

Appendix to:

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance Alpha-cypermethrin. EFSA Journal 2018;16(8):5403, 39 pp. doi:10.2903/j.efsa.2018.5403

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List of end points for the active substance and the representative formulation

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Alpha-cypermethrin
Function (<i>e.g.</i> fungicide)	Insecticide
Rapporteur Member State	Belgium
Co-rapporteur Member State	Greece

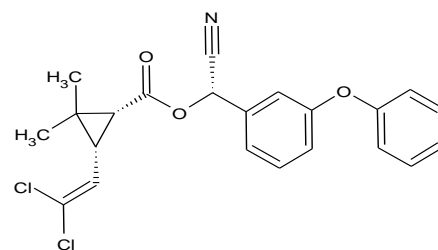
Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	Racemate comprising (<i>R</i>)- α -cyano-3-phenoxybenzyl (1 <i>S</i> ,3 <i>S</i>)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (<i>S</i>)- α -cyano-3-phenoxybenzyl (1 <i>R</i> ,3 <i>R</i>)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate or (<i>R</i>)- α -cyano-3 phenoxybenzyl-(1 <i>S</i>)- <i>cis</i> -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (<i>S</i>)- α -cyano-3 phenoxybenzyl-(1 <i>R</i>)- <i>cis</i> -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA)	(<i>R</i>)-cyano(3-phenoxyphenyl)methyl (1 <i>S</i> ,3 <i>S</i>)- <i>rel</i> -3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate (<i>Cis-II isomeric pair of cypermethrin</i>)
CIPAC No	454
CAS No	[67375-30-8]
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	454/TC (2013) min. 930 g/kg
Minimum purity of the active substance as manufactured	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	hexane max. 1 g/kg (not of concern at this level)
Molecular formula	C ₂₂ H ₁₉ Cl ₂ NO ₃

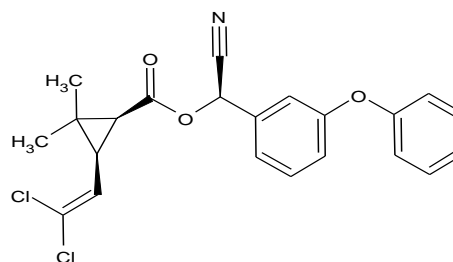
Molar mass

416.3 g/mol

Structural formula

[1*R cis* α*S*]

+

[1*S cis* α*R*]

Note:

1*R,S* describes the configuration at the carboxyl-bearing carbon atom (C-1) of the cyclopropane ring;
cis/trans describes the relationship to this carboxyl of the dichlorovinyl group at C-3;
α*R,S* describes the configuration at the 'alpha' (α) position, i.e. the carbon atom bearing the nitrile (-CN, cyano) functional group. By the C.A. denomination, this configuration is described by **1*R*** or **1*S***.

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	82.1 °C (99.3%)
Boiling point (state purity)	Cannot be determined at atmospheric pressure (a.s. decomposes at approx. 248°C)
Temperature of decomposition (state purity)	Approx. 248°C (99.3%)
Appearance (state purity)	Purified a.s. (99.8%): fine powder (solid), white, non-detectable odour a.s. as manufactured (96.3%) : crystalline powder (solid), creamy white, slight chemical odour
Vapour pressure (state temperature, state purity)	3.8 x 10 ⁻⁷ Pa at 20°C (99.3%) 8.5 x 10 ⁻⁷ Pa at 25°C (99.3%)
Henry's law constant (state temperature)	0.053 Pa m ³ mol ⁻¹ (20°C)
Solubility in water (state temperature, state purity and pH)	at 20°C (98%): 0.67 µg/L (pH 4) 3.97 µg/L (pH 7) 4.54 µg/L (pH 9) 1.25 µg/L (double distilled water) At 20°C (99.3%) 3 µg/L (pH 6.5)
Solubility in organic solvents (state temperature, state purity)	at 24°C (99.3%) toluene > 250 g/L solvent dichloromethane > 250 g/L solvent acetone > 250 g/L solvent ethyl acetate > 250 g/L solvent <i>n</i> -heptane 10 – 14 g/L solvent methanol 25 – 29 g/L solvent acetonitrile 200 – 250 g/L solvent
Surface tension (state concentration and temperature, state purity)	Not applicable, as alpha-cypermethrin technical is solid at ambient temperature and water solubility is < 1 mg/L
Partition coefficient (state temperature, pH and purity)	log Pow = 5.8 (99.3%) no effect of pH (no dissociation)
Dissociation constant (state purity)	no dissociation of the a.s.
UV/VIS absorption (max.) incl. ε (state purity, pH)	at λ _{max} (276 nm): ε = 2073 L.mol ⁻¹ .cm ⁻¹ at 300 nm : ε = 38.64 L.mol ⁻¹ .cm ⁻¹
Flammability (state purity)	not highly flammable (97.3%)
Explosive properties (state purity)	not explosive (97.3%)
Oxidising properties (state purity)	not oxidising (97.3%)

**Summary of representative uses evaluated, for which all risk assessments needed to be completed (name of active substance or the respective variant)
(Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)**

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks (m)	
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max			a.i./ha min max (*) (g/ha)
Cereals (barley, wheat, oats, rye, triticale)	North-/Central-/South-EU	FASTAC ME (BAS 310 55 I)	F	Chewing and Sucking Pests <i>RHOPPA</i> <i>Rhopalosiphum padi</i> <i>METODR</i> <i>Metopolophium dirhodum</i> <i>MACSAV</i> <i>Sitobion avenae</i> <i>LEMAME</i> <i>Oulema melanopus</i> <i>SITDMO</i> <i>Sitodiplosis mosellana</i> -All growth stages	ME	50 g/L	Spraying	BBCH 51-83	1-2	7 days	2.5 – 10	100 – 400	10	28	
Oilseed rape winter	North-/Central-/South-EU	FASTAC ME (BAS 310 55 I)	F	<i>CEUTNA</i> <i>Ceutorhynchus napi</i> <i>CEUTAS</i> <i>Ceutorhynchus assimilis</i> <i>MELIAE</i> <i>Meligethes aeneus</i> -Adults-	ME	50 g/L	Spraying	BBCH 51-59	1-2	7 days	2.5 – 10	100 – 400	10	28	
Lettuces	North-/Central-EU	FASTAC ME (BAS 310 55 I)	F	<i>NASORN</i> <i>Nasonovia ribisnigri</i> <i>APHISP</i> Other aphids -All growth stages-	ME	50 g/L	Spraying	BBCH 10-49	1-2	7 days	1 – 5	200 – 1000	10	3	
Lettuces	South-EU	FASTAC ME (BAS 310 55 I)	F	<i>NASORN</i> <i>Nasonovia ribisnigri</i> <i>APHISP</i> Other aphids -All growth stages-	ME	50 g/L	Spraying	BBCH 10-49	a) 1 b) 2	a) n.a. b) 7 days	a) 2 – 10 b) 1 – 5	200 – 1000	a) 20 b) 10	3	Max. total seasonal rate per crop: 20 g a.s./ha

Leafy brassica	North-/Central-EU	FASTAC ME (BAS 310 55 I)	F	<i>BRVCBR Brevicoryne brassicae</i> -All growth stages- <i>PIERSP Pieris sp</i> <i>PLUTMA Plutella maculipennis</i> -Larval stages-	ME	50 g/L	Spraying	BBCH 10-49	1-2	7 days	1 – 5	200 – 1000	10	3	
Leafy brassica	South-EU	FASTAC ME (BAS 310 55 I)	F	<i>BRVCBR Brevicoryne brassicae</i> -All growth stages- <i>PIERSP Pieris sp</i> <i>PLUTMA Plutella maculipennis</i> -Larval stages-	ME	50 g/L	Spraying	BBCH 10-49	a) 1 b) 2	a) n.a. b) 7 days	a) 2 – 10 b) 1 – 5	200 – 1000	a) 20 b) 10	3	Max. total seasonal rate per crop: 20 g a.s./ha
Cucumber, Courgette	North-/Central-EU	FASTAC ME (BAS 310 55 I)	G	<i>APHIGO Aphis gossypii</i> <i>MYZUPE Myzus persicae</i> <i>TRIAVA Trialeurodes vap.</i> <i>BEMITA Bemisia tabaci</i> -All growth stages-	ME	50 g/L	Spraying	BBCH 10-89	1	n.a.	2 – 15	200 – 1500	30	3	Permanent glasshouses
Cucumber, Courgette	South-EU	FASTAC ME (BAS 310 55 I)	G	<i>APHIGO Aphis gossypii</i> <i>MYZUPE Myzus persicae</i> <i>TRIAVA Trialeurodes vap.</i> <i>BEMITA Bemisia tabaci</i> -All growth stages-	ME	50 g/L	Spraying	BBCH 10-89	a) 1 b) 2	a) n.a. b) 7 days	a) 2 – 15 b) 1 – 7.5	200 – 1500	a) 30 b) 15	3	Permanent glasshouses Max. total seasonal rate per crop: 30 g a.s./ha

- * For uses where the column „Remarks“ is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthialvalicarb-isopropyl).
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (name of active substance or the respective variant)

Regulation (EC) N° 1107/2009 Article 8.1(g)

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s./hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

- | | |
|--|---|
| <ul style="list-style-type: none"> (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated | <ul style="list-style-type: none"> (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl). (j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha) (m) PHI - minimum pre-harvest interval |
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Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Alpha-cypermethrin exhibits high levels of efficacy on a broad range of crop-relevant noxious insects. Alpha-cypermethrin, contained in the crop protection product BAS 310 55 I, has been registered in many EU countries with different formulations based on detailed national assessments of the efficacy package in compliance with Regulation (EC) No 545/2011 and according to the Uniform Principles (Regulation (EC) No 546/2011), with which Member States authorities were satisfied.

To support the representative crop uses, BAS 310 55 I was tested in 231 trials across Europe in the EPPO-zones Maritime, Mediterranean, North East (N.E.) and South East (S.E.) at the dose rates of 0,2 l/ha and 0,4 l/ha or 0,6 l/ha respectively under various agronomical conditions (application systems, soil types, temperature, rainfall). However, a full assessment of the trials needs to be done in the framework of the registration of the formulations (MS level).

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

Alpha-cypermethrin has been applied since many years with several different formulations and different dose rates across a wide range of crops without any reports of a phytotoxic effect on treated or succeeding crops. Due to the broad range of crops in which the product has been used, most rotational crop possibilities have been appeared in practice. Therefore no negative impact on treated or succeeding crops is to be expected.

A more detailed assessment should be performed for products authorization applications.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Due to the broad range of crops in which the product has been used, most rotational crop possibilities have appeared in practice. Therefore no negative impact on adjacent or succeeding crops is to be expected.

A more detailed assessment should be performed for products authorization applications.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism none

Assessment not triggered since there are no relevant metabolisms in groundwater for alpha-cypermethrin

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	GC-FID (CIPAC Method 454)
Impurities in technical a.s. (analytical technique)	HPLC-UV and GC-FID
Plant protection product (analytical technique)	GC-FID

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin	Cypermethrin including other mixtures of constituent isomers (sum of isomers)
Food of animal origin	Cypermethrin including other mixtures of constituent isomers (sum of isomers)
Soil	Alpha-cypermethrin
Sediment	Alpha-cypermethrin
Water surface	Alpha-cypermethrin
drinking/ground	Alpha-cypermethrin
Air	Alpha-cypermethrin
Body fluids and tissues	Alpha-cypermethrin, 4-OH-PBA sulfate, DCVA glucuronide

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS: LOQ of 0.01 mg/kg (target) for each isomer corresponding to 0.01 mg/kg for Cis-I and Trans-III, 0.00695 mg/kg for alpha-cypermethrin (Cis-II) and 0.00429 mg/kg for Trans IV (high water, high acid, dry [high starch and high protein], oily) Independently validated.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS: LOQ of 0.01 mg/kg (target) for each isomer corresponding to 0.00695 mg/kg for alpha-cypermethrin (muscle, liver, kidney, milk, fat egg), 0.00429 mg/kg (for Trans-IV) Independently validated.
Soil (analytical technique and LOQ)	LC-MS/MS: LOQ of 0.001 mg/kg for each isomer
Water (analytical technique and LOQ)	LC-MS/MS: LOQ of 0.75 ng/L (target) corresponding to 0.825 ng/L for alpha-cypermethrin in surface and drinking water. Independently validated for surface and drinking water.
Air (analytical technique and LOQ)	GC-MS: LOQ of 0.06 µg/m ³ (alpha-cypermethrin)
Body fluids and tissues (analytical technique and LOQ)	LC-MS/MS: LOQ of 0.035 mg/L (alpha-cypermethrin) Data gap for 4-OH-PBA sulfate, DCVA glucuronide

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Alpha-cypermethrin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ¹ :	No classification with regard to physical and chemical properties
Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008:	/

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

² It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Based on urinary excretion, - after low dose (LD) (1-2 mg/kg bw): 40% - after high dose (HD) (20 mg/kg bw): 27%
Toxicokinetics	<p>Blood: (LD/HD: 2 / 20 mg/kg bw)</p> <p>C_{max} : LD: 1.3-1.5 mg/kg bw HD: 6.7-7.5 mg/kg bw</p> <p>T_{max}: LD: 6-7 mg/kg bw HD: 6-9 mg/kg bw</p> <p>T^{1/2}: LD: 2.8-4.4 h</p> <p>Fat: T^{1/2} (LD): 2.5-2.7h (initial phase d1-8) 17-26h (final phase d14-42)</p>
Distribution	In well perfused organs and fatty tissue
Potential for bioaccumulation	Higher amounts retained in skin and fat (up to 0.6% after 7 days) but no significant potential for bioaccumulation.
Rate and extent of excretion	<p>LD (2 mg/kg bw): 43-46% in urine*; 30-35% in faeces (*within 24h)</p> <p>HD (20 mg/kg bw): 27% in urine*; 24-28% in faeces (*within 96h)</p>
Metabolism in animals	<p>Moderately metabolised (~25% identified); main metabolites in urine (~16-17%): 4-OH-PBA sulfate and DCVA glucuronide</p> <p>α-cypermethrin excreted unchanged in faeces: 39-57%</p> <p>Hydrolytic cleavage of the ester bound and excretion of the cis cyclopropanecarboxylic acid moiety in free and conjugated form in urine. Minimal hydroxylation at the methyl groups attached to the cyclopropane- ring.</p> <p>Hydroxylation of the phenoxy-ring and cleavage of the ether bridge with loss of the phenyl ring.</p>
<i>In vitro</i> metabolism	Hepatic microsome metabolism: oxidation predominant in rat, and hydrolysis predominant in human .
Toxicologically relevant compounds (animals and plants)	Alpha-cypermethrin
Toxicologically relevant compounds (environment)	Alpha-cypermethrin

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD ₅₀ oral	40-80 mg/kg bw	H301
Rat LD ₅₀ dermal	> 2000 mg/kg bw	

Rat LC ₅₀ inhalation	1.33mg/L air /4h (nose-only)	H332 H335
Skin irritation	Non-irritant	-
Eye irritation	Non-irritant	-
Skin sensitisation	Not sensitising (GPMT)	-
Phototoxicity	No phototoxicity	-

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Neurotoxicity (rat, mouse, dog) Liver (rat, mouse)	
Relevant oral NOAEL	2 mg/kg bw per day (dog, 1-year) 13.1 mg/kg bw per day (rat, 90-day) 6.3 mg/kg bw per day (mouse, 90-day)	STOT-RE1 H372
Relevant dermal NOAEL	2000 mg/kg bw per day (rabbit, 28-day)	-
Relevant inhalation NOAEL	LOAEL 0.029 mg/L based on local adverse effects (rat, 14-day, complementary study)	-

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

<i>In vitro</i> studies	Ames test : Salmonella strains TA 98, TA 100, TA 1535, TA 1537 and TA 1538 ±S9 : Negative. L5178Y Mouse lymphoma cells: Negative. Chromosome aberrations in human lymphocytes ±S9: Negative	
<i>In vivo</i> studies	Micronucleus assay in mice (oral exposure): Negative. Chromosome aberrations in rat bone marrow (oral exposure): Equivocal. UDS <i>in vivo</i> after partial hepatectomy (oral exposure): Negative. Dominant lethal test in mice: Negative.	
Photomutagenicity	No data - Not required	
Potential for genotoxicity	Alpha-cypermethrin is unlikely to be genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: ↑urea levels and kidney weight Mouse: clinical signs, decreased BWG	-
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Relevant long-term NOAEL	0.5 mg/kg bw per day (rat, 2-year, cypermethrin) 3 mg/kg bw per day (mouse, 18-month)	-
Carcinogenicity (target organ, tumour type)	No treatment-related tumours (rat, mouse) Alpha-cypermethrin is unlikely to pose a carcinogenic hazard to humans	-
Relevant NOAEL for carcinogenicity	50 mg/kg bw per day (rat, 2-year, high dose) 35 mg/kg bw per day (mouse, 18-month, high dose)	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	<u>Rat multigeneration study</u> (cypermethrin): Parental toxicity: ↓body weight, ↓food intake Offspring's toxicity: ↓litter weight Reproductive toxicity: ↓pup survival at birth	-
Relevant parental NOAEL	10 mg/kg bw per day	-
Relevant reproductive NOAEL	10 mg/kg bw per day	-
Relevant offspring NOAEL	10 mg/kg bw per day	-

Developmental toxicity

Developmental target / critical effect	<u>Rat:</u> Maternal toxicity: ↑clinical signs, ↓body weight gain, ↓food intake Developmental toxicity: ↓body weight <u>Rabbit:</u> Maternal toxicity: ↓bw gain, ↓food intake Developmental toxicity: -	-
Relevant maternal NOAEL	<u>Rat:</u> 3 mg/kg bw per day <u>Rabbit:</u> 15 mg/kg bw per day	-
Relevant developmental NOAEL	<u>Rat:</u> 9 mg/kg bw per day <u>Rabbit:</u> 30 mg/kg bw per day	-

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity, rat	NOAEL= 4 mg/kg bw based on clinical signs	
Repeated neurotoxicity, rat	4-week NOAEL= 10 mg/kg bw per day, based on increased beta-galactosidase activity in nerves. 90-day NOAEL = 36 mg/kg bw per day (top dose)	
Additional studies:	Maternal NOAEL = 2 mg/kg bw per day,	

Developmental neurotoxicity, rat

based on decreased BWG at the end of gestation Neurodevelopmental NOAEL < 0.25 mg/kg bw per day based on clinical signs in pups	
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Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance:

Immunotoxicity study, 28d rat

Systemic and immunotoxic NOAEL > 34 mg/kg bw per d
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Endocrine disrupting properties

Intact male rat study, 15d

NOAEL = 3.5 mg/kg bw per day LOAEL = 6.6 mg/kg b.w./d, based upon a weakly ↓b.w. gain, prostate weight, very weak ↓in Cauda epididymis and seminal vesicles weight, and subtle total sperm counts.

Studies performed on metabolites or impurities

Group of hydroxylated derivatives of alpha-cypermethrin and their conjugates: unlikely to be genotoxic or to be more toxic than the parent.

Group of PBA and derivatives (4-OH-PBA, 4-OH-PBA sulfate, 3-PBA, 3-PBAldehyde): they could be initially considered unlikely to be of higher toxicity than the parent. Data gap for further studies submitted under confirmatory data on lambda-cyhalothrin.

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No detrimental effects on health in manufacturing personnel

Summary³ (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.00125	DNT, rat	200
Acute Reference Dose (ARfD)	0.00125	DNT, rat	200
Acceptable Operator Exposure Level (AOEL)	0.0005	DNT, rat	200 40%*
Acute Acceptable Operator Exposure Level (AAOEL)	0.0005	DNT, rat	200 40%*

*: 40% oral absorption value

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)Representative formulation (*indicate name, type e.g. EC and concentration of active substance*)

Concentrate: 3 % Spray dilution:0.7 %
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³ If available include also reference values for metabolites

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators	<p>Use:</p> <p>(i) Lettuces and leafy cabbages (field) 20g/ha, 1000L/ha, Tractor mounted boom sprayers, 1 application</p> <p>Exposure estimates (model): % of AOEL</p> <p>German model:</p> <table data-bbox="767 533 1377 607"> <tr> <td>Without PPE:</td> <td>100</td> </tr> <tr> <td>With PPE (gloves):</td> <td>16</td> </tr> </table> <p>UK POEM model</p> <table data-bbox="767 651 1377 725"> <tr> <td>Without PPE:</td> <td>232</td> </tr> <tr> <td>With PPE (gloves):</td> <td>28</td> </tr> </table> <p>AOEM</p> <table data-bbox="767 770 1377 844"> <tr> <td>Without PPE:</td> <td>871</td> </tr> <tr> <td>With PPE (gloves):</td> <td>79</td> </tr> </table>	Without PPE:	100	With PPE (gloves):	16	Without PPE:	232	With PPE (gloves):	28	Without PPE:	871	With PPE (gloves):	79
Without PPE:	100												
With PPE (gloves):	16												
Without PPE:	232												
With PPE (gloves):	28												
Without PPE:	871												
With PPE (gloves):	79												
	<p>(ii) Cucumbers and courgettes (greenhouse) 30g/ha, 1500L/ha, spray pistol/lance application, 1 application</p> <p><u>Greenhouse (S.E-model):</u></p> <table data-bbox="767 1003 1377 1077"> <tr> <td>Without PPE:</td> <td>100</td> </tr> <tr> <td>PPE (gloves):</td> <td>79</td> </tr> </table>	Without PPE:	100	PPE (gloves):	79								
Without PPE:	100												
PPE (gloves):	79												
Workers	<p><u>Europoem</u></p> <table data-bbox="767 1133 1377 1207"> <tr> <td>Without PPE:</td> <td>60</td> </tr> <tr> <td>PPE (gloves):</td> <td>14</td> </tr> </table>	Without PPE:	60	PPE (gloves):	14								
Without PPE:	60												
PPE (gloves):	14												
Bystanders and residents	<p><u>German model</u></p> <table data-bbox="767 1263 1377 1337"> <tr> <td>Adult bystanders</td> <td>1.9</td> </tr> <tr> <td>Children bystanders</td> <td>1.5</td> </tr> </table> <p>Adult residents 0.13</p> <p>Children resident 0.86</p> <p><u>EFSA model</u></p> <table data-bbox="767 1503 1377 1576"> <tr> <td>Adult residents</td> <td>56</td> </tr> <tr> <td>Children resident</td> <td>233</td> </tr> </table> <p><u>EFSA model + refinement*</u></p> <table data-bbox="767 1621 1377 1695"> <tr> <td>Adult residents</td> <td>12</td> </tr> <tr> <td>Children resident</td> <td>24</td> </tr> </table>	Adult bystanders	1.9	Children bystanders	1.5	Adult residents	56	Children resident	233	Adult residents	12	Children resident	24
Adult bystanders	1.9												
Children bystanders	1.5												
Adult residents	56												
Children resident	233												
Adult residents	12												
Children resident	24												
	<p>*: using data from air measurements</p>												

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]⁴ :

Peer review proposal⁵ for harmonised classification according to Regulation (EC) No 1272/2008:

Alpha-cypermethrin
Acute Tox 3; H301 Toxic if swallowed STOT SE 3; H335 May cause respiratory irritation STOT RE 2; H373; May cause damage to organs through prolonged or repeated exposure
In addition to the harmonised classification: Acute Tox 4; H332 Harmful if inhaled STOT RE 1 ; H372 “Causes damage to organs through prolonged or repeated exposure”,

⁴ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁵ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) OECD Guideline 501	Crop groups	Crop(s)	Application(s)	DAT (days)	
	Fruit crops	Apples ⁽¹⁾	Applied directly (via syringe) to fruits and leaves (application rate not specified); <i>cis</i> -cypermethrin [¹⁴ C-Ph / ¹⁴ C-Cy]; <i>trans</i> -cypermethrin [¹⁴ C-Ph]	26 (leaves); 22 (apples)	
	Root crops	-	-	-	
	Leafy crops	cabbage ⁽¹⁾	3 x 50 g a.s./ha (7.5N) Alpha-cypermethrin [¹⁴ C-benzyl]; <i>Cis</i> -cypermethrin [¹⁴ C-benzyl]	43 (at harvest)	
		lettuce	2 x 50 g a.s./ha (5N) Alpha-cypermethrin [¹⁴ C-benzyl / ¹⁴ C-cyclopropane]	3, 7	
	Cereals/grass crops	winter wheat	1 x 10 g a.s./ha (0.5N) 1 x 100 g a.s./ha (5N) Alpha-cypermethrin [¹⁴ C-benzyl / ¹⁴ C-vinyl]	57 (at harvest) 62 (at harvest)	
		spring wheat	2 x 80 g a.s./ha (8N) Alpha-cypermethrin [¹⁴ C-benzyl / ¹⁴ C-cyclopropane]	0, 7 (after 1st appl.); 0, 21, 42 (after 2nd appl.)	
	Pulses/Oilseeds	-	-	-	
Miscellaneous	-	-	-		
¹⁴ C-Ph: ¹⁴ C-[phenoxybenzyl]; ¹⁴ C-Cy: ¹⁴ C-cyclopropyl (labelling always tested separately) ⁽¹⁾ No stand-alone fully OECD guideline-compliant study (deficiencies noted).					
Rotational crops (metabolic pattern) OECD Guideline 502	Crop groups	Crop(s)	PBI (days)	Comments	
	Root crops	Sugar beet	29, 60, 120	Bare soil; 1 kg a.s./ha (33N) ¹⁴ C-benzyl cypermethrin (all crops) and ¹⁴ C-cyclopropyl cypermethrin (sugar beet only)	
	Leafy crops	Lettuce	29, 60, 120		
	Cereals (small grain)	Wheat	29, 60, 120		
	Pulses and oilseeds	Cotton	29, 60, 120		
Rotational crop and primary crop metabolism similar?	Metabolites' identification was not attempted in this study. However based on the representative uses and given the 33 fold application rate to bare soil further rotational crop metabolism data can be waived for representative uses, due to insignificant total residues expected at 1N.				
Processed commodities (standard hydrolysis study)	Conditions	Alpha-cypermethrin	3-phenoxy-benzaldehyde	DCVA	¹⁴ C-radiolabel

OECD Guideline 507

	20 min, 90°C, pH 4	95%	2.5%	-	Benzyl-label
	60 min, 100°C, pH 5	97%	2.4%	-	Benzyl-label
	20 min, 120°C, pH 6	86% 66%	13%	23%	Benzyl-label Cyclopropyl-label
	Results expressed as mean % of the applied radioactivity				
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes (for processed commodities involving pasteurization, boiling, baking and/or brewing); No (for processed commodities involving sterilisation and other processing operations combining high temperature/pH ≥ 6).				
	Cypermethrin is thermally unstable. There are indications that degradation of cypermethrin is significantly influenced by the food matrix: e.g. significant degradation also observed in tomato paste (pH 4.3-4.5) upon cold storage (12 days at 5°C); Significant degradation observed during canning of peeled tomatoes (Publication from the open literature). Main degradation products: 3-phenoxybenzaldehyde and DCVA The same residue definition as for primary crops is applicable to processed commodities upon finalisation of the assessment of the toxicological relevance of metabolites with the 3-phenoxybenzoyl moiety (3-PBAdehyde).				
Plant residue definition for monitoring (RD-Mo)	Cypermethrin including other mixtures of constituent isomers (sum of isomers)				
OECD Guidance, series on pesticides No 31					
Plant residue definition for risk assessment (RD-RA)	Cypermethrin including other mixtures of constituent isomers (sum of isomers) ⁽²⁾ – <i>Provisional (pending finalisation of the assessment of the genotoxic potential of 3-PBA and review of the preliminary conclusions in toxicology on the whole group of related metabolites bearing the 3-phenoxybenzoyl moiety (besides 3-PBA also e.g. PBAlde, 4-OH-PBA) once the confirmatory data on lambda-cyhalothrin have been peer reviewed).</i>				
Conversion factor (monitoring to risk assessment)	Open (Pending finalisation of residue definition for risk assessment)				

⁽²⁾ Occurrence data for all cypermethrin isomers to be considered but toxicity of alpha-cypermethrin to be considered.

