

FINAL REGISTRATION REPORT

Part B

Section 6

Mammalian Toxicology

Detailed summary of the risk assessment

Product code: SHA 0100 Y

Product name(s): DECIDE

Chemical active substance:

Deltamethrin, 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: SHARDA Cropchem España S.L.

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Table of Contents

6	Mammalian Toxicology (KCP 7)	5
6.1	Summary	5
6.2	Toxicological Information on Active Substance(s)	7
6.3	Toxicological Evaluation of Plant Protection Product.....	8
6.4	Toxicological Evaluation of Groundwater Metabolites.....	9
6.5	Dermal Absorption (KCP 7.3)	9
6.5.1	Justification for proposed values - Deltamethrin	10
6.6	Exposure Assessment of Plant Protection Product (KCP 7.2).....	10
6.6.1	Selection of critical use(s) and justification	10
6.6.2	Operator exposure (KCP 7.2.1)	11
6.6.2.1	Estimation of operator exposure	11
6.6.2.2	Measurement of operator exposure.....	12
6.6.3	Worker exposure (KCP 7.2.3)	12
6.6.3.1	Estimation of worker exposure	12
6.6.3.2	Refinement of generic DFR value (KCP 7.2)	16
6.6.3.3	Measurement of worker exposure.....	17
6.6.4	Resident and bystander exposure (KCP 7.2.2)	18
6.6.4.1	Estimation of resident and bystander exposure	18
6.6.4.2	Measurement of resident and/or bystander exposure.....	22
6.6.5	Combined exposure	22
Appendix 1	Lists of data considered in support of the evaluation	23
Appendix 2	Detailed evaluation of the studies relied upon.....	25
A 2.1	Statement on bridging possibilities	25
A 2.2	Acute oral toxicity (KCP 7.1.1)	26
A 2.3	Acute percutaneous (dermal) toxicity (KCP 7.1.2)	28
A 2.3.1	Study 1	28
A 2.4	Acute inhalation toxicity (KCP 7.1.3)	30
A 2.4.1	Study 1	30
A 2.5	Skin irritation (KCP 7.1.4).....	32
A 2.5.1	Study 1	32
A 2.5.2	Study 2	33
A 2.6	Eye irritation (KCP 7.1.5)	35
A 2.7	Skin sensitisation (KCP 7.1.6)	35
A 2.7.1	Study 1	36
A 2.8	Supplementary studies for combinations of plant protection products (KCP 7.1.7)	37
A 2.9	Data on co-formulants (KCP 7.4)	37
A 2.9.1	Material safety data sheet for each co-formulant.....	37
A 2.9.2	Available toxicological data for each co-formulant.....	37
A 2.10	Studies on dermal absorption (KCP 7.3)	37
A 2.11	Other/Special Studies	40
Appendix 3	Exposure calculations	41

A 3.1	Operator exposure calculations (KCP 7.2.1.1)	41
A 3.1.1	Calculations for Deltamethrin.....	41
Worker exposure	calculations (KCP 7.2.3.1).....	48
A 3.1.2	Calculations for Deltamethrin.....	49
A 3.2	Resident and bystander exposure calculations (KCP 7.2.2.1)	56
A 3.2.1	Calculations for Deltamethrin.....	56
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)	74

6 Mammalian Toxicology (KCP 7)

6.1 Summary

Table 6.1-1: Information on SHA 0100 Y/DECIDE *

Product name and code	SHA 0100 Y/DECIDE
Formulation type	Capsule suspension [Code: CS]
Active substance(s) (incl. content)	Deltamethrin; 50 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 SHA 0100 Y/DECIDE 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 for SHA 0100 Y/DECIDE according to Regulation (EC) No 1272/2008

Hazard class(es), categories	Eye Dam. 1,
Hazard pictograms or Code(s) for hazard pictogram(s)	GHS05,
Signal word	Danger
Hazard statement(s)	H318, H334
Precautionary statement(s)	P280, P305 + P351 + P338, P304+P340 , P310
Additional labelling phrases	To avoid risks to man and the environment, comply with the instructions for use. [EUH401]
	EUH208- Contains 1,2-benzisothiazolin-3-one (2634-33-5) and Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction. EUH066 -Repeated exposure may cause skin dryness or cracking
	Repeated exposure may cause skin dryness or cracking. [EUH066]

Table 6.1-3: Summary of risk assessment for operators, workers, residents and bystanders for SHA 0100 Y/DECIDE

	Crops	Result	PPE / Risk mitigation measures
Operators	Brassicas (cabbage, Brussels sprouts, cauliflower), strawberry, tomato	Acceptable	Work wear (arms, body and legs covered) M/L and A + gloves during M/L Potential exposure
	Ornamentals		Work wear (arms, body and legs covered) M/L and A Potential exposure
	Tomato		Gloves+coverall – greenhouse Potential exposure– greenhouse
Workers	Brassicas (cabbage, Brussels sprouts, cauliflower), tomato	Acceptable	Work wear (arms, body and legs covered) + gloves Work wear (arms, body and legs covered) – re entry period of 1.5 days after application Work wear (arms, body and legs covered) None
	Strawberry		Work wear (arms, body and legs covered) + gloves Work wear (arms, body and legs covered) – re entry period of 2 days Work wear (arms, body and legs covered) None
	Ornamentals		Work wear (arms, body and legs covered) + gloves Work wear (arms, body and legs covered) – re entry period of 4.5 days None
Residents		Acceptable	None
Bystanders		Acceptable	None

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

No unacceptable risk for operators, workers, residents and bystanders was identified when the product is used as intended. No specific PPE is necessary.

A summary of the critical uses and the overall conclusion regarding exposure for operators, workers and residents/bystanders 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. safen- er/synergist (L/ha)) critical gap for operator, worker, resident or by- stander exposure based on [Expo- sure model]	Acceptability of exposure as- sessment			
			Method / Kind (incl. applica- tion technique ***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. applica- tion rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Brassicas (cab- bage, Brussels sprouts, cauli- flower) (BBCH 11-43)	F	Spraying, LCTM	a) 1 b) 1	a) 0.0075 b) 0.0075	200 - 600	7	Guidance on the assessment of exposure of opera- tors, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874				
2	Strawberry (BBCH 11-81)	F	Spraying, LCTM	a) 1 b) 1	a) 0.0075 b) 0.0075	200 - 600	3					
3	Tomato (BBCH 11-85)	G, F	Spraying, LCTM	a) 1 b) 1	a) 0.0075 b) 0.0075	300 - 1000	3					
4	Ornamentals (BBCH 10-89)	F, G	Spraying, LCTM	a) 1 b) 1	a) 0.0075 b) 0.0075	300 - 1000	-					

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crop, 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)

Deltamethrin	
Common Name	Deltamethrin
CAS-No.	52918-63-5
Classification and proposed labelling	
With regard to toxicological endpoints (according to the criteria in Reg. 1272/2008, as amended)	<div> <div> Hazard classes (s), categories: Code(s) for hazard pictogram(s): Signal word: Hazard statement(s): Precautionary statement(s): </div> <div> Acute Tox. 3 (oral), Acute Tox. 3(inhalation) GHS06 Danger H301, H331 P261, P264, P270, P273,, P301+P310, P304+P340, P311, P330, P391, P403+P233, P405, EUH401 </div> </div>
Additional C&L proposal	-
Agreed EU endpoints	
AOEL systemic	0.0075 mg/kg bw/d
Reference	Review report 6504/VI/99-final (17 October 2002) Annex VI to CLP_ATP10 1 December 2018
Conditions to take into account/critical areas of concern with regard to toxicology	
According to Review Report for Deltamethrin	None

6.3 Toxicological Evaluation of Plant Protection Product

The classification of Deltamethrin 5% CS was performed by calculation. When considering the properties of the active ingredient (5% w/w) Deltamethrin 5% CS is classified as a Acute Tox. (oral) 3 and Acute Tox. (inhalation:gas) 3. When considering the properties of all co-formulants, Deltamethrin 5% CS is only classified toxicity in respect to eye corrosion/irritation.

A summary of the toxicological evaluation for SHA 0100 Y/DECIDE prepared for evaluation in non-European countries 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 0100 Y/DECIDE

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
LD ₅₀ oral, rat (OECD 423)	= 5000 mg/kg bw	Yes	None	XXX XXX M., 2018
LD ₅₀ dermal, rat (OECD 402)	> 2000 mg/kg bw	Yes	None	XXX XXX M., 2018
LC ₅₀ inhalation, rat (OECD 403)	> 0.15 mg/L air	Yes	None H331/ Acute Tox.3	S. B. XXX XXX, 2018

Skin irritation, RHE (OECD 431 and 439)	Non-irritant	Yes	None	P. S. XXX, 2017
Eye irritation, model system (OECD xxx) calculated	Damage	Yes	NA H318/Eye Dam.1	NA calculated
Skin sensitisation, CBA/Ca mice (OECD 429/LLNA)	Non-sensitising	Yes	None	S. B. XXX XXX, 2018
Supplementary studies for combinations of plant protection products	No data – not required			

Table 6.3-2: Additional toxicological information relevant for classification/labelling of SHA 0100 Y/DECIDE

	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)	Deltamethrin (5% (w/w))	H301, H331	Reg. 1272/2008	None H331
Toxicological properties of non-active substance(s) (relevant for classification of product)	co-formulant 1 (<0.00002% (w/w))	H302, H315, H318, H317	Reg. 1272/2008	H318
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 0.1 µg/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 0100 Y/DECIDE are presented in the following table.

Table 6.5-1: Dermal absorption rates for Deltamethrin in SHA 0100 Y/DECIDE

	Deltamethrin	
	Value	Reference
Concentrate	25% 5%	EFSA Journal 2017;15(6):4873– <i>In vitro</i> human skin
Dilution	70% 15%	EFSA Journal 2017;15(6):4873– <i>In vitro</i> human skin

6.5.1 Justification for proposed values - Deltamethrin

No data on dermal absorption for Deltamethrin in SHA 0100 Y/DECIDE is available. Justifications for default values according to Guidance on Dermal Absorption (EFSA Journal 2017;15(6):4873) are presented in the following table.

Proposed dermal absorption rates for Deltamethrin are based on dermal absorption studies on the comparable formulation Deltamethrin 5% CS. The study results are summarised in the following table. Full summaries of studies on the dermal absorption Deltamethrin 5% CS that have not previously been evaluated within an EU peer review process are described in detail in Appendix 2

Table 6.5-2: Default dermal absorption rates for Deltamethrin

	Value	Justification for value	Acceptability of justification
Concentrate	25% 5%	Product is a capsule suspension; other types of formulations. <i>In vitro</i> human skin	Acceptable
Dilution	70% 15%	Product is a capsule suspension; other types of formulations. <i>In vitro</i> human skin	Acceptable

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 0100 Y/DECIDE
Formulation type	CS
Category	Insecticide
Active substance(s) (incl. content)	Deltamethrin 50 g/L
AOEL systemic	0.0075 mg/kg bw/d
Inhalation absorption	100%
Oral absorption	100%
Dermal absorption	Concentrate: 25% 5% Dilution: 70% (Default) 15%

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 Ta-

ble 6.1-4. A list of all intended uses within the zone is given in Part B, Section 0.

Justification

There is only one intended GAP.

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 0100 Y/DECIDE according to the critical use(s) is presented in Table 6.6-2. The outcome of the estimation is presented in Table 6.6-3 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-2: Exposure models for intended uses

Critical use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), strawberry, tomato, ornamentals (max. 0.25 0.15 L 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 Dutch Greenhouse model

Table 6.6-3: Estimated operator exposure (longer term exposure)

		Deltamethrin	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to: Brassica vegetables (cabbage, Brussels sprouts, cauliflower), strawberry, tomato			
Application rate		0.0125 0.0075 kg a.s./ha	
Spray application (AOEM; 95 75 th percentile) Body weight: 60 kg	Potential exposure	0.0266921 0.0054167 0.0036874	356 72 49
	Work wear (arms, body and legs covered) M/L and A + gloves during M/L	0.0015000 0.0031674 0.0021282	20 42 28
Tractor mounted boom spray application outdoors to ornamentals			
Application rate		0.0125 0.0075 kg a.s./ha	
Spray application (AOEM; 95 75 th percentile) Body weight: 60 kg	Potential exposure	0.0132444 0.0027808 0.0018114	177 37 24
	Work wear (arms, body and legs covered) M/L and A	0.0066126 0.0014087 0.0009205	88 19 12

Table 6.6-4: Estimated operator exposure to Deltamethrin (indoor application) – Greenhouse use

Deltamethrin	Operator exposure mg/kg bw per day	% of AOEL used
	Dutch Greenhouse model	Dutch Greenhouse model
Potential exposure (no PPE)		
Tomato, ornamentals	1.7625 0.3875 0.2325	392 86 52
Potential exposure (with PPE*)		
Tomato, ornamentals	0.1875 0.0500 0.0300	42 11 7

*Gloves + coverall

Conclusion

According to the AOEM model, calculations, it can be concluded that the risk for the operator using DECIDE is acceptable without use of personal protective equipment. (Tractor mounted boom spray application outdoors to: Brassica vegetables (cabbage, Brussels sprouts, cauliflower), strawberry, tomato and Tractor mounted boom spray application outdoors to ornamentals According Dutch Greenhouse model calculations, it can be concluded that no risk for the operator using DECIDE (indoor application tomato – Greenhouse use) without PPE but using work gloves

Implication for labelling: None

Acceptable

6.6.2.2 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 consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

6.6.3 Worker exposure (KCP 7.2.3)

6.6.3.1 Estimation of worker exposure

Table 6.6-5 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 0100 Y/DECIDE according to the critical use(s). Outcome of the estimation is presented in Table 6.6-6 (longer term exposure). Detailed calculations are in Appendix 3.

