

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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)	beta-cyfluthrin
Function (<i>e.g.</i> fungicide)	Insecticide
Rapporteur Member State	Germany
Co-rapporteur Member State	Hungary

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

Chemical name (IUPAC)	<p>Cyano(4-fluoro-3-phenoxyphenyl)methyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate</p> <p>or</p> <p>3-(2,2-dichloro-vinyl)-2,2-dimethyl-cyclopropane-carboxylic acid cyano-(4-fluoro-3-phenoxy-phenyl)-methyl ester</p> <p>Diastereomer II</p> <p>(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl rel-(1S,3S)-3-(2,2- dichlo-rovinyl)-2,2-dimethylcyclopropanecarboxylate</p> <p>Diastereomer IV</p> <p>(R)-cyano(4-fluoro-3-phenoxyphenyl)methyl rel (1S,3R)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate</p>
Chemical name (CA)	<p>Cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, cyano (4-fluoro-3-phenoxyphenyl)methyl ester</p> <p>Diastereomer II</p> <p>cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (R)- cyano(4-fluoro-3-phenoxyphenyl)methyl ester, (1S,3S)-rel-</p> <p>Diastereomer IV</p> <p>cyclopropanecarboxylic acid, 3-(2,2-dichloroethenyl)-2,2-dimethyl-, (R)-cyano(4-fluoro-3-phenoxyphenyl)methyl ester, (1S,3R) rel-</p>
CIPAC No	482
CAS No	68359-37-5 (unstated stereochemistry)
EC No (EINECS or ELINCS)	269-855-7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

FAO Specification (including year of publication)

482/TC (1999) applicable to material from Bayer

Beta-cyfluthrin ≥ 965 g/kg

Diastereomer I maximum 2.0 %

Diastereomer II 30.0 – 40.0 %

Diastereomer III maximum 3.0 %

Diastereomer II 57.0 – 67.0 %

Minimum purity of the active substance as manufactured

Minimum purity 965 g/kg

Diastereomer II 300 - 400 g/kg

Diastereomer IV 570 - 670 g/kg

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

There are no relevant impurities in the technical material.

Molecular formula

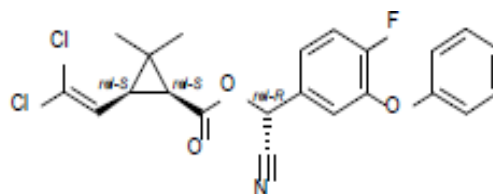
$C_{22}H_{18}Cl_2FNO_3$

Molar mass

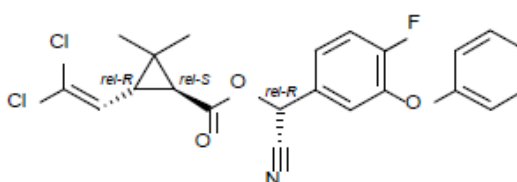
434.3 g/mol

Structural formula

Diastereomer II



Diastereomer IV



List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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

Melting point (state purity)	<p>Beta-cyfluthrin (98.8 %): 82 - 96 °C</p> <p>Isomer II (99.2 %): 80.7 °C</p> <p>Isomer IV (99.8 %): 106.2 °C</p>
Boiling point (state purity)	<p>Beta-cyfluthrin (98.8 %): The test item showed no boiling point at atmospheric condition, because it decomposed first at a temperature of approximately 210 °C.</p> <p>Isomer II (99.4 %): The test item showed no boiling point at atmospheric conditions because it decomposed first starting at a temperature of 260 °C (glass crucibles) and 270 °C (aluminium crucibles).</p> <p>Isomer IV (99.2 %): The test item showed no boiling point at atmospheric conditions because it decomposed first starting at a temperature of 255 °C (glass crucibles) and 260 °C (aluminium crucibles).</p>
Temperature of decomposition (state purity)	<p>Beta-cyfluthrin (98.8 %): approximately 210 °C.</p> <p>Isomer II (99.4 %): starting at a temperature of 260 °C (glass crucibles) and 270 °C (aluminium crucibles).</p> <p>Isomer IV (99.2 %): starting at a temperature of 255 °C (glass crucibles) and 260 °C (aluminium crucibles).</p>
Appearance (state purity)	<p>Beta-cyfluthrin (98.8 %): white powder</p> <p>Isomer II (99.4 %): white powder</p> <p>Isomer IV (99.2 %): white powder</p>
Vapour pressure (state temperature, state purity)	<p>Isomer II (99.4 %): 1.0 x 10⁻⁶ Pa at 25 °C</p> <p>Isomer IV (99.2 %): 4.6 x 10⁻⁶ Pa at 25 °C</p>
Henry's law constant	<p>Isomer II (99.4 %): 9.3 x 10⁻² Pa m³ mol⁻¹</p> <p>Isomer IV (99.2 %): 0.6 Pa m³ mol⁻¹</p>
Solubility in water (state temperature, state purity and pH)	<p>Isomer II (99.4 %): 2.1 µg/L at 20 °C (pH 6.4)</p> <p>Isomer IV (99.2 %): 1.6 µg/L at 20 °C (pH 6.4)</p>

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Solubility in organic solvents
(state temperature, state purity)

Solubility of Isomer II at 20 °C in g/L (99.3 %)

acetone	> 250
acetonitrile	> 250
dichloromethane	> 250
dimethylsulfoxide	> 250
ethylacetate	> 250
n-heptane	3.2
1-octanol	7.1
polyethyleneglycol	55
2-propanol	9.3
xylene	> 250

Solubility of Isomer IV at 20 °C in g/L (98.9 %)

acetone	> 250
acetonitrile	81
dichloromethane	> 250
dimethylsulfoxide	204
ethylacetate	> 250
n-heptane	1.2
1-octanol	2.8
polyethyleneglycol	27
2-propanol	4.3
xylene	103

Surface tension
(state concentration and temperature, state purity)

Not applicable - water solubility of the test item is lower than 1 mg/L.

Partition coefficient
(state temperature, pH and purity)

Isomer II (99.4 %): $\log P_{OW} = 5.9$ at 25 °C (pH 5.6)
Isomer IV (99.2 %): $\log P_{OW} = 5.8$ at 25 °C (pH 5.6)

Dissociation constant (state purity)

Not applicable; the substance does not have acid or alkaline properties. (Statement)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

UV/VIS absorption (max.) incl. ϵ
(state purity, pH)

Isomer II (99.3 %):		
λ_{max} [nm], ϵ [L mol ⁻¹ cm ⁻¹], pH		
204	41366	neutral
269	2129	neutral
276	2008	neutral
291	80	neutral
203	44498	acidic
269	2129	acidic
276	2008	acidic
291	80	acidic
220	29639	basic
295	1486	basic
Isomer IV (99.2 %):		
λ_{max} [nm], ϵ [L mol ⁻¹ cm ⁻¹], pH		
204	42545	neutral
269	2127	neutral
276	2000	neutral
291	85	neutral
204	42503	acidic
269	2042	acidic
276	1957	acidic
291	43	acidic
219	28888	basic
294	1617	basic
Beta-cyfluthrin technical is not flammable (99.1 %)		
Beta-cyfluthrin technical is neither explosive when heated in a closed tube, nor it is sensitive to shock, nor to friction. (98.8 %)		
Beta-cyfluthrin technical has no oxidizing properties. (99.1 %)		

Flammability (state purity)

Explosive properties (state purity)

Oxidising properties (state purity)

List of end points

Rapporteur Member State

Month and year

Active Substance (Name)

Germany	March 2017	beta-cyfluthrin
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Table Fehler! Kein Text mit angegebener Formatvorlage im Dokument.-1: GAP table - Supported Representative uses for products containing beta-Cyfluthrin (and imidacloprid)