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	Study I: 0.8 and 2	14	73N and 182N (¹⁴ C-B/ ¹⁴ Cy)
		Study II: 0.9	14	82 N (¹⁴ C-B/ ¹⁴ Cy)
	Cow	0.5	4	16 N (¹⁴ C-B)
	Goat	0.3-0.4	7	Ca. 11 N (¹⁴ C-B/ ¹⁴ Cy)
	Pig	-	-	-
	Fish	10 mg/kg feed	14	175 N (¹⁴ C-B/ ¹⁴ Cy)

	<p>Test substance: alpha-cypermethrin ¹⁴C-B: ¹⁴C-benzyl; ¹⁴C-Cy: ¹⁴C-cyclopropane The general metabolic pathway in rats and ruminants is comparable.</p>
Time needed to reach a plateau concentration in milk and eggs (days)	<p>Milk: 1-4 days Eggs: 6-8 days (hen metabolism study I); 12-13 days (hen metabolism study II); 21-24 days (hen feeding study)</p>
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Cypermethrin including other mixtures of constituent isomers (sum of isomers)
Animal residue definition for risk assessment (RD-RA)	Cypermethrin including other mixtures of constituent isomers (sum of isomers) ⁽³⁾ – Provisional (pending upon assessment of the relative toxicity of the individual cypermethrin isomers, in particular the enantiomer [1R-(1α(S*),3α)], the genotoxic potential of 3-PBA and the review of the preliminary conclusions in toxicology on the whole group of related metabolites with the 3-phenoxybenzoyl moiety).
Conversion factor (monitoring to risk assessment)	Open (Pending finalisation of residue definition for risk assessment)
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) (FAO, 2009)	Yes (Log P _{ow} =5.8 and distribution of residues between fat free muscle and fat in ruminant and poultry metabolism and feeding studies)

⁽³⁾: Occurrence data for all cypermethrin isomers to be considered but toxicity of alpha-cypermethrin to be considered.

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

<p>Confined rotational crop study (Quantitative aspect) OECD Guideline 502</p>	<p>Confined rotational crop study conducted with wheat, sugar beet, lettuces and cotton planted 29, 60 and 120 days after soil application with (¹⁴C-benzyl and ¹⁴C-cyclopropyl)-labelled Cypermethrin at a rate of 1 kg a.s./ha (33N) indicated that residue levels in rotational crops will be below 0.01 mg/kg when primary crops are treated at a 1N rate according to the representative uses.</p>
<p>Field rotational crop study OECD Guideline 504</p>	<p>1-3 treatments (to bare soil) at rate 20 g a.s./ha (alpha-cypermethrin); plant-back interval of ≤ 19 days on leafy crops (cabbage, lettuce), root crops (carrots), cereals (wheat):</p> <p><i>Cypermethrin isomer pairs cis-I, cis-II, trans-III:</i> each < LOQ (0.01 mg/kg) in all crop parts;</p> <p><i>Cypermethrin isomer pair trans-IV:</i> Root crops (carrot): < 0.01 mg/kg (root); <0.01 - 0.03 mg/kg (foliage) Cereals (wheat) whole plant, grain, straw: <0.01 mg/kg Leafy crops (lettuce, cabbage): ≤0.01 mg/kg</p>

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Plant products (Category)	Commodity	T (°C)	Stability (Months)
			Alpha-cypermethrin ⁽⁴⁾
High water content	lettuce leaves	≤ -18	12 ⁽⁴⁾
	tomato fruit	≤ -18	12 ⁽⁴⁾
	oilseed rape whole plants	- 20	12 ⁽⁴⁾
	cereal whole green plant	≤ -18	12 ⁽⁴⁾
High acid content	pineapple fruit	≤ - 20	24
High starch content	cereal grain	≤ -18	12 ⁽⁴⁾
	barley grain	≤ - 20	24
High oil content	oilseed rape seeds	- 20	12 ⁽⁴⁾
High protein content	bean seed	≤ - 20	24
Other	oilseed rape whole pods	- 20	6 ⁽⁴⁾
	cereal straw		12 ⁽⁴⁾
⁽⁴⁾ In most studies, the analytical method used determined the total cypermethrin residues (sum of isomers) and was not validated to be specific for alpha-cypermethrin isomers.			
Animal	Animal commodity	T (°C)	Stability (Month)
Cattle	Muscle	≤ -10°C	6
Cattle	Liver	≤ -10°C	6
Cattle	Kidney	≤ -10°C	6
Cattle	Milk	≤ -10°C	9
Cattle	Fat	≤ -10°C	6
Hen	Eggs	≤ -10°C	1.5
Upon frozen storage, residues of alpha-cypermethrin remain stable for at least 6 months in cattle tissues, at least 9 months in cattle milk and at least 1.5 month in hen eggs.			

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop (cGAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Representative uses						
Cucumbers (extrapolation to courgettes) (1 x 30 g/ha; PHI 3 days)	Indoor	1x 40 g/ha: 2 x <0.01, 0.012, 2 x 0.014, 0.02, 0.031, 0.037 Scaled down to cGAP rate (1x 30 g/ha): 2 x <0.01, 0.009, 0.011, 0.011, 0.015, 0.023, 0.028	Proportionality concept applied due to trials being conducted at rate >25% deviating from cGAP rate. Data gap: Sufficient residue trials on cucumbers compliant with the indoor GAP and supported by acceptable storage stability data are required in view of the identified acute intake concern.	0.05	0.028	0.011
Leafy brassica (2 x 10 g/ha; PHI 3 days)	NEU	Kales: 2x 12.5 g/ha: 0.23 ⁽⁵⁾ , 0.35, 0.38, 0.59 Scaled down to cGAP rate (2x10 g/ha): 0.23, 0.28, 0.30, 0.47	⁽⁵⁾ Level measured 3 days after single treatment (1x12.5 g/ha) (0.170 mg/kg found 3 days after 2 treatments). Scaling on this value not applicable. Data gap: 2 residue trials and 4 residue trials on kales and compliant respectively with the NEU and SEU outdoor GAP on leafy brassica to be extrapolated to the whole sub-group of leafy brassica.	1	0.47	0.29
Leafy brassica (1 x 20 g/ha; PHI 3 days)	SEU	Kales: 1x 25 g/ha: 0.28, 0.44 Scaled down to cGAP rate (1x20 g/ha): 0.22, 0.35				
Lettuces (2 x 10 g/ha; PHI 3 days)	NEU	2x 12.5 g/ha: <0.01, 0.021, 0.055 ⁽⁶⁾ , 0.072, 0.12, 0.13, 0.22, 0.24, 0.27, 0.72 Scaled down to cGAP rate (2x10 g/ha): <0.01, 0.017, 0.044, 0.057, 0.096, 0.104, 0.176, 0.192, 0.21, 0.58	⁽⁶⁾ Trial on open leaf lettuce variety; Proportionality concept could be applied due to all trials being overdosed (at rate 25% deviating from cGAP rate). Data gap: Sufficient residue trials on lettuces and compliant respectively with the NEU and	0.9	0.58	0.10

Crop (cGAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			SEU GAP are required in view of the identified acute intake concern.			
Lettuces (1 x 20 g/ha; PHI 3 days)	SEU	<i>1x 25 g/ha:</i> <0.01, 0.10, 0.11 ⁽⁶⁾ , 0.20 ⁽⁶⁾ , 0.21 ⁽⁶⁾ , 0.31 ⁽⁶⁾ , 0.32 ⁽⁶⁾ , 0.39 ⁽⁶⁾ , 0.41 ⁽⁶⁾ , 0.59 ⁽⁶⁾ Scaled down to cGAP rate (1x20 g/ha): <0.01, 0.08, 0.08, 2 x 0.16, 2 x 0.25, 0.31, 0.33, 0.47		0.8	0.47	0.21
		<i>2x12.5 g/ha:</i> 0.032 ⁽⁶⁾ , 0.037, 0.049 ⁽⁶⁾ , 0.075 ⁽⁶⁾ , 0.091 ⁽⁶⁾ 0.11 ⁽⁶⁾ , 0.21 ⁽⁶⁾ , 0.24 ⁽⁶⁾ Scaled down to cGAP rate (2x10 g/ha): 0.025, 0.03, 0.04, 0.06, 0.07, 0.088, 0.17, 0.19		0.4	0.19	0.07
Oilseed rape (seeds) (2 x 10 g/ha; PHI 28 days)	NEU	<i>2x 12.5 g/ha:</i> 10 x <0.01		0.07	0.01	0.01
	SEU	7 x <0.01, 0.012, 0.015, <0.05, 0.06			0.06	0.01
	NEU + SEU	17 x <0.01, 0.012, 0.015, <0.05, 0.06	Populations similar (U-test; $\alpha=0.05$) MRL proposal derived from merged datasets.		0.06	0.01
Barley (grain) (2 x 10 g/ha; PHI 28 days) (extrapolation to oats grain)	NEU	<i>2x 12.5 g/ha:</i> 0.02, 0.03, 0.031, 0.032, 0.035, 0.053, 0.077, 0.079 Scaled down to cGAP rate (2x10 g/ha): 0.016, 0.024, 0.025, 0.026, 0.028, 0.042, 0.062, 0.063	Proportionality concept applied due to all trials being overdosed (at rate ca. 25% deviating from cGAP rate).	0.15	0.063	0.027
	SEU	<i>2x 12.5 g/ha:</i> 0.024, 0.026, 0.035, 0.05, 0.066, 0.079, 0.083	Proportionality concept applied due to all trials being overdosed (at rate ca. 25% deviating from		0.066	0.034

Crop (cGAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
		Scaled down to cGAP rate (2x10 g/ha): 0.019, 0.021, 0.028, 0.040, 0.047, 0.063, 0.066	cGAP rate). Data gap: 1 additional residue trial on barley and compliant with the SEU GAP is required.			
	NEU + SEU	Scaled residue values: 0.016, 0.019, 0.021, 0.024, 0.025, 0.026, 0.028, 0.028, 0.040, 0.042, 0.047, 0.062, 0.063, 0.063, 0.066	Populations similar (U-test; $\alpha=0.05$); MRL proposal derived from merged scaled datasets.		0.066	0.028
Wheat (grain) (2 x 10 g/ha; PHI 28 days) (extrapolation to rye grain)	NEU	5 x <0.01		0.01*	0.01	0.01
	SEU	10 x <0.01			0.01	0.01
Barley (straw) (2 x 10 g/ha; PHI 28 days) (extrapolation to oats straw)	NEU	2x12.5 g/ha: 0.20, 0.25, 0.26, 0.35, 0.41, 0.47, 0.48, 0.49 Scaled down to cGAP rate (2x10 g/ha): 0.16, 0.2, 0.21, 0.28, 0.33, 0.37, 0.38, 0.39		n.a.	0.39	0.31
	SEU	2x12.5 g/ha: 0.21, 0.24, 2x 0.40, 0.43, 0.47, 0.68 Scaled down to cGAP rate (2x10 g/ha): 0.17, 0.19, 0.32, 0.32, 0.34, 0.37, 0.54		n.a.	0.54	0.32
	NEU + SEU	Scaled residue values: 0.16, 0.17, 0.19, 0.2, 0.21, 0.28, 0.32, 0.32, 0.33, 0.34, 0.37, 0.37, 0.38, 0.39, 0.54		n.a.	0.54	0.32
Wheat (straw) (2 x 10 g/ha; PHI 28 days) (extrapolation to rye straw)	NEU	2x12.5 g/ha: 0.29, 0.36, 2 x 0.40, 0.53 Scaled down to cGAP rate (2x10 g/ha): 0.23, 0.29, 0.32, 0.32, 0.42		n.a.	0.42	0.32
	SEU	2x12.5 g/ha: 0.18, 0.33, 0.35, 0.37, 0.47, 0.54, 0.62, 0.82, 2 x 1.04		n.a.	0.86	0.39

Crop (cGAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
		Scaled down to cGAP rate (2x10 g/ha): 0.14, 0.26, 0.28, 0.3, 0.37, 0.4, 0.43, 0.68, 0.68, 0.86				
	NEU + SEU	Scaled residue values: 0.14, 0.23, 0.26, 0.28, 0.29, 0.3, 0.32, 0.32, 0.37, 0.4, 0.42, 0.43, 0.68, 0.68, 0.86		n.a.	0.86	0.32
Barley & Wheat (straw) (2 x 10 g/ha; PHI 28 days)	NEU + SEU	Scaled residue values: 0.14, 0.16, 0.17, 0.19, 0.2, 0.21, 0.23, 0.26, 2 x 0.28, 0.29, 0.3, 4 x 0.32, 0.33, 0.34, 3 x 0.37, 0.38 0.39, 0.4, 0.42, 0.43, 0.54, 2 x 0.68, 0.86	Datasets on barley straw (n=16) and wheat straw (20) were merged, as populations are similar (U-test; $\alpha=0.05$). Extrapolation to rye and oats straw.	n.a.	0.86	0.32
MRL application						
Leafy brassica	See assessment for the representative use					
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	Region	Residue data (mg/kg)	Recommendations/comments			
The equivalence between the different formulations used in the residue trials was demonstrated from bridging studies conducted on fruit crops, potatoes and lettuces.						
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	Region	Residue data (mg/kg)	Recommendations/comments			
Nectar & pollen (oilseed rape)	Germany (4 locations)	Nectar: <0.01 – 0.046 Pollen: 0.34 – 1.2	Oilseed rape crop covered by tunnel; treated at 1x30 g/ha (BBCH 63-65); Only results for nectar collected from forager bees and pollen collected via pollen traps (1 DAA) are presented. Considerable reduction of residue levels was observed at later sampling occasions: <i>see conclusions DRAR Vol.1.</i>	-	-	-
Nectar & pollen (<i>Phacelia</i>)	Germany (1 location)	Nectar: <0.01 Pollen: <0.01 – 0.01	<i>Phacelia tanacetifolia</i> ; 1x30 g/ha at 80% flowering; pollen collected via pollen trap and nectar collected from hives (7 and/or 14 DAA)	-	-	-
Nectar & pollen	Germany (4	Honey/nectar: <0.01	<i>Phacelia tanacetifolia</i> ; 1x30 g/ha pollen and	-	-	-

Crop (cGAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
<i>(Phacelia)</i>	locations) and Italy (1 location)	Pollen: <0.01 – 0.026	honey/nectar collected from hives (7 and/or 14 DAA)			
<p>Considering that a low translocation of alpha-cypermethrin residues in the different plant parts was observed in the plant metabolism and taking into account the lipophilic properties of the active substance, further residue trials for the determination of residues of alpha-cypermethrin and its relevant metabolites in honey in regards to the representative uses are not required to address the data requirement for the determination of residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.</p>						

- (a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
 - (b): Residue levels in trials conducted according to GAP reported in ascending order (e.g. 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Monitoring** and **Risk Assessment**.
 - (c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
 - (d): **STMR**: Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets (STMR_{Mo}).
- (*): Residue trials not supported by the available storage stability data for total cypermethrin residues.

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Kale leaves	0.29		0.47	
Cereal straw (barley, oat, wheat, triticale, rye)	0.32	STMR (merged data wheat/barley)	0.83	HR (merged data wheat/barley)
Cereal grain (barley, oat)	0.028	STMR	0.028	STMR
Cereal grain (wheat, triticale, rye)	0.01	STMR	0.01	STMR
Brewer's grain (dried)	0.026	STMR-P = STMR (barley grain) x 0.93 (PF spent barley grain)	0.026	STMR-P = STMR (barley grain) x 0.93 (PF)
Canola / Rapeseed meal	0.01	STMR	0.01	STMR
Distiller's grain (dried)	0.026	STMR-P = STMR (barley grain) x 0.93 (PF spent barley grain)	0.026	STMR-P = STMR (barley grain) x 0.93 (PF spent barley grain)
Wheat gluten meal	0.059	STMR-P = STMR (wheat grain) x 5.85 (PF pearling barley dust/bran)	0.059	STMR-P = STMR (wheat grain) x 5.85 (PF pearling barley dust/bran)
Wheat, milled by-products (covering wheat bran)	0.059	STMR-P = STMR (wheat grain) x 5.85 (PF pearling barley dust/bran)	0.059	STMR-P = STMR (wheat grain) x 5.85 (PF pearling barley dust/bran)

**Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)
 OECD Guideline 505 and OECD Guidance, series on pesticides No 73**

MRL calculations	Ruminant				Pig/Swine		Poultry		Fish	
	Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.016	Ram/Ewe	0.020	Breeding	0.008	Broiler	0.002	Carp
	Dairy cattle	0.026	Lamb	0.026	Finishing	0.001	Layer	0.009	Trout	0.057
							Turkey	0.002	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		Yes		Yes		Yes		No	
Feeding study submitted	Yes		No		No		Yes		No (feeding level of metabolism study presented)	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level 0.1	Beef: 6 N Dairy: 3.8 N	Level 0.1	Lamb: 3.8 N Ewe: 5N	Level 0.1	Breed/Finish: 12.5 N /100 N	Level 0.1	B or T: 33 N Layer: 11 N	Level 10	Carp: 208 N Trout: 175 N
	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals	Estimated HR ^(a) at 1N	MRL proposals
Muscle	<0.05	0.05*	<0.05	0.05*	<0.05	0.05*	<0.05	0.05*	<0.01	0.05*
Fat	(0.020)	0.05*	(0.046)	0.05*	(0.012)	0.05*	<0.05	0.05*	<0.01	0.05*
Meat ^(b)	<0.05		<0.05		<0.05		<0.05			
Liver	<0.05	0.05*	<0.05	0.05*	<0.05	0.05*	<0.05	0.05*		
Kidney	<0.05	0.05*	<0.05	0.05*	<0.05	0.05*	-	0.05*		
Milk ^(a)	<0.01	0.01*	<0.01	0.01*						
Eggs							<0.01	0.05*		
Method of calculation ^(c)	Tf		Tf		Tf		Tf		residue levels estimated by extrapolation (Tf) from metabolism study results	

^(a): Estimated HR calculated at 1N level (**estimated mean level for milk**).

^(b): HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(c): The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
	Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.0103	Ram/Ewe	0.0088	Breeding	0.006	Broiler	0.002	Carp
	Dairy cattle	0.0165	Lamb	0.0112	Finishing	0.001	Layer	0.005	Trout	0.057
							Turkey	0.002		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level 0.1	Beef: 10 N Dairy: 6N	Level 0.1	Lamb: 9N Ewe:11.3N	Level 0.1	Breed/Finish 17N/100N	Level 0.1	B or T: 33N Layer: 20N	Level 10	Carp: 208 N Trout: 175 N
	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N	Mean level in feeding level	Estimated STMR ^(b) at 1N
Muscle	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.01	<0.01
Fat	0.056	<0.05	0.056	<0.05	0.056	<0.05	<0.05	<0.05	<0.01	<0.01
Meat ^(a)	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05		
Liver	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05		
Kidney	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	-	-		
Milk	<0.01	<0.01	<0.01	<0.01						
Eggs							<0.01	<0.01		
Method of calculation ^(c)	Tf		Tf		Tf		Tf		residue levels estimated by extrapolation (Tf) from metabolism study results	

^(a): STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

^(b): When the mean level is set at the LOQ, the STMR is set at the LOQ.

^(c): The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

Conversion Factors (CF) for monitoring to risk assessment

Not applicable; The relatively higher toxicological potency of alpha-cypermethrin compared to cypermethrin is considered in the risk assessment by applying the toxicological reference values for alpha-cypermethrin.

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies ^(a)	Processing Factor (PF)		Conversion Factor (CF _p) for RA ^(b)
		Individual values	Median PF	
Gherkins / washed	1	0.24, 0.55, 0.80 ⁽⁷⁾	0.55	-
Gherkin / wash water	1	0.42, 0.60, <0.67 ⁽⁷⁾	0.60	-
Gherkins / canned	1	0.39, 0.65, 1.2 ⁽⁷⁾	0.65	-
Gherkins / vegetable stock	1	<0.26, <0.50, <0.67 ⁽⁷⁾	<0.50	-
Barley / malt	2	0.22, 0.45, 0.59, 0.73, 0.74, 1.09	0.66	-
Barley / malt germs, malt culms	2	0.18, 1.37, 2.21, 2.50, 2.91, 5.09	2.4	-
Barley / spent grain	2	0.23, 0.76, 0.86, 1.0, 1.18, 1.68	0.93	-
Spent hops		0.18 (2x), 0.19, 0.32	0.19	-
Spent yeast		<0.03, <0.04, <0.05, <0.09	<0.05	-
Trub	1	<0.17, <0.53	<0.35	-
Yeast	1	<0.17, <0.53	<0.35	-
Beer	2	<0.03, <0.04, <0.05, <0.09, <0.17, <0.53	<0.07	-
Barley / flour (side product of dehulling barley)	1	6.48, 7.59, 8.35, 12.27	7.97	-
Barley / pearling dust/bran (side product of dehulling barley)	1	4.91, 5.50, 6.19, 6.55	5.85	-
Pot barley (dehulled barley)	1	0.04, 0.09, 0.12, 0.14	0.11	-
Rapeseed / meal (press cake)	2	<1, <1	<1	-
Rapeseed / oil (refined, crude)	1	<1	n.a.	-

⁽⁷⁾ mean of values determined for processed commodities derived from RAC samples originating from 2 dependent supervised residue trials

^(a): Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)

^(b): When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Consumer risk assessment limited to the representative uses⁽⁸⁾

⁽⁸⁾ The consumer dietary risk assessment cannot be finalised considering the provisional residue definitions for risk assessment in plants and animal commodities and the identified data gaps for additional residue trials on cucumbers, kales, lettuces and barley.

ADI	0.00125 mg/kg bw per day
TMDI according to EFSA PRIMo (rev.2)	Highest TMDI: 67% ADI (NL child)
NTMDI, according to (to be specified)	Not applicable
IEDI (% ADI), according to EFSA PRIMo (rev.2)	Not applicable
NEDI (% ADI), according to (to be specified)	
Factors included in the calculations	MRLs derived for the representative uses; MRL of 0.05* mg/kg for animal matrices and poultry eggs; MRL of 0.01* mg/kg for milk.
ARfD	0.00125 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo (rev.2)	2541% (kales – NL child) 1248% (lettuces – DE child) 131% (cucumbers – NL child) 104% (courgettes – UK toddler) 99.4% (Milk and milk products – UK infant) Max. 38% (barley grain – NL adult) 5.3% (rape seed – DE child)
NESTI (% ARfD), according to (to be specified)	Not applicable
Factors included in IESTI and NESTI	Highest residue values for the representative uses; 0.05 mg/kg for animal matrices and 0.01 mg/kg for milk and eggs.

Indicative scening of the safety of the current EU MRLs for cypermethin (sum of isomers) (as established by Commission Regulation(EU) No 2017/626).

TMDI (% ADI), according to EFSA PRIMo (rev.2)	Highest TMDI: 3309 % ADI (UK toddler)
NTMDI (% ADI), according to (to be specified)	Not applicable
IEDI (% ADI), according to EFSA PRIMo (rev.2)	Calculation not performed
NEDI (% ADI), according to (to be specified)	Not applicable
Factors included in the calculations	EU MRLs (Reg. (EU) No 2017/626)
IESTI (% ARfD, according to EFSA PRIMo rev.2)	21219 % ARfD (oranges) 14272 % ARfD (grapefruits) 13988 % ARfD (scaroles) 9423 % ARfD (peaches) 7921 % ARfD (orange juice) 4076 % ARfD (apple juice)
NESTI (% ARfD, according to (to be specified)	Not applicable

Factors included in IESTI and NESTI

EU MRLs (Reg. (EU) No 2017/626)

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Note: The safety of the derived MRLs can only be concluded once the assessment of the genotoxic potential of 3-phenoxybenzoic acid (3-PBA) and review of the preliminary conclusions on the whole group of related metabolites bearing the 3-phenoxybenzoyl moiety (i.e. 4-OH-PBA, 4-OH-PBA sulfate, 3-PBA, 3-PBAldehyde) is finalised. The proposed MRLs have therefore all to be considered tentative.

Code ^(a)	Commodity/Group	MRL/Import tolerance ^(b) (mg/kg) and Comments	
Plant commodities			
Representative uses			
0232010	Cucumbers	-	No MRL proposal (acute intake concern identified)
0232030	Courgettes	-	Extrapolation from cucumbers; No MRL proposal (acute intake concern identified)
0243000	Leafy brassica	-	No MRL proposal -Insufficient residue trials on kales to be extrapolated to the whole sub-group of leafy brassica (data gap) (acute intake concern identified for kales).
0251020	Lettuces	-	No MRL proposal (acute intake concern identified)
0401060	Oilseed rape seeds	0.07	
0500010	Barley	0.15	Provisional (Data gap: 1 additional residue trial on barley and compliant with the SEU GAP is required)
0500050	Oats	0.15	Provisional (Extrapolation from barley)
0500070	Rye	0.01*	Extrapolation from wheat
0500090	Wheat	0.01*	
MRL application			
0243000	Leafy brassica	-	No MRL proposal-Insufficient trials on kales to be extrapolated to the whole sub-group of leafy brassica (data gap) and acute intake concern identified for kales.
Animal commodities			
1000000 except 1020000	Products of animal origin – terrestrial animals	0.05*	MRL proposals derived considering representative uses only.
1020000	Milk	0.01*	For (cattle) milk, there is an acute intake concern for residues above 0.01 mg/kg. However, further method validation may be required to enforce an MRL at this level (see section 1).
1030000	Birds eggs	0.05*	
1100000	Products of animal origin –Fish, fish products and any other marine and freshwater food products	0.05*	EU MRLs for cypermethrin (sum of isomers) in <i>Salmonidae</i> fish (in muscle and skin in natural proportions: 0.05 mg/kg) have been established by Commission Regulation (EU) No 37/2010 for its use as a veterinary drug.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	32.0 – 41.4% after 91-120 days (n= 3), cyclopropane label 33.0 – 51.4% after 91-120 days (n = 4), benzyl label
Non-extractable residues after 100 days	23.5 – 36.9% after 91-120 days (n= 3), cyclopropane label 32.2 – 44.7% after 91-120 days (n = 4), benzyl label
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	DCVA , 13.6% (cis-DCVA) at 7 days (n=1), cyclopropane M310I017 , 7.5 – 8.4% at 7-30 days (n=7), cyclopropane and benzyl labels 3-PBA , 1.9 – 5.4% at 7 days (n=2), benzyl label The formation of trans isomers (trans-cypermethrin and trans-DCVA) from cis-cypermethrin is not observed.

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	7.8% after 90 days, benzyl-label (n=1) 6.6% after 90 days, cyclopropane-label (n=1)
Non-extractable residues after 100 days	29.6% after 90 days, benzyl-label (n=1) 14.0% after 90 days, cyclopropane-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	DCVA , max. 55.6% (cis-DCVA) after 120 days (n=1), cyclopropane label 3-PBA , max. 30.0% after 120 days (n=1), benzyl label M310I017 , max. 7.0% after 8 days (n=1), cyclopropane label The formation of trans isomers (trans-cypermethrin and trans-DCVA) from cis-cypermethrin is not observed.