Table 6.6-5: Exposure models for intended uses

Critical use(s)	Brassicas (cabbage, Brussels sprouts, cauliflower) (max. $2 \times 0.25 \times 1 \times 0.15$ L product/ha) Strawberry, tomato, ornamentals (max. $3 \times 0.25 \times 1 \times 0.15$ L 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 6.6-6: Estimated worker exposure (longer term exposure)

		Deltamethrin	
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Brassicas (cabbage, Brussels sprouts, cauliflower)			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		2×0.0125 kg a.s./ha 1×0.0075	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0223140 0.0078026 0.0026100	298 104 35
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0096181 0.0033632 0.0011250	128 45 15
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0022314 0.0007803 0.0002610	30 10 3.5
Brassicas (cabbage, Brussels sprouts, cauliflower) (Proposal of Re entry period of 1.5 days)			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days DFR: 2.12 µg/cm ² /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		2×0.0125 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0157686	210
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0067968	91

	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0015769	21
Tomato			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha 1 × 0.0075	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0225138 0.0105429 0.0026100	300 141 35
	Work wear (arms, body and legs covered) TC: 2500 cm ² /person/h	0.0097042 0.0045444 0.0011250	129 61 15
	Work wear (arms, body and legs covered) and gloves TC: 580 cm ² /person/h	0.0022514 0.0010543 0.0002610	30 14 3.5
Tomato (Proposal of Re-entry period of 1.5 days)			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT₅₀: 3 days DFR: 2.12 µg/cm²/kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0159098	212
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0068577	91
	Work wear (arms, body and legs covered) and gloves TC: 580 cm²/person/h	0.0015910	21
Strawberry			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha 1 × 0.0075	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0225138 0.0105429 0.0026100	300 141 35
	Work wear (arms, body and legs covered) TC: 3000 cm ² /person/h	0.0116451 0.0054532 0.0013500	155 73 18
	Work wear (arms, body and legs covered) and gloves TC: 750 cm ² /person/h	0.0029113 0.0013633	39 19

		0.0003375	5
Strawberry (Proposal of Re-entry period of 2 days)			
Reaching, picking /Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days DFR: 1.89 µg/cm ² /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.0141837	189
	Work wear (arms, body and legs covered) TC: 3000 cm ² /person/h	0.0073364	98
	Work wear (arms, body and legs covered) and gloves TC: 750 cm ² /person/h	0.0018341	25
Ornamentals			
Cutting, sorting, bundling, carrying/Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha 1 × 0.0075	
Body weight: 60 kg	Potential TC: 14000 cm ² /person/h	0.0543437 0.0254484 0.0063000	725 339 84
	Work wear (arms, body and legs covered) TC: 5000 cm ² /person/h	0.0194085 0.0090887 0.0022500	259 121 30
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h	0.0054344 0.0025448 0.0006300	73 34 8
Ornamentals (Proposal of Re-entry period of 4.5 days)			
Cutting, sorting, bundling, carrying/Outdoor Work rate: 8 hours/day, DT ₅₀ : 3 days DFR: 1.06 µg/cm ² /kg a.s./ha Interval between treatments: 10 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha	
Body weight: 60 kg	Potential TC: 14000 cm ² /person/h	0.0192015	256
	Work wear (arms, body and legs covered) TC: 5000 cm ² /person/h	0.0068577	91
	Work wear (arms, body and legs covered) and gloves TC: 1400 cm ² /person/h	0.0019201	26

Worker exposure estimates performed have shown that the exposure limit value (AOEL) will not be exceeded under the conditions of the intended uses and taking into account the use of personal protective equipment such as workwear (arms, body and legs covered) and gloves.

Conclusion

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

Acceptable

6.6.3.2 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).

Refinement

Proposal of Re-entry period

The Applicant propose to consider as refinement a re-entry period of 1.5 days, 2 days and 4.5 days. Therefore we propose to calculate DFR value at 1.5 days for Brassicas (cabbage, Brussels sprouts, cauliflower) and tomato, 2 days for strawberry and 4.5 days for ornamentals.

Body weight 60 kg.

For this calculation DT₅₀ value of 3 days is considered according to “EFSA Journal 2014;12(10):3874”.

DFR_t is calculated according the following formula:

$$DFR_T = DFR_0 \times e^{-k \cdot t}$$

Where:

DFR_T—Dislodgeable foliar residue at the time of re-entry (µg/cm²)

DFR₀—Dislodgeable foliar residue just after application (µg/cm²)

k——Degradation constant (days⁻¹), calculated from the half life time:

$$k = \ln(2)/DT_{50}$$

DT₅₀—Foliar half life time (days)

t——Re-entry interval (days)

——Dislodgeable foliar residue just after application is calculated as:

$$DFR_0 = DFR_{def} \times MAF$$

Where:

DFR_{def}—default value (If no DFR data for the specific compound are available, a conservative default value for the DFR may be taken as 3 µg/cm² per kg s.a/ha)

MAF_m—(multiple application factor for mean residue data for *n* application) is:

$$MAF = (1 - e^{-nki}) / (1 - e^{-ki})$$

where:

n is the number of applications

k is the rate constant for foliar dissipation $k = \ln(2)/DT_{50}$

i is the interval between applications (days)

DFR factor was calculated for each crop based on above formula and according to the EFSA Journal 2014;12(10):3874¹, corresponding to a half life_{foliar} of 3 days.

Brassicas (cabbage, Brussels sprouts, cauliflower):

For Brassicas (cabbage, Brussels sprouts, cauliflower), a number of 2 applications (n) and a 10 days interval (i) between applications is considered (worst case scenario) and MAF is 1.099. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.099 = 3.297 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 1.5 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k_r \cdot t} = 3.297 \mu\text{g}/\text{cm}^2 \times 0.7 = 2.3318 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def-ref} \times MAF = 2.3318 \mu\text{g}/\text{cm}^2 \text{ — the } DFR_{def-ref} = 2.12 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Tomato:

For tomato, a number of 3 applications (n) and a 10 days interval (i) between applications is considered (worst case scenario) and MAF is 1.109. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.109 = 3.327 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 1.5 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k_r \cdot t} = 3.327 \mu\text{g}/\text{cm}^2 \times 0.7 = 2.3527 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def-ref} \times MAF = 2.3527 \mu\text{g}/\text{cm}^2 \text{ — the } DFR_{def-ref} = 2.12 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Strawberry:

For strawberry, a number of 3 applications (n) and a 10 days interval (i) between applications is considered (worst case scenario) and MAF is 1.109. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.109 = 3.327 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 2 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k_r \cdot t} = 3.327 \mu\text{g}/\text{cm}^2 \times 0.62 = 2.0960 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def-ref} \times MAF = 2.0960 \mu\text{g}/\text{cm}^2 \text{ — the } DFR_{def-ref} = 1.89 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

Ornamentals:

For ornamentals, a number of 3 applications (n) and a 10 days interval (i) between applications is considered (worst case scenario) and MAF is 1.109. The following DFR value is calculated:

$$DFR_0 = DFR_{def} \times 1.109 = 3.327 \mu\text{g}/\text{cm}^2 \text{ (where } DFR_{def} = 3 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha)}$$

Therefore for 4.5 days of re-entry interval:

$$DFR_T = DFR_0 \times e^{-k_r \cdot t} = 3.327 \mu\text{g}/\text{cm}^2 \times 0.35 = 1.1763 \mu\text{g}/\text{cm}^2$$

$$\text{Therefore for } DFR_T = DFR_{def-ref} \times MAF = 1.1763 \mu\text{g}/\text{cm}^2 \text{ — the } DFR_{def-ref} = 1.06 \mu\text{g}/\text{cm}^2 \text{ per kg s.a/ha}$$

6.6.3.3 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.

¹ Guidance of EFSA (EFSA Journal 2014;12(10):3874): “Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products”

6.6.4 Resident and bystander exposure (KCP 7.2.2)

6.6.4.1 Estimation of resident and bystander exposure

The acute exposure assessment for bystanders covers the exposure that a resident could reasonably be expected to incur in a single day. Therefore, there is no need for a separate acute risk assessment for residents.

No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.

Table 6.6-7 shows the exposure model(s) used for estimation of resident and bystander exposure to Deltamethrin. The outcome of the estimation is presented in Table 6.6-8 (longer term resident exposure) and Table 6.6-9 (acute bystander exposure). Detailed calculations are in Appendix 3.

Acceptable

Table 6.6-7: Exposure models for intended uses

Critical use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower) (max. 2×0.25 1×0.15 L product/ha) Strawberry tomato, ornamentals (max. 3×0.25 1×0.15 L 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 6.6-8: Estimated resident exposure (longer term exposure)

		Deltamethrin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tractor mounted boom spray application outdoors to Brassica vegetables (cabbage, Brussels sprouts, cauliflower) Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		2×0.0125 kg a.s./ha 1×0.0075	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0011745 0.0002528 0.0001517	15.66 3.37 2.02

	Vapour (75 th perc.)	0.0010700	14.27
	Deposits (75 th perc.)	0.0001512 0.0000672 0.0000225	2.02 0.90 0.30
	Re-entry (75 th perc.)	0.0016231 0.0005675 0.0001898	21.64 7.57 2.53
	Sum (mean)	0.0031216 0.0017111 0.0013215	41.62 22.82 17.62
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0002811 0.0000603 0.0000362	3.75 0.80 0.48
	Vapour (75 th perc.)	0.0002300	3.07
	Deposits (75 th perc.)	0.000065 0.0000229 0.0000077	0.87 0.31 0.10
	Re-entry (75 th perc.)	0.0009017 0.0003153 0.0001055	12.02 4.20 1.41
	Sum (mean)	0.0011305 0.0005269 0.0003369	15.07 7.02 4.49
Tractor mounted boom spray application outdoors to strawberry Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha 1 × 0.0075	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0011745 0.0002528 0.0001517	15.66 3.37 2.02
	Vapour (75 th perc.)	0.0010700	14.27
	Deposits (75 th perc.)	0.0001512 0.0000908 0.0000225	2.02 1.21 0.30
	Re-entry (75 th perc.)	0.0016231 0.0007669 0.0001898	21.64 10.22 2.53
	Sum (mean)	0.0031216 0.0018873 0.0013215	41.62 25.16 17.62
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0002811 0.0018873 0.0000362	3.75 0.80 0.48
	Vapour (75 th perc.)	0.0002300	3.07
	Deposits (75 th perc.)	0.000065 0.0000310	0.87 0.41

		0.0000077	0.10
	Re-entry (75 th perc.)	0.0009017 0.0004260 0.0001055	12.02 5.68 1.41
	Sum (mean)	0.0011305 0.0006210 0.0003369	15.07 8.28 4.49
Tractor mounted boom spray application outdoors to tomato and ornamentals Buffer zone: 2-3(m) Drift reduction technology: no DT ₅₀ : 3 days 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 10 365 days			
Number of applications and application rate		3 × 0.0125 kg a.s./ha 1 × 0.0075	
	Drift (75 th perc.)	0.0007830 0.0002528 0.0001011	10.44 3.38 1.35
	Vapour (75 th perc.)	0.0010700	14.27
	Deposits (75 th perc.)	0.0001526 0.0000908 0.0000225	2.03 1.21 0.30
	Re-entry (75 th perc.)	0.0016376 0.0007669 0.0001898	21.83 10.22 2.53
	Sum (mean)	0.0029186 0.0018873 0.0012936	38.91 25.16 17.25
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0001874 0.0000603 0.0000241	2.50 0.80 0.32
	Vapour (75 th perc.)	0.0002300	3.07
	Deposits (75 th perc.)	0.0000661 0.0000310 0.0000077	0.88 0.41 0.10
	Re-entry (75 th perc.)	0.0009098 0.0004260 0.0001055	12.13 5.68 1.41
	Sum (mean)	0.0010928 0.0006210 0.0003312	14.57 8.28 4.42

Estimates of exposure to residents and / or bystanders have shown that the exposure limit (AOEL) for deltamethrin will not be exceeded under the conditions of intended use and taking into account the above mentioned risk mitigation measures (a buffer zone of 2-3 m should be maintained

Acceptable

Table 6.6-9: Estimated bystander exposure (acute exposure)

		Deltamethrin	
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AAOEL
Tractor mounted boom spray application outdoors to Brassica vegetables (cabbage, Brussels sprouts, cauliflower) Buffer zone: 2-3(m) Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha			
Application rate		0.0125 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0026618	35.49
	Vapour (95 th perc.)	0.0010700	14.27
	Deposits (95 th perc.)	0.0004543	6.06
	Re-entry (95 th perc.)	0.0016231	21.64
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0007240	9.65
	Vapour (95 th perc.)	0.0002300	3.07
	Deposits (95 th perc.)	0.0001976	2.63
	Re-entry (95 th perc.)	0.0009017	12.02
Tractor mounted boom spray application outdoors to strawberry Buffer zone: 2-3(m) Drift reduction technology: no DFR: 3 µg/cm ² /kg a.s./ha			
Application rate		0.0125 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0026618	35.49
	Vapour (95 th perc.)	0.0010700	14.27
	Deposits (95 th perc.)	0.0004584	6.11
	Re-entry (95 th perc.)	0.0016376	21.83
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0007240	9.65
	Vapour (95 th perc.)	0.0002300	3.07
	Deposits (95 th perc.)	0.0001993	2.66
	Re-entry (95 th perc.)	0.0009098	12.13
Tractor mounted boom spray application outdoors to tomato and ornamentals Buffer zone: 2-3(m) Drift reduction technology: no			

DFR: 3 µg/cm ² /kg a.s./ha			
Application rate		0.0125 kg a.s./ha	
Bystander child Body weight: 10 kg	Drift (95 th perc.)	0.0017745	23.66
	Vapour (95 th perc.)	0.0010700	14.27
	Deposits (95 th perc.)	0.0004584	6.11
	Re-entry (95 th perc.)	0.0016376	21.83
Bystander adult Body weight: 60 kg	Drift (95 th perc.)	0.0004827	6.44
	Vapour (95 th perc.)	0.0002300	3.07
	Deposits (95 th perc.)	0.0001993	2.66
	Re-entry (95 th perc.)	0.0009098	12.13