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. as (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	L product / ha max	Water L/ha min-max	kg as/ha min-max (l)		
Beet	EU	Montur Forte	F	<i>Chaetocnema</i> spp <i>Atomaria linearis</i> <i>Agriotes ssp.</i> <i>Pegomya hyoscyami</i> , <i>Pegomya betae</i> <i>Scutigerella immaculata</i> <i>Blaniulus guttulatus</i> Aphids Thrips	FS	IMD: 150 CYB: 80	Seed treatment	00	1	na	na	na	IMD: 0.0195 CYB: 0.0104	na	Sowing rate: 1.30 u/ha 1 u = 100 000 seeds Dose rate: 0.10 L Pdt/u 0.13 L Pdt/ha
Potato	North-Zone, Central Zone	Bulldock 25 EC	F	Sucking and biting insects	EC	CYB: 25	Foliar spray	10-49	2	14 days	0.3	150 - 500	CYB: 0,075	3	
Potato	South Zone	Bulldock 25 EC	F	Sucking and biting insects	EC	CYB: 25	Foliar spray	10-49	2	14 days	0.5	300 - 1000	CYB: 0,125	3	
Wheat	North-Zone, Central Zone	Bulldock 25 EC	F	Sucking and biting insects	EC	CYB: 25	Foliar spray	Winter cereals BBCH 11-29 (autumn) BBCH 49-75 (spring) Spring cereals BBCH 10-75	2	14 days	0.3	150 - 400	CYB: 0,075	21	

List of end points

Rapporteur Member State

Month and year

Active Substance (Name)

Germany	March 2017	beta-cyfluthrin
---------	------------	-----------------

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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. as (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	L product / ha max	Water L/ha min-max	kg as/ha min-max (l)		
Wheat	South Zone	Bulldock 25 EC	F	Sucking and biting insects	EC	CYB: 25	Foliar spray	Winter cereals BBCH 11-29 (autumn) BBCH 49-75 (spring) Spring cereals BBCH 10-75	2	14 days	0.5	150 - 400	CYB: 0,125	21	
Tomato	EU	Bulldock 25 EC	G	Sucking and biting insects	EC	CYB: 25	Foliar spray	all BBCH up to PHI	2	14 days	0.7	500 - 1000	CYB: 0,175	3	

Pdt = product, CYB = beta-Cyfluthrin; IMD = imidacloprid

<p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p>	<p>(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. benthiaivalicarb-isopropyl).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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 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. as (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg as /hL min-max (l)	Water L/ha min-max	kg as/ha min-max (l)		

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|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(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).</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of applications possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|---|--|

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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. as (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg as /hL min-max (l)	Water L/ha min-max	kg as/ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

- (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

- (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. benthiavalicarb-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
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- (m) PHI - minimum pre-harvest interval

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

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

Brief statement on whether representative uses GAPs are supported

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

Brief statement on whether representative uses GAPs are supported

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

Brief statement on whether representative uses GAPs are supported

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

Activity against target organism	Not relevant.
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List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

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 as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV

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	cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers))
Food of animal origin	cyfluthrin (cyfluthrin including other mixtures of constituent isomers (sum of isomers))
Soil	beta-cyfluthrin
Sediment	beta-cyfluthrin
Water surface	beta-cyfluthrin
drinking/ground	beta-cyfluthrin
Air	beta-cyfluthrin
Body fluids and tissues	beta-cyfluthrin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS multi residue method (with ions m/z 226, 206, 199 validated for confirmation); ILV available; applicable for all matrix groups, LOQ = 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-ECD (DB-1 column, applicable for all matrix groups); ILV available; confirmatory analysis by GC-ECD (DB-1701 column), LOQ = 0.01 mg/kg
Soil (analytical technique and LOQ)	GC-ECD (DB-1 column); confirmatory analysis by NCI-GC-MS (HP-5ms column), LOQ = 0.01 mg/kg
Water (analytical technique and LOQ)	Drinking water: LC-MS/MS (with transitions m/z 451→191 and m/z 451→127 validated for confirmation), ILV available, LOQ = 0.01 µg/L Surface water: primary and confirmatory methods are missing, which allow the determination of 0.0002 µg/L beta-cyfluthrin

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Air (analytical technique and LOQ)

GC-MS/MS (VF-5ms column, m/z 163→127 and m/z 226→206 validated for confirmation),
LOQ = 0.069 µg/m³ for each isomer

Body fluids and tissues (analytical technique and LOQ)

Body fluids (blood): LC-MS/MS (with transitions m/z 451→191 and m/z 451→127 validated for confirmation)
LOQ = 0.05 mg/L
Tissues: GC-ECD (DB-1 column); confirmatory analysis by GC-ECD (DB-1701 column), LOQ = 0.01 mg/L

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

Substance

Beta-cyfluthrin

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:

None

Peer review proposal ² for harmonised classification according to Regulation (EC) No 1272/2008:

None

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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

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

Cyfluthrin: ≈90 % (based on urinary (≈50 %), faecal (≈12 %) and biliary (≈33 %) excretion within 48 h (single intravenous/intraduodenal/ oral low/high dose (0.5/10 mg/kg bw))
50 % of the faecally excreted radioactivity is due to an absorbed and biliary eliminated amount.
Beta-cyfluthrin: ≈60 % (based on urinary (≈57 %) and faecal (≈30 %) excretion within 48 h; (single oral low/high dose (0.5/10 mg/kg bw))

Distribution

Widely distributed (highest values in fatty tissue, adrenals, kidney and liver)

Potential for accumulation

No evidence for accumulation

Rate and extent of excretion

Rapid and extensive (>90 % within 48 h), mainly via urine (60 %, 12 % via faeces, 33 % via bile)

Metabolism in animals

Extensively metabolised (>95 %); main metabolites at radiolabelled cyclopropyl-moiety: cis/trans DCVA, DCVA acyl glucuronide;
Radiolabelled fluorophenyl-moiety: sulphate conjugate of OH-FPB, FPB-acid.
Parent compound was only detected in faeces (up to 20 %).
Cleavage of the ester bond, oxidation, hydroxylation and conjugation.

In vitro metabolism

Rat liver microsomes: beta-cyfluthrin is extensively metabolised (11 metabolite fractions)
Human liver microsomes: limited metabolism rate (2 metabolite fractions)
All metabolite fractions observed in human microsomes were also found in rats in similar portions.

Toxicologically relevant compounds (animals and plants)

Parent compound (animals); metabolites showed less acute oral toxicity compared to parent compound, no point mutations.

Toxicologically relevant compounds (environment)

Parent compound

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

Rat LD₅₀ oral

14.3 mg/kg bw (cyfluthrin, cremophor/water)
- 1189 mg/kg bw (cyfluthrin, PEG 400)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

	<u>14.3 mg/kg bw:</u> batch 816170019, purity 94.9 %, <u>TOX9401946</u> <u>1189 mg/kg bw:</u> batch 16001/79, purity 83.6 %, <u>TOX9401853</u>	
Mouse LD ₅₀ oral	91 mg/kg bw (beta-cyfluthrin, PEG 400) - 609 mg/kg bw (cyfluthrin, PEG 400) <u>91 mg/kg bw:</u> batch 16002/84, purity 99.1 %, <u>TOX9550256</u> <u>609 mg/kg bw:</u> batch 16001/79 purity 83.6 %, <u>TOX9401853</u>	Cat 2 H300
Rat/Rabbit LD ₅₀ dermal	Rat: >2000 mg/kg bw (beta-cyfluthrin, PEG 400) batch FFEBCTQ043, purity 99.2 %, <u>ASB2014-7721</u>	
Rat LC ₅₀ inhalation	<u>Aerosol (ethanol/PEG 400)</u> 0.081 mg/L air (beta-cyfluthrin, 4h-exposure, head-nose only; highest attainable analyt. concentration 0.097 mg/L, <u>TOX9550264</u>) - >1.089 mg/L (cyfluthrin, 1h-exposure, nose only; highest attainable analyt. concentration 1.1 mg/L, <u>TOX9401853</u>) <u>Dust</u> 0.532 mg/L air (beta-cyfluthrin, 4h-exposure, head-nose only; highest attainable concentration 0.867 mg/L, <u>TOX9550264</u>) - 0.967 mg/L (beta-cyfluthrin, 4h-exposure, head/nose; highest attainable analyte. concentration 0.841 mg/L, <u>TOX9550261</u>)	Cat 2 H330
Skin irritation	Non-irritant (beta-cyfluthrin): <u>ASB2014-7723</u>	
Eye irritation	Non-irritant (beta-cyfluthrin): <u>TOX9550265</u> , <u>ASB2014-7724</u>	
Skin sensitisation	Non-sensitizer (cyfluthrin): (<u>ASB2007-2854</u> [M&K])	
Phototoxicity	The phototoxicity study conducted with beta-cyfluthrin is not acceptable.	