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	3-PBA , max. 17.9% after 30 days (n=1), benzyl label DCVA , max. 5.4% after 15 days (n=1), cyclopropane label The formation of trans isomers (trans-cypermethrin and trans-DCVA) from cis-cypermethrin is not observed.
Mineralisation at study end	1.9-6.2% after 15-30 days, benzyl-label (n=2) 5.4% after 15 days, cyclopropane-label (n=1)
Non-extractable residues at study end	10.8-13.3% after 15-30 days, benzyl-label (n=2) 15.0% after 15 days, cyclopropane-label (n=1)

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Trigger endpoints

Soil type	Estimated kinetic parameters	pH ^{a)}	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
Alpha-cypermethrin	Dark aerobic conditions No general trends can be drawn about the rate of degradation of specific isomers (R and S) of alpha-cypermethrin.						
Ipswich Sandy loam ^{d)}	k1: 0.08 k2: 0.009 g: 0.24	6.5 (KCl)	10°/50% MWHC	48.1 / 228.7	-	1.8	DFOP
Ipswich Sandy loam ^{d)}	α: 2.6 β: 60.4	6.5 (KCl)	20°/50% MWHC	18.3 / 84.8	-	3.5	FOMC
LUFA 5M Sandy loam ^{e)}	α: 0.8034 β: 2.7562	7.2 (CaCl ₂)	20°/50% MWHC	3.8 / 45.7	-	11.2	FOMC
Li10 Loamy sand ^{d)}	k1: 0.08 k2: 0.008 g: 0.4	6.1 (CaCl ₂)	20°/40% MWHC	28.3 / 196.3	-	1.3	DFOP
LUFA 2.2 Loamy sand ^{c)}	k1: 0.06 k2: 0.004 g: 0.50	5.4 (CaCl ₂)	20°/45% MWHC	35.0 / 329.4	-	1.7	DFOP
LUFA 2.3 Sandy loam ^{c)}	α: 1.77 β: 50.5	5.9 (CaCl ₂)	20°/50% MWHC	24.3 / 134.6	-	1.2	FOMC
Geometric mean (if not pH dependent)					-		-
pH dependence					no		

^{a)} Measured in calcium chloride solution

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Cyclopropyl label

^{d)} Benzyl label

^{e)} Benzyl labelled and cyclopropane labelled samples are considered as true replicates for kinetic analysis

Modelling endpoints

Alpha-cypermethrin	Dark aerobic conditions						
Soil type	Estimated kinetic parameters	pH ^{a)}	t. °C / % MWHC	DT ₅₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
Ipswich Sandy loam ^{d)}	/	6.5 (KCl)	10°/50% MWHC	-	-	-	-
Ipswich Sandy loam ^{d)}	α: 2.6 β: 60.4	6.5 (KCl)	20°/50% MWHC	25.5	25.5	3.5	FOMC (DT90/3.32)
LUFA 5M Sandy loam ^{e)}	α: 0.8034 β: 2.7562	7.2 (CaCl ₂)	20°/50% MWHC	13.8	10.3	11.2	FOMC (DT90/3.32)
Li10 Loamy sand ^{d)}	k1: 0.08 k2: 0.008 g: 0.4	6.1 (CaCl ₂)	20°/40% MWHC	75.3	75.3	1.3	DFOP (ln2/k2)
LUFA 2.2 Loamy sand ^{c)}	k1: 0.06 k2: 0.004 g: 0.50	5.4 (CaCl ₂)	20°/45% MWHC	133.3	117.3	1.7	DFOP (ln2/k2)
LUFA 2.3 Sandy loam ^{c)}	/	5.9 (CaCl ₂)	20°/50% MWHC	29.4	27.0	4.9	SFO
Geometric mean (if not pH dependent)					36.3		-
pH dependence				no			

^{a)} Measured in calcium chloride solution

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Cyclopropyl label

^{d)} Benzyl label

^{e)} Benzyl labelled and cyclopropane labelled samples are considered as true replicates for kinetic analysis

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Trigger endpoints

M310I017		Dark aerobic conditions - alpha-cypermethrin dosed studies						
Soil type		pH ^{a)}	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	f. f. k _f /k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
LUFA 5M Sandy loam ^{e)}	/	7.2	20°/50% MWHC	10.8/36.0	/	-	24.7	SFO (metabolite decline)
Li10 Loamy sand ^{d)}	/	6.1	20°/40% MWHC	22.6/75.1	/	-	13.5	DFOP-SFO
LUFA 2.2 Loamy sand ^{c)}	/	5.4	20°/45% MWHC	42.3/140.4	/	-	13.2	DFOP-SFO
LUFA 2.3 Sandy loam ^{c)}	/	5.9	20°/50% MWHC	4.9/16.2	/	-	16.1	FOMC-SFO
Geometric mean (if not pH dependent)						-		
Arithmetic mean					/			
pH dependence						No		

^{a)} Measured in calcium chloride solution

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Cyclopropyl label

^{d)} Benzyl label

^{e)} Benzyl labelled and cyclopropyl labelled samples are considered as true replicates for kinetic analysis

Modelling endpoints

M310I017		Dark aerobic conditions – alpha-cypermethrin dosed from which the f.f. was derived was 0.344						
Soil type		pH ^{a)}	t. °C / % MWHC	DT ₅₀ (d)	f. f. k _f /k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
LUFA 5M Sandy loam ^{e)}	/	7.2	20°/50% MWHC	10.8	-	8.1 ^{e)}	24.9	SFO (metabolite decline)
Li10 Loamy sand ^{d)}	/	6.1	20°/40% MWHC	22.6	0.215	22.6	13.5	DFOP-SFO
LUFA 2.2 Loamy sand ^{c)}	/	5.4	20°/45% MWHC	42.3	0.188	37.2	13.2	DFOP-SFO
LUFA 2.3 Sandy loam ^{c)}	/	5.9	20°/50% MWHC	3.1	0.629	2.8	15.5	SFO-SFO
Geometric mean (if not pH dependent)						11.8		
Arithmetic mean					0.344			
pH dependence,						No		

a) Measured in calcium chloride solution

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

c) Cyclopropyl label

d) Benzyl label

e) Benzyl labelled and cyclopropyl labelled samples are considered as true replicates for kinetic analysis

Trigger and modelling endpoints

(cis-)DCVA	Dark aerobic conditions - alpha-cypermethrin dosed studies and metabolite dosed studies							
Soil type		pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f /k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ ²)	Method of calculation
LUFA 5M Sandy loam ^{c) 1)}	/	7.2	20°/50% MWHC	5.2/17.1	-	3.9	7.6	SFO (metabolite decline)
Li10 ²⁾	/	6.0	20°/40% MWHC	13.5/45.0	-	13.4	12.2	SFO
LUFA 2.2 ²⁾	/	6.4	20°/40% MWHC	4.7/15.7	-	3.9	4.1	SFO
LUFA 5M ²⁾	/	6.9	20°/40% MWHC	11.1/36.8	-	7.7	12.5	SFO
LUFA 2.2 ³⁾ Loamy Sand	/	5.8	20°/45% MWHC	3.4/10	-	3.4	-	SFO
LUFA 3A – Loam ³⁾	/	7.1	20°/45% MWHC	2.7/10	-	2.4	-	SFO
PTRL - Clay loam ³⁾	/	6.8	20°/45% MWHC	8/27	-	6.9	-	SFO
Geometric mean (if not pH dependent)						5.1		
Arithmetic mean					-			
pH dependence						No		

^{a)} Measured in calcium chloride solution

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Cyclopropyl label

¹⁾ cis-DCVA in Michel and Hassink, 2014a (study submitted for the renewal on alpha-cypermethrin, Doc. No. 2014/1000641)

²⁾ cis-DCVA in Sacchi, 2015b (metabolite-dosed study, study submitted for the renewal on alpha-cypermethrin, Doc. No. 2015/3003982)

³⁾ cis-DCVA in Class and Dorn, 2003 (metabolite-dosed study, accepted in the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r).

Trigger and modelling endpoints

3-PBA		Dark aerobic conditions - metabolite dosed studies						
Soil type		pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f /k _{dp}	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ^2)	Method of calculation
Li10 ¹⁾	/	6.2	20°/40% MWHC	0.8/4.3	-	1.3	1.9	FOMC (DT90/3.32) α : 1.91; β : 1.83
LUFA 2.2 ¹⁾	/	5.3	20°/40% MWHC	0.3/2.6	-	0.6	3.0	FOMC (DT90/3.32) α : 1.05; β : 0.33
LUFA 5M ¹⁾	/	7.4	20°/40% MWHC	1.7/5.5	-	1.2	2.0	SFO
LUFA 2.2 Loamy Sand ²⁾	/	5.8	20°/45% MWHC	0.8/3.0	-	7 (slow phase)	-	bi-phasic
LUFA 3A – Loam ²⁾	/	7.1	20°/45% MWHC	1.7/7.0	-	2.7 (slow phase)	-	bi-phasic
PTRL - Clay loam ²⁾	/	6.8	20°/45% MWHC	5.0/16	-	4.3	-	SFO
Speyer 2.2, Loamy sand ³⁾	/	5.5	20°/50% MWHC	0.38/1.3	-	0.38	4.7	SFO
Speyer 2.3, Sandy loam ³⁾	/	6.6	20°/50% MWHC	0.8/2.8	-	0.79	3.9	SFO
Speyer 6S, Clay ³⁾	/	7.2	20°/50% MWHC	2.1/7	-	1.13	1.8	SFO
Geometric mean (if not pH dependent)						1.7		
Arithmetic mean					-			
pH dependence						No		

^{a)} Measured in calcium chloride solution

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

¹⁾ Sacchi, 2015a (metabolite-dosed study, study submitted for the renewal on alpha-cypermethrin, Doc. No. 2015/3003981)

²⁾ Class and Dorn, 2003 (metabolite-dosed study, accepted in the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r).

³⁾ Shepler, 2011 (metabolite-dosed study, accepted in EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance gamma-cyhalotrin. EFSA Journal (2014) 12,(2):3560, 93 pp; DOI: 10.2903/j.efsa.2014.3560)

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Alpha-cypermethrin	Aerobic conditions								
	Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ^2)	DT ₅₀ (d) Norm ^{b)} .	Method of calculation
Dollern, sandy loam	Germany (DE1)		5.5 ^{a)}	0-90	46.1	153	11.0	46.1	SFO
Ölbronn-Dürren, silt loam	Germany (DE2)		5.4 ^{a)}	0-90	12.9	43.0	12.5	12.9	SFO
Melbourne, loam	United Kingdom (UK)		6.3 ^{a)}	0-90	14.7	250.5	15.3	114.1	HS (ln2/k2) k1: 0.0472 k2: 0.0061 tb: 19.0
Letniza, silty clay loam	Bulgaria (BG)		6.9 ^{a)}	0-90	24.6	81.8	13.1	24.6	SFO
Almansa, sandy loam	Spain (ES)		7.6 ^{a)}	0-90	42.8	142.3	4.4	42.8	SFO
Barry d'Islemade, sandy clay loam	France (FR)		5.0 ^{a)}	0-90	8.0	38.7	3.5	11.7	FOMC (DT90/3.32) α : 2.3814 β : 23.8
Silt loam	Louisiana (USA)		6.2 ^{b)}	0-91	5.9	19.6	33.8	-	SFO
Sandy loam	Oklahoma (USA)		6.7 ^{b)}	0-91	6.3	20.9	6.3	-	SFO
Sand	New York (USA)		7.1 ^{b)}	0-91	3.4	27.9	13.5	-	FOMC α = 1.0718 β = 3.6844
Sandy loam	California (USA)		6.8 ^{b)}	0-91	4.0	13.4	8.4	-	SFO
Geometric mean (if not pH dependent)								30.7	
pH dependence					No				

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

^{c)} Measured in CaCl₂ in upper 15 cm

* The experts agreed at the Pesticides Peer Review Meeting 172 (Environmental Fate and Behaviour, 12 April 2018) that, based on the available similarity assessment, the US field studies can be considered representative for EU conditions.

(cis-)DCVA		Aerobic conditions alpha-cypermethrin dosed from which the f.f. was derived was 0.371								
Soil type	Location	X^{δ}	pH ^{a)}	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ^2)	DT ₅₀ (d) Norm ^{b)}	f. f. k_f / k_{dp}	Method of calculation
Letniza, silty clay loam	Bulgaria (BG)		6.9	0-90	16.0	53.2	34.3	16.0	0.371	SFO-SFO
Almansa, sandy loam	Spain (ES)		7.6	0-90	32.4	107.6	34.5	32.4	0.326	SFO-SFO
Geometric mean (if not pH dependent)								-		
Arithmetic mean									-	
pH dependence, Yes or No						No				

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

3-PBA		Aerobic conditions alpha-cypermethrin dosed from which the f.f. was derived was 0.437								
Soil type	Location	X^{δ}	pH ^{a)}	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ^2)	DT ₅₀ (d) Norm ^{b)}	f. f. k_f / k_{dp}	Method of calculation
Letniza, silty clay loam	Bulgaria (BG)		6.9	0-90	17.1	56.9	25.5	17.1	0.364	SFO-SFO
Almansa, sandy loam	Spain (ES)		7.6	0-90	35.8	119.0	25.4	35.8	0.437	SFO-SFO
Geometric mean (if not pH dependent)								-		
Arithmetic mean									-	
pH dependence, Yes or No						No				

^{c)} Measured in water

^{d)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)

 DT₅₀ of **33.1 days**

Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)

-

-

 Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean

-

-

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

 No accumulation in EU field studies since DT₉₀<1 year

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Alpha-cypermethrin	Dark anaerobic conditions						
Soil type	X ⁶	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C ^{b)}	St. (χ ²)	Method of calculation
LUFA 5M, sandy loam ^{c)}		7.9	20°	46.8/222	-	3.0	SFO
Geometric mean (if not pH dependent)					-		

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58

^{c)} Benzyl labelled and cyclopropane labelled samples are considered as true replicates for kinetic analysis

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

M310I017	Dark anaerobic conditions alpha cypermethrin dosed study							
Soil type	X ¹⁰	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _f / k _{dp}	DT ₅₀ (d) 20 °C ^{b)}	St. (χ ²)	Method of calculation
LUFA 5M, sandy loam ^{c)}	α = 1.99; β = 71.87	7.9	20°	29.9/156.1	-	29.9	3.2	FOMC (metabolite decline)
Geometric mean (if not p;H dependent)						-		
Arithmetic mean					-			

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

^{c)} Benzyl labelled and cyclopropane labelled samples are considered as true replicates for kinetic analysis

⁶ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Alpha-cypermethrin	Soil photolysis				
	Soil type	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d) calculated at °N	St. (χ^2)
Speyer F3, sandy silty loam	7.3	22°/45.7% MWHC	34.1 / 113.3 at °N *	5.5	SFO
Lufa 5M, sandy loam ^{b)}	7.9 ^{c)} / 8.0 ^{d)}	22°/55% MWHC	26.9 / 89.2 at 49°N 103.6 / 343.4 at 35°N	3.1	SFO

^{a)} Measured in water

^{b)} Benzyl labelled and cyclopropane labelled samples are considered as true replicates for kinetic analysis

^{c)} Benzyl labelled soil

^{d)} Cyclopropane labelled soil

* A data gap is identified for correcting the DT50 values in the study by van Dijk (1993) into days of natural summer sunlight at a latitude of 30-50°N.

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Alpha-cypermethrin							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Lufa 2.3	0.67	5.4	2366	353100	-	-	-
Lufa 2.2	1.72	5.8	4362	253632	-	-	-
Bruch West	1.62	7.1	3704	228622	-	-	-
Li10	0.95	6.3	3181	334804	-	-	-
Fiorentino Poggio Renatico 1	1.07	7.4	2927	273519	-	-	-
Geometric mean (if not pH dependent)*						284839	-
Arithmetic mean (if not pH dependent)						-	-
pH dependence			No				

^{a)} Measured in calcium chloride solution

* Only relevant after implementation of the published EFSA guidance. During the Pesticides Peer Review Meeting 172 (Environmental Fate and Behaviour, 12 April 2018), the experts agreed to use the geometric mean K_{Foc} value for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

3-PBA								
Soil Type	OC %	Soil pH (CaCl ₂)	Soil pH (H ₂ O)	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Engelstadt/Benz, silt loam ¹⁾	2.27	7.4	7.9 ^{a)}	1.823	80.3	1.038	46	0.7466
Ingelheim/Moers, sandy loam ¹⁾	1.33	7.6	8.1 ^{a)}	1.308	98.3	0.897	67	0.8165
Schwabenheim, silt loam ¹⁾	1.09	5.9	6.5 ^{a)}	1.927	176.8	0.949	87	0.7043
Speyer 2.2, loamy sand ¹⁾	2.29	5.9	6.5 ^{a)}	2.925	127.7	2.076	91	0.8608
LUFA 2.3, sandy loam ²⁾	0.98	6.4	6.9 ^{a)}	-	-	0.88	90.1	0.84
LUFA 6S, clay ²⁾	1.75	7.2	7.7 ^{a)}	-	-	1.06	60.5	0.88
Fraunhofer 02-A, silt loam ²⁾	1.30	-	6.6 ^{b)}	-	-	0.76	58.8	0.88
Drummer, silt clay ³⁾	2.56	-	6.4 ^{c)}	-	-	3.11	122	0.66
Thurston, sandy loam ³⁾	0.83	-	6.8 ^{c)}	-	-	0.98	118	0.65
Nixon, sandy loam ³⁾	1.14	-	5.6 ^{c)}	-	-	2.44	215	0.67
Speyer 2.2, Loamy sand ⁴⁾	2.1	5.5	6.1 ^{a)}	-	-	-	58	0.914
Speyer 2.3, Sandy loam ⁴⁾	1.0	6.6	7.1 ^{a)}	-	-	-	71	0.864
Speyer 6S, Clay ⁴⁾	1.7	7.2	7.7 ^{a)}	-	-	-	47	0.865
Geometric mean (n = 12, considering only soils with pH-H ₂ O > 5.6) ^{d) *}							72.7	-
Arithmetic mean (n = 12, considering only soils with pH-H ₂ O > 5.6) ^{d)}							-	0.81
pH dependence				Yes ^{e)}				

^{a)} Recalculated to pH-H₂O using the equation $\text{pH-H}_2\text{O} = 0.953 \text{ pH-CaCl}_2 + 0.85$ as presented in the Final Report of the FOCUS Ground Water Work Group (Sanco/13144/2010, version 3, 10 October 2014)

^{b)} Measured in H₂O

^{c)} pH assumed to be measured in water, although not explicitly stated in the DAR on zeta-cypermethrin (May 2008)

^{d)} Excluding the soil with pH 5.6 from the dataset would result in conservative mean adsorption values to be used for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling, as this acid soils is the soil within the dataset with the highest K_{foc} values.

^{e)} pH dependency of K_{foc} was tested with the Kendall's tau test and a significant correlation was found (at a significance level of 0.05) for the whole dataset (n=13). No significant pH-dependency (at a significance level of 0.05) is observed when excluding the sandy loam soil with pH 5.6 and the highest K_{foc} value of 215 mL/g from the dataset.

* Only relevant after implementation of the published EFSA guidance. During the Pesticides Peer Review Meeting 172 (Environmental Fate and Behaviour, 12 April 2018), the experts agreed to use the geometric mean K_{Foc} value for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling.

¹⁾ Holman 2002 (study submitted for the renewal on alpha-cypermethrin)

²⁾ Hein, 2009 (accepted in the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance beta-cypermethrin. EFSA Journal 2014;12(6):3717; DOI: 10.2903/j.efsa.2014.3717)

³⁾ Gravelle, 1994 (accepted in the EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance zeta-cypermethrin. EFSA Scientific Report (2008) 196, 1-119; DOI: 10.2903/j.efsa.2009.196r)

⁴⁾ LaMar and Quistad, 2010 (accepted in EFSA conclusion regarding the peer review of the pesticide risk assessment of the active substance gamma-cyhalotrin. EFSA Journal (2014) 12,(2):3560, 93 pp; DOI: 10.2903/j.efsa.2014.3560)

Cis-DCVA							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Bonnut, sandy loam ¹⁾	0.9	5.5	-	-	1.718	191	0.836
Chateauroux, silt loam ¹⁾	1.3	6.5	-	-	0.743	57	0.692
Thoree les pins, sandy loam ¹⁾	0.7	4.4	-	-	2.223	318	0.889
Pithiviers, clay loam ¹⁾	1.4	7.1	-	-	0.514	37	0.754
Ploudalmezeau, clay silt ¹⁾	1.5	6.4	-	-	0.711	47	0.728
Geometric mean (n = 3, considering only soils with pH > 5.5) ^{b) *}						46.3	-
Arithmetic mean (n = 3, considering only soils with pH > 5.5) ^{b)}						-	0.72
pH dependence				Yes			

^{a)} Measured in calcium chloride solution

^{b)} Excluding the soils with pH of 5.5 and 4.4 from the dataset would result in conservative mean adsorption values to be used for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling, as these acid soils are the soils within the dataset with the highest K_{foc} values.

* Only relevant after implementation of the published EFSA guidance. During the Pesticides Peer Review Meeting 172 (Environmental Fate and Behaviour, 12 April 2018), the experts agreed to use the geometric mean K_{Foc} value for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling.

¹⁾ cis-DCVA in Malinsky, 2005 (study submitted for the renewal on alpha-cypermethrin)

M310I017							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
Lufa 2.2, sandy loam	1.72	5.8	2393	139148	-	-	-
Lufa 2.3, loamy fine sand	0.67	5.4	1738	259437	-	-	-
Bruch west, sandy loam	1.62	7.1	2819	174041	-	-	-
Li10, loamy fine sand	0.95	6.3	2956	311179	-	-	-
Fiorentino Poggio Renatico 1, loam	1.07	7.4	3914	365806	-	-	-
Geometric mean (if not pH dependent)*						234901	-
Arithmetic mean (if not pH dependent)						-	-
pH dependence				No			

^{a)} Measured in calcium chloride solution

* Only relevant after implementation of the published EFSA guidance. During the Pesticides Peer Review Meeting 172 (Environmental Fate and Behaviour, 12 April 2018), the experts agreed to use the geometric mean K_{Foc} value for PEC_{gw}, PEC_{sw} and PEC_{sed} modelling.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

Not required, sufficient information from adsorption/desorption study
-

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching

(cypermethrin) No residue is found in the leachate (limit of determination 0.2 µg/l)
DCVA reached 20% AR in the leachates from the silty clay soil and 3-PBA was found in concentrations around 5-10%

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies

Not required as information on mobility of the parent and its metabolites 3-PBA, DCVA and M310I017 is available.
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Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1)

Hydrolytic degradation of the active substance and metabolites > 10 %

pH 4: hydrolytical stability (no degradation after 10 days) at 50°C

pH 4: hydrolytical stability (no degradation after 30 days) at 25°C

pH 5:

DT₅₀ of 60.4 days at 25°C (SFO)

pH 7:

DT₅₀ of 28.7 days at 50°C (SFO)

DT₅₀ of 5.7 days at 60°C (SFO)

DT₅₀ of 2.2 days at 75°C (SFO)

3-PBAld was detected in maximum amounts of 21.6% (50°C), 71.7% (60°C), and 61.5% (75°C).

pH 7:

DT₅₀ of 54.2 days at 25°C (SFO)

DT₅₀ of 85.3 days at 25°C (SFO)

pH 9:

DT₅₀ of 3.3 days at 25 °C (SFO)

DT₅₀ of 0.1 day at 50 °C (SFO)

3-PBAld was detected at maximum 88.4% (25°C) and 92.1% TAR (50°C) were measured. 3-PBAld occurred in increasing amount until these maximum values measured during the last sampling points, indicating some aqueous stability of this compound in water.

pH 9:

DT₅₀ of 4.5 days at 25°C (SFO)

DT₅₀ of 2.9 days at 50°C (SFO)

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %

Based on 8.4 hours of artificial light irradiation (1 solar day), DT₅₀ and DT₉₀ values of alpha-cypermethrin were 6.3 and 20.9 days, (benzyl label), respectively, and 3.4 and 11.7 days (cyclopropane label), respectively.

Major photolysis products (> 10% of applied radioactivity) :

3-PBAldehyde (max. 12.9% after 4 d, 4.1% after 15 d) (Bz-label)

3-PBA (max. 22.5% after 4 d, 8.5% after 15 d) (Bz-label)

DCVA, combination of cis and trans isomers (max. 43.7% after 8 d, 34.8% after 28 d) (Cp-label)

CO₂ : 21.4% after 15 d (Bz-label), 7.7% after 28 d (Cp-label)

Quantum yield of direct phototransformation in water at λ > 290 nm

$8.12 \times 10^{-3} \text{ mol} \cdot \text{Einstein}^{-1}$

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)

Not ready biodegradable

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Alpha-cypermethrin										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed ^{a)}	t. °C ^{b)}	DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test)		St. (χ ²)	DT ₅₀ /DT ₉₀ Water (pelagic test)		St. (χ ²)	Method of calculation
				At study temp	Normalised to x °C ^{c)}		At study temp (20°C)	Normalised to 12 °C ^{c)}		
Fresh water, low concentration, cyclopropyl-label	7.9	7.6	20°	-	-	-	3.1/43.0	6.6/91.8	9.9	DFOP
Fresh water, low concentration, benzyl-label	7.9	7.6	20°	-	-	-	2.3/86.8	4.9/185.3	9.8	DFOP
Fresh water, high concentration, cyclopropyl-label	7.9	7.6	20°	-	-	-	3.4/36.5	7.3/77.9	9.5	DFOP
Fresh water, low concentration, benzyl-label	7.9	7.6	20°	-	-	-	3.3/36.8	7.0/78.5	6.5	DFOP

^{a)} Measured in water

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling.

DCVA										
Max in total system 77.7% (cis-DCVA) after 59 days										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed ^{a)}	t. °C ^{b)}	DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test)		St. (χ ²)	DT ₅₀ /DT ₉₀ Water (pelagic test)		St. (χ ²)	Method of calculation
				At study temp	Normalised to x °C ^{c)}		At study temp	Normalised to x °C ^{c)}		
Fresh water, low concentration, cyclopropyl-label	7.9	7.6	20°	-	-	-	No reliable endpoints derived	-	-	-
Fresh water, high concentration, cyclopropyl-label	7.9	7.6	20°	-	-	-	No reliable endpoints derived	-	-	-

^{a)} Measured in water

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

3-PBA										
Max in total system 52.9% after 7 days										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed ^{a)}	t. °C ^{b)}	DT ₅₀ /DT ₉₀ whole sys. (suspended sediment test)		St. (χ ²)	DT ₅₀ /DT ₉₀ Water (pelagic test)		St. (χ ²)	Method of calculation
				At study temp	Normal ised to x °C ^{c)}		At study temp	Norm alised to x °C ^{c)}		
Fresh water, low concentration, benzyl-label	7.9	7.6	20°	-	-	-	No reliable endpoints derived	-	-	-
Fresh water, high concentration, benzyl-label	7.9	7.6	20°	-	-	-	45.2/150. 2	-	9.4	DFOP-SFO

^{a)} Measured in water

^{b)} Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C

^{c)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues. max x % after n d (suspended sediment test)	Non-extractable residues. max x % after n d (end of the study) (suspended sediment test)
Fresh water, low concentration, cyclopropyl-label	7.9	7.6	4.9% after 59 days	-	-
Fresh water, low concentration, benzyl-label	7.9	7.6	32.8% after 59 days	-	-
Fresh water, high concentration, cyclopropyl-label	7.9	7.6	3.5% after 59 days	-	-
Fresh water, low concentration, benzyl-label	7.9	7.6	37.6% after 59 days	-	-

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Trigger endpoints

Alpha-cypermethrin	Distribution : max in water 95.4% after 0 d. Max. sed 77.0% after 14 d The enantioselective effect on degradation behaviour in water and sediment is small and has no influence on risk assessment.									
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ ²)	DT ₅₀ /DT ₉₀ water	St. (χ ²)	DT ₅₀ /DT ₉₀ sed	St. (χ ²)	Method of calculation
System I (Rhine)	8.2	7.8 (KCl)	20°	4.5 /261.6 (FOMC)	7.8	0.1 / 2.6 (HS)	12.2	14.8 / 826.0 (FOMC)	4.6	/
System II (Judenweiher)	7.2	7.1 (KCl)	20°	4.6 /24.1 (FOMC)	6.3	0.2 / 5.1 (HS)	7.3	8.0 / 27.8 (HS)	5.0	/
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	13.5 /171.9 (DFOP)	3.0	0.3 / 8.5 (FOMC)	12.6	22.9 /229.3 (FOMC)	5.4	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	51.3 /276.3 (DFOP)	3.8	0.2 / 6.6 (FOMC)	14.2	81.0 /269.1 (SFO)	4.4	/

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

Modelling endpoints

Alpha-cypermethrin										
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ whole sys.	St. (χ ²)	DT ₅₀ water	St. (χ ²)	DT ₅₀ sed	St. (χ ²)	Method of calculation
System I (Rhine)	8.2	7.8 (KCl)	20°	56.4 ^{c)} (DFOP)	9.9	0.5 ^{d)} (HS)	12.2	248.8 ^{d)} (FOMC)	4.6	/
System II (Judenweiher)	7.2	7.1 (KCl)	20°	5.4 (SFO)	7.4	1.5 ^{d)} (HS)	7.3	8.2 (SFO)	9.1	/
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	20.6 (SFO)	11.6	2.6 ^{d)} (FOMC)	12.6	33.6 (SFO)	10.7	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	96.3 ^{c)} (DFOP)	3.8	2.0 ^{d)} (FOMC)	14.2	81.0 (SFO)	4.4	/
Geometric mean at 20°C ^{b)}				27.9		1.4		48.5		

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

^{c)} Calculated as $DT_{50} = \ln 2/k_2$

^{d)} Calculated as $DT_{50} = DT_{90}/3.32$

Trigger endpoints

3-PBA		Parent alpha-cypermethrin dosed studies, distribution (max in water 18% after 7 d. Max. sed 5.1% after 7 d). Max in total system 23.1% after 7 days,								
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ ²)	DT ₅₀ /DT ₉₀ water	St. (χ ²)	DT ₅₀ /DT ₉₀ sed	St. (χ ²)	Method of calculation
Benzyl, System I (Rhine)	8.2	7.8 (KCl)	20°	8.5/28.2 (SFO)	29.1	9.2/30.6 (SFO)	10.6	16.7/55.3 (SFO)	14.2	/
Benzyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	7.6/25.3 (SFO)	26.8	11.4/38.0 (SFO)	20.4	19.3/64.1 (SFO)	11.8	/
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	6.2 / 91.4 (HS)	3.8	11.6 / 195.7 (HS)	3.0	n.c.	/	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	n.c.	/	3.8 / 58.3 (HS)	11.5	n.c.	/	/

n.c. : not calculated due to either limited number of data points available (Berghauser Altrhein) or not observed in the sediment phase (Ranschgraben)

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

Modelling endpoints - Dissipation (for FOCUS Step 1-2)

3-PBA		Parent alpha-cypermethrin dosed studies, distribution (max in water 18% after 7 d. Max. sed 5.1% after 7 d). Max in total system 23.1% after 7 days								
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ whole sys.	St. (χ ²)	DT ₅₀ water	St. (χ ²)	DT ₅₀ sed	St. (χ ²)	Method of calculation
Benzyl, System I (Rhine)	8.2	7.8 (KCl)	20°	10.2 (SFO)	11.2	9.2 (SFO)	10.6	16.7 (SFO)	14.2	/
Benzyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	12.5 (SFO)	18.0	11.4 (SFO)	20.4	19.3 (SFO)	11.8	/
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	74.5 (HS)	3.8	161.2 (HS)	3.0	n.c.	/	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	n.c. (DT50 water used for geomean whole sys.)	/	17.6 (HS)	11.5	n.c.	/	/
Geometric mean at 20°C ^{b)}				20.2		23.4		18.1		

n.c. : not calculated due to either limited number of data points available (Berghauser Altrhein) or not observed in the sediment phase (Ranschgraben)