6.6.4.2 Measurement of resident and/or bystander exposure

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

6.6.5 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 7.1.1	XXX XXX M.	2018	Acute oral toxicity study (acute toxic class method) of Deltamethrin 5% CS in Wistar rat Eurofins report No. G13190 GLP, Unpublished	Y	SHARDA Cropchem Limited
KCP 7.1.2	XXX XXX M.	2018	Acute dermal toxicity study of Deltamethrin 5% CS in Wistar rat Eurofins report No. G13191 GLP, Unpublished	Y	SHARDA Cropchem Limited
KCP 7.1.3	S. B. XXX XXX	2018	Deltamethrin 5% CS: Acute inhalation toxicity study in Wistar rats Eurofins report No. G13192 GLP, Unpublished	Y	SHARDA Cropchem Limited
KCP 7.1.4	P. S. XXX	2017	Deltamethrin 5% CS – <i>In vitro</i> skin corrosion: reconstructed human epidermis (RHE) test method Eurofins report No. G13193 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 7.1.4	P. S. XXX	2017	Deltamethrin 5% CS – <i>In vitro</i> skin irritation: Reconstructed human epidermis test method Eurofins report No. G13194 GLP, Unpublished	N	SHARDA Cropchem Limited
KCP 7.1.6	S. B. XXX XXX	2018	Deltamethrin 5% CS: Local Lymph Node Assay (LLNA) in CBA/Ca mice Eurofins report No. G13195 GLP, Unpublished	Y	SHARDA Cropchem Limited
KCP 7.3.	XXX V XXX	2020	IN VITRO PERCUTANEOUS DERMAL ABSORPTION STUDY OF DELTAMETHRIN 5% CS, THROUGH HUMAN SKIN Eurofins , Report No.G18507 GLP, Unpublished	N	SHARDA Cropchem Ltd.

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

No additional study submitted.

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

The classification of Deltamethrin 5% CS was performed by calculation. The assessment of all acute toxicological properties of Deltamethrin 5% CS is derived from the classification of the active compound and co-formulants as shown below. For obvious confidentiality reasons, the names and percentages of co-formulants are disclosed in Part C:

Formulant	% of formulation	Acute Oral Toxicity	Acute Dermal Toxicity	Acute Inhalation Toxicity	Dermal Irritation	Ocular Irritation	Sensitising potential
Deltamethrin Technical	4.99	100 mg/kg, H301	> 2000 mg/kg ¹⁾	0.5 mg/l, H331	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 1	xxx	12600 mg/kg	> 10000 mg/kg	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 2	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Skin Irrit. 2, H315	Eye Dam.1, H318	Not sensitising ¹⁾
xxxxxxxxxxxxx	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Skin Corr. 1, H314	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 3	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 4	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 5	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
xxxxxxxxxxxxx	xxx	500 mg/kg ²⁾ H302	> 2000 mg/kg ¹⁾	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Skin Sens. 1 H317
Coformulant 6	xxx	1030 mg/kg, H302	> 5000 mg/kg	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Skin Sens. 1 H317
xxxxxxxxxxxxx	xxx	500 mg/kg ²⁾ H302	> 2000 mg/kg ¹⁾	*	Skin Irrit. 2, H315	Eye Dam. 1, H318	Skin Sens. 1 H317
xxxxxxxxxxxxx	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Skin Corr. 1, H314	Eye Dam.1, H318	Not sensitising ¹⁾
Coformulant 7	xxx	> 2000 mg/kg ¹⁾	> 5000 mg/kg	19.6 mg/l	Skin Corr. 1, H314	Not Irritating ¹⁾	Skin Sens. 1 H317
xxxxxxxxxxxxx	xxx	100 mg/kg ²⁾ , H301	300 mg/kg ²⁾ , H311	0.05 mg/l ²⁾ , H330	Skin Corr. 1B, H314	Not Irritating ¹⁾	Skin Sens. 1 H317
Coformulant 8	xxx	1890 mg/kg H302	1100 mg/kg, H312	1.5 mg/l ²⁾ , H332	Skin Irrit. 2, H315	Eye Dam. 1, H318	Not sensitising ¹⁾
Coformulant 9	xxx	> 5000 mg/kg	> 2000 mg/kg ¹⁾	> 4688 mg/m ³	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾
Coformulant 10	xxx	> 2000 mg/kg ¹⁾	> 2000 mg/kg ¹⁾	*	Not Irritating ¹⁾	Not Irritating ¹⁾	Not sensitising ¹⁾

* No Information / but in their MSDS are not classified acutely inhalation toxic

¹⁾ As co-formulant is not classified

- 2) According to the Regulation (EC) n°1272/2008, Oral: ATE = 500 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 3: H302; ATE = 100 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 3: H301; Dermal: ATE = 300 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 3: H311; Inhalation: ATE = 1.5 mg/l is used for the calculation for co-formulant classified as Acute Tox. 4; H332; ATE = 0.5 mg/l is used for the calculation for co-formulant classified as Acute Tox. 3; H331; ATE = 0.05 mg/kg is used for the calculation for co-formulant classified as Acute Tox. 2; H330.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values:

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

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_r \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)

i = the individual ingredient from 1 to n

n = the number of ingredients

ATE_i = Acute Toxicity Estimate of ingredient i.

A 2.2 Acute oral toxicity (KCP 7.1.1)

Comments of zRMS:	<p>According to the calculation method ATE_{mix} is 1 770mg/kg bw and then DECIDE should be classified Acute Tox.3/H302</p> <p>but</p> <p>Under the experimental conditions, the oral LD50 of SHA 0100 Y/DECIDE is 2000 mg/kg bw in rats. Therefore no classification is required according to Regulation (EC) No. 1272/2008.</p>
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The acute oral toxicity classification for Deltamethrin 5% CS was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{4.99}{100} + \frac{0.00002}{500} + \frac{0.0125}{500} + \frac{0.00025}{100} + \frac{12.46}{1890}} = 1770 \text{ mg/kg bw}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute oral toxicity of Deltamethrin 5% CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

The acute oral toxicity of Deltamethrin 5% CS was estimated to be 1770 mg/kg. Under the GHS classification system this component does trigger the value of the classification according to Regulation (EC) no. 1272/2008.

Based on the composition and in according to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is classified for Oral Acute Toxicity (H302). However, the applicant has an study of acute oral toxicity (OECD 423), and according to this study, Deltamethrin 5% CS has a LD50 = 5000 mg/kg body weight. Therefore, Deltamethrin 5% CS is **not classified**. No signal word or hazard statement is required for this hazard.

Reference	KCP 7.1.1
Report	Acute oral toxicity study (acute toxic class method) of Deltamethrin 5% CS in Wistar rat, XXX XXX M., 2018, report No. G13190
Guideline(s)	Yes, OECD Guidelines No. 423
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin 5% CS (Batch No. SCL-89521)
Species	Rat, Wistar
No. of animals (group size)	3 rats (females) / treatment step
Dose(s)	2000 mg/kg bw
Exposure	Once by gavage
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 1: Results of acute oral toxicity study in rats of SHA 0100 Y/DECIDE

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD ₅₀ (mg/kg bw) (14 days)
Female rats				
2000	0/0/3	-	-	5000 cut-off
Female rats				
2000	0/0/3	-	-	5000 cut-off

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 2: Summary of findings of acute oral toxicity study in rats of SHA 0100 Y/DECIDE

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the oral LD₅₀ of SHA 0100 Y/DECIDE is 5000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

Comments of zRMS:	<p>Under the calculated method and experimental conditions, the dermal LD₅₀ of DECIDE is 8828 mg/kg bw</p> <p>and</p> <p>Under the experimental conditions, the dermal LD₅₀ of SHA 0100 Y/DECIDE is higher than 2000 mg/kg bw in rats.</p> <p>Therefore, no classification is required according to Regulation (EC) No. 1272/2008.</p>
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The acute dermal toxicity classification for Deltamethrin 5% CS was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{0.00025}{300} + \frac{12.46}{1100}} = 8828 \text{ mg/kg bw}$$

Conclusion

The acute dermal toxicity of Deltamethrin 5% CS was estimated to be > 2000 mg/kg. Therefore, according to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.3.1 Study 1

Reference KCP 7.1.2

Report Acute dermal toxicity study of Deltamethrin 5% CS in Wistar rat, XXX XXX M., 2018, report No. G13191

Guideline(s)	Yes, OECD guidelines No. 402
Deviations	Yes, the Rat Rm 7535 was observed for clinical signs and pre-terminal deaths (mortality) once during first 30 minutes after application and at 1, 2.5, 3.5, 4.5, 5.5 and 6.5 hours after application on day of treatment instead of hourly intervals for 6 hours after application or more on the day of treatment. There was no impact of the deviation on the outcome of the study.
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin 5% CS (Batch No. SCL-89521)
Species	Rat, Wistar
No. of animals (group size)	3 female / group
Dose(s)	2000 mg/kg bw
Exposure	24 hours (dermal, semi-occlusive)
Vehicle/Dilution	None
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 3: Results of acute dermal toxicity study in rats of SHA 0100 Y/DECIDE

Dose (mg/kg bw)	Toxicological results *	Duration of signs	Time of death	LD ₅₀ (mg/kg bw) (14 days)
Male rats				
2000	0/0/3	-	-	> 2000
Female rats				
2000	0/0/3	-	-	> 2000

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 4: Summary of findings of acute dermal toxicity study in rats of SHA 0100 Y/DECIDE

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the dermal LD₅₀ of SHA 0100 Y/DECIDE is higher than 2000 mg/kg bw in rats. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.4 Acute inhalation toxicity (KCP 7.1.3)

Comments of zRMS:	<p>According to the calculation method DECIDE is not classified, acute inhalation toxicity was estimated 5.5 mg/l</p> <p>But and</p> <p>Under the experimental conditions, the inhalation LC₅₀ of SHA 0100 Y/DECIDE is higher than 0.15 mg/L air in rats (considering that maximum attainable concentration, no mortality occurred, no clinical signs of toxicity were observed and Body weight gain was considered to be normal and The necropsies performed at the end of the study revealed no apparent findings).</p> <p>Therefore classification Acute Tox.3/H331 is not required according to Regulation (EC) No. 1272/2008</p>
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The acute inhalation toxicity classification for Deltamethrin 5% CS was calculated:

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

$$ATE_{mix} = \frac{100}{\frac{4.99}{0.5} + \frac{0.00025}{0.05} + \frac{12.46}{1.5}} = 5.5 \text{ mg/l}$$

Details of the co-formulants and their classification and the calculation methodology that was used to assess the acute inhalation toxicity of Deltamethrin 5% CS can be found in an appendix to the confidential dossier of this submission (Registration Report, Part C).

Conclusion

The acute inhalation toxicity of Deltamethrin 5% CS was estimated to be > 5 mg/l. Therefore, according to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.4.1 Study 1

Reference	KCP 7.1.3
Report	Deltamethrin 5% CS: Acute inhalation toxicity study in Wistar rats, S.B. XXX XXX, 2018, report No. G13192
Guideline(s)	Yes, OECD guidelines No. 403
Deviations	No
GLP	Yes
Acceptability	Yes

Duplication No
 (if vertebrate study)

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin 5% CS (Batch No. SCL-89521)
Species	Rat, Wistar
No. of animals (group size)	6 rats (3 males, 3 females)
Concentration(s)	0.15 mg/L air
Exposure	4 hours (nose only)
Vehicle/Dilution	20% w/v of test item in Milli-Q water
Post exposure observation period	14 days
Remarks	None

Results and discussions

Table A 5: Concentration(s) and exposure conditions

Nominal conc. (mg/L air)	Actual conc. (mg/L air)	MMAD * (µm)	GSD ** (µm)
16	0.15 ± 0.07	1.28 ± 0.99	2.09

* MMAD = Mass Median Aerodynamic Diameter

** GSD = Geometric Standard Deviation

Table A 6: Results of acute inhalation toxicity study in rats of SHA 0100 Y/DECIDE

Concentration (mg/L air)	Toxicological results *	Duration of signs	Time of death	LC ₅₀ (mg/L air) (14 days)
Male rats				
0.15	0/0/3	-	-	> 0.15
Female rats				
0.15	0/0/3	-	-	> 0.15

* Number of animals which died/number of animals with clinical signs/number of animals used

Table A 7: Summary of findings of acute inhalation toxicity study in rats of SHA 0100 Y/DECIDE

Mortality	No mortality occurred.
Clinical signs	No clinical signs of toxicity were observed.
Body weight	Body weight gain was considered to be normal.
Macroscopic examination	The necropsies performed at the end of the study revealed no apparent findings.

Conclusion

Under the experimental conditions, the inhalation LC₅₀ of SHA 0100 Y/DECIDE is higher than 0.15 mg/L air in rats. Thus, classification is required according to Regulation (EC) No. 1272/2008.

A 2.5 Skin irritation (KCP 7.1.4)

Comments of zRMS:	Based on the composition and in accordance to the Regulation EC No. 1272/2008, DECIDE is not classified for skin irritation and Under the experimental conditions (<i>In vitro</i> skin corrosion: reconstructed human epidermis (RHE) and <i>In vitro</i> skin irritation: Reconstructed human epidermis tests methods), DECIDE is predicted to be non-corrosive. Therefore, no classification is required according to Regulation (EC) No. 1272/2008.
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The product contains < 1% of co-formulants considered as skin corrosion (classified as: Skin Corr. 1; H314), but the product contains > 10% of co-formulants considered as skin irritant (classified as: Skin Irrit. 2; H315). Under the GHS classification system this component get the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion

Based on the composition and in accordance to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is classified for skin irritation (H315). However, the applicant has studies of in vitro skin irritation (OECD 439) and in vitro skin corrosion (OECD 431), and according to these studies, Deltamethrin 5% CS is non-irritant. Therefore, Deltamethrin 5% CS is **not classified**. No signal word or hazard statement is required for this hazard.