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

Target / critical effect	Mortality at high doses (500 ppm ≈ 40 mg/kg bw/d) Behavioural/motor disturbances, reduced body weight development, choreoathetotic signs in rats and dogs	
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List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Relevant oral NOAELs

<p><u>Beta-cyfluthrin:</u> 28-d, rat: 1 mg/kg bw/d batch no.: 16002/84, purity: 98.5 % TOX9550271 90-d, dog: 2.4 mg/kg bw/d (60 ppm) batch no.: 16001/85, purity: 99.7 %) TOX9550274 <u>Cyfluthrin:</u> 1-year, dog: 2.4 mg/kg bw/d (100 ppm) batch no.: 4030059/BF9340-71 purity: 94.8-95.1 % TOX9800225</p>	
<p><u>Cyfluthrin:</u> 22/23-d, rat: local effects: 113 mg/kg bw/d systemic effects: 376 mg/kg bw/d batch no.: 2030025/BF9140-23 purity: 95.5-95.9 % TOX2001-1769</p>	
<p><u>Cyfluthrin:</u> 0.09 mg/L air (\approx0.02 mg/kg bw/d; rat, 6 h/day, head-nose exposure, 13-week, aerosol, 5 days per week) batch no: 816170019, purity: 94.9 % TOX9401887</p>	

Relevant dermal NOAEL

Relevant inhalation NOAEL

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

In vitro studies

<p>Ames: negative <u>Beta-cyfluthrin:</u> TOX9550277*, batch 16002/84, purity 98.5 % ASB2014-7875*, batch RD/Reg05-B-34-162/S-1, purity 98.6 % <u>Cyfluthrin:</u> TOX9401890*, batch 16001/79, purity 83.6 % TOX9401894*, batch Eg.3/81, purity 95 % TOX9401895*, batch unclear, purity 95 % <i>In vitro</i> HPRT/MLA: negative <u>Beta-cyfluthrin:</u> TOX9550280, batch 16001/85, purity 99.6 % <u>Cyfluthrin:</u> TOX9401899*, batch 3-03-0143, purity 94.7 % <i>In vitro</i> CA: negative <u>Cyfluthrin:</u> TOX9401901*, lot 233590478, purity 93.7 %</p>	
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List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

	<p><u>In vitro UDS**:</u> negative</p> <p><u>Beta-cyfluthrin:</u> TOX9550278, batch 16001/85, purity 99.5 %</p> <p>* supplementary studies ** submitted, but no guideline requirement</p>	
<i>In vivo</i> studies	<p><u>In vivo MN/CA:</u> negative</p> <p><u>Beta-cyfluthrin:</u> TOX9550279*, batch 16001/85, purity 99.6 %</p> <p><u>Cyfluthrin:</u> TOX9401891*, batch 16001/79, purity 83.6 %</p> <p>* supplementary studies</p>	
Photomutagenicity	Seems to be not triggered (Vol I, section 2.6.5).	
Potential for genotoxicity	No genotoxic potential (beta-cyfluthrin and cyfluthrin).	

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

Long-term effects (target organ/critical effect)	Body weight decreases, skin findings due to scratching (paresthesia)	
Relevant long-term NOAELs	<p><u>Cyfluthrin:</u> 2-yr, rat: 2.6 mg/kg bw/d (50 ppm) batch no.: 4030059/BF9340-71 purity: 93.9–95.1 %, TOX2001-1766</p> <p><u>Cyfluthrin:</u> 18-mo, mouse: males: 32 mg/kg bw/d (200 ppm); females: < 38 mg/kg bw/d (200 ppm) batch no: 030059/BF9340-71 purity: 93.9–95.1 %, TOX2001-1770</p>	
Carcinogenicity (target organ, tumour type)	No evidence for carcinogenicity	
Relevant NOAEL for carcinogenicity	None	

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

Reproduction target / critical effect	<p>Parental toxicity: Splaying of hindlimbs, bw reduction</p> <p>Offspring's toxicity: Coarse tremors, bw reduction during lactation</p>	Lact H362
Relevant parental NOAEL	<p><u>Cyfluthrin:</u> 3.3 mg/kg bw/d (50 ppm) batch no. 2030025 purity: 94.6–96.2 % TOX2001-1771</p>	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Relevant reproductive NOAEL

Cyfluthrin: 26.7 mg/kg bw/d (400 ppm)
batch no. 2030025 purity: 94.6–96.2 %
[TOX2001-1771](#)

Relevant offspring NOAEL

Cyfluthrin: 3.3 mg/kg bw/d (50 ppm)
batch no. 2030025 purity: 94.6–96.2 %
[TOX2001-1772](#) (supplemental to [TOX2001-1771](#))

Developmental toxicity

Developmental target / critical effect

Rat:
Maternal toxicity: Mortality, bw reduction, hypoactivity, locomotor incoordination, salivation).
Developmental toxicity: bw reduction, retarded ossification
Rabbit:
Maternal toxicity: Abortion
Developmental toxicity: No effects

Relevant maternal NOAEL

Beta-cyfluthrin+Cyfluthrin: Rat: 3 mg/kg bw/d
batch-no.: 3030125 purity: 96.5–97.3 %
[TOX2001-1773](#)
batch no: 16001/79; purity: ≈ 85 %
[TOX9401908](#)
Rabbit: 15 mg/kg bw/d
batch no. 816170019, purity: 95.0 %
[TOX9401914](#)

Relevant developmental NOAEL

Beta-cyfluthrin: Rat: 10 mg/kg bw/d
batch-no.: 3030125 purity: 96.5–97.3 %
[TOX2001-1773](#)
Cyfluthrin: batch no: 816170019, purity: 93.4 %)
[TOX9401909](#)
Rabbit: 45 mg/kg bw/d
batch no. 816170019, purity: 95.0 %
[TOX9401914](#)

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

Acute neurotoxicity

Beta-cyfluthrin: reversible clinical signs in FOB (reduced motor and locomotor activity)
NOAEL: 2 mg/kg bw
Batch: 3030125 / 0250074; purity: 96.9 % - 97.3 %
[TOX2001-1265](#)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Repeated neurotoxicity

Beta-cyfluthrin: Clinical signs (paresthesia), decreased bw
NOAEL: 2.02 mg/kg bw/d (30 ppm)
Batch: 3030125 / 0250074; purity: 96.5 %- 97.3 %
[TOX2001-1266](#)

Developmental neurotoxicity

Beta-cyfluthrin:
Maternal: Lower bw development during gestation and lactation, no evidence for neurotoxicity
Offspring: Reduced pup weight gain, FOB: minimal resistance during handling, reduced startle response

NOAEL maternal and offspring: 11 mg/kg bw/d (125 ppm)
Batch: 8030130/380566042; purity: 95.1 % - 97.6 %)
[ASB2007-2856](#)

Delayed neurotoxicity in laying hens

Cyfluthrin (6 studies): bw loss, clinical signs, mortality at doses > 4000 mg/kg bw. No evidence of delayed neurotoxic activity. Single and repeated oral (gavage) application. No NOAEL derived
[TOX9401916](#)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance

Cyfluthrin and some metabolites were less efficient inhibitors of Na⁺-, K⁺- or Mg²⁺-activated transport ATPases than other substances like ouabain or DDT ([TOX9401939](#)).