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

Modelling endpoints - Degradation (for FOCUS Step 3)

3-PBA		kinetic formation fraction (k_f/k_{dp}): in total system, formation fraction of 0.493 from alpha-cypermethrin				
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DegT ₅₀ /DegT ₉₀ whole system	St. (χ^2)	Method of calculation
Cyclopropyl, System I (Rhine)	8.2	7.8 (KCl)	20°	8.5 Ffm from parent:0.460	29.1	DFOP-SFO
Cyclopropyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	7.6 Ffm from parent:0.526	26.8	FOMC-SFO
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	No reliable endpoints could be derived	/	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	No reliable endpoints could be derived	/	/
Geometric mean at 20°C ^{b)}				8.0		
Arithmetic mean ffm				0.493		

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

Trigger endpoints

(cis-)DCVA		Parent alpha-cypermethrin dosed studies, distribution (max in water 47.3% after 14 d. Max. sed 19.5% after 14 d). Max in total system 66.8% after 14 days,								
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ /DT ₉₀ whole sys.	St. (χ^2)	DT ₅₀ /DT ₉₀ water	St. (χ^2)	DT ₅₀ /DT ₉₀ sed	St. (χ^2)	Method of calculation
Cyclopropyl, System I (Rhine)	8.2	7.8 (KCl)	20°	25.5/84.8 (SFO)	28.0	No reliable endpoints derived	-	36.4/120.8 (SFO)	12.7	/
Cyclopropyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	30.3/100.8 (SFO)	10.7	30.5/101.2 (SFO)	14.7	50.4/167.4 (SFO)	20.7	/
System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	20°	5.9 / 25.5 (DFOP)	0.3	6.6 / 30.0 (DFOP)	0.4	n.c.	/	/
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	n.c.	/	12.3 / 40.8 (SFO)	15.9	n.c.	/	/

n.c. : not calculated due to either limited number of data points available (Berghauser Altrhein) or not observed in the sediment phase (Ranschgraben)

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

Modelling endpoints - Dissipation (for FOCUS Step 1-2)

(cis-)DCVA	Parent alpha-cypermethrin dosed studies, distribution (max in water 47.3% after 14 d. Max. sed 19.5% after 14 d). Max in total system 66.8% after 14 days,									
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DT ₅₀ whole sys.	St. (χ^2)	DT ₅₀ water	St. (χ^2)	DT ₅₀ sed	St. (χ^2)	Method of calculation
Cyclopropyl, System I (Rhine)	8.2	7.8 (KCl)	20°	23.2 (SFO)	25.8	No reliable endpoints derived	-	36.4 (SFO)	12.7	/
Cyclopropyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	35.3 (SFO)	14.4	30.5 (SFO)	14.7	50.4 (SFO)	20.7	/
System III (Berghäuser Altrhein)	7.9	7.0 (CaCl ₂)	20°	6.6 (SFO)	11.4	7.4 (SFO)	12.3	n.c.		
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	n.c. (DT50 water used for geomean whole sys.)	/	12.3 (SFO)	15.9	n.c.		
Geometric mean at 20°C ^{b)}				16.1		14.1		42.8		

n.c. : not calculated due to either limited number of data points available (Berghäuser Altrhein) or not observed in the sediment phase (Ranschgraben)

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

Modelling endpoints - Degradation (for FOCUS Step 3)

(cis-)DCVA	Parent alpha-cypermethrin dosed studies, distribution (max in water 47.3% after 14 d. Max. sed 19.5% after 14 d). Max in total system 66.8% after 14 days, kinetic formation fraction (k_f/k_{dp}): in total system, formation fraction of 0.816 from alpha-cypermethrin					
Water / sediment system	pH water phase	pH sed ^{a)}	t. °C	DegT ₅₀ / DegT ₉₀ whole system	St. (χ^2)	Method of calculation
Cyclopropyl, System I (Rhine)	8.2	7.8 (KCl)	20°	25.5 Ffm from parent:0.706	28.0	FOMC-SFO
Cyclopropyl, System II (Judenweiher)	7.2	7.1 (KCl)	20°	30.3 Ffm from parent:0.957	10.7	FOMC-SFO
System III (Berghäuser Altrhein)	7.9	7.0 (CaCl ₂)	20°	4.4 Ffm from parent:0.599	20.4	DFOP-SFO
System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	20°	2.3 Ffm from parent:1.000	25.7	DFOP-SFO
Geometric mean at 20°C ^{b)}				9.4		

^{a)} Measured in [medium to be stated, usually calcium chloride solution or water]

^{b)} Normalised using a Q10 of 2.58

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Benzyl, System I (Rhine)	8.2	7.8 (KCl)	24.9% after 105 days	23.2% after 61 days	18.9% after 105 days
Benzyl, System II (Judenweiher)	7.2	7.1 (KCl)	53.1% after 105 days	37.3% after 30 days	21.2% after 105 days
Benzyl, System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	43.2% after 100 days	22.5% after 28 days	20.1% after 100 days
Benzyl, System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	33.4% after 100 days	20.5% after 57 days	15.9% after 100 days
Cyclopropyl, System I (Rhine)	8.2	7.8 (KCl)	33.2% after 105 days	16.9% after 60 days	16.2% after 105 days
Cyclopropyl, System II (Judenweiher)	7.2	7.1 (KCl)	40.0% after 105 days	37.1% after 105 days	37.1% after 105 days
Cyclopropyl, System III (Berghauser Altrhein)	7.9	7.0 (CaCl ₂)	42.6% after 100 days	32.7% after 57 days	27.8% after 100 days
Cyclopropyl, System IV (Ranschgraben)	7.3	5.9 (CaCl ₂)	32.0% after 100 days	28.1% after 79 days	26.0% after 100 days

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	DT ₅₀ of 5.99 hours derived by the Atkinson model (version 1.92). OH (12 h) concentration assumed = 1.5 x 10 ⁶ molecules/cm ³
Volatilisation	from plant surfaces (BBA guideline): Not studied - not required
	from soil surfaces (BBA guideline): Not studied – not required
Metabolites	-

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	<p><u>Soil</u>: Alpha-cypermethrin, DCVA, 3-PBA and M310I017</p> <p><u>Surface water</u>: Alpha-cypermethrin, DCVA and 3-PBA, 3-PBAldehyde and M310I017 (data gap for identification of the radioactive fractions RW7 and RW9)</p> <p><u>Sediment</u>: Alpha-cypermethrin, DCVA, 3-PBA, 3-PBAldehyde and M310I017</p> <p><u>Ground water</u>: Alpha-cypermethrin, DCVA, 3-PBA, carboxamide and M310I017</p> <p><u>Air</u>: Alpha-cypermethrin</p>
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Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5)

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	Monitoring data are available from two countries, from France (2000 to 2007) and from Finland (only 2005). In sum 18695 measurements are available from river waters, however only two of them were > LOQ.
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent: alpha-cypermethrin	DT ₅₀ (d): 46.1 days
Method of calculation	<p>Kinetics: SFO</p> <p>Field or Lab: worst case actual DT₅₀ from US + EU field studies.</p>

Application data

Crop: cabbage
 Depth of soil layer: 5cm
 Soil bulk density: 1.5g/cm³
 % plant interception: 25% crop interception
 Number of applications: 1
 Interval (d): -
 Application rate(s): 20 g a.s./ha

Note: RMS considers that the DT50 of 6.3 is not suitable, therefore only the initial PECsoil is acceptable.

PEC _(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.020		-	
Short term	24h	0.020	0.020	
	2d	0.019	0.020	
	4d	0.019	0.019	
Long term	7d	0.018	0.019	
	28d	0.013	0.016	
	50d	0.009	0.014	
	100d	0.004	0.010	
Plateau concentration	-			

Metabolite **M310I017**

Method of calculation

Molecular weight relative to the parent: 1.038
 DT₅₀ (d): 42.3 days
 Kinetics: SFO
 Field or Lab: worst case lab studies.

Application data

Application rate assumed: 1.3 g/ha (assumed **M310I017** is formed at a maximum of 8.4% of the applied dose)

PEC _(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.0017		-	

Metabolite **DCVA**

Method of calculation

Molecular weight relative to the parent: 0.502
 DT₅₀ (d): 13.5 days
 Kinetics: SFO
 Field or Lab: worst case lab studies.

Application data

Application rate assumed: 1.0 g/ha (assumed **DCVA** is formed at a maximum of 13.6% of the applied dose)

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
	Initial	0.0014		-

Metabolite 3-PBA	Molecular weight relative to the parent: 0.515			
Method of calculation	DT ₅₀ (d): 2.9 days (the correct value is 5 d)			
	Kinetics: SFO			
	Field or Lab: worst case lab studies.			
Application data	Application rate assumed: 2.2 g/ha (assumed 3-PBA is formed at a maximum of 28.6% of the applied dose)			
PEC_(s) (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.0029		-	

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

For FOCUS gw modelling, values used –

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.

Model(s) used: FOCUS-PEARL 4.4.4 and FOCUS-PELMO 5.5.3

Crop: Spring cereals, winter cereals, winter oilseed rape, cabbage

Crop uptake factor: 0

Parent alpha cypermethrin:

Molecular weight: 416.3

Water solubility (mg/L): 0.003 at pH 6.5 and 20°C

Vapour pressure: 3.8×10^{-7} Pa at 20°C

Geometric mean parent $DT_{50 \text{ lab/field}}$ of 33.1 days (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

K_{OC} : 284839 mL/g (geometric mean), $1/n = 1$ (default value)

Metabolite M310I017:

Molecular weight: 432.3

Water solubility (mg/L): 0.072 at 20°C

Vapour pressure: 1.0×10^{-10} Pa at 20°C (worst case assumption)

Geometric mean parent $DT_{50 \text{ lab}}$ of 11.8 days (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

K_{OC} : 234901 mL/g (geometric mean), $1/n = 1$ (default value)

Ffm: 0.344 from alpha-cypermethrin (for PEARL) ; Transformation rate of alpha-cypermethrin to M310I017 of 0.007204 (for PELMO)

Metabolite DCVA:

Molecular weight: 209.1

Water solubility (mg/L): 129 at pH 4.0 and 20°C

Vapour pressure: 1.0×10^{-10} Pa at 20°C (worst case assumption)

Geometric mean parent $DT_{50 \text{ lab}}$ of 4.8 days (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7) (Note: the correct value is 5.1 d).

K_{OC} : 46.3 mL/g (geometric mean), $1/n = 0.72$ (arithmetic mean)

Ffm: 1.0 from alpha-cypermethrin (for PEARL) ; Transformation rate of alpha-cypermethrin to DCVA of 0.020941 (for PELMO)

Metabolite 3-PBA:

Molecular weight: 214.2

Water solubility (mg/L): 24.7 at pH 4.2 and 20°C

Vapour pressure: 1.0×10^{-10} Pa at 20°C (worst case assumption)

Application rate

Geometric mean parent $DT_{50 \text{ lab}}$ of 1.1 day (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7) (Note: the correct value is 1.7 d).

K_{OC} : 78.5 mL/g (geometric mean), $1/n = 0.78$ (arithmetic mean) (Note: the correct values are 72.7 mL/g (geometric mean), $1/n = 0.81$ (arithmetic mean))

Ffm: 1.0 from alpha-cypermethrin (for PEARL) ; Transformation rate of alpha-cypermethrin to 3-PBA of 0.020941 (for PELMO)

For field and lysimeter studies : /

Spring cereals

Gross application rate: 10 g/ha.

Crop growth stage: BBCH 51

Canopy interception: 90% / 90%

Application rate net of interception: 1.0 g/ha.

No. of applications: 2

Application interval: 7 days

Time of application (absolute or relative application dates):

Scenario	1 st application	2 nd application
Châteaudun	11 th May	18 th May
Hamburg	11 th June	18 th June
Jokioinen	16 th June	23 rd June
Kremsmünster	11 th June	18 th June
Okehampton	11 th June	18 th June
Porto	11 th May	18 th May

Winter cereals

Gross application rate: 10 g/ha.

Crop growth stage: BBCH 51

Canopy interception: 90% / 90%

Application rate net of interception: 1.0 g/ha.

No. of applications: 2

Application interval: 7 days

Time of application (absolute or relative application dates):

Scenario	1 st application	2 nd application
Châteaudun	6 th May	13 th May
Hamburg	1 st June	8 th June
Jokioinen	6 th June	13 th June
Kremsmünster	1 st June	8 th June
Okehampton	23 rd May	30 th May
Piacenza	22 nd April	29 th April
Porto	21 st April	28 th April
Sevilla	22 nd March	29 th March
Thiva	21 st April	28 th April

Winter oilseed rape

Gross application rate: 10 g/ha.

Crop growth stage: BBCH 51

Canopy interception: 80% / 80%

Application rate net of interception: 2.0 g/ha.

No. of applications: 2

Application interval: 7 days

Time of application (absolute or relative application dates):

Scenario	1 st application	2 nd application
Châteaudun	17 th April	24 th April
Hamburg	5 th May	12 th May
Kremsmünster	5 th May	12 th May
Okehampton	28 th April	5 th May
Piacenza	28 th March	4 th April
Porto	17 th April	24 th April

Cabbage

Gross application rate: 20 g/ha.

Crop growth stage: BBCH 10

Canopy interception: 25%

Application rate net of interception: 15.0 g/ha.

No. of applications: 1

Application interval: -

Time of application (absolute or relative application dates):

Scenario	1 st application
Châteaudun, 1 st	21 st April
Châteaudun, 2 nd	1 st August
Hamburg, 1 st	21 st April
Hamburg, 2 nd	1 st August
Jokioinen	21 st May
Kremsmünster, 1 st	21 st April
Kremsmünster, 2 nd	1 st August
Porto, 1 st	1 st March
Porto, 2 nd	1 st August
Sevilla, 1 st	2 nd March
Sevilla, 2 nd	16 th June
Thiva,	16 th August

Tomatoes

Gross application rate: 30 g/ha.

Crop growth stage: BBCH 10

Canopy interception: 50%

Application rate net of interception: 15.0 g/ha.

No. of applications: 1

Application interval: -

Time of application (absolute or relative application dates):

Scenario	1 st application
Châteaudun	11 th May
Piacenza	11 th May
Porto	16 th March
Sevilla	16 th April
Thiva	11 th April


PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)
Spring cereals

PEARL 4.4.4 /Spring cereals	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001

PELMO 5.5.3 /Spring cereals	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001

Winter cereals

PEARL 4.4.4 / winter cereals	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001	

PELMO 5.5.3 / winter cereals	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001	<0.001	

Winter oilseed rape

PEARL 4.4.4 / winter oilseed rape	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001	
Kremsmunster	<0.001	<0.001	<0.001	<0.001	
Okehampton	<0.001	<0.001	<0.001	<0.001	
Piacenza	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	

PELMO 5.5.3 / winter oilseed rape	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001	<0.001	
Kremsmunster	<0.001	<0.001	<0.001	<0.001	
Okehampton	<0.001	<0.001	<0.001	<0.001	
Piacenza	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	

Cabbage

PEARL 4.4.4 /cabbage	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun, 1 st	<0.001	<0.001	<0.001	<0.001
	Chateaudun, 2 nd	<0.001	<0.001	<0.001	<0.001
	Hamburg, 1 st	<0.001	<0.001	<0.001	<0.001
	Hamburg, 2 nd	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster, 1 st	<0.001	<0.001	<0.001	<0.001
	Kremsmunster, 2 nd	<0.001	<0.001	<0.001	<0.001
	Porto, 1 st	<0.001	<0.001	<0.001	<0.001
	Porto, 2 nd	<0.001	<0.001	<0.001	<0.001
	Sevilla, 1 st	<0.001	<0.001	<0.001	<0.001
	Sevilla, 2 nd	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

PELMO 5.5.3 /cabbage	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun, 1 st	<0.001	<0.001	<0.001	<0.001
	Chateaudun, 2 nd	<0.001	<0.001	<0.001	<0.001
	Hamburg, 1 st	<0.001	<0.001	<0.001	<0.001
	Hamburg, 2 nd	<0.001	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001	<0.001
	Kremsmunster, 1 st	<0.001	<0.001	<0.001	<0.001
	Kremsmunster, 2 nd	<0.001	<0.001	<0.001	<0.001
	Porto, 1 st	<0.001	<0.001	<0.001	<0.001
	Porto, 2 nd	<0.001	<0.001	<0.001	<0.001
	Sevilla, 1 st	<0.001	<0.001	<0.001	<0.001
	Sevilla, 2 nd	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001

Tomatoes

PEARL 4.4.4 tomatoes	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	

PELMO 5.5.3 tomatoes	Scenario	Parent (µg/L)	Metabolites (µg/L)		
			M310I017	DCVA	3-PBA
	Chateaudun	<0.001	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	

PEC_(gw) From lysimeter / field studies

Parent	1 st year	2 nd year	3 rd year
Annual average (µg/L)	Not available	Not available	Not available

Metabolite X	1 st year	2 nd year	3 rd year
Annual average (µg/L)	Not available	Not available	Not available

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

<p>Parent Parameters used in FOCUSsw step 1 and 2</p>	<p>Version control no. of FOCUS calculator: STEPS1-2 in FOCUS version 3.2 Molecular weight (g/mol): 416.3 K_{OC} : 284839 mL/g (geometric mean) DT₅₀ soil (d): 33.1 days (geomean from combined Lab and field DT50's) DT₅₀ water/sediment system : 27.9 days (geomean from sediment water studies) DT₅₀ water : 27.9 days DT₅₀ sediment : 27.9 days <u>Vegetables, leafy</u> Crop interception (%): minimal crop cover</p>
<p>Parameters used in FOCUSsw step 3 (if performed)</p>	<p>Version control no.'s of FOCUS software: FOCUS-PRZM version 4.3.1, FOCUS-MACRO version 5.5.4, FOCUS-TOXSWA version 4.4.3, SWASH version 5.1 and SWAN version 4.0.1 Water solubility (mg/L): 0.003 mg/L Vapour pressure: 3.8 x 10⁻⁷ Pa at 20°C Koc (mL/g): 284839 mL/g (geometric mean) 1/n: 1 (default value) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 DT₅₀ water : 1000 days (default value) DT₅₀ sediment : 27.9 days Application method: ground spray</p>

Application rate

Vegetables, leafy (FOCUS Step 1-2)

Crop and growth stage: minimal crop cover

Number of applications: 2

Interval : 7 days

Application rate(s): 10 g a.s./ha

Application window: March-May, North and South Europe

Crop and growth stage: minimal crop cover

Number of applications: 1

Interval : -

Application rate(s): 20 g a.s./ha

Application window: March-May, North and South Europe

Vegetables, fruiting – Greenhouse (FOCUS Step 2) default drift value of 0.1%

Crop and growth stage: no interception

Number of applications: 2

Interval : 7 days

Application rate(s): 15 g a.s./ha

Application window: March-May, North and South Europe

Crop and growth stage: no interception

Number of applications: 1

Interval : -

Application rate(s): 30 g a.s./ha

Application window: March-May, North and South Europe

Spring and winter cereals (FOCUS Step 3-4)

Crop and growth stage: BBCH 51 - 83

Number of applications: 2

Interval (d): variable (PAT)

Application rate(s): 10 g a.s./ha

Application window: 70 days to 28 days before harvest

Winter oilseed rape (FOCUS Step 3-4)

Crop and growth stage: BBCH 51 - 59

Number of applications: 2

Interval (d): variable (PAT)

Application rate(s): 10 g a.s./ha

Application window: 84 days to 47 days before harvest

Vegetables leafy (FOCUS Step 3-4)

Crop and growth stage: BBCH 10 - 49

Number of applications: 2

Interval (d): variable (PAT)

Application rate(s): 10 g a.s./ha
 Application window: early application: 1 day after emergence to 37 days later; late application: 40 days before harvest to 3 days before harvest

Crop and growth stage: BBCH 10 - 49
 Number of applications: 1
 Interval (d): -
 Application rate(s): 20 g a.s./ha
 Application window: 1 day after emergence to 3 days before harvest

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.201		49.869	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.201		49.869	

FOCUS STEP 2 Scenario North Europe	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.092		4.054	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.082		7.415	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.184		8.108	

FOCUS STEP 2 Scenario South Europe	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.092		7.494	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.082		13.825	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.184		14.987	

FOCUS STEP 2 Scenario Greenhouse	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, fruiting; 2 x 15 g a.s. ha ⁻¹	0 h	0.005		0.063	
Vegetables, fruiting; 1 x 30 g a.s. ha ⁻¹	0 h	0.010		0.067	

FOCUS Step 3-4 PEC's in surface water

For Step 4: D = Drift mitigation by no-spray buffer zones [m] ; N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following single application of 10 g as/ha to spring cereals

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D1	ditch	0.053 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D1	stream	0.046 Drift	0.011 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
D3	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.045 Drift	0.011 Drift	0.002 Drift	0.016 Drift	0.008 Drift	0.009 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.045 Drift	0.011 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
R4	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following twofold application of 10 g as/ha to spring cereals

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D1	ditch	0.048 Drift	0.012 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.007 Drift
D1	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D3	ditch	0.047 Drift	0.012 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.039 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R4	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following single application of 10 g as/ha to winter cereals

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D1	ditch	0.056 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D1	stream	0.046 Drift	0.011 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
D2	ditch	0.056 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D2	stream	0.047 Drift	0.012 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
D3	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.045 Drift	0.011 Drift	0.002 Drift	0.016 Drift	0.008 Drift	0.009 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
D6	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
R1	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R3	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
R4	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following twofold application of 10 g as/ha to winter cereals

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D1	ditch	0.053 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D1	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D2	ditch	0.051 Drift	0.013 Drift	0.002 Drift	0.013 Drift	0.007 Drift	0.007 Drift
D2	stream	0.041 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
D3	ditch	0.046 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.039 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
D6	ditch	0.051 Drift	0.013 Drift	0.002 Drift	0.013 Drift	0.007 Drift	0.007 Drift
R1	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R3	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R4	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following single application of 10 g as/ha to winter oilseed rape

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D2	ditch	0.053 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D2	stream	0.047 Drift	0.012 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
D3	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.044 Drift	0.011 Drift	0.002 Drift	0.016 Drift	0.008 Drift	0.008 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.044 Drift	0.011 Drift	0.002 Drift	0.016 Drift	0.008 Drift	0.009 Drift
R1	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R3	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following twofold application of 10 g as/ha to winter oilseed rape

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D2	ditch	0.047 Drift	0.012 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D2	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D3	ditch	0.046 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.038 Drift	0.010 Drift	0.002 Drift	0.013 Drift	0.007 Drift	0.007 Drift
D5	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D5	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R1	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1	stream	0.029 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R3	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

PEC_{sw,max} of alpha-cypermethrin following single application of 10 g as/ha to vegetables, leafy, early application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D3, 1 st	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D3, 2 nd	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.041 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
D6	ditch	0.051 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R1, 1 st	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 1 st	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R1, 2 nd	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 2 nd	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R2, 1 st	stream	0.045 Drift	0.011 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
R2, 2 nd	stream	0.046 Drift	0.012 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
R3, 1 st	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
R3, 2 nd	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
R4, 1 st	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R4, 2 nd	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.007 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{sw,max} of alpha-cypermethrin following single application of 10 g as/ha to vegetables, leafy, late application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D3, 1 st	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D3, 2 nd	ditch	0.052 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.008 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.037 Drift	0.009 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
D6	ditch	0.051 Drift	0.013 Drift	0.003 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R1, 1 st	pond	0.002 Drift	<0.001 Drift	<0.001 Run-off	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 1 st	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R1, 2 nd	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 2 nd	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R2, 1 st	stream	0.046 Drift	0.012 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
R2, 2 nd	stream	0.046 Drift	0.011 Drift	0.002 Drift	0.017 Drift	0.008 Drift	0.009 Drift
R3, 1 st	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
R3, 2 nd	stream	0.048 Drift	0.012 Drift	0.003 Drift	0.018 Drift	0.009 Drift	0.009 Drift
R4, 1 st	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
R4, 2 nd	stream	0.034 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{sw,max} of alpha-cypermethrin following twofold application of 10 g as/ha to vegetables, leafy, early application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D3, 1 st	ditch	0.046 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D3, 2 nd	ditch	0.046 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.036 Drift	0.009 Drift	0.002 Drift	0.013 Drift	0.006 Drift	0.007 Drift
D6	ditch	0.044 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
R1, 1 st	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 1 st	stream	0.029 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R1, 2 nd	pond	0.002 Drift	<0.001 Drift	<0.001 Run-off	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 2 nd	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R2, 1 st	stream	0.039 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R2, 2 nd	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R3, 1 st	stream	0.041 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R3, 2 nd	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R4, 1 st	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R4, 2 nd	stream	0.029 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{sw,max} of alpha-cypermethrin following twofold application of 10 g as/ha to vegetables, leafy, late application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD ^a + 75N	0mD ^a + 95N	5mD	5mD + 50N	10mD
D3, 1 st	ditch	0.046 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D3, 2 nd	ditch	0.045 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D4	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
D4	stream	0.035 Drift	0.009 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
D6	ditch	0.045 Drift	0.011 Drift	0.002 Drift	0.012 Drift	0.006 Drift	0.006 Drift
R1, 1 st	pond	0.002 Drift	<0.001 Drift	<0.001 Drift	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 1 st	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R1, 2 nd	pond	0.002 Drift	<0.001 Drift	<0.001 Run-off	0.002 Drift	<0.001 Drift	0.001 Drift
R1, 2 nd	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R2, 1 st	stream	0.040 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R2, 2 nd	stream	0.039 Drift	0.010 Drift	0.002 Drift	0.014 Drift	0.007 Drift	0.007 Drift
R3, 1 st	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R3, 2 nd	stream	0.042 Drift	0.010 Drift	0.002 Drift	0.015 Drift	0.007 Drift	0.008 Drift
R4, 1 st	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift
R4, 2 nd	stream	0.030 Drift	0.007 Drift	0.001 Drift	0.010 Drift	0.005 Drift	0.005 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{sw,max} of alpha-cypermethrin following single application of 20 g as/ha to vegetables, leafy, early application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD + 95N ^a	5mD	5mD + 75N	10mD + 50N	15mD
D3, 1 st	ditch	0.104 Drift	0.005 Drift	0.028 Drift	0.007 Drift	0.008 Drift	0.010 Drift
D3, 2 nd	ditch	0.104 Drift	0.005 Drift	0.028 Drift	0.007 Drift	0.008 Drift	0.010 Drift
D4	pond	0.004 Drift	<0.001 Drift	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
D4	stream	0.081 Drift	0.004 Drift	0.030 Drift	0.007 Drift	0.008 Drift	0.011 Drift
D6	ditch	0.101 Drift	0.005 Drift	0.027 Drift	0.007 Drift	0.007 Drift	0.010 Drift
R1, 1 st	pond	0.004 Drift	<0.001 Drift	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
R1, 1 st	stream	0.068 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R1, 2 nd	pond	0.004 Drift	<0.001 Drift	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
R1, 2 nd	stream	0.069 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R2, 1 st	stream	0.090 Drift	0.004 Drift	0.033 Drift	0.008 Drift	0.009 Drift	0.012 Drift
R2, 2 nd	stream	0.092 Drift	0.005 Drift	0.033 Drift	0.008 Drift	0.009 Drift	0.012 Drift
R3, 1 st	stream	0.096 Drift	0.005 Drift	0.035 Drift	0.009 Drift	0.009 Drift	0.013 Drift
R3, 2 nd	stream	0.096 Drift	0.005 Drift	0.035 Drift	0.009 Drift	0.009 Drift	0.013 Drift
R4, 1 st	stream	0.068 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R4, 2 nd	stream	0.068 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{sw,max} of alpha-cypermethrin following single application of 20 g as/ha to vegetables, leafy, late application

Location	Water body	PEC _{sw,max} [$\mu\text{g L}^{-1}$] and main entry route					
		Step 3	Step 4				
		Edge-of-Field	0mD + 95N ^a	5mD	5mD + 75N	10mD + 50N	15mD
D3, 1 st	ditch	0.104 Drift	0.005 Drift	0.028 Drift	0.007 Drift	0.008 Drift	0.010 Drift
D3, 2 nd	ditch	0.103 Drift	0.005 Drift	0.028 Drift	0.007 Drift	0.008 Drift	0.010 Drift
D4	pond	0.004 Drift	<0.001 Drift	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
D4	stream	0.074 Drift	0.004 Drift	0.027 Drift	0.007 Drift	0.007 Drift	0.010 Drift
D6	ditch	0.103 Drift	0.005 Drift	0.028 Drift	0.007 Drift	0.007 Drift	0.010 Drift
R1, 1 st	pond	0.004 Drift	<0.001 Run-off	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
R1, 1 st	stream	0.069 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R1, 2 nd	pond	0.004 Drift	<0.001 Drift	0.003 Drift	<0.001 Drift	0.001 Drift	0.002 Drift
R1, 2 nd	stream	0.069 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R2, 1 st	stream	0.092 Drift	0.005 Drift	0.033 Drift	0.008 Drift	0.009 Drift	0.012 Drift
R2, 2 nd	stream	0.091 Drift	0.005 Drift	0.035 Drift	0.008 Drift	0.009 Drift	0.012 Drift
R3, 1 st	stream	0.097 Drift	0.005 Drift	0.035 Drift	0.009 Drift	0.009 Drift	0.013 Drift
R3, 2 nd	stream	0.096 Drift	0.005 Drift	0.035 Drift	0.009 Drift	0.009 Drift	0.013 Drift
R4, 1 st	stream	0.068 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift
R4, 2 nd	stream	0.069 Drift	0.003 Drift	0.025 Drift	0.006 Drift	0.007 Drift	0.009 Drift