A 2.5.1 Study 1

Reference	KCP 7.1.4
Report	Deltamethrin 5% CS – <i>In vitro</i> skin corrosion: reconstructed human epidermis (RHE) test method, P. S. XXX, 2017, report No. G13193
Guideline(s)	Yes, OECD guideline No. 431
Deviations	Yes, it is considered that the NC meets the acceptance if the mean OD value of the 2 tissues is ≥ 0.6 and ≤ 1.5 for every exposure time but the mean OD of NC was 0.55405 in the 240 minutes exposure which is slightly less than the acceptance limit of ≥ 0.6 .
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin 5% CS (Batch No. SCL-89521)
Test system	EpiSkin kit (<i>in vitro</i> reconstructed human epidermis)
Number	2 epidermis units per test item

Exposure	50µL of positive control (glacial acetic acid) 50µL of negative control (Sodium chloride (NaCl) 0.9% (w/v)) 50µL of the test item
Vehicle/Dilution	None
Remarks	None

Results and discussions

Table A 8: Mean OD values of Individual Epidermis Units (240-minutes Exposure)

	Absorption (OD ₅₇₀)	
	R1	R2
Negative control	0.5527	0.5554
Positive control	0.0866	0.08765
Test Item	0.90545	0.91825

Table A 9: True OD values of individual epidermis units (240-minutes exposure)

	Absorption (OD ₅₇₀)	
	R1	R2
Negative control	0.51125	0.51395
Positive control	0.864	0.8768
Test Item	0.04515	0.0462

Table A 10: Individual tissue viability of epidermis (relative) (240-minutes exposure)

	% Individual viability			
	R1	R2	Mean viability	Variability
Positive control	8.81	9.01	8.91	-2.24
Test Item	168.55	171.05	169.8	-1.48

Negative control means: 0.5126

Skin corrosion is expressed as the remaining cell viability after exposure to the test items. The relative mean tissue viability obtained after 3, 60 and 240 minutes treatment duration with the test item compared to the negative control tissues was 116.06, 115.91 and 169.8%, respectively. The positive control had a mean cell viability of 8.91% after 240 minutes exposure.

Conclusion

Under the experimental conditions, SHA 0100 Y/DECIDE is predicted to be non-corrosive. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.5.2 Study 2

Reference	KCP 7.1.4
Report	Deltamethrin 5% CS – <i>In vitro</i> skin irritation: Reconstructed human epidermis test method, P. S. XXX, 2017, report No. G13194
Guideline(s)	Yes, OECD guideline No. 439
Deviations	No
GLP	Yes
Acceptability	Yes

Duplication No
 (if vertebrate study)

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin % CS (Batch No. SCL-89521)
Test system	EpiSkin kit (<i>in vitro</i> reconstructed human epidermis)
Number	3 epidermis units per test item
Exposure	<u>Negative control:</u> 10µL of Phosphate Buffered Saline (PBS) <u>Positive control:</u> 10µL of Sodium 5% aqueous Sodium Dodecyl Sulfate (SDS) <u>Test system:</u> 10µL of the test item
Vehicle/Dilution	None
Remarks	None

Results and discussions

Table A 11: Mean OD value of Individual Epidermis Units

	Absorption (OD ₅₇₀)		
	R1	R2	R3
Negative control	0.7442	0.7442	0.7435
Positive control	0.0776	0.07905	0.07795
Test item	0.92145	0.92675	0.92065

Table A 12: True OD value of Individual Epidermis Units

	Absorption (OD ₅₇₀)				
	R1	R2	R3	Mean	SD
Negative control	0.70308	0.70308	0.70238	0.70285	0.0004
Positive control	0.03648	0.03793	0.03683	0.03708	0.0008
Test item	0.88033	0.88563	0.87953	0.88183	0.00332

Table A 13: Individual tissue viability of Epidermis Units (relative)

	% Individual viability				
	R1	R2	R3	Mean	SD
Positive control	5.19	5.40	5.24	5.28	0.110
Test item	125.25	126.01	125.14	125.47	0.474

Negative control means: 0.70285

The relative mean tissue viability obtained after 15 minutes treatment with the test item compared to the negative control tissues was 125.47%.

The positive control had a mean cell viability of 5.28% after 15 minutes exposure.

Conclusion

Under the experimental conditions, SHA 0100 Y/DECIDE is predicted to be non-irritant. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

A 2.6 Eye irritation (KCP 7.1.5)

Comments of zRMS:	Based on the composition and in accordance to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is classified as Eye Dam.1/H318, with pictogram GHS05 “Danger” is proposed.
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The product contains > 3% of co-formulants considered as eye damage (classified as: Eye Dam. 1; H318). Under the GHS classification system this component does trigger the value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion

Based on the composition and in accordance to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is classified as Eye Damage, therefore the hazard statement **H318** with pictogram GHS05 and pictogram “Danger” is proposed.

No new study has been submitted.

A 2.7 Skin sensitisation (KCP 7.1.6)

Comments of zRMS:	Based on the composition and in accordance to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is not classified as skin sensitiser but with the statement “EUH208: Contains 1,2-benzisothiazolin-3-one (2634-33-5) and Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.” and Under the experimental conditions, DECIDE is not a skin sensitiser with EUH208 . Therefore no classification is required according to Regulation (EC) No. 1272/2008
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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 is below the additive trigger value of the classification according to Regulation (EC) no. 1272/2008.

Conclusion

According to the Regulation EC No. 1272/2008, Deltamethrin 5% CS is not classified. No signal word or hazard statement is required for this hazard.

However, the Deltamethrin 5% CS contains ≥ 0.005 – $< 0.05\%$ of 1,2-benzisothiazol-3(2H)-one (CAS: 2634-33-5) which has specific limit concentration ($C \geq 0.05\%$) and contains ≥ 0.00015 – $< 0.0015\%$ of Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1), therefore the statement “**EUH208**: Contains 1,2-benzisothiazolin-3-one (2634-33-5) and Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC

no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1). May produce an allergic reaction.” is proposed.

A 2.7.1 Study 1

Reference	KCP 7.1.6
Report	Deltamethrin 5% CS: Local Lymph Node Assay (LLNA) in CBA/Ca mice, S. B. XXX XXX, 2018, report No. G13195
Guideline(s)	Yes, OECD guideline No. 429
Deviations	No
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material (Lot/Batch No.)	Deltamethrin 5% CS (Batch No. SCL-89521)
Species	Mice CBA/Ca
No. of animals (group size)	6 female mice /group
Range finding	No
Exposure (concentration(s), no. of applications)	<u>Vehicle control group:</u> 25µL of DMSO (Dimethyl sulfoxide) <u>Positive control group</u> 25µL of 25% v/v α-hexylcinnamaldehyde (HCA) in DMSO <u>Test item groups</u> 25µL of 25% v/v test item in DMSO 25µL of 50% v/v of test item in DMSO 25µL of undiluted test item
Vehicle	DMSO (Dimethyl sulfoxide)
Pretreatment prior to topical application	No
Reliability check	α-hexylcinnamaldehyde (HCA) at 25% v/v
Remarks	None

Results and discussions

Table A 14: Results of skin sensitisation study of SHA 0100 Y/DECIDE

	24 hours	48 hours	Total number of animals affected
	After LLNA		
SHA 0100 Y/DECIDE	0/6	0/6	0

	24 hours	48 hours	Total number of animals affected
SHA 0100 Y/DECIDE	0/6	0/6	0
SHA 0100 Y/DECIDE	0/6	0/6	0
Test vehicle control group	0/6	0/6	0
Positive control	3/6	5/6	5

* Number of animals with positive dermal response (scores of 1-3) /number of animals in dose group

Clinical signs:	No clinical signs of toxicity were observed.
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Conclusion

Under the experimental conditions, SHA 0100 Y/DECIDE is not a skin sensitizer. Thus, no classification is required according to Regulation (EC) No. 1272/2008.

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

No data available.

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)

~~According to the new EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873 adopted: 24 May 2017) a default dermal absorption value 25 % (concentrate) and 70% (diluted) of may be applied for products that are organic solvent based^(a) or other^(b)~~

^(a): ~~Formulation types: emulsifiable concentrate (EC), emulsion, oil in water (EW), suspo-emulsion (SE), dispersible concentrate (DC), oil miscible liquids (OL/OF), oil based suspension concentrates (OD), emulsion for seed treatment (ES), microemulsion (ME).~~

^(b): ~~Formulation types: bait concentrate (CB), capsule suspension (CS), gel for direct application (GEL/GD), bait, ready for use (RB), mixture of capsule suspension and suspension concentrate (ZC), seed coated with a pesti-~~

vide (PS), experimental solution of active substances in solvent (AI).

Comparative dermal absorption, in vitro using rat and human skin

Comments of zRMS:	Study is acceptable
	5.0% of dose for undiluted Deltamethrin 5% CS (concentrate) 15 % of dose for actual spray strength used in the field dilution

Reference	KCP 7.3
Report	IN VITRO PERCUTANEOUS DERMAL ABSORPTION STUDY OF DELTAMETHRIN 5% CS, THROUGH HUMAN SKIN, XXX V XXX, 2020, G18507
Guideline(s)	OECD Guideline 428 "Skin Absorption: in vitro Method" April 2004
Deviations	Yes
GLP	Yes
Acceptability	Yes
Duplication (if vertebrate study)	No

Materials and methods

Test material	Name (Lot/Batch No.)	Deltamethrin
	Test preparation	radioformulation
	Specific activity	69.0 mCi/mmol
	Radiochemical purity	99.9 %
Product	Name (Lot/Batch No.)	Deltamethrin 5% CS (SCL-12589)
	Company code	S020-223
	Concentration a.s.	50.71 g/L
	Formulation type	Capsule suspension (CS)
Blank product	Name (Lot/Batch No.)	Deltamethrin Blank Formulation (SCL-89145)
	Concentration a.s.	0 g/L

Test system		
Diffusion cell	Cell type	dynamic
	(if dynamic) Flow rate	1.8 mL/h
	Exposed skin area	0.64 cm ²
Membrane	Skin type	isolated epidermis
	Skin thickness range	0.2– 0.4 mm
	Skin donors age	20, 53, 39, 32 years
	Skin donors sex	m, m, f, m
	Location	abdomen
	Source	ZenBio Laboratory, Vendor - Life Technologies India Pvt Ltd.
	Integrity test	yes
Receptor	Receptor medium	Scintillation liquid (Ultima Gold™)
	Solubility in receptor medium	n
Sample Time	Exposure time	8 h
Sampling	Sample intervals	24 h
Washing		At 8 h using water and a mild soap solution (3% Dove)

Final Procedure	Tape stripping	y
	TS1-2 analysed separately	n
Remarks:		
Tested doses	Concentrate	Spray dilution
Total concentration [g.L ⁻¹]	50.735	0.01
Area dose [µg/cm ²]	509.07 ± 3.17	0.1 ± 0.002
Specific activity [MBq/ml-1]	3.94	0.052
No. of donors	8	8

Results and discussions

Table A 15: In-vitro dermal penetration of Deltamethrin formulated DELTAMETHRIN 5% CS through human skin - Recovery data

Dose group	High dose (Formulation concentrate)		Low dose (Spray dilution 1:5000)	
Target concentration [g.L ⁻¹]	50.735		0.01	
Mean actual applied dose [µg/cm ²]	509.07 ± 3.17		0.1 ± 0.002	
Number of replicates (n)	8		8	
	Recovery [%]		Recovery [%]	
	Mean	S.D.	Mean	S.D.
Dislodgeable dose				
Skin washing	94.3723	5.9483	81.6407	6.2557
Donor chamber wash	0.9203	0.6318	1.1217	0.4155
Dose associated to skin				
Tape strips: 1 st sample, strips 1 + 2	1.944	0.636	5.517	1.490
Tape strips: 2 nd sample; strips 3 - n	2.000	0.477	2.599	0.520
Stripped skin	1.608	0.320	5.225	0.760
Absorbed dose	2.359	0.448	11.336	1.309
Receptor fluid	0.6394	0.2282	5.5115	0.7902
Receptor chamber wash	0.1117	0.0417	0.6003	0.1355
Total recovery¹	101.496	5.359	102.215	5.938
Absorption essentially complete at end of study (>75% absorption within half the study duration) [% Absorption at t _{0.5}]	No (29%)		No (36%)	
If yes: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding all tape strips)	N/A	N/A	N/A	1.722
If no: Absorption = receptor fluid + receptor chamber washes + skin sample (excluding tape strips 1 and 2) ²	4.359	0.709	4.359	3.141
Absorption estimate normalised ³	4.359 ± 0.84 x 0.709		13.936 ± 0.84x1.113	
Relevant absorption estimate	4.359 ± 0.60		13.936 ± 0.93	
Absorption estimates used for risk assessment⁴	5.0%		15%	

¹ Values may not calculate exactly due to rounding of figures

² In accordance with the EFSA Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665 and EFSA Journal 2017;15(6):4873) the radioactivity in the second tape-strip pool (3rd to nth tape strip) is considered potentially absorbable if less than 75% of the absorption occurred in the first half of the study. Finally, the skin preparation is also considered potentially absorbable

³ In accordance with the EFSA Guidance on Dermal Absorption (2017), dermal absorption should be calculated as follows: Absorption (mean value) + ks, where s is the sample standard deviation. The multiplication factor required depends on the number of replicates and is given in Table 1 of EFSA Guidance.

According to the Table 1 of EFSA Guidance for n = 8 the Multiplication factor (k) is 0.84.