Exposure of rats to cyfluthrin led to reflectory respiratory changes associated with effects on thermoregulation and the acid-base status ([TOX9401940](#)).

Cyfluthrin aerosol (up to 101 mg/m³ air) had no relevant impact on the arterial blood gases of rats but led to hypothermia ([TOX9401870](#), [Z14816](#)).

Oral administration of up to 500 mg/kg bw cyfluthrin to rats (PEG 400) had no impact on body temperature ([TOX9401863](#)).

A reduced acute toxicity of cyfluthrin was observed in an antidote study with musaril ([TOX9401941](#)).

Combined administration of cyfluthrin with other insecticides (unless omethoate) resulted in sub-additive acute toxic effect ([TOX9401950](#), [TOX9401946](#), [TOX9401947](#), [TOX9401948](#), [TOX9401949](#)).

Beta-cyfluthrin led to lower LD₅₀ values than cyfluthrin following i.p. injection ([TOX9550269](#), [TOX9550270](#), [TOX9401853](#), [TOX9401854](#)).

The s.c. LD₅₀ for cyfluthrin in PEG 400 was >2500 mg/kg bw in mice ([TOX9401853](#)).

The RD₅₀ values for beta-cyfluthrin in PEG 400/ethanol were 38 and 37 mg/m³ air for rats and mice, respectively ([TOX9550263](#), [TOX9550262](#)). After cyfluthrin administration the RD₅₀ value in rat was a bit higher ([TOX9550272](#)).

Mechanism studies

Cyfluthrin was detected in serum, fat and brain of rats following feed or gavage exposure ([TOX2001-1768](#)).
batch: 910420ELB09, purity 94.5 %
Cyfluthrin and beta-cyfluthrin exposure was associated with oxidative stress *in vivo* and *in vitro*, respectively([ASB2015-888](#), [ASB2015-790](#)).

Immunotoxicity

Human volunteer studies

1-h inhalation exposure to approx. 0.1 mg cyfluthrin/m ³ air appeared to be in the range of an irritant threshold concentration for humans (TOX2001-879)	STOT-SE cat. 3 May cause respiratory irritation (supported by developmental toxicity studies in rats)
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Indications for adverse effects on hormonal systems

The examined endpoints on reproduction did not indicate endocrine disrupting properties of (beta-) cyfluthrin.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Studies performed on metabolites or impurities

3-Phenoxy-4-fluorobenzyl alcohol:

Rat LD₅₀ oral: 1599 (male), 1600-1800 mg/kg bw (female), no batch given, purity 98.25 %, [TOX9401933](#)*

Ames test: negative, batch 21101986, purity 98.25 %, [TOX9401936](#)*

3-Phenoxy-4-fluorobenzaldehyde:

Rat LD₅₀ oral: 1248 (male), 1040 mg/kg bw (female), lot 2419, purity 98 %, [TOX9401927](#)

Rat LD₅₀ (dermal): >5000 mg/kg bw, lot 2419, purity 98 %, [TOX9401927](#)

Rat acute inhalation (vapour: 50 g): no dead animal, lot 2419, purity 98 %, [TOX9401927](#)*

Rabbit skin/eye irritation: negative, lot 2419, purity 98 %, [TOX9401927](#)

Ames test: negative, batch 816488001, purity 98.7 %, [TOX9401928](#)*

3-Phenoxy-4-fluorobenzoic acid:

Rat LD₅₀ oral: >5000 mg/kg bw (male, female), no batch given, purity 95.4 %, [TOX9401930](#)*

3-(4'-Hydroxyphenoxy)-4-fluorobenzoic acid:

Rat LD₅₀ oral: >1000 mg/kg bw (male, female), no batch given, purity 98 %, [TOX9401934](#)*

Ames test: negative, batch 4266, purity 98 %, [TOX9401935](#)*

3-Phenoxy-4-fluorobenzoic acid amide:

Rat LD₅₀ oral: >5000 mg/kg bw (male, female), no batch given, purity probable 98.2 % (HPLC) or 98.6 % (GC), [TOX9401929](#)*

Ames test: negative, no batch given, purity 98.8 %, [TOX9401938](#)*

±,-(R,S)-α-Carboxy-[3-phenoxy-4-fluoro]benzyl-1-(R,S)-trans-3-(2',2'-dichloroethen-1'-yl)-2,2-dimethylcyclopropanecarboxylic acid ester:

Rat LD₅₀ oral: >2500 mg/kg bw (male, female), no batch given, purity 99.1 %, [TOX9401931](#)*

±,-(R,S)-α-Carboxamido-[3-phenoxy-4-fluoro]benzyl-1-(R,S)-trans-3-(2,2-dichloroethen-1-yl)-2,2-dimethyl-cyclopropanecarboxylic acid ester:

Rat LD₅₀ oral: >2500 mg/kg bw (male, female), no batch given, purity 94.2 %, [TOX9401932](#)*

FCR 1272-Phenoxyethylester:

Rat LD₅₀ oral: >2500 mg/kg bw (male, female), batch KTS9818-1-2, purity 97.2 %, [TOX2002-1390](#)

Ames test: negative, batch KTS9818-1-2, purity 97.2-97.8 %, [TOX2002-1391](#)*

* supplementary studies

Other sources

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List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

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

No adverse effects in manufacturing personnel reported. Occupational medical surveillance of workers did not reveal any unwanted effects. Skin symptoms after dermal contact (paresthesia, pruritus, tautness, reddening of the facial skin) and signs of irritation in the oro-pharyngeal cavity or coughing after inhalative exposure to cyfluthrin in workers. TOX2001-879	STOT-SE cat. 3 May cause respiratory irritation
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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)	0.01	rat, 4-week	100
Acute Reference Dose (ARfD)	0.01	rat, 4-week	100
Acceptable Operator Exposure Level (AOEL systemic)	0.01	rat, 4-week	100
Acceptable Operator Exposure Level (AOEL inhalative)	0.000243	Rat, 13-week	100

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*)

Montur Forte FS 230 (beta-cyfluthrin 80 g/L):
0.1 % for the concentrate (80 g/L); 0.3 % for the intermediate dose (40 g/L), and 0.7 % for the low dose (11.4 g/L), applied dose approx. 10 µL/cm² (exposure area 1 cm² skin); based on an *in vitro* dermal absorption study in human skin ([ASB2014-7895](#))

Bulldock EC 25:
Human skin: 13 % for the concentrate (26.5 g/L, applied dose approx. 268 ± 4 µg/cm²) and 37 % for the dilution (0.013 g/L, applied dose approx. 0.13 µg/cm²); based on an *in vitro* dermal absorption study in rat and human skin membranes ([ASB2014-7885](#))

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

Operators

Bulldock 25 EC
Use: potatoes and wheat, tractor mounted equipment, application rate 0.0125 kg as/ha
Exposure estimates (model): % of AOEL_{syst./inhal.}
UK POEM
Without PPE: 241/34.3