^a Standard Step 3 buffer according to FOCUS (d = 0.5 m, s = 1.0 m)

D = Drift mitigation by no-spray buffer zones [m]

N = Drift mitigation by drift reducing nozzles [%]

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

FOCUS Step 3-4 PEC's in sediment

PEC_{SED,max} of alpha-cypermethrin after application of 10 g as/ha to spring cereals

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Spring cereals	
		Single	Multiple
D1	ditch	0.355	0.491
D1	stream	0.228	0.213
D3	ditch	0.266	0.355
D4	pond	0.029	0.048
D4	stream	0.140	0.148
D5	pond	0.031	0.048
D5	stream	0.070	0.153
R4	stream	0.465	0.518

PEC_{SED,max} of alpha-cypermethrin after application of 10 g as/ha to winter cereals

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Winter cereals	
		Single	Multiple
D1	ditch	0.366	0.630
D1	stream	0.228	0.270
D2	ditch	0.358	0.583
D2	stream	0.319	0.419
D3	ditch	0.259	0.292
D4	pond	0.029	0.048
D4	stream	0.149	0.151
D5	pond	0.031	0.049
D5	stream	0.177	0.172
D6	ditch	0.356	0.569
R1	pond	0.035	0.058
R1	stream	0.183	0.331
R3	stream	0.169	0.154
R4	stream	0.350	0.412

PEC_{SED,max} of alpha-cypermethrin after application of 10 g as/ha to winter oilseed rape

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Winter oilseed rape	
		Single	Multiple
D2	ditch	0.368	0.475
D2	stream	0.328	0.285
D3	ditch	0.258	0.292
D4	pond	0.031	0.050
D4	stream	0.100	0.117
D5	pond	0.033	0.052
D5	stream	0.056	0.080
R1	pond	0.033	0.057
R1	stream	0.150	0.338
R3	stream	0.150	0.227

PEC_{SED,max} of alpha-cypermethrin after application of 10 g as/ha to vegetables, leafy, early application

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Vegetables, leafy	
		Single	Multiple
D3, 1 st	ditch	0.251	0.300
D3, 2 nd	ditch	0.256	0.311
D4	pond	0.032	0.051
D4	stream	0.048	0.054
D6,	ditch	0.153	0.158
R1, 1 st	pond	0.055	0.105
R1, 1 st	stream	1.215	2.417
R1, 2 nd	pond	0.052	0.102
R1, 2 nd	stream	1.076	2.282
R2, 1 st	stream	0.305	0.586
R2, 2 nd	stream	1.486	3.050
R3, 1 st	stream	0.759	1.533
R3, 2 nd	stream	0.216	0.388
R4, 1 st	stream	0.974	1.954
R4, 2 nd	Stream	0.296	0.645

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{SED,max} of alpha-cypermethrin after application of 10 g as/ha to vegetables, leafy, late application

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]	
		Vegetables, leafy	
		Single	Multiple
D3, 1 st	ditch	0.253	0.295
D3, 2 nd	ditch	0.221	0.264
D4	pond	0.030	0.049
D4	stream	0.026	0.045
D6,	ditch	0.200	0.174
R1, 1 st	pond	0.054	0.082
R1, 1 st	stream	0.720	1.455
R1, 2 nd	pond	0.060	0.136
R1, 2 nd	stream	1.155	2.839
R2, 1 st	stream	0.142	0.339
R2, 2 nd	stream	2.663	5.388
R3, 1 st	stream	0.764	2.318
R3, 2 nd	stream	1.276	1.681
R4, 1 st	stream	1.132	2.412
R4, 2 nd	Stream	1.167	2.620

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{SED,max} of alpha-cypermethrin after application of 20 g as/ha to vegetables, leafy, early application

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]
		Vegetables, leafy
		Single
D3, 1 st	ditch	0.500
D3, 2 nd	ditch	0.511
D4	pond	0.063
D4	stream	0.096
D6	ditch	0.304
R1, 1 st	pond	0.109
R1, 1 st	stream	2.430
R1, 2 nd	pond	0.104
R1, 2 nd	stream	2.152
R2, 1 st	stream	0.611
R2, 2 nd	stream	2.973
R3, 1 st	stream	1.519
R3, 2 nd	stream	0.431
R4, 1 st	stream	1.949
R4, 2 nd	stream	0.592

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

PEC_{SED,max} of alpha-cypermethrin after application of 20 g as/ha to vegetables, leafy, late application

Location	Water body	PEC _{sed,max} [$\mu\text{g kg}^{-1}$]
		Vegetables, leafy
		Single
D3, 1 st	ditch	0.504
D3, 2 nd	ditch	0.441
D4	pond	0.060
D4	stream	0.053
D6	ditch	0.400
R1, 1 st	pond	0.107
R1, 1 st	stream	1.439
R1, 2 nd	pond	0.121
R1, 2 nd	stream	2.309
R2, 1 st	stream	0.283
R2, 2 nd	stream	5.326
R3, 1 st	stream	1.528
R3, 2 nd	stream	2.552
R4, 1 st	stream	2.265
R4, 2 nd	stream	2.335

1st = 1st season vegetables leafy

2nd = 2nd season vegetables leafy

Metabolite **M310I017**

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 432.3
 Soil or water metabolite: soil metabolite
 Koc: 234901 mL/g (geometric mean)
 DT₅₀ soil : 11.8 days (geomean lab DT₅₀'s)
 DT₅₀ water/sediment system : 1000 days (conservative assumption)
 DT₅₀ water : 1000 days (conservative assumption)
 DT₅₀ sediment : 1000 days (conservative assumption)
 Crop interception (%): minimal crop cover
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 10⁻⁰⁵ %
 Soil: 8.4%

Parameters used in FOCUSsw step 3 (if performed)

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Application rate

Vegetables, leafy (FOCUS Step 1-2)
 Crop and growth stage: minimal crop cover
 Number of applications: 2
 Interval : 7 days
 Application rate(s): 10 g a.s./ha
 Application window: March-May, North and South Europe

Crop and growth stage: minimal crop cover
 Number of applications: 1
 Interval : -
 Application rate(s): 20 g a.s./ha
 Application window: March-May, North and South Europe

Main routes of entry

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FOCUS STEP 1 Scenario	Day after overall maximum	M310I017 PEC _{SW} (µg/L)		M310I017 PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.002		4.348	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.002		4.348	

FOCUS STEP 2 Scenario North Europe	Day after overall maximum	M310I017 PEC _{SW} (µg/L)		M310I017 PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	<0.001		0.258	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	<0.001		0.429	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	<0.001		0.516	

FOCUS STEP 2 Scenario South Europe	Day after overall maximum	M310I017 PEC _{SW} (µg/L)		M310I017 PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	<0.001		0.516	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	<0.001		0.857	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	<0.001		1.031	

Metabolite DCVAParameters used in FOCUS_{sw} step 1 and 2

Molecular weight: 209.1
 Soil or water metabolite: soil and water metabolite
 Water solubility (mg/L): 129 mg/L at 20°C
 Koc: 46.3 mL/g (geometric mean)
 DT₅₀ soil: 4.8 days (geomean lab DT₅₀'s) (Note: the correct value is 5.1 d).
 DT₅₀ water/sediment system : 16.1 days (geomean)
 DT₅₀ water : 16.1 days (DT₅₀ of whole system)
 DT₅₀ sediment : 16.1 days (DT₅₀ of whole system)
 Crop interception (%): minimal crop cover
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 66.6%
 Soil: 13.6%

Parameters used in FOCUS_{sw} step 3 (if performed)

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Application rate

<p><u>Vegetables, leafy (FOCUS Step 1-2)</u></p> <p>Crop and growth stage: minimal crop cover</p> <p>Number of applications: 2</p> <p>Interval : 7 days</p> <p>Application rate(s): 10 g a.s./ha</p> <p>Application window: March-May, North and South Europe</p> <p>Crop and growth stage: minimal crop cover</p> <p>Number of applications: 1</p> <p>Interval : -</p> <p>Application rate(s): 20 g a.s./ha</p> <p>Application window: March-May, North and South Europe</p> <p><u>Vegetables, fruiting – Greenhouse (FOCUS Step 2) default drift value of 0.1%</u></p> <p>Crop and growth stage: no interception</p> <p>Number of applications: 2</p> <p>Interval : 7 days</p> <p>Application rate(s): 15 g a.s./ha</p> <p>Application window: March-May, North and South Europe</p> <p>Crop and growth stage: no interception</p> <p>Number of applications: 1</p> <p>Interval : -</p> <p>Application rate(s): 30 g a.s./ha</p> <p>Application window: March-May, North and South Europe</p>
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Main routes of entry

FOCUS STEP 1 Scenario	Day after overall maximum	DCVA PEC _{SW} (µg/L)		DCVA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	2.591		1.171	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	2.591		1.171	

FOCUS STEP 2 Scenario North Europe	Day after overall maximum	DCVA PEC _{SW} (µg/L)		DCVA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.188		0.083	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.333		0.148	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.376		0.166	

FOCUS STEP 2 Scenario South Europe	Day after overall maximum	DCVA PEC _{SW} (µg/L)		DCVA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.351		0.159	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.628		0.285	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.702		0.317	

FOCUS STEP 2 Scenario Greenhouse	Day after overall maximum	DCVA PEC _{SW} (µg/L)		DCVA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, fruiting; 2 x 15 g a.s. ha ⁻¹	0 h	0.003		0.001	
Vegetables, fruiting; 1 x 30 g a.s. ha ⁻¹	0 h	0.003		0.001	

Metabolite **3-PBA**

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 214.2
 Soil or water metabolite: soil and water metabolite
 Water solubility (mg/L): 24.68 mg/L at 20°C
 Koc: 78.5 mL/g (geometric mean) (Note: the correct value is 72.7 mL/g (geometric mean),)
 DT₅₀ soil : 1.1 days (geomean lab DT50's) (Note: the correct value is 1.7 d).
 DT₅₀ water/sediment system : 20.2 days (geomean)
 DT₅₀ water : 20.2 days (DT₅₀ of whole system)
 DT₅₀ sediment : 20.2 days (DT₅₀ of whole system)
 Crop interception (%): minimal crop cover
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 23.1%
 Soil: 28.6%

Parameters used in FOCUSsw step 3 (if performed)

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Application rate

Vegetables, leafy (FOCUS Step 1-2)
 Crop and growth stage: minimal crop cover
 Number of applications: 2
 Interval : 7 days
 Application rate(s): 10 g a.s./ha
 Application window: March-May, North and South Europe

Crop and growth stage: minimal crop cover
 Number of applications: 1
 Interval : -
 Application rate(s): 20 g a.s./ha
 Application window: March-May, North and South Europe

Vegetables, fruiting – Greenhouse (FOCUS Step 2) default drift value of 0.1%
 Crop and growth stage: no interception
 Number of applications: 2
 Interval : 7 days
 Application rate(s): 15 g a.s./ha
 Application window: March-May, North and South Europe

Crop and growth stage: no interception
 Number of applications: 1
 Interval : -
 Application rate(s): 30 g a.s./ha
 Application window: March-May, North and South Europe

Main routes of entry

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FOCUS STEP 1 Scenario	Day after overall maximum	3-PBA PEC _{SW} (µg/L)		3-PBA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	1.627		1.260	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	1.627		1.260	

FOCUS STEP 2 Scenario North Europe	Day after overall maximum	3-PBA PEC _{SW} (µg/L)		3-PBA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.064		0.048	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.108		0.084	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.128		0.096	

FOCUS STEP 2 Scenario South Europe	Day after overall maximum	3-PBA PEC _{SW} (µg/L)		3-PBA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.119		0.091	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.209		0.161	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.237		0.182	

FOCUS STEP 2 Scenario Greenhouse	Day after overall maximum	3-PBA PEC _{SW} (µg/L)		3-PBA PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, fruiting; 2 x 15 g a.s. ha ⁻¹	0 h	0.001		<0.001	
Vegetables, fruiting; 1 x 30 g a.s. ha ⁻¹	0 h	0.001		<0.001	

Metabolite **3-PBAldehyde**

Parameters used in FOCUSsw step 1 and 2

Molecular weight: 198.2
 Soil or water metabolite: water metabolite
 Water solubility (mg/L): 51.49 mg/L at 20°C
 Koc: 1 mL/g (worst-case assumption)
 DT₅₀ soil : -
 DT₅₀ water/sediment system : 1000 days (conservative assumption)
 DT₅₀ water : 1000 days (conservative assumption)
 DT₅₀ sediment : 1000 days (conservative assumption)
 Crop interception (%): minimal crop cover
 Maximum occurrence observed (% molar basis with respect to the parent)
 Total Water and Sediment: 15.9%
 Soil: -%

Parameters used in FOCUSsw step 3 (if performed)

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Application rate

Vegetables, leafy (FOCUS Step 1-2)

Crop and growth stage: minimal crop cover
 Number of applications: 2
 Interval : 7 days
 Application rate(s): 10 g a.s./ha
 Application window: March-May, North and South Europe

Crop and growth stage: minimal crop cover
 Number of applications: 1
 Interval : -
 Application rate(s): 20 g a.s./ha
 Application window: March-May, North and South Europe

Vegetables, fruiting – Greenhouse (FOCUS Step 2) default drift value of 0.1%

Crop and growth stage: no interception
 Number of applications: 2
 Interval : 7 days
 Application rate(s): 15 g a.s./ha
 Application window: March-May, North and South Europe

Crop and growth stage: no interception
 Number of applications: 1
 Interval : -
 Application rate(s): 30 g a.s./ha
 Application window: March-May, North and South Europe

Main routes of entry

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FOCUS STEP 1 Scenario	Day after overall maximum	3-PBAdehyde PEC _{SW} (µg/L)		3-PBAdehyde PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.518		-	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.518		-	

FOCUS STEP 2 Scenario North Europe	Day after overall maximum	3-PBAdehyde PEC _{SW} (µg/L)		3-PBAdehyde PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.042		-	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.077		-	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.083		-	

FOCUS STEP 2 Scenario South Europe	Day after overall maximum	3-PBAdehyde PEC _{SW} (µg/L)		3-PBAdehyde PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, leafy; 1 x 10 g a.s. ha ⁻¹	0 h	0.044		-	
Vegetables, leafy; 2 x 10 g a.s. ha ⁻¹	0 h	0.142		-	
Vegetables, leafy; 1 x 20 g a.s. ha ⁻¹	0 h	0.153		-	

FOCUS STEP 2 Scenario Greenhouse	Day after overall maximum	3-PBAdehyde PEC _{SW} (µg/L)		3-PBAdehyde PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Vegetables, fruiting; 2 x 15 g a.s. ha ⁻¹	0 h	<0.001		-	
Vegetables, fruiting; 1 x 30 g a.s. ha ⁻¹	0 h	<0.001		-	

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation

Not applicable

PEC

Maximum concentration

Not relevant

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Bobwhite quail <i>Colinus virginianus</i>	a.s.	Acute	LD ₅₀	> 2025 mg a.s./kg bw ^a
Zebra finch <i>Taeniopygia guttata</i>	a.s.	Acute	LD ₅₀	1360 mg a.s./kg bw ^a
Bobwhite quail <i>Colinus virginianus</i>	Preparation (BAS 310 51 I)	Acute	LD ₅₀	> 2000 mg prep./kg bw (> 100 mg a.s./kg bw)
Bobwhite quail <i>Colinus virginianus</i>	a.s.	Long-term	NOEL	16 mg a.s./kg bw/day
Mammals				
Rat	a.s.	Acute	LD ₅₀	57 mg a.s./kg bw
Rat	a.s.	Acute	LD ₅₀	310 mg a.s./kg bw
Rat	a.s.	Acute	LD ₅₀	40-80 mg a.s./kg bw
Mouse	a.s.	Acute	LD ₅₀	35 mg a.s./kg bw
Mouse	a.s.	Acute	LD ₅₀	50 mg a.s./kg bw
Rat	Preparation (BAS 310 55 I)	Acute	LD ₅₀	> 300 mg prep./kg bw (> 15.15 mg a.s./kg bw)
Rat	a.s.	Long-term	NOAEL	9 mg a.s./kg bw/day
<p>Endocrine disrupting properties (Annex Part A, points 8.1.5)</p> <p>Based on reproductive studies with birds and mammals, there are no indications that alpha-cypermethrin has endocrine disruptive potential. However, as there are currently no defined criteria for identifying endocrine disruptors, it is difficult to draw a firm conclusion</p> <p>At Pesticides Peer Review Meeting 175 on mammalian toxicology, a data gap for a male pubertal assay was set. At Pesticides Peer Review Meeting 177 on ecotoxicology, the majority of the experts agreed that, pending on the outcome of the data gap in the mammalian toxicology section, further consideration may be needed on potential endocrine effects in non-target organisms.</p>				

Additional higher tier studies (Annex Part A, points 10.1.1.2):

No additional higher tier studies have been provided.

Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):

A study with the African clawed frog (*Xenopus laevis*) has been submitted, in which only the aquatic stages were tested. From this study, an LC₅₀ for embryos of 30.6 µg a.s./L and an LC₅₀ for larvae of 6.9 µg a.s./L were derived.

Alpha-cypermethrin was administered either in a gelatine capsule without first being dissolved in a carrier, or by dissolving the test item in 0.5 aqueous carboxy methyl cellulose as a carrier. From the acute toxicity studies performed with mammals, it is however clear that the carrier used affects the toxicity of alpha-cypermethrin, with a higher toxicity in oil-based carriers compared to aqueous carriers. This endpoint is thus derived from a study that may not have been worst case in terms of the method of administration or the carrier used

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Cereals at BBCH 51-83, 2 x 10 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	2.22	747 ¹	10
All	Small omnivorous bird	Long-term	0.55	29.1	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1.66	36.8 ²	10
All	Small herbivorous mammal	Long-term	0.41	21.97	5
¹ a geomean LD ₅₀ of 1660 mg a.s./kg bw, calculated from the LD ₅₀ for Bobwhite quail (<i>Colinus virginianus</i>) and Zebra finch (<i>Taeniopygia guttata</i>), was used in the risk assessment to calculate this TER value.					
² a geomean LD ₅₀ value of 61 mg a.s./kg bw, calculated based on the available and relevant acute toxicity studies on mice (2) and rats (3), was used in the risk assessment to calculate this TER value.					
Risk from bioaccumulation and food chain behaviour [indicate when not relevant i.e if Log kow≤3]					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.028	581	5
Earthworm-eating mammals		Long-term	0.0029	4492	5
Fish-eating birds		Long-term	0.029	549	5
Fish-eating mammals		Long-term	0.026	345	5
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC_{dw}xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		5
Puddle scenario, Screening step					
1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed					
2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (< 0.011)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (< 0.306)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (< 1.17)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (< 2.07)	5

Oilseed rape at BBCH 51-59, 2 x 10 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	2.22	747 ¹	10
All	Small omnivorous bird	Long-term	0.55	29.1	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1.66	36.8 ²	10
All	Small herbivorous mammal	Long-term	0.41	21.97	5
¹ a geomean LD ₅₀ of 1660 mg a.s./kg bw, calculated from the LD ₅₀ for Bobwhite quail (<i>Colinus virginianus</i>) and Zebra finch (<i>Taeniopygia guttata</i>), was used in the risk assessment to calculate this TER value.					
² a geomean LD ₅₀ value of 61 mg a.s./kg bw, calculated based on the available and relevant acute toxicity studies on mice (2) and rats (3), was used in the risk assessment to calculate this TER value.					
Risk from bioaccumulation and food chain behaviour [indicate when not relevant i.e if Log K _{ow} ≤ 3]					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.028	581	5
Earthworm-eating mammals		Long-term	0.0029	4492	5
Fish-eating birds		Long-term	0.029	549	5
Fish-eating mammals		Long-term	0.026	345	5
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC_{d,w}xDWR	TER	Trigger
Leaf scenario	Birds	acute	Not relevant		5
Puddle scenario, Screening step					
1) Application rate (g a.s./ha)/relevant endpoint <50 (K _{oc} <500 L/kg), TER calculation not needed					
2) Application rate (g a.s./ha)/relevant endpoint <3000 (K _{oc} ≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (< 0.011)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (< 0.306)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (< 1.17)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (< 2.07)	5

Leafy vegetables (lettuce and leafy cabbage) at BBCH 10-49, 2 x 10 g a.s./ha or 1 x 20 g a.s./ha

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	3.18	523 ¹	10
All	Small omnivorous bird	Long-term	0.69	23.3	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	2.73	22.4 ²	10
All	Small herbivorous mammal	Long-term	0.77	11.74	5
¹ a geomean LD ₅₀ of 1660 mg a.s./kg bw, calculated from the LD ₅₀ for Bobwhite quail (<i>Colinus virginianus</i>) and Zebra finch (<i>Taeniopygia guttata</i>), was used in the risk assessment to calculate this TER value.					
² a geomean LD ₅₀ value of 61 mg a.s./kg bw, calculated based on the available and relevant acute toxicity studies on mice (2) and rats (3), was used in the risk assessment to calculate this TER value.					
Risk from bioaccumulation and food chain behaviour [indicate when not relevant i.e if Log K _{ow} ≤ 3]					

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger	
Earthworm-eating birds	Long-term	0.028	581	5	
Earthworm-eating mammals	Long-term	0.0029	4492	5	
Fish-eating birds	Long-term	0.018	878	5	
Fish-eating mammals	Long-term	0.017	553	5	
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} × DWR	TER	Trigger
Leaf scenario	Birds	acute	9.2	180	5
Puddle scenario, Screening step					
1) Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed					
2) Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	Not needed	Case 2 (< 0.012)	10
Puddle scenario	Mammals	acute	Not needed	Case 2 (< 0.327)	10
Puddle scenario	Birds	Long-term	Not needed	Case 2 (< 1.25)	5
Puddle scenario	Mammals	Long-term	Not needed	Case 2 (< 2.22)	5

Cucumber/courgette at BBCH 10-89, 2 x 15 g a.s./ha or 1 x 30 g a.s./ha (glasshouse use only, restricted to permanent structures)

No risk assessment required, as no exposure to birds and mammals is expected from the use in permanent greenhouses.

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Laboratory tests				
Fish				
Rainbow trout (<i>Oncorhynchus mykiss</i>)	BAS 310 51 I	Acute 96 hr (static)	Mortality, LC ₅₀	46 µg prep./L (2.3 µg a.s./L) (mm)
Fathead minnow (<i>Pimephales promelas</i>)	Alpha-cypermethrin	Acute 96 hr (flow-through)	Mortality, LC ₅₀	0.93 µg a.s./L (mm)
Fathead minnow (<i>Pimephales promelas</i>)	Alpha-cypermethrin	Chronic, 34 day (flow-through)	Larval survival, NOEC	0.03 µg a.s./L (mm) ²
Bluegill sunfish (<i>Lepomis macrochirus</i>)	cis-DCVA	Acute 96 hr (static)	Mortality, LC ₅₀	> 102800 µg/L (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Bluegill sunfish (<i>Lepomis macrochirus</i>)	3-PBA	Acute 96 hr (static)	Mortality, LC ₅₀	> 103200 µg/L (mm)
Amphibians				
African clawed frog (<i>Xenopus laevis</i>)	Alpha-cypermethrin	Acute, 96 hr (semi-static)	Mortality, LC ₅₀ (embryos) Mortality, LC ₅₀ (larvae)	30.6 µg a.s./L (mm) 6.9 µg a.s./L (mm)
Aquatic invertebrates				
Water flea (<i>Daphnia magna</i>)	BAS 310 51 I	Acute, 48 h (static)	Mortality, EC ₅₀	2.19 µg prep/L (0.109 µg a.s./L) (mm)
Phantom midge (<i>Chaoborus crystallinus</i>)	Alpha-cypermethrin	Acute, 48 h (static)	Mortality, EC ₅₀	0.04454 µg a.s./L (mm)
Water flea (<i>Daphnia magna</i>)	Alpha-cypermethrin	Chronic, 21 d (semi-static)	Development and reproduction, NOEC	0.0177 µg a.s./L (mm)
Water flea (<i>Daphnia magna</i>)	cis-DCVA	Acute, 48 h (static)	Mortality, EC ₅₀	61900 µg/L (nom)
Water flea (<i>Daphnia magna</i>)	3-PBA	Acute, 48 h (static)	Mortality, EC ₅₀	39000 µg/L (nom)
Sediment-dwelling organisms				
Midge (<i>Chironomus riparius</i>)	Alpha-cypermethrin	Acute 48 h (static)	Mortality, EC ₅₀	0.0126 µg a.s./L (mm)
Midge (<i>Chironomus riparius</i>)	Alpha-cypermethrin	Chronic, 28 d, spiked water (static)	NOEC EC ₅₀ EC ₂₀ EC ₁₀	0.024 µg a.s./L (nom) 0.227 µg a.s./L (nom) 0.057 µg a.s./L (nom) 0.028 µg a.s./L (nom)
Midge (<i>Chironomus riparius</i>)	Alpha-cypermethrin	Chronic, 28 d, spiked sediment (static)	NOEC EC ₅₀ EC ₂₀ EC ₁₀	45.0 µg a.s./kg dry sediment _(mm) 101.4 µg a.s./kg dry sediment _(mm) 58.5 µg a.s./kg dry sediment _(mm) 51.4 µg a.s./kg dry sediment _(mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Blackworm (<i>Lumbriculus variegatus</i>)	Alpha-cypermethrin	Chronic, 28 d, spiked sediment (static)	NOEC EC ₅₀ EC ₂₀ EC ₁₀	71.3 µg a.s./kg dry sediment _(im) 155 µg a.s./kg dry sediment _(im) 75.7 µg a.s./kg dry sediment _(im) 52.0 µg a.s./kg dry sediment _(im)
Nematode (<i>Caenorhabditis elegans</i>)	Alpha-cypermethrin	Chronic, 96 h, spiked sediment (static)	NOEC	28600 µg a.s./kg dry sediment _(mm)
Algae				
Green microalgae (<i>Pseudo-kirchneriella subcapitata</i>)	Alpha-cypermethrin	Chronic, 96 h (static)	Growth rate: E _r C ₅₀ NOEC _r	≥ 83.6 µg a.s./L _(mm) 83.6 µg a.s./L _(mm)
Green microalgae (<i>Pseudo-kirchneriella subcapitata</i>)	Alpha-cypermethrin	Chronic, 72 h (static)	Growth rate: E _r C ₅₀ Biomass: E _b C ₅₀ E _b C ₁₀	≥ 898.5 µg a.s./L _(mm) ≥ 898.5 µg a.s./L _(mm) < 28.4 µg a.s./L _(mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Green microalgae (<i>Pseudo-kirchneriella subcapitata</i>)	BAS 310 51 I	Chronic, 72 h (static)	Growth rate: E _r C ₅₀ E _r C ₂₀ E _r C ₁₀ Yield: E _y C ₅₀ E _y C ₂₀ E _y C ₁₀	27560 µg prep./L (1378 µg a.s./L) (mm) 12300 µg prep./L (614 µg a.s./L) (mm) 7670 µg prep./L (383 µg a.s./L) (mm) 8480 µg prep./L (423 µg a.s./L) (mm) 3080 µg prep./L (154 µg a.s./L) (mm) 1700 µg prep./L (85 µg a.s./L) (mm)
Fresh water diatom (<i>Navicula pelliculosa</i>)	Alpha-cypermethrin	Chronic, 96 h (static)	Growth rate: E _r C ₅₀ NOEC _r Yield: E _y C ₅₀ NOEC _y	≥ 70.3 µg a.s./L (mm) ≥ 70.3 µg a.s./L (mm) ≥ 70.3 µg a.s./L (mm) ≥ 70.3 µg a.s./L (mm)
Blue-green algae (<i>Anabaena flos-aquae</i>)	Alpha-cypermethrin	Chronic, 96 h (static)	Growth rate: E _r C ₅₀ NOEC _r Yield: E _y C ₅₀ NOEC _y	≥ 27.0 µg a.s./L (mm) ≥ 27.0 µg a.s./L (mm) ≥ 27.0 µg a.s./L (mm) ≥ 27.0 µg a.s./L (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Marine diatom (<i>Skeletonema costatum</i>)	Alpha-cypermethrin	Chronic, 96 h (static)	Growth rate: E _r C ₅₀ NOEC _r Yield: E _y C ₅₀ NOEC _y	≥ 33.4 µg a.s./L (mm) ≥ 33.4 µg a.s./L (mm) ≥ 33.4 µg a.s./L (mm) ≥ 33.4 µg a.s./L (mm)
Green microalgae (<i>Pseudo-kirchneriella subcapitata</i>)	cis-DCVA	Chronic, 72 h (static)	Growth rate: E _r C ₅₀ E _r C ₂₀ E _r C ₁₀ Biomass: E _b C ₅₀ E _b C ₂₀ E _b C ₁₀	70000 µg/L (nom) 32300 µg/L (nom) 25400 µg/L (nom) 31600 µg/L (nom) 17900 µg/L (nom) 14200 µg/L (nom)
Green microalgae (<i>Pseudo-kirchneriella subcapitata</i>)	3-PBA	Chronic, 72 h (static)	Growth rate: E _r C ₅₀ E _r C ₂₀ E _r C ₁₀ Biomass: E _b C ₅₀ E _b C ₂₀ E _b C ₁₀	85000 µg/L (nom) 44900 µg/L (nom) 28500 µg/L (nom) 38100 µg/L (nom) 11300 µg/L (nom) 6880 µg/L (nom)
Higher plant				
<i>Lemna gibba</i>	Alpha-cypermethrin	Chronic, 7 d (static)	Fronds number and dry weight: E _y C ₅₀ E _r C ₅₀	≥ 1.39 µg a.s./L (mm) ≥ 1.39 µg a.s./L (mm)
Water milfoil (<i>Myriophyllum elatinoides</i>)	3-PBA	Chronic, 14 d (static)	Growth inhibition, NOEC	3280 µg/L (nom)
<p>Further testing on aquatic organisms</p> <p><i>Acute risk to fish: Geomean approach</i></p> <p>Based on the available acute toxicity data for two fish species (<i>Oncorhynchus mykiss</i>, LC₅₀ = 2.3 µg a.s./L, and <i>Pimephales promelas</i>, LC₅₀ = 0.93 µg a.s./L), a geometric mean LC₅₀ of 1.46 µg a.s./L was calculated. Taking into account the assessment factor of 100 of the Tier 1 assessment, a geomean RAC_{SW,ac} of 0.0146 µg a.s./L was determined.</p>				