⁴ Relevant absorption estimate was rounded to the required number of significant figures.

N/A: not applicable

Conclusion/endpoint: 5.0 % of dose for undiluted Deltamethrin 5% CS (concentrate)
15 % of dose for actual spray strength used in the field dilution

Other/Special Studies

No data submitted.

Appendix 3 Exposure calculations

A 3.1 Operator exposure calculations (KCP 7.2.1.1)

A 3.1.1 Calculations for Deltamethrin

Table A 16: Input parameters considered for the estimation of operator exposure

Formulation type	CS		Crop type	Brassica vegetables (cabbage, Brussels sprouts, cauliflower); strawberry, tomato
Application rate (AR)	0.0125	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.0075	mg/kg bw/d	Water-soluble bag	No

Substance	Deltamethrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate=0,0125 kg a.s. /ha	Spray dilution = 0,0625 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10-3Pa
Scenario	Brassica vegetables / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 5	Dermal for in use dilution = 15	Oral = 100	Inhalation = 100	
RVNAS	0,0075 mg/kg bw/day		RVAAS	0,0075 mg/kg bw/day	
DFR	3 µg a.s./cm2 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		0,0054	% of RVNAS	72,22%
	Acute systemic exposure mg/kg bw/day		0,0681	% of RVAAS	907,33%
Mixing and Loading	Gloves = No		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 17: Estimation of longer term operator exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			Protective gloves	
Specific exposure value	845.5948366	µg/person	6.3390240	µg/person
Systemic exposure	14.0932473	mg/kg bw/d	0.1056504	mg/kg bw/d
Body			Work wear	
Specific exposure value	640.8965729	µg/person	3.9174565	µg/person
Systemic exposure	10.6816095	mg/kg bw/d	0.0652909	mg/kg bw/d
Head			None	

Specific exposure value	8.1068106	µg/person	8.1068106	µg/person
Systemic exposure	0.1351135	mg/kg bw/d	0.1351135	mg/kg bw/d
<u>Inhalation</u>			None	
Specific exposure value	3.2185028	µg/person	3.2185028	µg/person
Systemic exposure	0.0536417	mg/kg bw/d	0.0536417	mg/kg bw/d
Application				
<u>Hands</u>			None	
Specific exposure value	64.8914787	µg/person	64.8914787	µg/person
Systemic exposure	1.0815246	mg/kg bw/d	1.0815246	mg/kg bw/d
<u>Body</u>			Work wear	
Specific exposure value	36.2830437	µg/person	0.9953051	µg/person
Systemic exposure	0.6047174	mg/kg bw/d	0.0165884	mg/kg bw/d
<u>Head</u>			None	
Specific exposure value	1.7148610	µg/person	1.7148610	µg/person
Systemic exposure	0.0285810	mg/kg bw/d	0.0285810	mg/kg bw/d
<u>Inhalation</u>			None	
Specific exposure value	0.8183277	µg/person	0.8183277	µg/person
Systemic exposure	0.0136388	mg/kg bw/d	0.0136388	mg/kg bw/d
Total				
Total systemic exposure	0.0266921	mg/kg bw/d	0.0015000	mg/kg bw/d
% of AOEL	355.89	%	20.00	%

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,3250042	0,1900467	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0054167	0,0031674	
% of RVNAS	72,22%	42,23%	

Table A 18: Input parameters considered for the estimation of operator exposure

Formulation type	CS	Crop type	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), strawberry, tomato
Application rate (AR)	0.0075 kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	50 ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	5 % (concentr.)	Indoor/outdoor	Outdoor
	15 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal
AOEL	0.0075 mg/kg bw/d	Water soluble bag	No

Table A 19: Estimation of longer term operator exposure towards Deltamethrin according to EFSA guidance

	Potential	With work wear + PPE/RPE
	Mixing and loading	
Hands		None

Specific exposure value	114.1317549	µg/person	114.1317549	µg/person
Systemic exposure	1.9021959	mg/kg bw/d	1.9021959	mg/kg bw/d
Body			Work wear	
Specific exposure value	89.5104630	µg/person	0.4981890	µg/person
Systemic exposure	1.4918410	mg/kg bw/d	0.0083031	mg/kg bw/d
Head			None	
Specific exposure value	0.9728173	µg/person	0.9728173	µg/person
Systemic exposure	0.0162136	mg/kg bw/d	0.0162136	mg/kg bw/d
Inhalation			None	
Specific exposure value	2.7645962	µg/person	2.7645962	µg/person
Systemic exposure	0.0460766	mg/kg bw/d	0.0460766	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	8.3431901	µg/person	8.3431901	µg/person
Systemic exposure	0.1390532	mg/kg bw/d	0.1390532	mg/kg bw/d
Body			Work wear	
Specific exposure value	4.6649628	µg/person	0.1279678	µg/person
Systemic exposure	0.0777494	mg/kg bw/d	0.0021328	mg/kg bw/d
Head			None	
Specific exposure value	0.2204821	µg/person	0.2204821	µg/person
Systemic exposure	0.0036747	mg/kg bw/d	0.0036747	mg/kg bw/d
Inhalation			None	
Specific exposure value	0.6335502	µg/person	0.6335502	µg/person
Systemic exposure	0.0105592	mg/kg bw/d	0.0105592	mg/kg bw/d
Total				
Total systemic exposure	0.0036874	mg/kg bw/d	0.0021282	mg/kg bw/d
% of AOEL	49.16	%	28.38	%

Table A 20: Input parameters considered for the estimation of operator exposure

Formulation type	CS		Crop type	Ornamentals
Application rate (AR)	0.0125	kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	10	ha	Application equipment	Vehicle-mounted
Dermal absorption (DA)	25	% (concentr.)	Indoor/outdoor	Outdoor
	70	% (dilution)	Closed cabin	No
Inhalation absorption (IA)	100	%	Drift reduction	No
Body weight (BW)	60	kg/person	Cultivation	Normal
AOEL	0.0075	mg/kg bw/d	Water soluble bag	No

Substance	Deltamethrin	Formulation = Soluble concentrates, emulsifiable concentrate, etc.	Application rate-0,0125 kg a.s. /ha	Spray dilution = 0,0625 g a.s./l	Vapour pressure = low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Scenario	Ornamentals / Outdoor / Downward spraying / Vehicle-mounted			Buffer = 2-3	Number applications = 3, Application interval = 10 days
Percentage Absorption	Dermal for product = 5	Dermal for in use dilution = 15	Oral = 100	Inhalation = 100	
RVNAS	0,0075 mg/kg bw/day		RVAAS	0,0075 mg/kg bw/day	
DFR	3 µg a.s./cm2 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		0,0028	% of RVNAS	37,08%
	Acute systemic exposure mg/kg bw/day		0,0394	% of RVAAS	525,37%
Mixing and Loading		Gloves = No	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 21: Estimation of longer term operator exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear + PPE/RPE	
Mixing and loading				
Hands			None	
Specific exposure value	244.9481953	µg/person	244.9481953	µg/person
Systemic exposure	4.0824699	mg/kg bw/d	4.0824699	mg/kg bw/d
Body			Work wear	
Specific exposure value	206.7573533	µg/person	0.9407151	µg/person
Systemic exposure	3.4459559	mg/kg bw/d	0.0156786	mg/kg bw/d
Head			None	
Specific exposure value	1.6213621	µg/person	1.6213621	µg/person
Systemic exposure	0.0270227	mg/kg bw/d	0.0270227	mg/kg bw/d
Inhalation			None	
Specific exposure value	1.9936110	µg/person	1.9936110	µg/person
Systemic exposure	0.0332268	mg/kg bw/d	0.0332268	mg/kg bw/d
Application				
Hands			None	
Specific exposure value	141.7785864	µg/person	141.7785864	µg/person
Systemic exposure	2.3629764	mg/kg bw/d	2.3629764	mg/kg bw/d
Body			Work wear	
Specific exposure value	194.5246871	µg/person	2.4326642	µg/person
Systemic exposure	3.2420781	mg/kg bw/d	0.0405444	mg/kg bw/d
Head			None	
Specific exposure value	1.1646632	µg/person	1.1646632	µg/person
Systemic exposure	0.0194111	mg/kg bw/d	0.0194111	mg/kg bw/d
Inhalation			None	
Specific exposure value	1.8755480	µg/person	1.8755480	µg/person

Systemic exposure	0.0312591	mg/kg bw/d	0.0312591	mg/kg bw/d
Total				
Total systemic exposure	0.0132444	mg/kg bw/d	0.0066126	mg/kg bw/d
% of AOEL	176.59	%	88.17	%

	Without RPE/PPE	With RPE/PPE	
Longer term			
Total systemic exposure from mixing, loading and application (mg a.s./day)	0,1668491	0,0845232	
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0,0027808	0,0014087	
% of RVNAS	37,08%	18,78%	

Table A 22: Input parameters considered for the estimation of operator exposure

Formulation type	CS	Crop type	Ornamentals
Application rate (AR)	0.0075 kg a.s./ha	Application method	Downward spraying
Area treated per day (A)	10 ha	Application equipment	Vehicle-mounted
Derma absorption (DA)	5 % (concentr.)	Indoor/outdoor	Outdoor
	15 % (dilution)	Closed cabin	No
Inhalation absorption (IA)	100 %	Drift reduction	No
Body weight (BW)	60 kg/person	Cultivation	Normal
AOEL	0.0075 mg/kg bw/d	Water soluble bag	No

Table A 23: Estimation of longer term operator exposure towards Deltamethrin according to EFSA guidance

	Potential	With work wear + PPE/RPE
Mixing and loading		
Hands		None
Specific exposure value	33.0611851 µg/person	33.0611851 µg/person
Systemic exposure	0.5510198 mg/kg bw/d	0.5510198 mg/kg bw/d
Body		Work wear
Specific exposure value	28.8766506 µg/person	0.1196322 µg/person
Systemic exposure	0.4812775 mg/kg bw/d	0.0019939 mg/kg bw/d
Head		None
Specific exposure value	0.1945635 µg/person	0.1945635 µg/person
Systemic exposure	0.0032427 mg/kg bw/d	0.0032427 mg/kg bw/d
Inhalation		None
Specific exposure value	1.7124513 µg/person	1.7124513 µg/person
Systemic exposure	0.0285409 mg/kg bw/d	0.0285409 mg/kg bw/d
Application		
Hands		None
Specific exposure value	18.2286754 µg/person	18.2286754 µg/person
Systemic exposure	0.3038113 mg/kg bw/d	0.3038113 mg/kg bw/d
Body		Work wear
Specific exposure value	25.0103169 µg/person	0.3127711 µg/person

Systemic exposure	0.4168386	mg/kg bw/d	0.0052129	mg/kg bw/d
Head			None	
Specific exposure value	0.1497424	µg/person	0.1497424	µg/person
Systemic exposure	0.0024957	mg/kg bw/d	0.0024957	mg/kg bw/d
Inhalation			None	
Specific exposure value	1.4520513	µg/person	1.4520513	µg/person
Systemic exposure	0.0242009	mg/kg bw/d	0.0242009	mg/kg bw/d
Total				
Total systemic exposure	0.0018114	mg/kg bw/d	0.0009205	mg/kg bw/d
% of AOEL	24.15	%	12.27	%

Table A 24: Dutch Greenhouse model for Deltamethrin

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form	-	-	Application including mixing and loading	
a.s.	Deltamethrin	-	-	-
Parameter		Value	Unit	References, comments
MANUAL SPRAYING in greenhouses			-	-
AR	Application rate	0,0125	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
-	-	-	-	-
Inhalation Exposure			-	without PPE
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		0,0125	mg a.s./ day	IE = SV x AR x A
-	-	-	-	-
Inhalation Exposure (with PPE)			-	with PPE
-	PPE factor	1	-	Non powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
Inhalation Exposure (with PPE)		0,0125	mg a.s./ day	IE(PPE) = (1/PPE factor) x IE
-	-	-	-	-
Dermal Exposure			-	without PPE
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	For dusting see note* (Dutch model)
Dermal Exposure		2,5	mg a.s./ day	DE = SV x AR x A
-	-	-	-	-
Dermal Exposure (with PPE)			-	with PPE
-	PPE factor	10	-	Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		0,25	mg a.s./ day	DE(PPE) = (1/PPE factor) x DE
-	-	-	-	-
Internal exposure			-	-
IA	Inhalation Absorption	100	%	-
DA	Dermal Absorption	70	%	-
-	AOEL	0,45	mg a.s./ day	based on 60 kg bw
-	-	-	-	-
-	-	Without PPE	With PPE	-

-	Internal exposure	[mg a.s./ day]	[mg a.s./ day]	-
-	Inhalation	0,0125	0,0125	$IE(int) = IE \times (IA/100)$
-	Dermal	1,7500	0,1750	$DE(int) = DE \times (DA/100)$
-	Total	1,7625	0,1875	sum
-	-	-	-	-
-	% AOEL	-	-	-
-	Inhalation	3	3	$\%AOEL = 100 \times IE(int) / AOEL$
-	Dermal	389	39	$\%AOEL = 100 \times DE(int) / AOEL$
-	Total	392	42	sum

