7300 cm ² /hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm ² /hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm ²
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm ²
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm ² /h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm ² /h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm ² /h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm ² /h

Table A 16: Refined estimation of longer term resident exposure towards lambda-cyhalothrin according to EFSA guidance

1.1 1-3 year old child					
	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0025221	0,0004280	0,0002882	0,0031641	0,0045456
Total systemic exposure per kg body weight (mg/kg)	0,0002522	0,0000428	0,0000288	0,0003164	0,0004546
% of RVNAS	40,03%	6,79%	4,58%	50,22%	72,15%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0036169	0,0005520	0,0007665	0,0105469	0,0112416
Total systemic exposure per kg body weight (mg/kg)	0,0000603	0,0000092	0,0000128	0,0001758	0,0001874
% of RVNAS	9,57%	1,46%	2,03%	27,90%	29,74%

Appendix 4 Detailed evaluation of exposure and/or DFR studies relied upon (KCP 7.2, KCP 7.2.1.1, KCP 7.2.2.1, KCP 7.2.3.1)

Appendix 5 Not relevant.