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<p><i>Chronic risk to fish: refined exposure laboratory studies</i></p> <p>A refined exposure early-life stage (ELS) study was available, in which <i>Pimephales promelas</i> was exposed to two peaks of (nominal) 0.15 and 0.30 µg a.s./L, with an interval of 7 days. As no significant effects on survival or growth could be observed in any of the treatments, a NOEC of 0.30 µg a.s./L was derived from this study. This study was considered acceptable for use in a Tier 2 chronic risk assessment for fish. Based on the available FOCUS Step 2 exposure profile for the proposed permanent glasshouse use in fruiting vegetables (single application of 30 g a.s./ha and twofold application of 15 g a.s./ha), it was demonstrated that the exposure regime in the refined exposure ELS study covered the FOCUS Step 2 exposure profile. Thus, for these uses the Tier 2 RAC of ≥ 0.030 µg a.s./L could be considered a valid refinement. A low chronic risk to fish could be demonstrated for these uses.</p> <p>For the outdoor uses in cereals, oilseed rape and leafy vegetables, however, detailed exposure profiles for the different FOCUS scenarios are not available.</p> <p><i>Acute and chronic risk to aquatic invertebrates</i></p> <p>An additional acute toxicity study with <i>Daphnia magna</i>, investigating the influence of humic acid and green algae on the toxicity of BAS 310 55 I, was available. This study showed a marked reduction in toxicity when organic matter was present, which is the result of a lower bioavailability of alpha-cypermethrin to <i>Daphnia magna</i>. As a refinement, the higher EC₅₀ value of 0.52 µg a.s./L obtained from this study could potentially be used to derive a refined RAC_{SW} for the acute risk assessment. However, based on the available Tier 1 toxicity data, <i>Daphnia magna</i> is not the most sensitive species following acute exposure. Therefore, a risk assessment based on the refined endpoint for <i>Daphnia magna</i> is not considered to fully cover the acute risk to aquatic invertebrates.</p> <p>A refined exposure chronic toxicity study was available, in which <i>Daphnia magna</i> was exposed to two peaks of up to 0.1060 µg a.s./L, applied with a 7 day interval. At the highest dose of 0.1060 µg a.s./L there was a slight but significant reduction in body length (3.2%), which was however not considered biologically relevant. Further, at the highest concentration of 0.1060 µg a.s./L, a mortality of 30% occurred whereas no mortality occurred in either the control and the solvent control. Although this effect is not statistically significant, it could be considered biologically relevant. Based on these results, a NOEC of 0.0875 µg a.s./L was derived from this study. This NOEC was considered acceptable for use in a Tier 2 chronic risk assessment. However, as <i>Daphnia magna</i> was not considered representative for all aquatic invertebrates (based on acute toxicity data and data from mesocosm studies, insects are shown to be more sensitive), this Tier 2 assessment is considered valid only for <i>Daphnia magna</i>.</p> <p>In total, eight mesocosm studies are available, in which alpha-cypermethrin was applied one, two or three times. In two of these studies, alpha-cypermethrin was applied as the representative formulation (BAS 310 55 I). In the other studies, alpha-cypermethrin was applied as the formulation BAS 310 03 I. As the toxicity of the two formulations is driven by the active ingredient and considered comparable with respect to effects on aquatic organisms, and the results from the mesocosm studies with both formulation are highly comparable, all available mesocosms can be considered together. In five out of the eight mesocosm studies, no analytical measurements were performed to measure the target concentrations in the pond water. The results from these studies were not considered suitable for use in a quantitative risk assessment (i.e. the NOEC and NOEAEC values from these studies cannot be used as a basis to derive a RAC value). However, as the results from these studies are highly similar to those from the fully reliable studies, they can be used as supportive information in a weight of evidence approach. From the available mesocosm data, an overall NOEC of 0.003 µg a.s./L and NOEAEC of 0.0385 µg a.s./L were derived for one application, and an overall NOEC of 0.004 µg a.s./L and NOEAEC of 0.017 µg a.s./L were derived for two applications of alpha-cypermethrin (for an interval of approximately one week).</p> <p>In addition to the mesocosm studies, additional higher tier studies have been submitted. For example a number of laboratory toxicity studies with additional aquatic invertebrate species are available, which confirm the finding of the mesocosm studies that <i>Chaoborus crystallinus</i> is the most sensitive aquatic invertebrate species.</p> <p>It was agreed at Pesticides Peer Review Meeting 177 that the overall mesocosm NOEC of 0.004 µg a.s./L could be used in a risk assessment for both 1 and 2 applications. Applying an AF of 2 to this NOEC, an ETO-RAC of 0.002 µg a.s./L was obtained. Initially, the RMS proposed a risk assessment based on the ecological recovery option. However, at Pesticides Peer Review Meeting 177 it was agreed not to consider the recovery</p>				

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<p>option as applicable in the risk assessment. This was based on the argument that species with a poor recovery potential are not well represented in the mesocosm studies. Furthermore, the exposure pattern of some of the most vulnerable species (i.e. <i>Gammarus</i>, <i>Cloeon dipterum</i>, identified on the basis of their life cycle and on the basis of the available laboratory studies) might differ from the one relevant for <i>Chaoborus</i>. While <i>Chaoborus</i> lives predominantly in the water column, where alpha-cypermethrin is likely to quickly disappear from, these other species are living more on the bottom/sediment surface, where alpha-cypermethrin is likely to be present for longer periods.</p>				
Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Fathead minnow (<i>Pimephales promelas</i>)	Alpha-cypermethrin	Chronic, 32 d (flow-through) Pulse exposure	NOEC	0.30 µg a.s./L (nom)
Water flea (<i>Daphnia magna</i>)	BAS 310 55 I	Acute, 48h (static) Bioavailability study	EC ₅₀ , in M4 medium EC ₅₀ , in presence of humic acid EC ₅₀ , in presence of algae	0.18 µg a.s./L (mm) 0.52 µg a.s./L (mm) 0.69 µg a.s./L (mm)
Water flea (<i>Daphnia magna</i>)	Alpha-cypermethrin	Chronic, 21 d (semi-static) Pulse exposure	NOEC	0.0875 µg a.s./L (mm)
Aquatic community in outdoor mesocosms; single treatment. Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 03 I	145 d, Outdoor mesocosm	NOEC NOEAEC	0.003 µg a.s./L (nom) ³ 0.012 µg a.s./L (nom) ³
Aquatic community in outdoor mesocosms; single treatment. Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 03 I	126 d, Outdoor mesocosm	NOEC NOEAEC	0.003 µg a.s./L (nom) 0.015 µg a.s./L (nom)
Aquatic community in outdoor mesocosms; three applications. Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 03 I	119 d, Outdoor mesocosm	NOEC	0.0006 µg a.s./L (nom) ³

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Aquatic community in outdoor mesocosms; single treatment Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 03 I	139 d, Outdoor mesocosm	NOEAEC	0.015 µg a.s./L (nom)
Aquatic community in outdoor mesocosms; one or three applications Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 03 I	162 d, Outdoor mesocosm	NOEC NOEAEC	0.0006 µg a.s./L (nom) ³ 0.015 µg a.s./L (nom) ³
<i>Chaoborus crystallinus</i> in outdoor mesocosms; two applications	BAS 310 03 I	8 weeks, Outdoor mesocosm	NOEC	0.020 µg a.s./L (nom) ³
Aquatic community in outdoor mesocosms; two applications Endpoints: impact on macroinvertebrates and zooplankton	BAS 310 55 I	62 d, Outdoor mesocosm	NOEC NOEAEC	0.0006 µg a.s./L (nom) ³ 0.0135 µg a.s./L (nom) ³
Aquatic community in outdoor mesocosms; one or two applications Endpoints: impact on macroinvertebrates, zooplankton and planktonic algae	BAS 310 55 I	12 weeks, Outdoor mesocosm	NOEC NOEAEC, 1 appl. NOEAEC, 2 appl.	0.00403 µg a.s./L (im) 0.017 µg a.s./L (im) 0.0385 µg a.s./L (im)
Several species of aquatic invertebrates	BAS 310 03 I	Acute, 24 h (static) Laboratory toxicity test	NOEC / EC ₅₀	0.000011 - 4.7 µg a.s./L
Several species of aquatic macroinvertebrates	BAS 310 03 I	Acute, 48 and 96 h (static) Laboratory toxicity test	NOEC / EC ₅₀	0.53 - 48.01 µg a.s./L
<i>Cloeon dipterum</i> & <i>Gammarus roeseli</i>	BAS 310 03 I	Acute, 1 to 28 d (static) Laboratory toxicity test (microcosm)	NOEC / EC ₅₀	0.003 - 7.3 µg a.s./L

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<i>Chaoborus crystalinus</i>	-	<i>Chaoborus</i> population development in mesocosms	Analysis of raw data of 19 mesocosm studies provides information on <i>Chaoborus</i> populations and their influence on the zooplankton community structure	
Chironomid midge larvae	Dominex 100 EC	Field efficacy trial	After application of 10 to 30 g a.s./ha (trial 1) or 6 to 20 g a.s./ha (trial 2): A clear effect on chironomid larvae after application of the test item, followed by recovery. No complete recovery by the end of the study (29 days in trial 1; 24 days in trial 2)	

Potential endocrine disrupting properties (Annex Part A, point 8.2.3)

Based on the specific long-term *in vivo* studies reported in the DRAR there are no indications that alpha-cypermethrin has endocrine-specific effects on fish. Further, the results from the mammalian assays also do not indicate specific endocrine-disruptive activity of alpha-cypermethrin. However, as there are currently no defined criteria for identifying endocrine disruptors, it is difficult to draw a firm conclusion.

At Pesticides Peer Review Meeting 175 on mammalian toxicology, a data gap for a male pubertal assay was set. At Pesticides Peer Review Meeting 177 on ecotoxicology, the majority of the experts agreed that, pending on the outcome of the data gap in the mammalian toxicology section, further consideration may be needed on potential endocrine effects in non-target organisms.

¹ (_{nom}) nominal concentration; (_{mm}) mean measured concentration; (_{im}) initial measured concentrations; prep.: preparation; a.s.: active substance

² As two of the validity criteria of the relevant test guideline (OECD 210) were not fulfilled, this study is formally not valid. However, given the fact that there was a clear dose-response relationship, and the endpoint was in the range that would be expected based on data for related substances, it was agreed at Pesticides Peer Review Expert Meeting 177 that this study can be used with care in the risk assessment, but only because there are no suitable alternatives.

³ Endpoint obtained from a mesocosm study where the concentration of the test item in the ponds was not analytically verified. This endpoint is not acceptable for use in a quantitative risk assessment (i.e. cannot be used as a basis to derive a RAC values). However, it can be used as additional information in the risk assessment for aquatic invertebrates.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Alpha-cypermethrin	DCVA	3-PBA	3-PBAld	M310I017	Carboxamide
logP _{OW}	5.8	3.15	2.48 ²⁾	3.5 ²⁾	unknown	5.5 ²⁾
Steady-state bioconcentration factor (BCF) (total wet weight)	910 ¹⁾	-	-	-	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-	-	-	-	-	-
Annex VI Trigger for the bioconcentration factor	-	-	-	-	-	-
Clearance time (days) (CT ₅₀)	6.9-8.6 days	-	-	-	-	-
(CT ₉₀)	-	-	-	-	-	-

Level and nature of residues (%) in organisms after the 14 day depuration phase	-	-	-	-	-	-
Higher tier study	Not needed					

¹⁾ based on total ¹⁴C. As the study from which this bioconcentration factor was derived was performed in accordance with a previous version of OECD Test Guideline 305, the lipid content of the fish tissue was not measured. It was therefore not possible to normalize the bioconcentration factor to 5% lipid content.

Additional uncertainties regarding this BCF value were identified at Pesticides Peer Review Expert Meeting 177, which are related to the exposure route in the study (exposure through the water phase). According to OECD Test Guideline 305, testing via aqueous exposure becomes difficult for substances with a low $P_{OW} > 5$ and a low water solubility (such as alpha-cypermethrin). Testing via dietary exposure might result in a different BCF value.

²⁾ no data was available within the alpha-cypermethrin renewal dossier to determine a log P_{OW} for these metabolites. These log P_{OW} values were obtained from the DRAR for renewal of the active substance cypermethrin (Belgium 2017).

Regulatory acceptable concentrations used in the risk assessment

Alpha- cypermethrin						
	Species group	Level of assessment	Most sensitive species	Endpoint	AF	RAC
Acute effect assessment	Fish	Tier 1	<i>Pimephales promelas</i>	LC ₅₀ = 0.93 µg a.s./L	100	0.0093 µg a.s./L
		Tier 2 (geomean-approach)	Data for 2 fish species	Geomean LC ₅₀ = 1.46 µg a.s./L	100	0.0146 µg a.s./L
	Aquatic invertebrates	Tier 1	<i>Chironomus riparius</i>	EC ₅₀ = 0.0126 µg a.s./L	100	0.000126 µg a.s./L
		Tier 3 (mesocosms)	Natural populations in ponds	NOEC = 0.004 µg a.s./L	2	0.002 µg a.s./L ¹
Chronic effect assessment	Fish	Tier 1	<i>Pimephales promelas</i>	NOEC = 0.03 µg a.s./L	10	0.003 µg a.s./L
		Tier 2 (refined exposure approach)	<i>Pimephales promelas</i>	NOEC = 0.30 µg a.s./L	10	0.030 µg a.s./L ²
	Aquatic invertebrates	Tier 1	<i>Daphnia magna</i>	NOEC = 0.0177 µg a.s./L	10	0.00177 µg a.s./L
		Tier 3 (mesocosms)	Natural populations in ponds	NOEC = 0.004 µg a.s./L	2	0.002 µg a.s./L ¹
		Tier 1	<i>Chironomus riparius</i>	NOEC = 45.0 µg a.s./kg dry sediment	10	4.5 µg a.s./kg dry sediment
	Algae	Tier 1	<i>Anabaena flos-aquae</i>	E _r C ₅₀ ≥ 27.0 µg a.s./L	10	≥ 2.70 µg a.s./L
	Aquatic plants	Tier 1	<i>Lemna gibba</i>	E _r C ₅₀ ≥ 1.39 µg a.s./L	10	≥ 0.139 µg a.s./L
Metabolite DCVA						
Acute effect assessment	Fish	Tier 1	<i>Lepomis macrochirus</i>	LC ₅₀ > 102800 µg a.s./L	100	1028 µg/L
	Aquatic invertebrates	Tier 1	<i>Daphnia magna</i>	EC ₅₀ = 61900 µg a.s./L	100	619 µg/L
Chronic effect assessment	Algae	Tier 1	<i>Pseudokirchneriella subcapitata</i>	E _r C ₅₀ = 70000 µg a.s./L	10	7000 µg/L
Metabolite 3-PBA						
Acute effect	Fish	Tier 1	<i>Lepomis</i>	LC ₅₀ > 103200	100	1032 µg/L

assessment			<i>macrochirus</i>	µg a.s./L		
	Aquatic invertebrates	Tier 1	<i>Daphnia magna</i>	EC ₅₀ = 39000 µg a.s./L	100	390 µg/L
Chronic effect assessment	Algae	Tier 1	<i>Pseudokirchneriella subcapitata</i>	E _r C ₅₀ = 85000 µg a.s./L	10	8500 µg/L
	Aquatic plants	Tier 1	<i>Myriophyllum elatinoides</i>	NOEC = 3280 µg a.s./L	10	328 µg a.s./L

Notes: AF: Assessment Factor; ¹ETO-RAC (ecological threshold option); ²Endpoint currently only used for the proposed permanent glasshouse use of BAS 310 55 I in cucumber/courgette, as no detailed FOCUS exposure profiles are available for the proposed outdoor uses.

Comparison of the RAC and endpoint for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

Note that below only the comparison of the respective endpoints and the RAC from the highest available Tier is included

FOCUS_{sw} step 1-3 – Comparison of RACs and global maximum PEC_{SW/SED} for alpha-cypermethrin – Cereals at 1-2 x 10 g a.s./ha (the worst-case PEC_{SW} and PEC_{SED} for either spring or winter cereals are used).

Scenario	fish acute	fish chronic	Aquatic invertebrates (acute and chronic)	Algae	Higher plant	Sed. Dwelling organisms prolonged
	<i>Geomean approach</i>	<i>Pimephales promelas</i>	<i>Natural populations in ponds</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>
Level of assessment	Tier 2	Tier 1	Tier 3	Tier 1	Tier 1	Tier 1
RAC	0.0146 µg/L	0.003 µg/L	0.002 µg/L ¹	≥ 2.70 µg/L	0.139 µg/L	4.5 µg/kg dry sediment
FOCUS Step 1 PEC values	0.201	0.201	0.201	0.201	0.201	49.869
FOCUS Step 2 PEC values						
North Europe	0.184	0.184	0.184	0.184	0.184	14987
South Europe	0.184	0.184	0.184	0.184	0.184	8.108
FOCUS Step 3 PEC values						
D1 / ditch	0.056	0.056	0.056	-	0.056	0.630
D1 / stream	0.046	0.046	0.046	-	0.046	0.270
D2 / ditch	0.056	0.056	0.056	-	0.056	0.583
D2 / stream	0.047	0.047	0.047	-	0.047	0.419
D3 / ditch	0.052	0.052	0.052	-	0.052	0.292
D4 / pond	0.002	0.002	0.002	-	0.002	0.048
D4 / stream	0.045	0.045	0.045	-	0.045	0.151
D5 / pond	0.002	0.002	0.002	-	0.002	0.049
D5 / stream	0.048	0.048	0.048	-	0.048	0.177
D6 / ditch	0.052	0.052	0.052	-	0.052	0.569
R1 / pond	0.002	0.002	0.002	-	0.002	0.058
R1 / stream	0.034	0.034	0.034	-	0.034	0.331
R3 / stream	0.048	0.048	0.048	-	0.048	0.169
R4 / stream	0.034	0.034	0.034	-	0.034	0.412

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 4 – Comparison of RACs and global maximum PEC_{sw} for alpha-cypermethrin – Cereals at 1-2 x 10 g a.s./ha (the worst-case PEC_{sw} and PEC_{SED} for either spring or winter cereals are used).

Scenario	fish acute				fish chronic				Aquatic invertebrates (acute and chronic)			
	<i>Geomean approach</i>				<i>Pimephales promelas</i>				<i>Natural populations in ponds</i>			
Level of assessment	Tier 2				Tier 1				Tier 3			
RAC	0.0146 µg/L				0.003 µg/L				0.002 µg/L ¹			
Mitigation options	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N
FOCUS Step 4 PEC values												
D1 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D1 / stream	0.011	0.002	0.017	0.008	0.011	0.002	0.017	0.008	0.011	0.002	0.017	0.008
D2 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D2 / stream	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008
D3 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D4 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
D4 / stream	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008
D5 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
D5 / stream	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009
D6 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
R1 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
R1 / stream	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006
R3 / stream	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009
R4 / stream	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006

Notes: D = Drift mitigation by no-spray buffer zones; N = Drift mitigation by drift reducing nozzles; values in bold exceed the relevant RAC, indicating an unacceptable risk; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 1-3 – Comparison of RACs and global maximum PEC_{SW/SED} for alpha-cypermethrin – Winter oilseed rape at 1-2 x 10 g a.s./ha

Scenario	fish acute	fish chronic	Aquatic invertebrates (acute and chronic)	Algae	Higher plant	Sed. Dwelling organisms prolonged
	<i>Geomean approach</i>	<i>Pimephales promelas</i>	<i>Natural populations in ponds</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>
Level of assessment	Tier 2	Tier 1	Tier 3	Tier 1	Tier 1	Tier 1
RAC	0.0146 µg/L	0.003 µg/L	0.002 µg/L ¹	≥ 2.70 µg/L	0.139 µg/L	4.5 µg/kg dry sediment
FOCUS Step 1 PEC values	0.201	0.201	0.201	0.201	0.201	49.869
FOCUS Step 2 PEC values						
North Europe	0.184	0.184	0.184	0.184	0.184	14987
South Europe	0.184	0.184	0.184	0.184	0.184	8.108
FOCUS Step 3 PEC values						
D2 / ditch	0.053	0.053	0.053	-	0.053	0.475
D2 / stream	0.047	0.047	0.047	-	0.047	0.328
D3 / ditch	0.052	0.052	0.052	-	0.052	0.292
D4 / pond	0.002	0.002	0.002	-	0.002	0.050
D4 / stream	0.044	0.044	0.044	-	0.044	0.117
D5 / pond	0.002	0.002	0.002	-	0.002	0.052
D5 / stream	0.044	0.044	0.044	-	0.044	0.080
R1 / pond	0.002	0.002	0.002	-	0.002	0.057
R1 / stream	0.034	0.034	0.034	-	0.034	0.338
R3 / stream	0.048	0.048	0.048	-	0.048	0.227

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 4 – Comparison of RACs and global maximum PEC_{sw} for alpha-cypermethrin – Winter oilseed rape at 1-2 x 10 g a.s./ha

Scenario	fish acute				fish chronic				Aquatic invertebrates (acute and chronic)			
	<i>Geomean approach</i>				<i>Pimephales promelas</i>				<i>Natural populations in ponds</i>			
Level of assessment	Tier 2				Tier 1				Tier 3			
RAC	0.0146 µg/L				0.003 µg/L				0.002 µg/L ¹			
Mitigation options	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N
FOCUS Step 4 PEC values												
D2 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D2 / stream	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008
D3 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D4 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
D4 / stream	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008
D5 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
D5 / stream	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008	0.011	0.002	0.016	0.008
R1 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
R1 / stream	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006
R3 / stream	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009

Notes: D = Drift mitigation by no-spray buffer zones; N = Drift mitigation by drift reducing nozzles; values in bold exceed the relevant RAC, indicating an unacceptable risk;
¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 1-3 – Comparison of RACs and global maximum PEC_{SW/SED} for alpha-cypermethrin – Leafy vegetables (lettuce and leafy cabbage) at 1-2 x 10 g a.s./ha

Scenario	fish acute	fish chronic	Aquatic invertebrates (acute and chronic)	Algae	Higher plant	Sed. Dwelling organisms prolonged
	<i>Geomean approach</i>	<i>Pimephales promelas</i>	<i>Natural populations in ponds</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>
Level of assessment	Tier 2	Tier 1	Tier 3	Tier 1	Tier 1	Tier 1
RAC	0.0146 µg/L	0.003 µg/L	0.002 µg/L ¹	≥ 2.70 µg/L	0.139 µg/L	4.5 µg/kg dry sediment
FOCUS Step 1 PEC values	0.201	0.201	0.201	0.201	0.201	49.869
FOCUS Step 2 PEC values						
North Europe	0.184	0.184	0.184	0.184	0.184	14987
South Europe	0.184	0.184	0.184	0.184	0.184	8.108
FOCUS Step 3 PEC values						
D3 / ditch	0.052	0.052	0.052	-	0.052	0.311
D4 / pond	0.002	0.002	0.002	-	0.002	0.051
D4 / stream	0.041	0.041	0.041	-	0.041	0.054
D6 / ditch	0.051	0.051	0.051	-	0.051	0.200
R1 / pond	0.002	0.002	0.002	-	0.002	0.136
R1 / stream	0.034	0.034	0.034	-	0.034	2.839
R2 / stream	0.046	0.046	0.046	-	0.046	5.388
R3 / stream	0.048	0.048	0.048	-	0.048	2.318
R4 / stream	0.034	0.034	0.034	-	0.034	2.620

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 4 – Comparison of RACs and global maximum PEC_{sw} for alpha-cypermethrin – Leafy vegetables (lettuce and leafy cabbage) at 1-2 x 10 g a.s./ha

Scenario	fish acute				fish chronic				Aquatic invertebrates (acute and chronic)			
	<i>Geomean approach</i>				<i>Pimephales promelas</i>				<i>Natural populations in ponds</i>			
Level of assessment	Tier 2				Tier 1				Tier 3			
RAC	0.0146 µg/L				0.003 µg/L				0.002 µg/L ¹			
Mitigation options	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N
FOCUS Step 4 PEC values												
D3 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
D4 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
D4 / stream	0.010	0.002	0.015	0.007	0.010	0.002	0.015	0.007	0.010	0.002	0.015	0.007
D6 / ditch	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007	0.013	0.003	0.014	0.007
R1 / pond	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	<0.001
R1 / stream	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006
R2 / stream	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008	0.012	0.002	0.017	0.008
R3 / stream	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009	0.012	0.003	0.018	0.009
R4 / stream	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006	0.009	0.002	0.013	0.006

Notes: D = Drift mitigation by no-spray buffer zones; N = Drift mitigation by drift reducing nozzles; values in bold exceed the relevant RAC, indicating an unacceptable risk;
¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 1-3 – Comparison of RACs and global maximum PEC_{SW/SED} for alpha-cypermethrin – Leafy vegetables (lettuce and leafy cabbage) at 1 x 20 g a.s./ha

Scenario	fish acute	fish chronic	Aquatic invertebrates (acute and chronic)	Algae	Higher plant	Sed. Dwelling organisms prolonged
	<i>Geomean approach</i>	<i>Pimephales promelas</i>	<i>Natural populations in ponds</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>
Level of assessment	Tier 2	Tier 1	Tier 3	Tier 1	Tier 1	Tier 1
RAC	0.0146 µg/L	0.003 µg/L	0.002 µg/L ¹	≥ 2.70 µg/L	0.139 µg/L	4.5 µg/kg dry sediment
FOCUS Step 1 PEC values	0.201	0.201	0.201	0.201	0.201	49.869
FOCUS Step 2 PEC values						
North Europe	0.184	0.184	0.184	0.184	0.184	14987
South Europe	0.184	0.184	0.184	0.184	0.184	8.108
FOCUS Step 3 PEC values						
D3 / ditch	0.104	0.104	0.104	-	0.104	0.511
D4 / pond	0.004	0.004	0.004	-	0.004	0.063
D4 / stream	0.081	0.081	0.081	-	0.081	0.096
D6 / ditch	0.103	0.103	0.103	-	0.103	0.400
R1 / pond	0.004	0.004	0.004	-	0.004	0.121
R1 / stream	0.069	0.069	0.069	-	0.069	2.430
R2 / stream	0.092	0.092	0.092	-	0.092	5.326
R3 / stream	0.097	0.097	0.097	-	0.097	2.552
R4 / stream	0.069	0.069	0.069	-	0.069	2.335

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 4 – Comparison of RACs and global maximum PEC_{sw} for alpha-cypermethrin – Leafy vegetables (lettuce and leafy cabbage) at 1 x 20 g a.s./ha