³ If available include also reference values for metabolites

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

Workers

PPE (gloves m/L + gloves appl.):	37/34.3
<u>German model</u>	
Without PPE:	38/2.4
<u>Use: tomatoes, greenhouse, handheld equipment, application rate 0.0175 kg as/ha</u>	
<u>German model/Mich, 1996:</u>	
Without PPE:	157/16.3
PPE (gloves m/L):	91/16.3
<i>Montur Forte FS 230</i>	
<u>Use: beet, seed treatment, application rate 0.0104 kg as/ha</u>	
<u>Exposure estimates (model):</u>	<u>% of AOEL-S/inhal.</u>
<u>Seed TROPEX (70 kg body weight)</u>	
Without PPE:	270/10797
PPE (gloves, coverall, RPE):	29/ 864
<u>Seed TROPEX (60 kg body weight)</u>	
Without PPE:	315/12596
PPE (gloves, coverall, RPE):	34/ 1007
<u>Exposure studies (60 kg body weight), different operators for mixing/loading, seed coating and storage logistics</u>	
Without RPE:	- / 1347
RPE (during all tasks):	- /60
<i>Bulldock 25 EC</i>	
<u>Krebs et al. (2000)</u>	<u>% of AOELsyst./inhal.</u>
Without PPE:	43/*
<i>Montur Forte FS 230</i>	
<u>Seed TROPEX (70 kg bw)</u>	<u>% of AOELsyst./inhal.</u>
With PPE (gloves, coverall):	27/874
With PPE (gloves, coverall, RPE):	27/70
<u>Seed TROPEX (60 kg bw)</u>	<u>% of AOELsyst./inhal.</u>
With PPE (gloves, coverall):	32/1020
With PPE (gloves, coverall, RPE):	32/82
<i>Bulldock 25 EC</i>	
<u>Martin et al. (2008)</u>	<u>% of AOELsyst./inhal.</u>
Bystander (adult):	2.1/0.02
Bystander (child):	1.7/0.05
Resident (adult):	0.3/n.r.
Resident (child):	0.4/n.r.

Bystanders and residents

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 2 Mammalian Toxicology

<i>Montur Forte FS 230</i>	
<u>Martin et al.(2008)</u>	<u>% of AOEL_{syst./inhal.}</u>
Bystander (adult):	0.4/10.6
Bystander (child):	0.6/22.7
Resident (adult):	0.01/**
Resident (child):	0.2/**

* covered by operator exposure

**** covered by bystander exposure**

n.r.: not relevant

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

Substance :	Beta-cyfluthrin
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 :	Danger, Acute Tox. 2, H300*: Fatal if swallowed Danger, Acute Tox. 2, H330*: Fatal if inhaled
Peer review proposal ⁵ for harmonised classification according to Regulation (EC) No 1272/2008:	Lact., H362: May cause harm to breast-fed children Irritant, STOT SE 3, H335: May cause respiratory irritation

* Minimum classification based on the translation table in Annex VII to Regulation (EC) No 1272/2008. Annex VI, section 1.2.1 clarifies: if there is access to data or other information as specified in Part 1 of Annex I that lead to classification in a more severe category compared to the minimum classification, classification in the more severe category must then be applied.

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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

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	Tomato ^a	Brushing	1-35
		Apple ^a	Fruit spraying	0-28
	Root crops	Potato ^a	Foliar spraying	0-98
		Sugar beet ^b	Seed treatment	Commercial harvest
	Leafy crops	-	-	-
	Cereals/grass crops	Wheat ^a	Foliar spraying	1-21
	Pulses/Oilseeds	Soybean ^a	Foliar spraying	4-84 (leaves only); 88 (leaves, stalks, seeds)
		Cotton ^a	Foliar spraying (exp.1/2/4) Cotton boll spraying (exp. 3)	Leaves: 0-63 (exp.1) 7-37 (exp.2) 85 (exp. 4) Bolls: 53 (exp. 3)
	Miscellaneous			
^a Non-GLP-study, not complying with OECD 501. ^b GLP-study, complying with OECD 501. Metabolism after seed treatment fully acceptable. Metabolism data in crops after foliar application show coherent picture over all test systems investigated. Non-GLP and non-guideline compliant data are considered acceptable for regulatory decisions. However, severe limitations of the data base are outlined in Vol.3, B.7.				
Rotational crops (metabolic pattern) OECD Guideline 502	Crop groups	Crop(s)	PBI (days)	Comments
	Root/tuber crops	Red beet (root, leaf)	36, 121, 285	Limited efforts to identify the nature of residues in harvested crop (and soil) samples.
	Leafy crops	Kale	36, 121, 285	Indications for incorporation of radioactivity into natural plant constituents.
	Cereal (small grain)	Wheat (head, stalk foliage)	36, 121, 285	
	Other	-	-	
Rotational crop and primary crop metabolism similar?	Non-GLP study, not complying with OECD 502. Rotational crop studies are triggered by behaviour of parent in soil. Potential differences in the nature of residues between primary and rotational crops are not observed. The data package, although not comprising a stand-alone-study, is considered acceptable under conditions relevant for the assessment of representative uses within this RAR. Limitations of the data base are outlined in Vol.3, B.7.			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

Processed commodities (standard hydrolysis study) OECD Guideline 507	Conditions	Parent	FPBacid	FPBald	M7	Others
	20 min, 90°C, pH 4	106.5 %	-	-	-	-
	60 min, 100°C, pH 5	99.7 %	-	-	-	-
	20 min, 120°C, pH 6	12.1 %	4.9 %	33.6 %	21.9 %	5 compounds 1.3-6.2 %
Residue pattern in processed commodities similar to residue pattern in raw commodities?	GLP-study, complying with OECD 507. Residue pattern in processed commodities differs to RAC for conditions representative for sterilisation (relevant for tomato processing). No identification of major metabolite M7 performed (study outside data requirements). Similar for other processes.					
Plant residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers) Global residue definition, foliar and seed treatment uses					
Plant residue definition for risk assessment (RD-RA)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers) Global residue definition, foliar and seed treatment uses					
Conversion factor (monitoring to risk assessment)	None.					

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	5 ^c 3000 ^c	5 1	530N >300000N
	Goat/Cow	0.5 ^c ; 0.5 ^d ; 0.11 ^e , 1 ^e	5; 5; 7; 7	5-155N
	Pig	-	-	-
	Fish	10.6 mg/kg DM ^f	14	-
	^c Livestock: Non-GLP study, not complying with OECD 503 ^d Livestock: GLP study, not complying with OECD 503 ^e Livestock: GLP study, complying with OECD 503 ^f Fish: GLP-study, complying with SANCO/11187/2013 rev. 3 N rates referring to representative uses. Sufficient information available to allow for firm conclusions on livestock and fish metabolism.			
Time needed to reach a plateau concentration in milk and eggs (days)	Eggs: >96 hours Milk: 2-3 days			
Animal residue definition for monitoring (RD-Mo) OECD Guidance, series on pesticides No 31	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)			
Animal residue definition for risk assessment (RD-RA)	Cyfluthrin, including other mixtures of constituent isomers (sum of isomers)			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) (FAO, 2009)	Yes.