OPERATOR EXPOSURE		DUTCH GREENHOUSE MODEL																					
form		Application including mixing and loading																					
a.s.	Deltamethrin																						
Parameter	Value	Unit	References, comments																				
MANUAL SPRAYING in greenhouses																							
AR Application rate	0,0125	kg a.s./ha	summary of intended uses																				
A Area treated	1	ha/ day	Dutch model																				
Inhalation Exposure																							
SV Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE																				
Inhalation Exposure (without PPE)	0,0125	mg a.s./ day	For dusting see note* (Dutch model) $IE = SV \times AR \times A$																				
Inhalation Exposure (with PPE)																							
PPE-factor	1		with PPE Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)																				
Inhalation Exposure (with PPE)	0,0125	mg a.s./ day	$IE(PPE) = (1/PPE\ factor) \times IE$																				
Dermal Exposure																							
SV Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE																				
Dermal Exposure	2,5	mg a.s./ day	For dusting see note* (Dutch model) $DE = SV \times AR \times A$																				
Dermal Exposure (with PPE)																							
PPE-factor	10		with PPE Gloves + coverall: 10 (Dutch model)																				
Dermal Exposure (with PPE)	0,25	mg a.s./ day	$DE(PPE) = (1/PPE\ factor) \times DE$																				
Internal exposure																							
IA Inhalation Absorption	100	%																					
DA Dermal Absorption	15	%																					
AOEL	0,45	mg a.s./ day	based on 70 kg bw																				
<table border="1"> <thead> <tr> <th></th> <th>Without PPE</th> <th>With PPE</th> <th></th> </tr> </thead> <tbody> <tr> <td>Internal exposure [mg a.s./ day]</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Inhalation</td> <td>0,0125</td> <td>0,0125</td> <td>$IE(int) = IE \times (IA/100)$</td> </tr> <tr> <td>Dermal</td> <td>0,3750</td> <td>0,0375</td> <td>$DE(int) = DE \times (DA/100)$</td> </tr> <tr> <td>Total</td> <td>0,3875</td> <td>0,0500</td> <td>sum</td> </tr> </tbody> </table>					Without PPE	With PPE		Internal exposure [mg a.s./ day]				Inhalation	0,0125	0,0125	$IE(int) = IE \times (IA/100)$	Dermal	0,3750	0,0375	$DE(int) = DE \times (DA/100)$	Total	0,3875	0,0500	sum
	Without PPE	With PPE																					
Internal exposure [mg a.s./ day]																							
Inhalation	0,0125	0,0125	$IE(int) = IE \times (IA/100)$																				
Dermal	0,3750	0,0375	$DE(int) = DE \times (DA/100)$																				
Total	0,3875	0,0500	sum																				

	% AOEL			
	Inhalation	3	3	$\%AOEL = 100 \times IE(int) / AOEL$
	Dermal	83	8	$\%AOEL = 100 \times DE(int) / AOEL$
	Total	86	11	sum

OPERATOR EXPOSURE			DUTCH GREENHOUSE MODEL	
form			Application including mixing and loading	
a.s.	Deltamethrin			
Parameter		Value	Unit	References, comments
MANUAL SPRAYING in greenhouses				
AR	Application rate	0.0075	kg a.s./ha	summary of intended uses
A	Area treated	1	ha/ day	Dutch model
Inhalation Exposure				
SV	Surrogate Exposure Value	1	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
Inhalation Exposure (without PPE)		0.0075	mg a.s./ day	$IE = SV \times AR \times A$
Inhalation Exposure (with PPE)				
	PPE-factor	1		Non-powered mask filtertype 2 (most conservative): 10; more advanced RPE: see note** (Dutch model)
Inhalation Exposure (with PPE)		0.0075	mg a.s./ day	$IE(PPE) = (1/PPE \text{ factor}) \times IE$
Dermal Exposure				
SV	Surrogate Exposure Value	200	mg a.s./ kg a.s.	without PPE For dusting see note* (Dutch model)
Dermal Exposure		1.5	mg a.s./ day	$DE = SV \times AR \times A$
Dermal Exposure (with PPE)				
	PPE-factor	10		Gloves + coverall: 10 (Dutch model)
Dermal Exposure (with PPE)		0.15	mg a.s./ day	$DE(PPE) = (1/PPE\text{-factor}) \times DE$
Internal exposure				
IA	Inhalation Absorption	100	%	
DA	Dermal Absorption	15	%	
	AOEL	0.45	mg a.s./ day	based on 60 kg bw
			Without PPE	With PPE
Internal exposure			[mg a.s. / day]	[mg a.s. / day]
	Inhalation	0.0075	0.0075	$IE(int) = IE \times (IA/100)$
	Dermal	0.2250	0.0225	$DE(int) = DE \times (DA/100)$
	Total	0.2325	0.0300	sum
	% AOEL			
	Inhalation	2	2	$\%AOEL = 100 \times IE(int) /$

				AOEL
	Dermal	50	5	%AOEL = 100 x DE(int) / AOEL
	Total	52	7	sum

A 3.2 Worker exposure calculations (KCP 7.2.3.1)

A 3.2.1 Calculations for Deltamethrin

Table A 25: Input parameters considered for the estimation of worker exposure

Intended-use(s)	Brassica-vegetables (cabbage, Brussels-sprouts; cauliflower), outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	2	Inhalation absorption (IA)	100	%
Interval between applications	10 days	Work rate per day (WR)	8	h/d
Half-life of active substance	3 days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.1	TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.0075 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

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	0,0125 kg a.s./ha
Number of applications	2
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	1,8
Dermal absorption of the product	5,00%
Dermal absorption of the in-use dilution	15,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0375 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 26: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0223140	mg/kg bw/d	0.0096181	mg/kg bw/d	0.0022314	mg/kg bw/d
% of AOEL	297.52	%	128.24	%	29.75	%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,4681558	0,2017913	0,0468156
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0078026	0,0033632	0,0007803
% of RVNAS	104,03%	44,84%	10,40%

Table A 27: Input parameters considered for the estimation of worker exposure for re-entry period of 1.5 days

Intended use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), outdoor		Dislodgeable foliar residue (DFR)	2.12	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	2		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	3	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.1		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 28: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance for re-entry period of 1.5 days

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0157686	mg/kg bw/d	0.0067968	mg/kg bw/d	0.0015769	mg/kg bw/d
% of AOEL	210.25	%	90.62	%	21.02	%

Table A 29: Input parameters considered for the estimation of worker exposure

Intended use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), reaching, picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0075	kg a.s./ha	Dermal absorption (DA)	15	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 30: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0026100	mg/kg bw/d	0.0011250	mg/kg bw/d	0.0002610	mg/kg bw/d
% of AOEL	34.80	%	15.00	%	33.48	%

Table A 31: Input parameters considered for the estimation of worker exposure

Intended use(s)	Tomato, outdoor	Dislodgeable foliar residue (DFR)	3	$\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$
Application rate (AR)	0.0125 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3	Inhalation absorption (IA)	100	%
Interval between applications	10 days	Work rate per day (WR)	8	h/d
Half-life of active substance	3 days	TC dermal (potential)	5800	cm^2/h
Multiple application factor (MAF)	1.1	TC dermal (work wear)	2500	cm^2/h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	580	cm^2/h
AOEL	0.0075 mg/kg bw/d	Task specific factor inhalation	-	$\text{ha}/\text{h} \times 10^{-3}$

Crop type	Fruiting 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	0,0125 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	5,00%
Dermal absorption of the in-use dilution	15,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0375 $\mu\text{g a.s.}/\text{cm}^2$
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 $\text{ha}/\text{hr} \times 10^{(-3)}$
Inhalation transfer coefficient for cutting ornamentals	NA $\text{ha}/\text{hr} \times 10^{(-3)}$
Inhalation transfer coefficient for sorting / bundling ornamentals	NA $\text{ha}/\text{hr} \times 10^{(-3)}$

Table A 32: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
$(\text{DFR} \times \text{TC} \times \text{WR} \times \text{AR} \times \text{MAF} \times \text{DA}) / \text{BW}$						
Systemic exposure	0.0225138	mg/kg bw/d	0.0097042	mg/kg bw/d	0.0022514	mg/kg bw/d
% of AOEL	300.18	%	129.39	%	30.02	%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,6325755	0,2726619	0,0632576
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0105429	0,0045444	0,0010543
% of RVNAS	140,57%	60,59%	14,06%

Table A 33: Input parameters considered for the estimation of worker exposure for re-entry period of 1.5 days

Intended use(s)	Tomato, outdoor	Dislodgeable foliar residue (DFR)	2.12	$\mu\text{g}/\text{cm}^2/\text{kg a.s.}/\text{ha}$
Application rate (AR)	0.0125 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3	Inhalation absorption (IA)	100	%
Interval between applications	10 days	Work rate per day (WR)	8	h/d
Half-life of active substance	3 days	TC dermal (potential)	5800	cm^2/h
Multiple application factor (MAF)	1.1	TC dermal (work wear)	2500	cm^2/h

Body-weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 34: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance for re-entry period of 1.5 days

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0159098	mg/kg bw/d	0.0068577	mg/kg bw/d	0.0015910	mg/kg bw/d
% of AOEL	212.13	%	91.44	%	21.21	%

Table A 35: Input parameters considered for the estimation of worker exposure

Intended use(s)	Tomato, reaching, picking, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0075	kg a.s./ha	Dermal absorption (DA)	15	% (worst case)
Number of applications (NA)	1		Inhalation absorption (IA)	100	%
Interval between applications	365	days	Work rate per day (WR)	8	h/d
Half-life of active substance	30	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.0		TC dermal (work wear)	2500	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	580	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 36: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0026100	mg/kg bw/d	0.0011250	mg/kg bw/d	0.0002610	mg/kg bw/d
% of AOEL	34.80	%	15.00	%	3.48	%

Table A 37: Input parameters considered for the estimation of worker exposure

Intended use(s)	Strawberry, outdoor		Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	3	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.1		TC dermal (work wear)	3000	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	750	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Crop type	Low berries and other small fruits
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 forearm
Application rate of active substance	0,0125 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	5,00%
Dermal absorption of the in-use dilution	15,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0375 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	3000 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	750 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 38: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0225138	mg/kg bw/d	0.0116451	mg/kg bw/d	0.0029113	mg/kg bw/d
% of AOEL	300.18	%	155.27	%	38.82	%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	0,6325755	0,3271942	0,0817986
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0105429	0,0054532	0,0013633
% of RVNAS	140,57%	72,71%	18,18%

Table A 39: Input parameters considered for the estimation of worker exposure for re-entry period of 2 days

Intended use(s)	Strawberry, outdoor		Dislodgeable foliar residue (DFR)	1.89	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	3	days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.1		TC dermal (work wear)	3000	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	750	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 40: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance for re-entry period of 2 days

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0141837	mg/kg bw/d	0.0073364	mg/kg bw/d	0.0018341	mg/kg bw/d
% of AOEL	189.12	%	97.82	%	24.45	%

Table A 41: Input parameters considered for the estimation of worker exposure

Intended use(s)	Strawberry, reaching, picking, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0075 kg a.s./ha	Dermal absorption (DA)	15	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	365 days	Work rate per day (WR)	8	h/d
Half-life of active substance	30 days	TC dermal (potential)	5800	cm ² /h
Multiple application factor (MAF)	1.0	TC dermal (work wear)	3000	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	750	cm ² /h
AOEL	0.0075 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 42: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential	With work wear	With work wear and gloves
Worker (re-entry): Dermal exposure after application			
(DFR x TC x WR x AR x MAF x DA) / BW			
Systemic exposure	0.0026100 mg/kg bw/d	0.0013500 mg/kg bw/d	0.0003375 mg/kg bw/d
% of AOEL	34.80 %	18.00 %	4.50 %

Table A 43: Input parameters considered for the estimation of worker exposure

Intended-use(s)	Ornamentals, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125 kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3	Inhalation absorption (IA)	100	%
Interval between applications	10 days	Work rate per day (WR)	8	h/d
Half-life of active substance	3 days	TC dermal (potential)	14000	cm ² /h
Multiple application factor (MAF)	1.1	TC dermal (work wear)	5000	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	1400	cm ² /h
AOEL	0.0075 mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Crop type	Ornamentals
Indoor or outdoor	Outdoor
Application method	Downward spraying
Application equipment	Vehicle-mounted
Worker's task	Cutting, sorting, bundling, carrying
Main body parts in contact with foliage	Hand and body
Application rate of active substance	0,0125 kg a.s./ha
Number of applications	3
Interval between multiple applications	10 days
Half-life of active substance	30 days
Multiple application factor	2,4
Dermal absorption of the product	5,00%
Dermal absorption of the in-use dilution	15,00%
Dislodgeable foliar residue (i_AppRate*i_DFR)	0,0375 µg a.s./cm ²
Working hours	8 hr
Dermal transfer coefficient - Total potential exposure	14000 cm ² /hr
Dermal transfer coefficient - arms, body and legs covered	5000 cm ² /hr
Dermal transfer coefficient - hands, arms, body and legs covered	1400 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 44: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0543437	mg/kg bw/d	0.0194085	mg/kg bw/d	0.0054344	mg/kg bw/d
% of AOEL	724.58	%	258.78	%	72.46	%

	Potential exposure	Work wear - arms, body and legs covered	Working wear and gloves
Total systemic exposure (mg a.s./day)	1,5269065	0,5453237	0,1526906
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0254484	0,0090887	0,0025448
% of RVNAS	339,31%	121,18%	33,93%

Table A 45: Input parameters considered for the estimation of worker exposure for re-entry period of 4.5 days

Intended use(s)	Ornamentals, outdoor		Dislodgeable foliar residue (DFR)	1.06	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0125	kg a.s./ha	Dermal absorption (DA)	70	% (worst case)
Number of applications (NA)	3		Inhalation absorption (IA)	100	%
Interval between applications	10	days	Work rate per day (WR)	8	h/d
Half-life of active substance	3	days	TC dermal (potential)	14000	cm ² /h
Multiple application factor (MAF)	1.1		TC dermal (work wear)	5000	cm ² /h
Body weight (BW)	60	kg/person	TC dermal (work wear, gloves)	1400	cm ² /h
AOEL	0.0075	mg/kg bw/d	Task specific factor inhalation	-	ha/h x 10 ⁻³

Table A 46: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance for re-entry period of 4.5 days