Scenario		fish acute				fish chronic				Aquatic invertebrates (acute and chronic)			
		<i>Geomean approach</i>				<i>Pimephales promelas</i>				<i>Natural populations in ponds</i>			
Level of assessment		Tier 2				Tier 1				Tier 3			
RAC		0.0146 µg/L				0.003 µg/L				0.002 µg/L ¹			
Mitigation options	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N	75% N	95% N	5 m D	5 m D + 50% N	
FOCUS Step 4 PEC values													
D3 / ditch	0.005	0.028	0.007	0.008	0.005	0.028	0.007	0.008	0.005	0.028	0.007	0.008	
D4 / pond	<0.001	0.003	<0.001	0.001	<0.001	0.003	<0.001	0.001	<0.001	0.003	<0.001	0.001	
D4 / stream	0.004	0.030	0.007	0.008	0.004	0.030	0.007	0.008	0.004	0.030	0.007	0.008	
D6 / ditch	0.005	0.028	0.007	0.007	0.005	0.028	0.007	0.007	0.005	0.028	0.007	0.007	
R1 / pond	<0.001	0.003	<0.001	0.001	<0.001	0.003	<0.001	0.001	<0.001	0.003	<0.001	0.001	
R1 / stream	0.003	0.025	0.006	0.007	0.003	0.025	0.006	0.007	0.003	0.025	0.006	0.007	
R2 / stream	0.005	0.033	0.008	0.009	0.005	0.033	0.008	0.009	0.005	0.033	0.008	0.009	
R3 / stream	0.005	0.035	0.009	0.009	0.005	0.035	0.009	0.009	0.005	0.035	0.009	0.009	
R4 / stream	0.003	0.025	0.006	0.007	0.003	0.025	0.006	0.007	0.003	0.025	0.006	0.007	

Notes: D = Drift mitigation by no-spray buffer zones; N = Drift mitigation by drift reducing nozzles; values in bold exceed the relevant RAC, indicating an unacceptable risk;
¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 2 – Comparison of RACs and worst-case PEC_{SW/SED} for alpha-cypermethrin – Fruiting vegetables (cucumber and courgette) at 1 x 30 g a.s./ha (permanent glasshouse use)

Scenario	fish acute	fish chronic	Aquatic invertebrates (acute and chronic)	Algae	Higher plant	Sed. Dwelling organisms prolonged
	<i>Geomean approach</i>	<i>Pimephales promelas</i>	<i>Natural populations in ponds</i>	<i>Anabaena flos-aquae</i>	<i>Lemna gibba</i>	<i>Chironomus riparius</i>
Level of assessment	Tier 2	Tier 2	Tier 3	Tier 1	Tier 1	Tier 1
RAC	0.0146 µg/L	0.030 µg/L	0.002 µg/L ¹	≥ 2.70 µg/L	0.139 µg/L	4.5 µg/kg dry sediment
FOCUS Step 2 PEC values						
Europe – drift only	0.010	0.010	0.010	0.010	0.010	0.067

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary; ¹ETO-RAC (ecological threshold option)

FOCUS_{sw} step 1 – Comparison of RACs and global maximum PEC_{SW/SED} for the metabolite DCVA – All proposed outdoor uses in cereals and oilseed rape (at 1-2 x 10 g a.s./ha), leafy vegetables (at 1-2 x 10 g a.s./ha and 1 x 20 g a.s./ha) and the proposed permanent glasshouse use in fruiting vegetables

Scenario	fish acute	Aquatic invertebrates (acute and chronic)	Algae
	<i>Lepomis macrochirus</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>
Level of assessment	Tier 1	Tier 1	Tier 1
RAC	1028 µg/L	619 µg/L	7000 µg/L
FOCUS Step 1 PEC values			
Europe – outdoor uses	2.591	2.591	2.591
Europe –permanent glasshouse uses	0.003	0.003	0.003

Note: PEC values in bold indicate that the PEC_{SW/SED} exceeds the RAC, and thus that further consideration is necessary

FOCUS_{sw} step 1 – Comparison of RACs and global maximum PEC_{SW/SED} for the metabolite 3-PBA – All proposed outdoor uses in cereals and oilseed rape (at 1-2 x 10 g a.s./ha), leafy vegetables (at 1-2 x 10 g a.s./ha and 1 x 20 g a.s./ha) and the proposed permanent glasshouse use in fruiting vegetables

Scenario	fish acute	Aquatic invertebrates (acute and chronic)	Algae	Higher Plant
	<i>Lepomis macrochirus</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>	<i>Myriophyllum elatinoides</i>
Level of assessment	Tier 1	Tier 1	Tier 1	Tier 1
RAC	1032 µg/L	390 µg/L	8500 µg/L	328 µg a.s./L
FOCUS Step 1 PEC values				
Europe – outdoor uses	1.627	1.627	1.627	1.627
Europe – permanent glasshouse uses	0.001	0.001	0.001	0.001

Note: PEC values in bold indicate that the $PEC_{SW/SED}$ exceeds the RAC, and thus that further consideration is necessary

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Acute, adult toxicity	Oral toxicity (LD ₅₀)	0.059 µg a.s./bee ¹
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Acute, adult toxicity	Contact toxicity (LD ₅₀)	0.033 µg a.s./bee ¹
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Acute, adult toxicity	Oral toxicity (LD ₅₀)	0.246 µg a.s./bee
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Acute, adult toxicity	Contact toxicity (LD ₅₀)	0.030 µg a.s./bee
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Acute, adult toxicity	Oral toxicity (LD ₅₀)	2.99 µg prep./bee (0.15 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Acute, adult toxicity	Contact toxicity (LD ₅₀)	1.68 µg prep./bee (0.08 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Acute, adult toxicity	Oral toxicity (LD ₅₀)	3.26 µg prep./bee (0.17 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Acute, adult toxicity	Contact toxicity (LD ₅₀)	1.58 µg prep./bee (0.08 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Acute, adult toxicity	Oral toxicity (LD ₅₀)	0.359 µg prep./bee (0.018 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Acute, adult toxicity	Contact toxicity (LD ₅₀)	0.319 µg prep./bee (0.016 µg a.s./bee)
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Chronic (10d), adult toxicity	LDD ₅₀	0.11 µg a.s./bee/day
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	Chronic (7d), larval toxicity ²	NOED	≥ 0.008 µg a.s./larva
Bumblebee (<i>Bombus terrestris</i>)	Alpha-cypermethrin	Acute, adult toxicity	Oral toxicity (LD ₅₀)	0.54 µg a.s./bee
Bumblebee (<i>Bombus terrestris</i>)	Alpha-cypermethrin	Acute, adult toxicity	Contact toxicity (LD ₅₀)	0.29 µg a.s./bee
Bumblebee (<i>Bombus terrestris</i>)	BAS 310 55 I	Acute, adult toxicity	Oral toxicity (LD ₅₀)	> 26.4 µg prep./bee (> 1.325 µg a.s./bee)
Bumblebee (<i>Bombus terrestris</i>)	BAS 310 55 I	Acute, adult toxicity	Contact toxicity (LD ₅₀)	> 17.9 µg prep./bee (> 0.9 µg a.s./bee)

¹⁾ study not fully in line with the currently accepted test guidelines

Potential for accumulative toxicity: *not assessed*.

Semi-field test (Cage and tunnel test)

In total, three cage studies and five tunnel tests are available, in which the representative formulation BAS 310 55 I or the minor change formulation BAS 310 51 I were applied at a rate of 15 and 30 g a.s./ha, either during

or after bee flight. All available studies showed consistent results, which are summarized below.			
Species	Test substance	Type of test	Results
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Tunnel test in <i>Phacelia tanacetifolia</i>	Clear but short-lasting effects on adult bee mortality and flight density after application during bee flight at 0.3 and 0.6 L product/ha (equivalent to 15 and 30 g a.s./ha). No notable effects on mortality of pupae. No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Tunnel test in <i>Phacelia tanacetifolia</i>	Only limited, non-statistically significant and temporary effects on mortality and flight density after application after bee flight at 0.6 L product/ha (30 g a.s./ha). Moderate statistically significant effects on mortality and foraging activity, which were also temporary, following application during bee flight at 0.3 L product/ha (15 g a.s./ha). No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Tunnel test in <i>Phacelia tanacetifolia</i> ³	Clear but temporary effects on adult bee mortality, flight density and behaviour after application during bee flight at 0.6 L product/ha (equivalent to 30 g a.s./ha). No notable effects on mortality of pupae. No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Cage test in <i>Phacelia tanacetifolia</i>	Temporary, short lasting and slight effects on mortality, flight density and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No conclusion can be drawn from the brood data. No notable effects on the colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Cage test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality and flight density after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Cage test in <i>Phacelia tanacetifolia</i>	Slight and temporary effects on mortality and flight density after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No notable effects on brood and colony. No unacceptable effects on mortality and flight density following application after bee flight at 0.6 L product/ha (30 g a.s./ha). No unacceptable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 3101 55 I	Tunnel test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality, flight density and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). Slight and temporary effects on mortality and flight density after application after bee flight at 0.6 L product/ha (30 g a.s./ha). In the absence of a pollen source in the crop the amount of pollen in the combs decreased during the test period, thereby reducing the bee brood. Taking this into consideration, no unacceptable effects on brood and colony were observed.

Honeybee (<i>Apis mellifera</i>)	BAS 3101 55 I	Tunnel test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality and flight density after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No unacceptable effects on brood and colony. No significant effects following application after bee flight at 0.6 L product/ha (30 g a.s./ha). No notable effects on brood and colony.
<p>Field tests</p> <p>In total, five field effect studies are available, in which the representative formulation BAS 310 55 I or the minor change formulation BAS 310 51 I were applied at a rate of 15 and 30 g a.s./ha, either during or after bee flight. All available studies showed consistent results, which are summarized below.</p> <p>In addition, five field exposure studies are available, in which residues of alpha-cypermethrin in pollen, nectar and/or flowers were measured. Note that some of the field exposure studies were done at the same time, and were reported in the same study report, as the field effect studies.</p>			
Species	Test substance	Type of test	Results
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Field test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality and flight density after application during bee flight at 0.3 L product/ha (15 g a.s./ha). No notable effects on brood and colony observed, but the results for the colony strength assessment were considered unreliable. Slight and temporary effects on mortality following application after bee flight at 0.6 L (30 g a.s./ha). No notable effects on brood and colony observed, but the results for the colony strength assessment were considered unreliable.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Field test in <i>Phacelia tanacetifolia</i>	No significant effects after application after bee flight at 0.6 L product/ha (30 g a.s./ha). No notable effects on brood and colony. Clear but temporary effects on bee mortality, flight density and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). The size of the colonies did not increase, while the control did. The results from this study can therefore not be considered to exclude effects on colony strength.
Honeybee (<i>Apis mellifera</i>)	BAS 310 51 I	Field test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on flight density and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No significant effects on bee mortality. No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Field test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality, flight density and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No notable effects on brood and colony.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Field test in <i>Phacelia tanacetifolia</i>	Clear but temporary effects on mortality and behaviour after application during bee flight at 0.6 L product/ha (30 g a.s./ha). No significant effects on foraging activity. No notable effects on brood and colony observed, but the results for the colony strength assessment were

			considered unreliable. After application of 2 x 0.3 L/ha (2 x 15 g a.s./ha): moderate effects on mortality and foraging activity after the 1 st application, no unacceptable effects on mortality and foraging activity after the 2 nd application. No notable effects on brood and colony observed, but the results for the colony strength assessment were considered unreliable.
Honeybee (<i>Apis mellifera</i>)	Several alpha-cypermethrin containing formulations ¹	Residue analysis in honey/nectar and pollen from treated <i>Phacelia tanacetifolia</i> fields	Residues derived from in-hive samples (7 DAA and 14 DAA) from honeybee effect studies : Treated pollen showed residues of alpha-cypermethrin ranging from 0.003 to 0.012 mg/kg 7 DAA, and from < 0.003 to 0.026 mg/kg 14 DAA, depending on the study site. No alpha-cypermethrin was detected (LOD 0.003 mg/kg) in any honey/nectar specimens of the aforementioned field trials.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Residue analysis in honey/nectar and pollen from treated <i>Phacelia tanacetifolia</i> fields	Residues derived through bee sampling (1DAA) and from in-hive samples (7DAA) from honeybee field effect study: Treated pollen showed residues of alpha-cypermethrin ranging from 0.06 to 0.38 mg/kg at 1DAA (bee sampling) and from <LOQ to 0.03 mg/kg at 7DAA (in-hive sampling). No measurable alpha-cypermethrin residues (LOQ = 0.01 mg/kg) were detected in any of the honey/nectar specimens at 1 DAA and 7DAA.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Residue analysis in honey/nectar and pollen from treated <i>Phacelia tanacetifolia</i> fields	Residues derived from in-hive samples (7DAA and 14DAA) from honeybee effect study: Treated pollen showed residues of alpha-cypermethrin ranging from <LOQ to 0.03 mg/kg at 7DAA, and <LOQ at 14 DAA. No measurable alpha-cypermethrin residues (LOQ = 0.01 mg/kg) were detected in any of the honey/nectar specimens at 7DAA and 14 DAA.
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Residue analysis in flowers, nectar and pollen from treated oilseed rape	Applied rate: 30 g alpha-cypermethrin/ha; highest residues were found in pollen (hand sampling) with 90 th percentile 9.37 mg a.s./kg and an average of 6.52 mg a.s./kg
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	Residue analysis in flowers, nectar and pollen from treated oilseed rape	Applied rate: 30 g alpha-cypermethrin /ha; highest residues were found in pollen. For pollen obtained through hand sampling: 90 th percentile 9.088 mg a.s./kg and an average of 7.90 mg a.s./kg. For pollen obtained through bee sampling: 90 th percentile 0.978 mg a.s./kg and an average of 0.632 mg a.s./kg

¹ BAS 310 40 I (100 g/L EC formulation), BAS 310 06 I (50 g/L EC formulation), BAS 310 08 I (15% WG formulation) and BAS 310 41 I (100 g/L SC formulation)

² Bee larvae were fed contaminated food for 4 days (day 3 to 6), in line with the OECD Test Guideline 239 (honeybee larval toxicity, repeated exposure). The EFSA Guidance Document for bees (2013) however recommends a 5 day feeding/exposure period.

³ Because of a relatively high mortality in the control, and a higher pre-treatment mortality in the reference item treatment compared to the control, the reliability of the results from this study could be questioned. Therefore, this study is only considered as supportive information.

Tier 1 Risk assessment according to SANCO/10329/2002 and EPPO (2010)

Risk assessment for Cereals at 1-2 x 10 g a.s./ha and oilseed rape at 1-2 x 10 g a.s./ha

Species	Test substance	Risk quotient	HQ	Trigger
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	HQ _{oral}	169	50
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	HQ _{contact}	333	50
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	HQ _{oral}	552	50
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	HQ _{contact}	612	50
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	TER _{CH,adult}	< 0.354	1
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	TER _{CH,larvae}	≥ 0.409	1

Note: HQ and TER values in bold exceed, respectively are below, the trigger, indicating that further consideration is required.

Risk assessment for Lettuce and leafy cabbage at 1-2 x 10 g a.s./ha or 1 x 20 g a.s./ha

Species	Test substance	Risk quotient	HQ	Trigger
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	HQ _{oral}	339	50
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	HQ _{contact}	667	50
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	HQ _{oral}	1104	50
Honeybee (<i>Apis mellifera</i>)	BAS 310 55 I	HQ _{contact}	1243	50
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	TER _{CH,adult}	< 0.354	1
Honeybee (<i>Apis mellifera</i>)	Alpha-cypermethrin	TER _{CH,larvae}	≥ 0.409	1

Note: HQ and TER values in bold exceed, respectively are below, the trigger, indicating that further consideration is required.

Risk assessment for Cucumber and courgette at 1-2 x 15 g a.s./ha or 1 x 30 g a.s./ha (indoor use – restricted to permanent greenhouses)

No risk assessment required as no exposure to bees is expected from the use in permanent greenhouses.

Tier 1 Risk assessment according to EFSA (2013)

Risk assessment for Cereals at 1-2 x 10 g a.s./ha, oilseed rape at 1-2 x 10 g a.s./ha, and lettuce and leafy cabbage at 1-2 x 10 g a.s./ha or 1 x 20 g a.s./ha.

For the use in cucumber and courgette at 1-2 x 15 g a.s./ha or 1 x 30 g a.s./ha, which is restricted to permanent greenhouses, no exposure to bees is expected. Therefore, no risk assessment is required for this use.

Acute contact exposure for adult honeybees – screening step

Test substance	Crop	Application rate (g/ha)	LD ₅₀ (µg/bee)	HQ	Trigger value
Alpha-cypermethrin	Cereals	10	0.030	333	42
	Oilseed rape	10	0.030	333	42
	Leafy vegetables ¹⁾	20	0.030	667	42
BAS 310 55 I	Cereals	198.2 ²⁾	0.319	621	42
	Oilseed rape	198.2 ²⁾	0.319	621	42

	Leafy vegetables ¹⁾	396.4 ²⁾	0.319	1243	42
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¹⁾ the proposed use in lettuce and leafy cabbage ²⁾ maximum application rate in mL/ha multiplied by the product density of 0.991 g/cm³; TER values shown in bold are below the trigger.

Acute contact exposure of adult honeybees – Tier 1

Test substance: alpha-cypermethrin							
Crop	Scenario	BBCH	Appl. Rate (g/ha)	f _{dep}	LD ₅₀ (µg/bee)	HQ	Trigger
Cereals	treated crop	≥ 40	10	1	0.030	333	42
	weeds	≥ 40	10	0.3		100	
	field margin	≥ 40	10	0.028		9.33	
Oilseed rape	treated crop	≥ 40	10	1		333	
	weeds	≥ 40	10	0.25		83.3	
	field margin	≥ 40	10	0.028		9.33	
Leafy vegetables ¹⁾	weeds	< 50	20	1		667	
	field margin	< 50	20	0.028		18.67	
Test substance: BAS 310 55 I							
Crop	Scenario	BBCH	Appl. Rate (g/ha) ²⁾	f _{dep}	LD ₅₀ (µg/bee)	HQ	Trigger
Cereals	treated crop	≥ 40	198.2	1	0.319	621	42
	weeds	≥ 40	198.2	0.3		186	
	field margin	≥ 40	198.2	0.028		17.4	
Oilseed rape	treated crop	≥ 40	198.2	1		621	
	weeds	≥ 40	198.2	0.25		155	
	field margin	≥ 40	198.2	0.028		17.4	
Leafy vegetables ¹⁾	weeds	< 50	396.4	1		1243	
	field margin	< 50	396.4	0.028		34.8	

¹⁾ the proposed use in lettuce and leafy cabbage; ²⁾ maximum application rate in mL/ha multiplied by the product density of 0.991 g/cm³; TER values shown in bold are below the trigger.

Acute and chronic oral exposure of adult honeybees and honeybee larvae – screening step

Type of assessment	Test substance	Crop	Application rate (kg a.s./ha)	SV	Endpoint	ETR	Trigger value
Acute oral exposure adult bees	Alpha-cypermethrin	Cereals	0.010	7.6	0.059 µg a.s./bee	1.29	0.2
		Oilseed rape	0.010	7.6		1.29	0.2
		Lettuce	0.020	7.6		2.58	0.2
		Leafy cabbage	0.020	7.6		2.58	0.2
	BAS 310 55 I	Cereals	0.198 ¹⁾	7.6	0.359 µg product/bee	4.19	0.2
		Oilseed rape	0.198 ¹⁾	7.6		4.19	0.2
		Lettuce	0.396 ¹⁾	7.6		8.38	0.2
		Leafy cabbage	0.396 ¹⁾	7.6		8.38	0.2
Chronic oral exposure adult bees	Alpha-cypermethrin	Cereals	0.010	7.6	0.11 µg a.s./bee/day	0.69	0.03
		Oilseed rape	0.010	7.6		0.69	0.03
		Lettuce	0.020	7.6		1.38	0.03
		Leafy cabbage	0.020	7.6		1.38	0.03
Chronic oral exposure larvae	Alpha-cypermethrin	Cereals	0.010	4.4	≥ 0.008 µg a.s./larvae per developmental period	5.5	0.2
		Oilseed rape	0.010	4.4		5.5	0.2
		Lettuce	0.020	4.4		11.0	0.2
		Leafy cabbage	0.020	4.4		11.0	0.2

¹⁾ maximum application rate in L/ha multiplied by the product density of 0.991 g/cm³; SV: Shortcut value; **bold** values exceed the trigger, indicating a potential risk.

Acute oral exposure of adult honeybees – Tier 1 (ETR values calculated based on toxicity data for the active substance alpha-cypermethrin)

Crop	Scenario	BBCH	Appl. rate (kg a.s./ha)	E _f	SV	Endpoint (µg a.s./bee)	ETR	Trigger value
Cereals	Treated crop	40-69	0.01	1	0.92	0.059	0.16	0.2
		≥ 70		1	0		0	
	Weeds	40-69		0.3	3.7		0.19	
		≥ 70		0.3	3.7		0.19	
	Field margin	40-69		0.0092	3.7		0.006	
		≥ 70		0.0092	3.7		0.006	
	Adjacent crop	40-69		0.0033	7.6		0.004	
		≥ 70		0.0033	7.6		0.004	
Succeeding crop	40-69	1	0.7	0.12				
	≥ 70	1	0.7	0.12				
Oilseed rape	Treated crop	40-69	0.01	1	7.6	0.059	1.29	0.2
	Weeds	40-69		0.25	3.7		0.16	
	Field margin	40-69		0.0092	3.7		0.006	
	Adjacent crop	40-69		0.0033	7.6		0.004	
	Succeeding crop	40-69		1	0.7		0.12	
Lettuce / Leafy cabbage	Treated crop	10-49	0.02	1	0	0.059	0	0.2
	Weeds	10-49		1	3.7		1.25	
	Field margin	10-49		0.0092	3.7		0.012	
	Adjacent crop	10-49		0.0033	7.6		0.009	
	Succeeding crop	10-49		1	0.7		0.24	

SV: Shortcut value; E_f: exposure factor; bold values exceed the trigger, indicating a potential risk

Acute oral exposure of adult honeybees – Tier 1 (ETR values calculated based on toxicity data for the representative formulation BAS 310 55 I)

Crop	Scenario	BBCH	Appl. rate (kg a.s./ha) ¹⁾	E _f	SV	Endpoint (µg a.s./bee)	ETR	Trigger value
Cereals	Treated crop	40-69	0.198	1	0.92	0.359	0.51	0.2
		≥ 70		1	0		0	
	Weeds	40-69		0.3	3.7		0.61	
		≥ 70		0.3	3.7		0.61	
	Field margin	40-69		0.0092	3.7		0.019	
		≥ 70		0.0092	3.7		0.019	
	Adjacent crop	40-69		0.0033	7.6		0.014	
		≥ 70		0.0033	7.6		0.014	
Succeeding crop	40-69	1	0.7	0.39				
	≥ 70	1	0.7	0.39				
Oilseed rape	Treated crop	40-69	0.198	1	7.6	0.359	4.19	0.2
	Weeds	40-69		0.25	3.7		0.51	
	Field margin	40-69		0.0092	3.7		0.018	
	Adjacent crop	40-69		0.0033	7.6		0.014	
	Succeeding crop	40-69		1	0.7		0.39	

Lettuce / Leafy cabbage	Treated crop	10-49	0.396	1	0	0.359	0	0.2
	Weeds	10-49		1	3.7		4.08	
	Field margin	10-49		0.0092	3.7		0.038	
	Adjacent crop	10-49		0.0033	7.6		0.028	
	Succeeding crop	10-49		1	0.7		0.77	

¹⁾ maximum application rate in L/ha multiplied by the product density of 0.991 g/cm³; SV: Shortcut value; E_f: exposure factor; bold values exceed the trigger, indicating a potential risk

Chronic oral exposure of adult honeybees – Tier 1.

Crop	Scenario	BBCH	Appl. rate (kg a.s./ha)	E _f	SV	twa	Endpoint (µg a.s./bee/day)	ETR	Trigger value
cereals	Treated crop	40-69	0.01	1	0.92	0.72	0.11	0.060	0.03
		≥ 70		1	0			0	
	Weeds	40-69		0.3	2.9			0.057	
		≥ 70		0.3	2.9			0.057	
	Field margin	40-69		0.0092	2.9			0.002	
		≥ 70		0.0092	2.9			0.002	
	Adjacent crop	40-69		0.0033	5.8			0.001	
		≥ 70		0.0033	5.8			0.001	
Succeeding crop	40-69	1	0.54	0.035					
	≥ 70	1	0.54	0.035					
oilseed rape	Treated crop	40-69	0.01	1	5.8	0.72	0.11	0.38	0.03
	Weeds	40-69		0.25	2.9			0.047	
	Field margin	40-69		0.0092	2.9			0.002	
	Adjacent crop	40-69		0.0033	5.8			0.001	
	Succeeding crop	40-69		1	0.54			0.035	
Lettuce / Leafy cabbage	Treated crop	10-49	0.02	1	0	0.72	0.11	0	0.03
	Weeds	10-49		1	2.9			0.38	
	Field margin	10-49		0.0092	2.9			0.003	
	Adjacent crop	10-49		0.0033	5.8			0.003	
	Succeeding crop	10-49		1	0.54			0.071	

SV: Shortcut value; E_f: exposure factor; bold values exceed the trigger, indicating a potential risk

Chronic oral exposure of honeybee larvae – Tier 1.

Crop	Scenario	BBCH	Appl. rate (kg a.s./ha)	E _f	SV	twa	Endpoint (µg a.s./larva)	ETR	Trigger value
Cereals	Treated crop	40-69	0.01	1	0.15	0.85	≥ 0.008	≤ 0.16	0.2
		≥ 70		1	0			0	
	Weeds	40-69		0.3	2.2			≤ 0.70	
		≥ 70		0.3	2.2			≤ 0.70	
	Field margin	40-69		0.0092	2.2			≤ 0.022	
		≥ 70		0.0092	2.2			≤ 0.022	
	Adjacent crop	40-69		0.0033	4.4			≤ 0.015	
		≥ 70		0.0033	4.4			≤ 0.015	
	Succeeding crop	40-69		1	0.4			≤ 0.43	
		≥ 70		1	0.4			≤ 0.42	

Oilseed rape	Treated crop	40-69	0.01	1	4.4	0.85	≥ 0.008	\leq 4.68	0.2
	Weeds	40-69		0.25	2.2			\leq 0.58	
	Field margin	40-69		0.0092	2.2			\leq 0.022	
	Adjacent crop	40-69		0.0033	4.4			\leq 0.015	
	Succeeding crop	40-69		1	0.2			\leq 0.21	
Lettuce / Leafy cabbage	Treated crop	10-49	0.02	1	0	0.85	≥ 0.008	0	0.2
	Weeds	10-49		1	2.2			\leq 4.68	
	Field margin	10-49		0.0092	2.2			\leq 0.043	
	Adjacent crop	10-49		0.0033	4.4			\leq 0.031	
	Succeeding crop	10-49		1	0.4			\leq 0.85	

SV: Shortcut value; E_f : exposure factor; bold values exceed the trigger, indicating a potential risk

Exposure to contaminated guttation water

Type of assessment	Water consumption (μL)	PEC ($\mu\text{g}/\mu\text{L}$) ¹	Endpoint	ETR	Trigger
Acute oral exposure adult bees	11.4	0.000003	0.059 μg a.s./bee	0.00058	0.2
Chronic oral exposure adult bees	11.4	0.00000162	0.11 μg a.s./bee/day	0.00017	0.03
Chronic oral exposure larvae	111	0.00000216	≥ 0.008 μg a.s./ larvae per developmental period	≤ 0.030	0.2

¹based on a maximum water solubility of 3 $\mu\text{g}/\text{L}$ for alpha-cypermethrin; bold values exceed the trigger, indicating a potential risk

Exposure to contaminated surface water

Type of assessment	Crop	Water consumption (μL)	PEC ($\mu\text{g}/\mu\text{L}$)	Endpoint	ETR	Trigger
Acute oral exposure adult bees	All proposed uses	11.4	0.201×10^{-6}	0.059 μg a.s./bee	3.884×10^{-5}	0.2
Chronic oral exposure adult bees	All proposed uses	11.4	0.201×10^{-6}	0.11 μg a.s./bee/day	2.083×10^{-5}	0.03
Chronic oral exposure larvae	All proposed uses	111	0.201×10^{-6}	≥ 0.008 μg a.s./ larvae per developmental period	≤ 0.00279	0.2

bold values exceed the trigger, indicating a potential risk

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity

Species	Test Substance	End point	Toxicity
<i>Typhlodromus pyri</i>	BAS 310 51 I	Mortality, LR ₅₀ Reproduction, ER ₅₀	0.038 mL prep./ha (1.90 mg a.s./ha) Effects on reproduction were not assessed
<i>Aphidius rhopalosiphi</i>	BAS 310 51 I	Mortality, LR ₅₀ Reproduction, ER ₅₀	0.631 mL prep./ha (31.49 mg a.s./ha) Effects on reproduction were not assessed

First tier risk assessment for – Cereals at 1-2 x 10 g a.s./ha, oilseed rape at 1-2 x 10 g a.s./ha, lettuce and leafy cabbage at 1-2 x 10 g a.s./ha or 1 x 20 g a.s./ha.

For the use in cucumber and courgette at 1-2 x 15 g a.s./ha or 1 x 30 g a.s./ha, which is restricted to permanent greenhouses, no exposure to bees is expected. Therefore, no risk assessment is required for this use.