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

Confined rotational crop study (Quantitative aspect) OECD Guideline 502	<p>Non-GLP study, not complying with OECD 502.</p> <p>A quantitative transfer of radioactivity from cyfluthrin treated soil into rotational crops is demonstrated after application of 988 g as/ha (28N rate). TRRs in samples were highest in cereals (up to 0.348 mg/kg in heads). While parent cyfluthrin was detected in soil organic extracts of early samples (90 % of TRR at day 0 and 55 % at days 36 and 106), no cyfluthrin or its metabolites were identified in any rotational crop sample. Indications for incorporation of radioactivity into natural plant constituents are presented. It is not clear, in which chemical structure the radioactivity is taken up by plants.</p> <p>The data package, although not comprising a stand-alone-study, is considered complete under conditions relevant for the assessment of representative uses within this RAR. Limitations of the data base are outlined in Vol.3, B.7.</p>
Field rotational crop study OECD Guideline 504	<p>GLP study, not complying with OECD 504.</p> <p>The study, which is based on a targeted study design (limited number of crops, trials, PBI, samplings, regional spread) and on fully validated analytical methods for all matrices, supports the conclusions of other studies (primary and rotational crop metabolism, field trials, environmental fate), that no residues of beta-cyfluthrin are expected in rotational crops after treatment according to GAP.</p> <p>The data package, although not comprising a stand-alone-study, is considered complete under conditions relevant for the assessment of representative uses within this RAR. Limitations of the data base are outlined in Vol.3, B.7.</p>

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

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)			
			Cyfluthrin			
High water content	Head lettuce ^g	-24	26			
	Corn, wheat (green) ^g	-24	26			
	Apple, melon, tomato, cucumber, sugar cane raw, molasse ^g	-23	38			
High oil content	-	-	-			
High protein content	-	-	-			
High starch content	Corn, potato, wheat ^g	-23	38			
High acid content	-	-	-			
Miscellaneous	Peanut shells	-23	38			
^g GLP study, study design complying with OECD 506 in relevant points. Limitations of the data base are outlined in Vol.3, B.7.						
Animal	Animal commodity	T (°C)	Stability (Months)			
			Cyfluthrin			
Cow	Muscle ^{h,i}	-18 to -23	5			
Cow	Liver ^{h,i}	-18 to -23	3			
Cow	Kidney ^{h,i}	-18 to -23	1			
Cow	Milk ^{h,i}	Not reported	39			
Cow	Fat ^{h,i}	-18 to -23	5			
	Egg	No data	No data			
^h non-GLP study, not complying with OECD 506. ⁱ Based on data with incurred residues Limitations of the data base are outlined in Vol.3, B.7.						

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

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	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						
Sugar beet (root)	N+SEU	<0.01(10)	Combined data set fully acceptable.	0.01*	0.01	0.01
Sugar beet (leaf)	N+SEU	<0.01(10)	Combined data set fully acceptable.	0.01*	0.01	0.01
Tomato	Indoor	<0.01(3), 0.011(2), 0.012, 0.014, 0.016		0.03	0.016	0.011
Potato	NEU	<0.01(4)		0.01*	0.01	0.01
Potato	SEU	<0.01(3)		0.01*	0.01	0.01
Wheat (grain)	NEU	<0.01(3), 0.013, 0.016, <0.02(3)		0.04	0.02	0.013
Wheat (grain)	SEU	<0.01 (4)	Residue data set incomplete.	open	open	open
Wheat (straw)	NEU	0.72, 0.78, 0.24, 0.33, 0.83, 0.85, 0.18, 1.1				
Wheat (straw)	SEU	0.43, 0.71, 0.78, 0.42	Residue data set incomplete.			
Summary of the data on formulation equivalence; OECD Guideline 509						
Crop	Region	Residue data (mg/kg)	Recommendations/comments			
Sugar beet	N+SEU	No comparative assessment required.	Representative FS formulation.			
Tomato	Indoor	No comparative assessment required.	Representative EC formulation.			
Potato	N+SEU	No comparative assessment required.	Representative EC formulation.			
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			
Wheat (grain)	NEU	<0.01(2), 0.013, 0.016	Representative EC formulation			
Wheat (grain)	NEU	<0.01, <0.02(3)	Comparable SC formulation			
Wheat (grain)	SEU	No comparative assessment required.	Representative EC formulation			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

Crop	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)
Wheat (straw)	NEU	0.24, 0.33, 0.83, 0.85	Representative EC formulation			
Wheat (straw)	NEU	0.18, 0.72, 0.78, 1.1	Comparable SC formulation			
Wheat (straw)	SEU	No comparative assessment required.	Representative EC formulation			

- (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}).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	Comment	(mg/kg)	Comment
Representative uses				
Sugar beet leaves	0.01 ^a	all values <LOQ	0.01 ^a	all values <LOQ
Potato	0.01 ^a	all values <LOQ	0.01 ^a	all values <LOQ
Wheat grain	0.01		0.01 ^b	median residue
Wheat straw	0.72		1.1	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

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

Study designs follow largely OECD 505

MRL calculations

Highest expected intake
(mg/kg bw/d)
(mg/kg DM for fish)

Intake >0.004 mg/kg bw

Feeding study submitted

Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**

Muscle

Fat

Meat^(b)

Liver

Kidney

Milk^(a)

Eggs

Method of calculation^(c)

Ruminant				Pig/Swine		Poultry		Fish	
Beef cattle	0.006	Ram/Ewe	0.017	Breeding	0.001	Broiler	0.001	Carp	-
Dairy cattle	0.010	Lamb	0.022	Finishing	0.001	Layer	0.009	Trout	-
						Turkey	0.001	Fish intake >0.1 mg/kg DM	
Yes		Yes		No		Yes		Open	
Yes		Yes		No		Yes		No	
Level	Beef: 25-696N Dairy: 16-434N	Level	Lamb: 7-206N Ewe: 9-260N	Level	N rate Breed/Finish 178-5762	Level	Turkey: 760-7619N Layer: 90-901N	Level	N rate Carp/Trout
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
<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	-	-
0.022	0.03	0.048	0.05	<0.01	0.01*	<0.01	0.01*	-	-
<0.01		<0.01		<0.01		<0.01			
<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*		
<0.01	0.01*	<0.01	0.01*	<0.01	0.01*	<0.01	0.01*		
<0.01	0.01*	<0.01	0.01*						
<0.01	0.01*	<0.01	0.01*			<0.01	0.01*		
Tf		Tf		Tf		Tf			

^(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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

STMR calculations	Ruminant				Pig/Swine		Poultry		Fish	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.004	Ram/Ewe	0.012	Breeding	0.001	Broiler	0.001	Carp	-
	Dairy cattle	0.007	Lamb	0.015	Finishing	0.001	Layer	0.006	Trout	-
							Turkey	0.001		
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and N rates	Level	Beef: 37-1024N Dairy: 23-639N	Level	Lamb: 11-310N Ewe: 14-391N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	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	<0.1 mg/kg at 639N	<0.01	<0.1 mg/kg at 310N	<0.01	<0.1 mg/kg at 4899N	<0.01	<0.01 mg/kg at 240N max	<0.01	-	-
Fat	0.25 mg/kg at 23N	0.011	0.25 mg/kg at 14N	0.018	0.25 mg/kg at 178N	<0.01	<0.01 mg/kg at 240N max	<0.01	-	-
Meat ^(a)	-	<0.01	-	<0.01	-	<0.01		<0.01		
Liver	0.13 mg/kg at 229N	<0.01	0.13 mg/kg at 111N	<0.01	0.13 mg/kg at 1753N	<0.01	<0.01 mg/kg at 240N max	<0.01		
Kidney	0.17 mg/kg at 229N	<0.01	0.17 mg/kg at 111N	<0.01	0.17 mg/kg at 1753N	<0.01				
Milk	0.14 mg/kg at 229N	<0.01	0.14 mg/kg at 111N	<0.01						
Eggs							<0.01 mg/kg at 240N max	<0.01		
Method of calculation ^(c)	Tf		Tf		Tf		Tf			

^(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.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Germany	March 2017	beta-cyfluthrin

Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Not relevant.

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

Study compliant to OECD 508

Study compliant to OECD 508				
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	
Representative uses				
Washed tomatoes	2	0.82, 0.79	0.81	-
Canned tomatoes	2	0.05, 0.12	0.08	-
Tomato wet pomace	2	3.1, 3.2	3.14	-
Tomato raw juice	2	0.45, 0.12	0.28	-
Tomato raw puree	2	0.82, 0.47	0.64	-

^(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)

Including all uses (representative uses and uses related to an MRL application).