	Potential		With work wear		With work wear and gloves	
Worker (re-entry): Dermal exposure after application						
(DFR x TC x WR x AR x MAF x DA) / BW						
Systemic exposure	0.0192015	mg/kg bw/d	0.0068577	mg/kg bw/d	0.0019201	mg/kg bw/d
% of AOEL	256.02	%	91.44	%	25.60	%

Table A 47: Input parameters considered for the estimation of worker exposure

Intended use(s)	Ornamentals, cutting, sorting, bundling, carrying, outdoor	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s./ha
Application rate (AR)	0.0075 kg a.s./ha	Dermal absorption (DA)	15	% (worst case)
Number of applications (NA)	1	Inhalation absorption (IA)	100	%
Interval between applications	365 days	Work rate per day (WR)	8	h/d
Half-life of active substance	30 days	TC dermal (potential)	14000	cm ² /h
Multiple application factor (MAF)	1.0	TC dermal (work wear)	5000	cm ² /h
Body weight (BW)	60 kg/person	TC dermal (work wear, gloves)	1400	cm ² /h
AOEL	0.0075 mg/kg bw/d	Task specific factor inhalation	1	ha/h x 10 ⁻³

Table A 48: Estimation of longer term worker exposure towards Deltamethrin according to EFSA guidance

	Potential	With work wear	With work wear and gloves
Worker (re-entry): Dermal exposure after application			
(DFR x TC x WR x AR x MAF x DA) / BW			
Systemic exposure	0.0063000 mg/kg bw/d	0.0022500 mg/kg bw/d	0.0006300 mg/kg bw/d
% of AOEL	84.00 %	30.00 %	8.40 %

A 3.3 Resident and bystander exposure calculations (KCP 7.2.2.1)

A 3.3.1 Calculations for Deltamethrin

Table A 49: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), spraying		Drift reduction (DR)		%
Application rate (AR)	0.0125	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) – 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) – mean	4.10	%
Number of applications (NA)	2		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	3	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.1		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption	100	%	Light clothing adjustment factor	18	%

(IA)			(CF)		
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.0075	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) – 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) – 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{DM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) – mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) – mean	0.00009	mL spray dilution (adult)	TC entry into treated crops – 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops – mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Croptype	Brassica 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	0,0125 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,0625 g a.s./l
Dermal absorption of product	5,00%
Dermal absorption of in-use dilution	15,00%
Oral absorption	100,00%
Dislodgeable foliar residue (I_AppRate*i_DFR)	0,0375 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Concentration in air	0,001 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 50: Estimation of longer term resident exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray-drift (75 th pere.)					
(SD x DA x (1 – CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0002811	mg/kg bw/d	Systemic exposure	0.0011745	mg/kg bw/d
% of AOEL:	3.75	%	% of AOEL:	15.66	%
Vapour (75 th pere.)					
(VC x IR x IA)/ BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	3.07	%	% of AOEL:	14.27	%
Surface deposits (75 th pere.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0000655	mg/kg bw/d	Systemic exposure	0.0001400	mg/kg bw/d
<u>Hand-to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000073	mg/kg bw/d

<u>Object-to-mouth</u>							
AR x MAF x D x DR _{QM} x IgR x OA / BW							
			Systemic exposure	0.0000038	mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0000655	mg/kg bw/d	Systemic exposure	0.0001512	mg/kg bw/d		
% of AOEL:	0.87	%	% of AOEL:	2.02	%		
Entry into treated crops (75 th perc.)							
<u>Dermal</u>							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0009017	mg/kg bw/d	Systemic exposure	0.0016231	mg/kg bw/d		
<u>Hand-to-mouth</u>							
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Object-to-mouth</u>							
AR x MAF x 100% x DR _{QM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0009017	mg/kg bw/d	Systemic exposure	0.0016231	mg/kg bw/d		
% of AOEL:	12.02	%	% of AOEL:	21.64	%		
All pathways (mean)							
Systemic exposure			-0.0011305	mg/kg bw/d	Systemic exposure	-0.0031216	mg/kg bw/d
% of AOEL:	15.07	%	% of AOEL:		41.62	%	

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)	0,0025276	0,0107000	0,0006717	0,0056754	0,0171114
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0002528	0,0010700	0,0000672	0,0005675	0,0017111
% of RVNAS	3,37%	14,27%	0,90%	7,57%	22,82%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0036194	0,0138000	0,0013749	0,0189179	0,0316118
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0000603	0,0002300	0,0000229	0,0003153	0,0005269
% of RVNAS	0,80%	3,07%	0,31%	4,20%	7,02%

Table A 51: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Strawberry, spraying		Drift reduction (DR)		%
Application rate (AR)	0.0125	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ³ /h (adult)
				2600	cm ³ /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) – 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) – mean	4.10	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applica-	10	days	Exposure duration dermal (H _D)	2	h

tions					
Half-life of active substance	3	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.1		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.0075	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) – 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) – 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) – mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) – mean	0.00009	mL spray dilution (adult)	TC entry into treated crops – 75 th perc.	7500	cm ³ /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ³ /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops – mean:	5980	cm ³ /h (adult)
	8.31	m ³ /d (child)		1794	cm ³ /h (child)

Croptype	Low berries and other small fruits
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	0,0125 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,0625 g a.s./l
Dermal absorption of product	5,00%
Dermal absorption of in-use dilution	15,00%
Oral absorption	100,00%
Dislodgeable foliar residue (I_AppRate*i_DFR)	0,0375 µg a.s./cm ²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Concentration in air	0,001 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 52: Estimation of longer term resident exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (75 th pere.)					
(SD x DA x (1 – CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0002811	mg/kg bw/d	Systemic exposure	0.0011745	mg/kg bw/d
% of AOEL:	3.75	%	% of AOEL:	15.66	%
Vapour (75 th pere.)					
(VC x IR x IA)/ BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	3.07	%	% of AOEL:	14.27	%
Surface deposits (75 th pere.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0000661	mg/kg bw/d	Systemic exposure	0.0001413	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000074	mg/kg bw/d

<u>Object-to-mouth</u>							
AR x MAF x D x DR _{QM} x IgR x OA / BW							
			Systemic exposure	0.0000039	mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0000661	mg/kg bw/d	Systemic exposure	0.0001526	mg/kg bw/d		
% of AOEL:	0.88	%	% of AOEL:	2.03	%		
Entry into treated crops (75 th perc.)							
<u>Dermal</u>							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d		
<u>Hand-to-mouth</u>							
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Object-to-mouth</u>							
AR x MAF x 100% x DR _{QM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d		
% of AOEL:	12.13	%	% of AOEL:	21.83	%		
All pathways (mean)							
Systemic exposure			-0.0011373	mg/kg bw/d	Systemic exposure	-0.0031342	mg/kg bw/d
% of AOEL:	15.16	%	% of AOEL:		41.79	%	

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)	0,0025276	0,0107000	0,0009077	0,0076686	0,0188734
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0002528	0,0010700	0,0000908	0,0007669	0,0018873
% of RVNAS	3,37%	14,27%	1,21%	10,22%	25,16%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0036194	0,0138000	0,0018577	0,0255621	0,0372629
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0000603	0,0002300	0,0000310	0,0004260	0,0006210
% of RVNAS	0,80%	3,07%	0,41%	5,68%	8,28%

Table A 53: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower), strawberry, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.0075	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300 2600	cm ² /h (adult) cm ² /h (child)
Minimum water volume (V)	200	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%
Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%

Interval between applications	365	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	15	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.0075	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 54: Estimation of longer term resident exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0000362	mg/kg bw/d	Systemic exposure	0.0001517	mg/kg bw/d
% of AOEL:	0.48	%	% of AOEL:	2.02	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	3.07	%	% of AOEL:	14.27	%
Surface deposits (75 th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0000077	mg/kg bw/d	Systemic exposure	0.0000164	mg/kg bw/d
Hand to mouth					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					

			Systemic exposure	0.0000040	mg/kg bw/d		
Object to mouth							
AR x MAF x D x DR _{OM} x IgR x OA / BW							
			Systemic exposure	0.0000021	mg/kg bw/d		
Total							
Systemic exposure	0.0000077	mg/kg bw/d	Systemic exposure	0.0000225	mg/kg bw/d		
% of AOEL:	0.10	%	% of AOEL:	0.30	%		
Entry into treated crops (75 th perc.)							
Dermal							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0001055	mg/kg bw/d	Systemic exposure	0.0001898	mg/kg bw/d		
Hand to mouth							
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
Object to mouth							
AR x MAF x 100% x DR _{OM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
Total							
Systemic exposure	0.0001055	mg/kg bw/d	Systemic exposure	0.0001898	mg/kg bw/d		
% of AOEL:	1.41	%	% of AOEL:	2.53	%		
All pathways (mean)							
Systemic exposure			0.0003369	mg/kg bw/d	Systemic exposure	0.0013215	mg/kg bw/d
% of AOEL:	4.49	%	% of AOEL:		17.62	%	

Table A 55: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Tomato, ornamentals, spraying		Drift reduction (DR)		%
Application rate (AR)	0.0125	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ³ /h (adult)
				2600	cm ³ /h (child)
Minimum water volume (V)	300	L/ha	Drift on surface (D) —75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) —mean	4.10	%
Number of applications (NA)	3		Turf Transferable Residues (TTR)	5	%
Interval between applications	10	days	Exposure duration dermal (H _D)	2	h
Half life of active substance	3	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.1		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%

Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.0075	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD)– 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI)– 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD)– mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ³ /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD)– mean	0.00009	mL spray dilution (adult)	TC entry into treated crops – 75 th perc.	7500	cm ³ /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ³ /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops – mean:	5980	cm ³ /h (adult)
	8.31	m ³ /d (child)		1794	cm ³ /h (child)

Croptype	Ornamentals
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	0,0125 kg a.s./ha
Concentration of active substance (in-use dilution for liquid applications)	0,0625 g a.s./l
Dermal absorption of product	5,00%
Dermal absorption of in-use dilution	15,00%
Oral absorption	100,00%
Dislodgeable foliar residue (I_AppRate*i_DFR)	0,0375 µg a.s./cm²
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10 ⁻³ Pa
Concentration in air	0,001 mg/m³
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 m³/day/kg
Breathing rate child (1-3 year old)	1,07 m³/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 cm²/hour
Transfer coeff. of surface deposits-child (1-3 year old)	2600 cm²/hour
Saliva extraction percentage	50,00%
Surface area of hands mouthed	20 cm²
Frequency of hand to mouth activity	9,5 events/hour
Ingestion rate for mouthing of grass per day	25 cm²
Dislodgeable residues percentage transferability for object to mouth	20,00%
Transfer coefficient for entry into treated crops (75th percentile) - adult	7500 cm²/h
Transfer coefficient for entry into treated crops (75th percentile) - child	2250 cm²/h
Transfer coefficient for entry into treated crops (mean) - adult	5980 cm²/h
Transfer coefficient for entry into treated crops (mean) - child	1794 cm²/h

Table A 56: Estimation of longer term resident exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray-drift (75 th perc.)					
(SD × DA × (1 – CF) + SI) × AR × MAF × V × DR / BW					
Systemic exposure	0.0001874	mg/kg bw/d	Systemic exposure	0.0007830	mg/kg bw/d
% of AOEL:	2.50	%	% of AOEL:	10.44	%
Vapour (75 th perc.)					
(VC × IR × IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	3.07	%	% of AOEL:	14.27	%
Surface deposits (75 th perc.)					
Dermal					
AR × MAF × D × TTR × TC × H _D × DA / BW					
Systemic exposure	0.0000661	mg/kg bw/d	Systemic exposure	0.0001413	mg/kg bw/d
Hand-to-mouth					

AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure	0.0000074	mg/kg bw/d		
<u>Object to mouth</u>							
AR x MAF x D x DR _{OM} x IgR x OA / BW							
			Systemic exposure	0.0000039	mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0000661	mg/kg bw/d	Systemic exposure	0.0001526	mg/kg bw/d		
% of AOEL:	0.88	%	% of AOEL:	2.03	%		
Entry into treated crops (75 th perc.)							
<u>Dermal</u>							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d		
<u>Hand to mouth</u>							
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Object to mouth</u>							
AR x MAF x 100% x DR _{OM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
<u>Total</u>							
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d		
% of AOEL:	12.13	%	% of AOEL:	21.83	%		
All pathways (mean)							
Systemic exposure			-0.0010928	mg/kg bw/d	Systemic exposure	-0.0029186	mg/kg bw/d
% of AOEL:	14.57	%	% of AOEL:		38.91	%	

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)	0,0025276	0,0107000	0,0009077	0,0076686	0,0188734
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0002528	0,0010700	0,0000908	0,0007669	0,0018873
% of RVNAS	3,37%	14,27%	1,21%	10,22%	25,16%
1.2 Adult					
	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0,0036194	0,0138000	0,0018577	0,0255621	0,0372629
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0000603	0,0002300	0,0000310	0,0004260	0,0006210
% of RVNAS	0,80%	3,07%	0,41%	5,68%	8,28%

Table A 57: Input parameters considered for the estimation of longer term resident exposure

Intended use(s)	Tomato, ornamentals, downward spraying		Drift reduction (DR)		%
Application rate (AR)	0.0075	kg a.s./ha	Transfer coefficient surface deposits (TC)	7300	cm ² /h (adult)
				2600	cm ² /h (child)
Minimum water volume (V)	300	L/ha	Drift on surface (D) - 75 th perc.	5.60	%
Buffer strip	2-3	m	Drift on surface (D) - mean	4.10	%