Test substance	Species	Effect (LR ₅₀ g a.s./ha)	HQ in-field	HQ off-field ¹	Trigger
BAS 310 55 I	<i>Typhlodromus pyri</i>	0.0019	10526	291.6	2
BAS 310 55 I	<i>Aphidius rhopalosiphi</i>	0.03149	635	17.6	2

¹HQ value calculated for the use in lettuce and leafy cabbage, for which a distance of 1 m was assumed to calculate the drift rate. The off-field exposure for this use covers the off-field exposure for the proposed use in cereals and oilseed rape.

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect ¹	ER ₅₀
<i>Typhlodromus pyri</i>	Nymphs	BAS 310 51 I, Natural substrate (bean leaf disks)	7 days of exposure	0.25 – 4 mL prep./ha, Fresh residues	Mortality, reproduction	LR ₅₀ = 0.264 mL product/ha (= 13.7 mg a.s./ha) No effects on reproduction up to 0.25 mL product/ha (12.5 mg a.s./ha). Reproduction at higher doses not assessed	-

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect ¹	ER ₅₀
<i>Typhlodromus pyri</i>	Nymphs	BAS 310 55 I, Leaf discs from treated potted vine plants (either upper leaf surface or lower leaf surface)	7 days of exposure	9, 17, 30 g a.s./ha and 2 x 15 g a.s./ha (7-day interval), Fresh or aged residues of 7, 28, 56, 84, 112, 140 and 168 days	Mortality, reproduction	<p><u>Exposure to fresh and aged-residues on lower leaf surface:</u> no unacceptable effects (< 50%) on survival and reproduction on DAT 28 at 180 mL/ha (9 g a.s./ha), on DAT 56 at 340 and 600 mL/ha (17 and 30 g a.s./ha) and on DAT 112 at 2 x 300 mL/ha (2 x 15 g a.s./ha)</p> <p><u>Exposure to fresh and aged-residues on upper leaf surface:</u> no unacceptable effects (<50%) on survival and reproduction on DAT 56 at 180 mL/ha (9 g a.s./ha). On DAT 168 at 340 mL/ha (17 g a.s./ha) the effect on reproduction of 50.3% was still slightly above the 50% trigger. Effects on survival >50% still occurred at 600 mL/ha (30 g a.s./ha) and at 2 x 300 mL/ha (2 x 15 g a.s./ha) on DAT 168.</p>	-

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect ¹	ER ₅₀
<i>Aphidius rhopalosiphi</i>	Adults	BAS 310 51 I, barley seedlings	48 h of exposure	3.76 – 120 mL prep./ha, fresh residues	Mortality, reproduction	LR ₅₀ = 76.1 mL product/ha (3.80 g a.s./ha) 10.7-20.0% effects on reproduction up to 60 mL product/ha (2.99 mg a.s./ha). Reproduction at higher doses not assessed.	-
<i>Coccinella septempunctata</i>	Larvae	BAS 310 51 I, detached bean leaves	11-15 days of exposure	0.125 – 2 mL prep./ha, fresh residues	Mortality, reproduction	LR ₅₀ = 1.04 mL product/ha (= 51.90 mg a.s./ha) Reproduction was comparable to the control for treatments up to 1.0 mL product/ha (=49.90 mg a.s./ha). Reproduction at higher rates was not assessed.	-
<i>Chrysoperla carnea</i>	Larvae	BAS 310 51 I, detached bean leaves	13-19 days of exposure	2 – 160 mL prep./ha, fresh residues	Mortality, reproduction	LR ₅₀ = 58.7 mL product/ha (= 2.88 g a.s./ha) Reproduction was comparable to the control for treatments up to 80 mL product/ha (= 3.99 g a.s./ha). Reproduction at higher rates was not assessed.	-

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)	End point	% effect ¹	ER ₅₀
<i>Orius laevigatus</i>	Nymphs	BAS 310 51 I, detached bean leaves	9 days of exposure	0.5 – 8.0 mL prep./ha, fresh residues	Mortality, reproduction	LR ₅₀ = 2.24 mL product/ha (= 111.78 mg a.s./ha) 11.61 – 18.02 % effects on reproduction up to 2 mL product/ha (= 99.8 mg a.s./ha). Reproduction at higher rates was not assessed.	-
<i>Aleochara bilineata</i>	Adults	BAS 310 51 I, on a worst-case natural soil	28 days of exposure	7.6 – 120 mL prep./ha, fresh residues	reproduction	26.3 % effect on reproduction at 120 mL product/ha (5.99 g a.s./ha)	-

¹ A positive value indicates a decrease in reproduction, relative to the control

Risk assessment based on extended lab and aged residue tests for – Cereals at 1-2 x 10 g a.s./ha, oilseed rape at 1-2 x 10 g a.s./ha, lettuce and leafy cabbage at 1-2 x 10 g a.s./ha or 1 x 20 g a.s./ha.

For the use in cucumber and courgette at 1-2 x 15 g a.s./ha or 1 x 30 g a.s./ha, which is restricted to permanent greenhouses, no exposure to bees is expected. Therefore, no risk assessment is required for this use.

Species	Endpoints	In-field rate	Off-field rate ¹
<i>Typhlodromus pyri</i>	LR ₅₀ = 0.0137 g a.s./ha No effects > 50% on reproduction up to 0.0125 g a.s./ha	20 g a.s./ha	0.0554 g a.s./ha²
<i>Typhlodromus pyri</i>	<u>Exposure to lower leaf surface:</u> no unacceptable effects on survival and reproduction on DAT 28 at 180 mL/ha (9 g a.s./ha), on DAT 56 at 340 and 600 mL/ha (17 and 30 g a.s./ha) and on DAT 112 at 2 x 300 mL/ha (2 x 15 g a.s./ha) <u>Exposure to upper leaf surface:</u> no unacceptable effects on survival and reproduction on DAT 56 at 180 mL/ha (9 g a.s./ha). On DAT 168 at 340 mL/ha (17 g a.s./ha) the effect on reproduction of 50.3% was still slightly above the 50% trigger. Effects on survival >50% still occurred at 600 mL/ha (30 g a.s./ha) and at 2 x 300 mL/ha (2 x 15 g a.s./ha) on DAT 168.	20 g a.s./ha	- ⁴

Species	Endpoints	In-field rate	Off-field rate ¹
<i>Aphidius rhopalosiphi</i>	LR ₅₀ = 3.80 g a.s./ha No effects > 50% on reproduction up to 2.99 g a.s./ha	20 g a.s./ha	0.554 g a.s./ha ³
<i>Coccinella septempunctata</i>	LR ₅₀ = 0.0519 g a.s./ha No effects > 50% on reproduction up to 0.0499 g a.s./ha	20 g a.s./ha	0.0554 g a.s./ha²
<i>Chrysoperla carnea</i>	LR ₅₀ = 2.88 g a.s./ha No effects > 50% on reproduction up to 3.99 g a.s./ha	20 g a.s./ha	0.0554 g a.s./ha ²
<i>Orius laevigatus</i>	LR ₅₀ = 0.112 g a.s./ha No effects > 50% on reproduction up to 0.0998 g a.s./ha	20 g a.s./ha	0.0554 g a.s./ha ²
<i>Aleochara bilineata</i>	No unacceptable effects on reproduction up to 5.99 g a.s./ha	20 g a.s./ha	0.0554 g a.s./ha ²

¹Off-field rate a calculated for the use in lettuce and leafy cabbage, for which a distance of 1 m was assumed to calculate the drift rate. The off-field exposure for this use covers the off-field exposure for the proposed use in cereals and oilseed rape.

²off-field rate calculated for 2D exposure

³off field rate calculated for 3D exposure

⁴An aged-residue study is not considered appropriate to address the off-field risk. In order to allow re-colonisation of the in-field area, which is more realistic than real recovery in case of an insecticide, no effect should be allowed to occur in the off-field area

Semi-field tests

No additional semi-field tests have been submitted

Field studies

Three new field studies with the representative formulation BAS 310 55 I have been submitted, of which two assess the effects on mites in in-crop areas, and one assesses the effects on arthropod communities in off-crop areas. The study in off-crop areas consisted of two assessments, which are reported in two separate study reports. Both assessments were performed at the same time on the same field, and investigated either the complete non-target arthropod community or the non-target mite community. In addition, two in-crop field studies have been carried out with the SC formulation BAS 310 03 I. Although performed with another formulation, these two in-crop field studies are considered to be representative for the risk assessment for BAS 310 55 I

Species	Test substance	Crop	Application rates/ effects
In-crop field studies			
Predatory mites (Acari: Phytoseiidae), Natural populations	BAS 310 55 I	Vineyard (Northern France)	2 × 0.15 L product/ha (= 2 × 7.6 g a.s./ha) → At the end of the study period (112 days after the 2 nd application), mite populations in the plots treated with BAS 310 55 I were recovering. However, there was still a statistically significant effect of 37.46% compared to the control. As this effect is < 50%, it was considered that there were no unacceptable effects at 2 × 0.15 L BAS 310 55 I/ha.

Predatory mites (Acari: Phytoseiidae), Natural populations	BAS 310 55 I	Vineyard (Southern France)	$2 \times 0.15 \text{ L product/ha}$ (= $2 \times 7.6 \text{ g a.s./ha}$) → At the end of the study period (56 days after the 2 nd application), mite populations in the plots treated with BAS 310 55 I were recovering. However, there was still a statistically significant effect of 38.51% compared to the control. As this effect is < 50%, it was considered that there were no unacceptable effects at $2 \times 0.15 \text{ L BAS 310 55 I/ha}$.
Natural arthropod populations	BAS 310 03 I	Cereals (Germany)	$2 \times 15 \text{ g a.s./ha}$ and $3 \times 15 \text{ g a.s./ha}$ → short-term effects on a wide range of non-target arthropods; no unacceptable long-term effects beyond one season
Natural arthropod populations	BAS 310 03 I	Cereals/fallow (Southern France)	$2 \times 15 \text{ g a.s./ha}$ and $3 \times 15 \text{ g a.s./ha}$ → short-term effects on a wide range of non-target arthropods; no unacceptable long-term effects beyond one season
Off-crop field studies			
Natural arthropod populations	BAS 310 55 I	Grassland (South-West France)	$1, 3, 9, 27$ and 52 mL product/ha → slight effects on 2 taxa at 9 mL product/ha , no unacceptable long-term effects. Short-term effects on 2 taxa at 27 mL product/ha and on 6 taxa at 52 mL product/ha . Recovery occurred within 2 months after application community NOER = 52 mL/ha population NOEAER = 9 mL/ha population NOER = 1 mL/ha ¹⁾
Natural mite populations	BAS 310 55 I	Grassland (South-West France)	$1, 3, 9, 27$ and 52 mL product/ha → no unacceptable long-term effects on non-target mites community NOER = 52 mL/ha population NOER = 52 mL/ha
Additional specific test			
No additional specific tests have been submitted.			

¹⁾ At Pesticides Peer Review Meeting 177, the NOER from this study was set at 1 mL product/ha , based on a visual observation of the results, which indicated effects of more than 50% for some taxa at 3 mL product/ha , even though this is not supported by statistical relevance. There is however uncertainty on the statistical power of this field study. Taking this into account, the endpoints from this study should be used with care. Member States should pay attention on whether to conditions in the study are representative for the conditions in their country

Risk assessment based on field studies for – Cereals at $1\text{-}2 \times 10 \text{ g a.s./ha}$, oilseed rape at $1\text{-}2 \times 10 \text{ g a.s./ha}$, lettuce and leafy cabbage at $1\text{-}2 \times 10 \text{ g a.s./ha}$ or $1 \times 20 \text{ g a.s./ha}$, and cucumber and courgette at $1\text{-}2 \times 15 \text{ g a.s./ha}$ or $1 \times 30 \text{ g a.s./ha}$.

In-field risk assessment:

As the two available field studies which were performed with BAS 310 55 I were performed with an application rate below the maximum intended use pattern, no conclusion can be drawn from these studies in the higher tier assessment. However, based on the results from the studies with the formulation BAS 310 03 I, it can be concluded that an application of up to $3 \times 15 \text{ g a.s./ha}$ caused no unacceptable effect on the population development of ground- and foliar dwelling arthropods under field conditions in cereals (no long-term effects beyond one season). Therefore, the in-field risk to non-target terrestrial arthropods can be considered acceptable for the proposed uses of BAS 310 55 I in cereals. At Pesticides Peer Review Meeting 177, it was agreed that the results from these studies can be extrapolated to oilseed rape, but not to lettuce and leafy vegetables. Consequently, the in-field risk to non-target terrestrial arthropods can also be considered acceptable for the proposed uses of BAS 310 55 I in oilseed rape. For the proposed uses in lettuce and leafy vegetables, a higher tier in-field risk assessment for non-target terrestrial arthropods could not be performed, and an acceptable risk

could not be concluded.							
Off-field risk assessment:							
From the available studies in the off-crop area, a NOER of 0.051 g a.s./ha was derived following expert consultation at Pesticides Peer Review Meeting 177. Although there were some uncertainties regarding this endpoint, which are mainly related to the statistical power of the study, it was agreed that this endpoint could be used in a higher-tier off-field risk assessment, without an additional safety factor. This results in a Regulatory Acceptable Concentration (RAC) for the off-field area of 0.051 g a.s./ha. Based on this RAC, the risk could be considered acceptable for all proposed uses, provided that no-spray buffer zones are applied.							
Crop	Application rate (g a.s./ha)	MAF	In-field PER (g a.s./ha)	Distance from the edge of the crop (m)	Drift factor % drift/100	3D Off-field PER (g a.s./ha)	RAC (g a.s./ha)
Cereals	10	1.7	17	1	0.0238	0.405	0.051
				5	0.0047	0.080	
				10	0.0024	0.041	
Oilseed rape	10	1.7	17	1	0.0238	0.405	
				5	0.0047	0.080	
				10	0.0024	0.041	
Lettuce	20	1	20	1	0.0277	0.554	
				5	0.0057	0.114	
				10	0.0029	0.058	
				15	0.0020	0.040	
Leafy cabbage	20	1	20	1	0.0277	0.554	
				5	0.0057	0.114	
				10	0.0029	0.058	
				15	0.0020	0.040	

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Earthworms					
Earthworm (<i>Eisenia fetida</i>)	Alpha-cypermethrin	Mixed with soil after application to quartz sand /10%	Chronic	Mortality, growth, reproduction	NOEC ≥ 4 mg a.s./kg d.w. soil NOEC _{CORR} ≥ 2 mg a.s./kg d.w. soil

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Earthworm (<i>Eisenia fetida</i>)	BAS 310 51 I	Mixed with soil as a solution / 5%	Chronic	Mortality Growth, reproduction	<p>EC₅₀ > 22.50 mg prep./kg d.w. soil (> 1.28 mg a.s./kg d.w. soil)</p> <p>EC_{50,CORR} > 11.28 mg prep./kg d.w. soil (> 0.64 mg a.s./kg d.w. soil)</p> <p>NOEC ≥ 22.55 mg prep./kg d.w. soil (≥ 1.28 mg a.s./kg d.w.soil)</p> <p>NOEC_{CORR} ≥ 11.28 mg prep./kg d.w. soil (≥ 0.64 mg a.s./kg d.w.soil)</p>
Earthworm (<i>Eisenia fetida</i>)	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.2% OM	Chronic	Mortality Growth, reproduction	<p>LC₅₀ = 762 mg a.s./kg d.w. soil</p> <p>LC_{50,CORR} = 381 mg a.s./kg d.w. soil</p> <p>EC₅₀ = 31 mg a.s./kg d.w. soil</p> <p>EC_{50,CORR} = 15.5 mg a.s./kg d.w. soil</p> <p>NOEC < 4.65 mg a.s./kg d.w.soil</p> <p>NOEC_{CORR} < 2.33 mg a.s./kg d.w.soil</p>
Earthworm (<i>Eisenia fetida</i>)	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.1% OM	Chronic	Growth, reproduction	<p>EC₅₀ = 23.8 mg a.s./kg d.w. soil²</p> <p>EC_{50,CORR} = 11.9 mg a.s./kg d.w. soil²</p> <p>EC₁₀ = 4.8 mg a.s./kg d.w. soil²</p> <p>EC_{10,CORR} = 2.4 mg a.s./kg d.w. soil²</p>

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
Potworm (<i>Enchytraeus crypticus</i>)	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.2% OM	Chronic	Mortality Growth, reproduction	LC ₅₀ = 31.4 mg a.s./kg d.w. soil LC _{50,CORR} = 15.7 mg a.s./kg d.w. soil EC ₅₀ = 4.91 mg a.s./kg d.w. soil EC _{50,CORR} = 2.46 mg a.s./kg d.w. soil EC ₁₀ = 0.99 mg a.s./kg d.w. soil EC _{10,CORR} = 0.495 mg a.s./kg d.w. soil NOEC = 2.51 mg a.s./kg d.w.soil NOEC _{CORR} = 1.26 mg a.s./kg d.w.soil
Potworm (<i>Enchytraeus crypticus</i>)	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.1% OM	Chronic	Growth, reproduction	EC ₅₀ = 0.76 mg a.s./kg d.w. soil ² EC _{50,CORR} = 0.38 mg a.s./kg d.w. soil ² EC ₁₀ = 0.12 mg a.s./kg d.w. soil ² EC _{10,CORR} = 0.06 mg a.s./kg d.w. soil ²
Earthworm (<i>Eisenia fetida</i>)	cis-DCVA	Mixed with soil after application to quartz sand /10%	Chronic	Reproduction	NOEC = 6.25 mg/kg d.w. soil NOEC _{CORR} = 3.13 mg/kg d.w. soil
Earthworm (<i>Eisenia fetida</i>)	3-PBA	Mixed with soil after application to quartz sand /10%	Chronic	Reproduction	NOEC = 4.8 mg/kg d.w. soil NOEC _{CORR} = 2.4 mg/kg d.w. soil
Other soil macroorganisms					

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
<i>Folsomia candida</i>	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.2% OM	Chronic	Mortality Reproduction	<p>LC₅₀ > 258 mg a.s./kg d.w. soil</p> <p>LC_{50,CORR} > 129 mg a.s./kg d.w. soil</p> <p>EC₅₀ = 60.3 mg a.s./kg d.w. soil</p> <p>EC_{50,CORR} = 30.15 mg a.s./kg d.w. soil</p> <p>EC₁₀ = 3.69 mg a.s./kg d.w. soil</p> <p>EC_{10,CORR} = 1.845 mg a.s./kg d.w. soil</p> <p>NOEC = 8.43 mg a.s./kg d.w. soil</p> <p>NOEC_{CORR} = 4.215 mg a.s./kg d.w. soil</p>
<i>Folsomia candida</i>	BAS 310 51 I	Mixed with soil as a solution / 5%	Chronic	Mortality Reproduction	<p>LC₅₀ > 100 mg prep./kg d.w. soil (5.0 mg a.s./kg d.w. soil)</p> <p>LC_{50,CORR} > 2.5 mg a.s./kg d.w. soil</p> <p>NOEC = 50 mg prep./kg d.w. soil (2.5 mg a.s./kg d.w. soil)</p> <p>NOEC_{CORR} = 1.25 mg a.s./kg d.w. soil</p> <p>EC₅₀ = 82.1 mg prep./kg d.w. soil (4.11 mg a.s./kg d.w. soil)</p> <p>EC_{50,CORR} = 2.055 mg a.s./kg d.w. soil</p> <p>EC₂₀ = 39.5 mg prep./kg d.w. soil (1.98 mg a.s./kg d.w. soil)</p> <p>EC_{20,CORR} = 0.99 mg a.s./kg d.w. soil</p> <p>EC₁₀ = 26.9 mg prep./kg d.w. soil (1.35 mg a.s./kg d.w. soil)</p> <p>EC_{10,CORR} = 0.675 mg a.s./kg d.w. soil</p> <p>NOEC = 25 mg prep./kg d.w. soil (1.25 mg a.s./kg d.w. soil)</p> <p>NOEC_{CORR} = 0.625 mg a.s./kg d.w. soil</p>

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
<i>Folsomia candida</i>	<i>cis</i> -DCVA	Mixed with soil after application to quartz sand / 5%	Chronic	Mortality	LC ₅₀ > 8 mg /kg d.w. soil LC _{50,CORR} > 4 mg/kg d.w. soil NOEC ≥ 8 mg/kg d.w. soil NOEC _{CORR} ≥ 4 mg/kg d.w. soil
				Reproduction	EC ₅₀ > 8 mg /kg d.w. soil EC _{50,CORR} > 4 mg/kg d.w. soil NOEC ≥ 8 mg/kg d.w. soil NOEC _{CORR} ≥ 4 mg/kg d.w. soil
<i>Folsomia candida</i>	3-PBA	Mixed with soil after application to quartz sand / 5%	Chronic	Mortality	LC ₅₀ = 400 mg /kg d.w. soil LC _{50,CORR} = 200 mg/kg d.w. soil NOEC = 200 mg/kg d.w. soil NOEC _{CORR} = 100 mg/kg d.w. soil
				Reproduction	EC ₅₀ > 400 mg /kg d.w. soil EC _{50,CORR} > 200 mg/kg d.w. soil NOEC = 200 mg/kg d.w. soil NOEC _{CORR} = 100 mg/kg d.w. soil
<i>Hypoaspis aculeifer</i>	Alpha-cypermethrin	Mixed with soil as a solution in acetone / natural soil with 2.1% OM	Chronic	Growth, reproduction	EC ₅₀ = 3.2 mg a.s./kg d.w. soil ² EC _{50,CORR} = 1.6 mg a.s./kg d.w. soil ² EC ₁₀ = 0.5 mg a.s./kg d.w. soil ² EC _{10,CORR} = 0.25 mg a.s./kg d.w. soil ²

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
<i>Hypoaspis aculeifer</i>	BAS 310 55 I	Mixed with soil as a solution / 5%	Chronic	Mortality	<p>LC₅₀ > 100 mg prep./kg d.w. soil (5.0 mg a.s./kg d.w. soil)</p> <p>LC_{50,CORR} > 2.5 mg a.s./kg d.w. soil</p> <p>NOEC ≥ 100 mg prep./kg d.w. soil (5.0 mg a.s./kg d.w. soil)</p> <p>NOEC_{CORR} ≥ 2.5 mg a.s./kg d.w. soil</p>
				Reproduction	<p>EC₅₀ > 100 mg prep./kg d.w. soil (5.0 mg a.s./kg d.w. soil)</p> <p>EC_{50,CORR} = 2.5 mg a.s./kg d.w. soil</p> <p>NOEC = 25 mg prep./kg d.w. soil (1.25 mg a.s./kg d.w. soil)</p> <p>NOEC_{CORR} = 0.625 mg a.s./kg d.w. soil</p>
<i>Hypoaspis aculeifer</i>	<i>cis</i> -DCVA	Mixed with soil after application to quartz sand / 5%	Chronic	Mortality	<p>LC₅₀ > 500 mg /kg d.w. soil</p> <p>LC_{50,CORR} > 250 mg/kg d.w. soil</p> <p>NOEC ≥ 500 mg/kg d.w. soil</p> <p>NOEC_{CORR} ≥ 250 mg/kg d.w. soil</p>
				Reproduction	<p>EC₅₀ > 500 mg /kg d.w. soil</p> <p>EC_{50,CORR} > 250 mg/kg d.w. soil</p> <p>NOEC = 125 mg/kg d.w. soil</p> <p>NOEC_{CORR} = 62.5 mg/kg d.w. soil</p>

Test organism	Test substance	Application method of test a.s./ OM ¹	Time scale	End point	Toxicity
<i>Hypoaspis aculeifer</i>	3-PBA	Mixed with soil after application to quartz sand / 5%	Chronic	Mortality	LC ₅₀ >1000 mg /kg d.w. soil LC _{50,CORR} > 500 mg/kg d.w. soil NOEC ≥ 1000 mg/kg d.w. soil NOEC _{CORR} ≥ 500 mg/kg d.w. soil
				Reproduction	EC ₅₀ > 1000 mg /kg d.w. soil EC _{50,CORR} > 500 mg/kg d.w. soil NOEC ≥ 1000 mg/kg d.w. soil NOEC _{CORR} ≥ 500 mg/kg d.w. soil

¹To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %);

²Endpoint derived from a study investigating the effects of alpha-cypermethrin on soil organisms communities. As SANCO/10329/2002 rev. 2 does not foresee testing of soil organisms communities, these endpoints are considered as supportive information only.

Higher tier testing (e.g. modelling or field studies)

A field study to test the potential effects and potential recovery of field populations of earthworms after application of BAS 310 55 I at a rate of 0.3 L and 0.6 L/ha (equivalent to 15.3 and 30.7 g a.s./ha). Application of 0.3 L BAS 310 55 I/ha had no adverse effects on the field populations of earthworms. The application of 0.6 L BAS 310 55 I also had no adverse effects on total earthworm abundance and biomass but caused a statistically significant reduction in adult biomass of *A. caliginosa* about 11 months after application. However, this reduction was ecologically not relevant (reduction < 30%).

Nitrogen transformation	Alpha-cypermethrin	Maximum tested rate of 100 mg a.s./kg d.w. soil; silty sand soil	4.47 % effect at day 28 at 100 mg a.s./kg d.w.soil.
	BAS 310 51 I	Maximum tested rate of 7.97 mg prep./kg d.w. soil; loamy sand soil	3.9% effect at day 28 at 7.97 mg prep./kg d.w. soil (= 0.4 mg a.s./kg d.w. soil)
	<i>cis</i> -DCVA	Maximum tested rate of 0.0114 mg/kg d.w. soil; loamy sand soil	7.09 % effect at day 28 at 0.0114 mg/kg d.w. soil
	3-PBA	Maximum tested rate of 0.02 mg/kg d.w. soil; loamy sand soil	10.42 % effect at day 28 at 0.02 mg/kg d.w. soil.

Toxicity/exposure ratios for soil organisms

Cereals at 1-2 x 10 g a.s./ha, oilseed rape at 1-2 x 10 g a.s./ha, lettuce and leafy cabbage at 1-2 x 10 g a.s./ha or 1 x 20 g a.s./ha, and cucumber and courgette at 1-2 x 15 g a.s./ha or 1 x 30 g a.s./ha.

Test organism	Test substance	Time scale	Soil PEC ¹	TER	Trigger
Earthworms					
<i>Eisenia fetida</i>	Alpha-cypermethrin	Chronic	0.0200	≥ 100	5
	BAS 310 55 I	Chronic	0.0200	≥ 32	5
	3-PBA	Chronic	0.0029	828	5
	DCVA	Chronic	0.0014	2232	5
Other soil macroorganisms					
<i>Folsomia candida</i>	Alpha-cypermethrin	Chronic	0.0200	92.25	5
	BAS 310 55 I	Chronic	0.0200	31.25	5
	3-PBA	Chronic	0.0029	34483	5
	DCVA	Chronic	0.0014	≥ 2857	5
<i>Hypoaspis aculeifer</i>	BAS 310 55 I	Chronic	0.0200	31.25	5
	3-PBA	Chronic	0.0029	≥ 172414	5
	DCVA	Chronic	0.0014	44643	5

¹Maximum PEC soil values were used

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not provided as ER ₅₀ test are available

Laboratory dose response tests

Species	Test substance	ER ₅₀ (g/ha) vegetative vigour	ER ₅₀ (g/ha) emergence	Exposure ¹ (g/ha)	TER	Trigger
onion (<i>Allium cepa</i> L.), oats (<i>Avena sativa</i> L.), pea (<i>Pisum sativum</i> L.), rapeseed (<i>Brassica napus</i> L.), carrot (<i>Daucus carota</i> L.), sunflower (<i>Helianthus annuus</i> L.)	BAS 310 55 I	> 2.0 L prep./ha (> 100 g a.s./ha)	> 2.0 L prep./ha (> 100 g a.s./ha)	1) 0.277 g a.s./ha 2) 0.554 g a.s./ha	1) 361 2) 181	5

Extended laboratory studies : None

Semi-field and field test: None

Note: 1) For the use in cereals and oilseed rape; 2) for the use in lettuce and leafy cabbage;

¹ Exposure has been estimated based on Ganzelmeier drift data with a standard drift distance of 1 m for the use in cereals, oilseed rape, lettuce and leafy cabbage.

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	EC ₅₀ > 1000 mg a.s./L
<i>Pseudomonas sp</i>	No data available

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

No data available

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds¹

Compartment	
soil	alpha-cypermethrin
water	alpha-cypermethrin
sediment	alpha-cypermethrin
groundwater	alpha-cypermethrin

¹ metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Alpha-cypermethrin
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended] ⁷ :	H400 H410 M-factor = 1000
Peer review proposal ⁸ for harmonised classification according to Regulation (EC) No 1272/2008:	<p>Category Acute 1 Endpoint: 0.0126 µg a.s./L [48h EC50 <i>Chironomus riparius</i>] H400 (M-factor = 10000)</p> <p>Category Chronic 1 Endpoint: 0.0177 µg a.s./L [Chronic NOEC <i>Daphnia magna</i>] H410 (M-factor = 1000)</p>

⁷ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