ADI

TMDI according to EFSA PRIMo

IEDI (% ADI), according to EFSA PRIMo

Factors included in the calculations

0.01 mg/kg bw per day

Highest TMDI: 129 % ADI (UK toddler)

Not calculated

none

ARfD

IESTI (% ARfD), according to EFSA PRIMo

Factors included in IESTI and NESTI

0.01 mg/kg bw

Highest IESTI: 874 % ARfD (Scarole)

Existing MRL input values

Consumer risk assessment limited to the representative uses

TMDI (% ADI), according to EFSA PRIMo

IEDI (% ADI), according to EFSA PRIMo

Factors included in the calculations

Highest TMDI: 6 % ADI (NL child)

Not calculated

Residues at MRL levels conforming to representative uses

IESTI (% ARfD, according to EFSA PRIMo)

Factors included in IESTI and NESTI

Highest IESTI: 17 % ARfD (tomato)

Residues at MRL levels conforming to representative uses

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

MRLs do not need to be proposed based on representative uses pending submission of additional residue data (S-EU, wheat grain).

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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	47.3 % after 94 d, [¹⁴ C-fluorophenyl]-label (n = 1) 41.0 – 44.1 % after 91 d, [¹⁴ C-cyclopropane]-label (n = 3)
Non-extractable residues after 100 days	33.4 % after 94 d, [¹⁴ C-fluorophenyl]-label (n = 1) 29.2 – 45.7 % after 91 d, [¹⁴ C-cyclopropane]-label (n = 3)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	FPB-acid: 12.7 % after 7 d, [¹⁴ C-fluorophenyl]-label (n = 1) DCVA: 11.2 % after 3 d – 40.5 % after 7 d, [¹⁴ C-cyclopropane]-label (n = 3)

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

Mineralisation after 100 days	8.1 % after 91 d, [¹⁴ C-fluorophenyl]-label (n = 1) 4.7 % after 91 d, [¹⁴ C-cyclopropane]-label (n = 1)
Non-extractable residues after 100 days	8.7 % after 91 d, [¹⁴ C-fluorophenyl]-label (n = 1) 4.4 % after 91 d, [¹⁴ C-cyclopropane]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	FPB-acid: 63,9 % at 91 d (n = 1) DCVA: 75,7 % at 120 d (n = 1) [¹⁴ C-fluorophenyl]-label & [¹⁴ C-cyclopropane]-label

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)	FPB-acid: 22.3 % at 18 d, 2.1 % at 1 d
Mineralisation at study end	1.8 % after 18 d, [¹⁴ C-fluorophenyl]-label (n = 1)
Non-extractable residues at study end	16 % after 91 d, [¹⁴ C-fluorophenyl]-label (n = 1)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Parent	Dark aerobic conditions						
Soil type	--	pH ^{a)}	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa ^{b)}	St. (χ^2)	Method of calculation
sandy clay loam		4.9	20 °C / 30.9	15.8 / 194	89.5	2.2	DFOP
silt loam		5.5	20 °C / 26.3	8.5 / 66	17.7	3.1	FOMC
sandy loam		7.1	20 °C / 11.2	5.9 / 67	16.7	2.8	FOMC
sandy loam		6.9	20 °C / 13.2	12.3 / 88	23.6	1.6	FOMC
Geometric mean (if not pH dependent)					28.1		
pH dependence: no							

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

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

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)

Metabolite DCVA	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was beta-cyfluthrin							
Soil type	--	pH ^{a)} CaCl ₂	t. °C / gravimetric moisture % w/w	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
sandy clay loam		4.9	20 °C / 30.9	4.7 / 16	0.766	4.2	6.9	DFOP-SFO
silt loam		5.5	20 °C / 26.3	1.7 / 5.5	0.849	1.5	1.9	FOMC-SFO
sandy loam		7.1	20 °C / 11.2	8.5 / 28	1.0	7.1	20.6	FOMC-SFO
Geometric mean (if not pH dependent)						3.5		
Arithmetic mean					0.872			
pH dependence: no								

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

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Metabolite FPB-acid	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was beta-cyfluthrin							
Soil type	--	pH ^{a)} CaCl ₂	t. °C / gravimetric moisture % w/w	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
sandy loam		6.9	20 °C / 13.2	2.9 / 9.8	0.812	2.6	3.6	FOMC-SFO
silt loam		5.4	20 °C / 35.6	1.0 / 3.4	-	1.0	3.7	SFO
silt loam		6.2	20 °C / 30.9	0.9 / 2.9	-	0.8	3.5	SFO
clay loam		7.3	20 °C / 46.9	1.0 / 3.2	-	1.0		SFO
Geometric mean (if not pH dependent)						1.2		
Arithmetic mean					0.872			
pH dependence: no								

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

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

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)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	--	pH ^{a)}	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ^2)	DT ₅₀ (d) Norm ^{b)} .	Method of calculation
loam	S-France		7.4	0 - 10	45	258	10.9	-	HS
loam	N-France		8.3	0 - 10	29.7	99	17.4	-	SFO
silty clay	Spain		8.1	0 - 10	3.3	52	18	-	FOMC
clay loam	Germany		7.2	0 - 10	27.9	359	12.9	-	HS
Geometric mean (if not pH dependent)									
pH dependence: no									

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

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

List of end points

Rapporteur Member State **Month and year** **Active substance and Plant Protection Product (Name)**

Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230
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Section 4 Environmental fate and behaviour

Metabolites	No data on metabolites from field dissipation studies.									
Soil type	Location	X^8	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
--										
Geometric mean (if not pH dependent)										
Arithmetic mean										
pH dependence, Yes or No										

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

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

As no temperature/moisture normalisation is provided, no combined endpoints for modelling can be derived.

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

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration

Not required.

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)

Parent	Dark anaerobic conditions						
Soil type	Label	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C ^{b)}	St. (χ^2)	Method of calculation
Madera sandy loam (CA, USA) (Total)	FL	7.8	20 ± 2°C / 11.2 at 1/3 bar	23.4 / 216.5	—	1.499	FOMC
	CY			29.5 / 180.6		4.661	FOMC
Geometric mean (if not pH dependent)							

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Met 1	No data provided.							
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
Geometric mean (if not pH dependent)								
Arithmetic mean								

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

^{b)} Normalised using a Q10 of 2.58

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

Parent	Soil photolysis					
Soil type	X ⁶	pH ^{a)}	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d) calculated at 30-50°N	St. (χ ²)	Method of calculation
Silt loam		6.7	1.55	41.6		

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

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.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Parent							
Soil Type	OC %	Soil pH ^{a)}	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
sandy loam	1.26	5.1	810	64286			
silt loam	0.9	7.3	1116	124000			
loamy sand	0.69	6.0	1244	180290			
loamy sand	1.12	6.7	1321	117946			
clay loam	2.44	6.5 (H ₂ O)	1793	73484			
Arithmetic mean					1257	112000	
Geometric mean					1216	104491	
Arithmetic mean							
pH dependence: no							

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

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)

Metabolite FPB-acid							
Soil Type	OC %	Soil pH ^{a)} CaCl ₂	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
sandy loam	1.0	5.3			1.23	123	0.749
clay loam	2.1	5.7			1.80	86	0.60
silt loam	2.07	6.5			1.03	50	0.595
sandy loam	1.64	6.1			0.65	39	0.733
loam	2.08	5.6			1.39	67	0.609
sandy clay loam	3.4	4.9			14.42	424	0.664
sandy loam	0.52	7.1			0.62	124	0.799
silt loam	1.04	5.5			1.76	176	0.561
Geometric mean (if not pH dependent)							
Arithmetic mean (if not pH dependent)							
pH dependence: yes							