Number of applications (NA)	1		Turf Transferable Residues (TTR)	5	%
Interval between applications	365	days	Exposure duration dermal (H _D)	2	h
Half-life of active substance	30	days	Exposure duration inhal. (H _I)	24	h
Multiple application factor (MAF)	1.0		Exposure duration entry into treated crops (H _E)	0.25	h
Body weight (BW)	60	kg/person (adults)	Airborne Concentration of Vapour (VC)	0.001	mg/m ³
	10	kg/person (children)			
Dermal absorption (DA)	15	% ('worst case')	Dislodgeable foliar residue (DFR)	3	µg/cm ² /kg a.s.
Inhalation absorption (IA)	100	%	Light clothing adjustment factor (CF)	18	%
Oral absorption (OA)	100	%	Saliva Extraction Factor (SE)	50	%
AOEL	0.0075	mg/kg bw/d	Surface Area of Hands (SA)	20	cm ²
Spray drift dermal (SD) - 75 th perc.	0.47	mL spray dilution (adult)	Frequency of Hand to Mouth (Freq)	20	events/h
	0.327	mL spray dilution (child)			
Spray drift inhal. (SI) - 75 th perc.	0.00010	mL spray dilution (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	0.00022	mL spray dilution (child)			
Spray drift dermal (SD) - mean	0.22318	mL spray dilution (adult)	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
	0.18	mL spray dilution (child)			
Spray drift inhal. (SD) - mean	0.00009	mL spray dilution (adult)	TC entry into treated crops - 75 th perc.	7500	cm ² /h (adult)
	0.00017	mL spray dilution (child)		2250	cm ² /h (child)
Inhalation rate (IR)	16.57	m ³ /d (adult)	TC entry into treated crops - mean:	5980	cm ² /h (adult)
	8.31	m ³ /d (child)		1794	cm ² /h (child)

Table A 58: Estimation of longer term resident exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (75 th perc.)					
(SD x DA x (1- CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0000241	mg/kg bw/d	Systemic exposure	0.0001011	mg/kg bw/d
% of AOEL:	0.32	%	% of AOEL:	1.35	%
Vapour (75 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AOEL:	3.07	%	% of AOEL:	14.27	%
Surface deposits (75 th perc.)					
Dermal					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0000077	mg/kg bw/d	Systemic exposure	0.0000164	mg/kg bw/d

Hand to mouth							
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure	0.0000040	mg/kg bw/d		
Object to mouth							
AR x MAF x D x DR _{OM} x IgR x OA / BW							
			Systemic exposure	0.0000021	mg/kg bw/d		
Total							
Systemic exposure	0.0000077	mg/kg bw/d	Systemic exposure	0.0000225	mg/kg bw/d		
% of AOEL:	0.10	%	% of AOEL:	0.30	%		
Entry into treated crops (75 th perc.)							
Dermal							
AR x MAF x TC x H _D x DFR x DA / BW							
Systemic exposure	0.0001055	mg/kg bw/d	Systemic exposure	0.0001898	mg/kg bw/d		
Hand to mouth							
AR x MAF x 100% x TTR x x SE x SA x Freq x H _D x OA / BW							
			Systemic exposure		mg/kg bw/d		
Object to mouth							
AR x MAF x 100% x DR _{OM} x IgR x OA / BW							
			Systemic exposure		mg/kg bw/d		
Total							
Systemic exposure	0.0001055	mg/kg bw/d	Systemic exposure	0.0001898	mg/kg bw/d		
% of AOEL:	1.41	%	% of AOEL:	2.53	%		
All pathways (mean)							
Systemic exposure			0.0003312	mg/kg bw/d	Systemic exposure	0.0012936	mg/kg bw/d
% of AOEL:	4.42	%	% of AOEL:		17.25	%	

Table A 59: Input parameters considered for the estimation of acute bystander exposure

Intended use(s)	Brassica vegetables (cabbage, Brussels sprouts, cauliflower); spraying		Drift on surface (D) – 90 th perc.	8.50	%
Application rate (AR)	0.0125	kg a.s./ha	Turf transferable residues (TTR)	5	%
Minimum water volume (V)	200	L/ha	Exposure duration dermal (H _D)	2	h
Buffer strip	2-3	m	Exposure duration inhal. (H _I)	24	h
Body weight (BW)	60	kg/person (adults)	Exposure duration entry into treated crops (H _E)	0.25	h
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Airborne concentration of vapour (VC)	0.001	mg/m ³
Inhalation absorption (IA)	100	%	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Oral absorption (OA)	100	%	Light clothing adjustment factor (CF)	18	%
AAOEL	0.0075	mg/kg bw/d	Saliva extraction factor (SE)	50	%
Spray drift dermal (SD) – 95 th perc.	1.21	mL spray dilution (adult)	Surface area of hands (SA)	20	cm ²
	0.74	mL spray dilution (child)			

Spray-drift inhal. (SI) – 95 th perc.	0.00050	mL-spray-dilution (adult)	Frequency of hand-to-mouth (freq)	20	events/h
	0.00112	mL-spray-dilution (child)			
Inhalation rate (IR)	0.23	m ³ /d (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	1.07	m ³ /d (child)			
Drift reduction (DR)		%	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ³ /d
Transfer coefficient surface deposits (TC)	14500	cm ² /h (adult)	TC entry into treated crops – 95 th perc.	7500	cm ² /h (adult)
	5200	cm ² /h (child)		2250	cm ² /h (child)

Table A 60: Estimation of acute bystander exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (95 th perc.)					
(SD x DA x (1–CF) + SI) x AR x MAF x V x DR/ BW					
Systemic exposure	0.0007240	mg/kg bw/d	Systemic exposure	0.0026618	mg/kg bw/d
% of AAOEL	9.65	%	% of AAOEL	35.49	%
Vapour (95 th perc.)					
(VC x IR x IA) / BW					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AAOEL	3.07	%	% of AAOEL	14.27	%
Surface deposits (95 th perc.)					
<u>Dermal</u>					
AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0001976	mg/kg bw/d	Systemic exposure	0.0004251	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000234	mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000058	mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0001976	mg/kg bw/d	Systemic exposure	0.0004543	mg/kg bw/d
% of AAOEL	2.63	%	% of AAOEL	6.06	%
Entry into treated crops (95 th perc.)					
<u>Dermal</u>					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure	0.0009017	mg/kg bw/d	Systemic exposure	0.0016231	mg/kg bw/d
<u>Hand to mouth</u>					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
<u>Object to mouth</u>					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d

Total					
Systemic exposure	0.0009017	mg/kg bw/d	Systemic exposure	0.0016231	mg/kg bw/d
% of AAOEL	12.02	%	% of AAOEL	21.64	%

Table A 61: Input parameters considered for the estimation of acute bystander exposure

Intended use(s)	Strawberry, spraying		Drift on surface (D) – 90 th perc.	8.50	%
Application rate (AR)	0.0125	kg a.s./ha	Turf transferable residues (TTR)	5	%
Minimum water volume (V)	200	L/ha	Exposure duration dermal (H _D)	2	h
Buffer strip	2-3	m	Exposure duration inhal. (H _I)	24	h
Body weight (BW)	60	kg/person (adults)	Exposure duration entry into treated crops (H _E)	0.25	h
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Airborne concentration of vapour (VC)	0.001	mg/m ³
Inhalation absorption (IA)	100	%	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Oral absorption (OA)	100	%	Light clothing adjustment factor (CF)	18	%
AAOEL	0.0075	mg/kg bw/d	Saliva extraction factor (SE)	50	%
Spray drift dermal (SD) – 95 th perc.	1.21	mL spray dilution (adult)	Surface area of hands (SA)	20	cm ²
	0.74	mL spray dilution (child)			
Spray drift inhal. (SI) – 95 th perc.	0.00050	mL spray dilution (adult)	Frequency of hand-to-mouth (freq)	20	events/h
	0.00112	mL spray dilution (child)			
Inhalation rate (IR)	0.23	m ³ /d (adult)	Dislodgeable residues object to mouth (DR _{OM})	20	%
	1.07	m ³ /d (child)			
Drift reduction (DR)		%	Ingestion Rate for Mouthing of Grass (IgR)	25	cm ² /d
Transfer coefficient surface deposits (TC)	14500	cm ² /h (adult)	TC entry into treated crops – 95 th perc.	7500	cm ² /h (adult)
	5200	cm ² /h (child)		2250	cm ² /h (child)

Table A 62: Estimation of acute bystander exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (95 th perc.)					
$(SD \times DA \times (1 - CF) + SI) \times AR \times MAF \times V \times DR / BW$					
Systemic exposure	0.0007240	mg/kg bw/d	Systemic exposure	0.0026618	mg/kg bw/d
% of AAOEL	9.65	%	% of AAOEL	35.49	%
Vapour (95 th perc.)					
$(VC \times IR \times IA) / BW$					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AAOEL	3.07	%	% of AAOEL	14.27	%
Surface deposits (95 th perc.)					
Dermal					

AR x MAF x D x TTR x TC x H _D x DA / BW					
Systemic exposure	0.0001993	mg/kg bw/d	Systemic exposure	0.0004289	mg/kg bw/d
Hand-to-mouth					
AR x MAF x D x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure	0.0000236	mg/kg bw/d
Object-to-mouth					
AR x MAF x D x DR _{OM} x IgR x OA / BW					
			Systemic exposure	0.0000059	mg/kg bw/d
Total					
Systemic exposure	0.0001993	mg/kg bw/d	Systemic exposure	0.0004584	mg/kg bw/d
% of AAOEL	2.66	%	% of AAOEL	6.11	%
Entry into treated crops (95th pere.)					
Dermal					
AR x MAF x TC x H _D x DFR x DA / BW					
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d
Hand-to-mouth					
AR x MAF x 100% x TTR x SE x SA x Freq x H _D x OA / BW					
			Systemic exposure		mg/kg bw/d
Object-to-mouth					
AR x MAF x 100% x DR _{OM} x IgR x OA / BW					
			Systemic exposure		mg/kg bw/d
Total					
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d
% of AAOEL	12.13	%	% of AAOEL	21.83	%

Table A 63: Input parameters considered for the estimation of acute bystander exposure

Intended use(s)	Tomato, ornamentals, spraying		Drift on surface (D) – 90 th pere.	8.50	%
Application rate (AR)	0.0125	kg a.s./ha	Turf transferable residues (TTR)	5	%
Minimum water volume (V)	300	L/ha	Exposure duration dermal (H _D)	2	h
Buffer strip	2-3	m	Exposure duration inhal. (H _I)	24	h
Body weight (BW)	60	kg/person (adults)	Exposure duration entry into treated crops (H _E)	0.25	h
	10	kg/person (children)			
Dermal absorption (DA)	70	% ('worst case')	Airborne concentration of vapour (VC)	0.001	mg/m ³
Inhalation absorption (IA)	100	%	Dislodgeable foliar residue (DFR)	1	µg/cm ² /kg a.s.
Oral absorption (OA)	100	%	Light clothing adjustment factor (CF)	18	%
AAOEL	0.0075	mg/kg bw/d	Saliva extraction factor (SE)	50	%
Spray drift dermal (SD) – 95 th pere.	1.21	mL spray dilution (adult)	Surface area of hands (SA)	20	cm ²
	0.74	mL spray dilution (child)			
Spray drift inhal. (SI) – 95 th pere.	0.00050	mL spray dilution (adult)	Frequency of hand-to-mouth (freq)	20	events/h

	0.00112	mL-spray-dilution (child)			
Inhalation-rate (IR)	0.23	m³/d (adult)	Dislodgeable residues object-to-mouth (DR _{OM})	20	%
	1.07	m³/d (child)			
Drift reduction (DR)		%	Ingestion Rate for Mouthing of Grass (IgR)	25	cm³/d
Transfer coefficient surface deposits (TC)	14500	cm²/h (adult)	TC entry into treated crops—95 th -perc.	7500	cm²/h (adult)
	5200	cm²/h (child)		2250	cm²/h (child)

Table A 64: Estimation of acute bystander exposure towards Deltamethrin according to EFSA guidance

Adult			Child		
Spray drift (95 th perc.)					
$(SD \times DA \times (1 - CF) + SI) \times AR \times MAF \times V \times DR / BW$					
Systemic exposure	0.0004827	mg/kg bw/d	Systemic exposure	0.0017745	mg/kg bw/d
% of AAOEL	6.44	%	% of AAOEL	23.66	%
Vapour (95 th perc.)					
$(VC \times IR \times IA) / BW$					
Systemic exposure	0.0002300	mg/kg bw/d	Systemic exposure	0.0010700	mg/kg bw/d
% of AAOEL	3.07	%	% of AAOEL	14.27	%
Surface deposits (95 th perc.)					
<u>Dermal</u>					
$AR \times MAF \times D \times TTR \times TC \times H_D \times DA / BW$					
Systemic exposure	0.0001993	mg/kg bw/d	Systemic exposure	0.0004289	mg/kg bw/d
<u>Hand-to-mouth</u>					
$AR \times MAF \times D \times TTR \times SE \times SA \times Freq \times H_D \times OA / BW$					
			Systemic exposure	0.0000236	mg/kg bw/d
<u>Object-to-mouth</u>					
$AR \times MAF \times D \times DR_{OM} \times IgR \times OA / BW$					
			Systemic exposure	0.0000059	mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0001993	mg/kg bw/d	Systemic exposure	0.0004584	mg/kg bw/d
% of AAOEL	2.66	%	% of AAOEL	6.11	%
Entry into treated crops (95 th perc.)					
<u>Dermal</u>					
$AR \times MAF \times TC \times H_D \times DFR \times DA / BW$					
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d
<u>Hand-to-mouth</u>					
$AR \times MAF \times 100\% \times TTR \times SE \times SA \times Freq \times H_D \times OA / BW$					
			Systemic exposure		mg/kg bw/d
<u>Object-to-mouth</u>					
$AR \times MAF \times 100\% \times DR_{OM} \times IgR \times OA / BW$					
			Systemic exposure		mg/kg bw/d
<u>Total</u>					
Systemic exposure	0.0009098	mg/kg bw/d	Systemic exposure	0.0016376	mg/kg bw/d

% of AAOEL	12.13	%	% of AAOEL	21.83	%
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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)

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