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Metabolite DCVA							
Soil Type	OC %	Soil pH ^{a)} CaCl ₂	K _d (mL/g)	K _{doc} (mL/g)	K _F (mL/g)	K _{Foc} (mL/g)	1/n
sand	0.59	6.0			0.184	31.05	0.884
clay loam	1.6	7.5			0.224	13.95	0.871
sandy loam	0.8	4.3			2.893	356.15	0.957
sandy loam	2.0	5.1			1.4857	74.3	0.8845
silt loam	0.9	6.3			0.4331	14.9	0.7429
loam	4.4	7.3			0.3946	9.0	0.8878
loamy sand	2.0	5.9			0.5381	26.9	0.7895
silt loam	2.9	5.2			1.8673	64.4	0.8844
Geometric mean(if not pH dependent)							
Arithmetic mean (if not pH dependent)							
pH dependence: yes							

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

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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

Time period: 16 d Elution: 0.01 M CaCl ₂ Soils: clay loam (OM = 1.59, pH = 7.86) clay loam (OM = 0.22, pH = 8.71) Column: 40 × 4 cm
Cyfluthrin not found in leachate

Aged column leaching

Ageing: 0, 30 and 90 d Soil: Speyer BBA 2.1 (OC = 0.69) Column length: 26 cm
Leachate: 2 - 6 % total radioactivity 1 % active substance < 1 - 4 % FPB acid, < 1 % FPB aldehyde < 1 % CONH ₂ cyfluthrin > 80 % total residues/radioactivity retained in top third of the column

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

Elution: 545.8 mL (silty clay) and 373.8 mL (loamy sand) of distilled water Soils: Hagerstown silty clay (pH = 5.5, OM = 4.31 %) Tifton loamy sand (pH = 4.9, OM = 0.98) Column length: 30.5 cm
in bottom 12 - 18 cm: < 4 - 20 % DCVA < 1 - 15 % FPB acid

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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

Duration	180 d
location	Torre-Pacheco (Murcia, Spain)
Number of lysimeter	8 lysimeter
Dimensions of lysimeter	3.5 m × 4m × 1 m depth
Crop cultivation	none
Application rate (g/ha)	0.5 L of solution of 70 mL ha/L of 5% cyfluthrin
Soil properties	Soil A: clay loam (OM = 1.59, pH = 7.86, sand 37%, silt 30%, clay 33%) Soil B: clay loam (OM = 0.22, pH = 8.71, sand 37%, silt 33%, clay 30%)
Application date	7.05.2008
Total artificial precipitation	900 L
No cyfluthrin found in leachate	

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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: > 1 year at 20 °C

pH 7: 160 d (isomers III + IV) - 270 d (isomers I+ II) at 20 °C

pH 9:
33 h (isomers III + IV) - 42 h (isomers I+ II) at 20 °C
metabolite DCVA: stable pH 4, 7, 9

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 %

Natural light, 40 °N; DT₅₀ 5.88 – 4.99 days (spring and summer)

Quantum yield of direct phototransformation in water at $\lambda > 290$ nm

0.001149 mol · Einstein⁻¹

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

Readily biodegradable
(yes/no)

no data

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed ^{a)}	t. °C ^{c)}	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	Normalise d to x °C ^{c)}		At study temp	Norma lised to x °C ^{c)}		
Fresh (river Rhine, DE)	7.7 – 8.3	–	25				4	–	–	Pseudo-SFO
Metabolite FPB-acid				Max in total system: 69.7 % after 21 days ^{b)}						
Metabolite 4'-OH-FPB-acid				Max in total system: 2.3 % after 14 days ^{b)}						
Metabolite COOH-cyfluthrin				Max in total system: 2.5 % after 3 days ^{b)}						

^{a)} No sediment was added to the system.

^{b)} No DT₅₀ provided.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)

Parent	Distribution: max in water 40.14% after 0.5 h. Max. in sediment 68.36% after 6 h.									
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
Barmener	5.1-8.1	6.9	20	14.4 / 47.9	5.0	0.7 / 2.3	12.8	14.3 / 47.6 FOMC	5.4	DFOP decline fit
Genkel	4.6-8.0	4.6	20	53.0 / 103.7	9.8	0.4 / 1.3 SFO	19.6	81.5 / 180.8 HS	11.8	FOMC decline fit
Geometric mean at 20°C ^{b)}				27.6		0.5		34.1		

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

^{b)} Normalised using a Q10 of 2.58

Metabolite DCVA	Distribution: in water maximum 36 % applied at 2 d, in sediment maximum 23.7 % applied at 100 kinetic formation fraction (k_f/k_{dp}): not determined									
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
Genkel	4.6-8.0	4.6	20	113.8/378	10.5					DFOP-SFO
Geometric mean at 20°C ^{b)}										

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

^{b)} Normalised using a Q10 of 2.58

FPB-aldehyde	Distribution: in water maximum 1.1 % applied at 1 d, in sediment maximum 15.7 % applied at 1 d kinetic formation fraction (k_f/k_{dp}): not determined									
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
Lienden	7.0 – 8.3	7.8	22	10	23.1			11.2 / 37.1	15.1	SFO decline fit
Ijzendoorn	7.0 – 8.3	6.8	22	4.3	4.8			2.2 / 7.3	5.6	FOMC decline fit
Geometric mean at 20°C ^{b)}				6.6				5.0		

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

^{d)} Normalised using a Q10 of 2.58

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

FPB-acid	Distribution: in sediment maximum 24.3 % applied at 1 d, in water maximum 29.1 % applied at 11 d kinetic formation fraction (k_f/k_{dp}): not determined									
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
Lienden	7.0 – 8.3	7.8	22	7.8 / 25.9 SFO	2.7			5.2 / 17.3	3.8	FOMC decline fit
Ijzendoorn	7.0 – 8.3	6.8	22	4.0 / 13.3 SFO	4.1			5.5 / 18.4	7	FOMC decline fit
Geometric mean at 20°C ^{b)}										

^{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)
Barmener	5.1-8.1	6.9	36.72% after 100 d	28.7% after 14 d	12.19% after 100 d
Genkel	4.6-8.0	4.6	14.2% after 100 d	26.03% after 100 d	26.03% after 100 d

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

Direct photolysis in air

no data

Photochemical oxidative degradation in air

DT₅₀ of 17.8 hours derived by the Atkinson model (version 1.4). OH (24 h) concentration assumed = 5×10^5 OH/cm³

Volatilisation

from plant surfaces (BBA guideline): 18 % after 24 h

from soil surfaces (BBA guideline): 9 % after 24 h

Metabolites

n.a.

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

Soil:	beta-cyfluthrin, DCVA, FPB-acid
Surface water:	beta-cyfluthrin, DCVA, FPB-acid, FPB-aldehyde
Sediment:	beta-cyfluthrin, DCVA, FPB-acid, FPB-aldehyde
Ground water:	–
Air:	–

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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)	Not available.
Surface water (indicate location and type of study)	Not available.
Ground water (indicate location and type of study)	Not available.
Air (indicate location and type of study)	Not available.

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

Parent	Field or Lab: HS-kinetic, $k_1 = 0.0249$ (DT ₅₀ 27.8 d), $k_2 = 0.00485$ (DT ₅₀ 143 d), $t_b = 28$ d (maximum field, Robinson 2014d)
Method of calculation	
Application data	Crop: potato Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ % plant interception: 15 % Number of applications: 2 Interval (d): 14 Application rate(s): 12.5 g as/ha

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.0242	
Short term 24h			0.0241	0.0244
2d			0.0235	0.0241
4d			0.0224	0.0236
Long term 7d			0.0208	0.0227
28d			0.0142	0.0185
50d			0.0128	0.0163

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
100d			0.0102	0.0142
Plateau concentration	n. a.			

Metabolite DCVA
Method of calculation

Molecular weight relative to the parent: 209.1
DT₅₀ (d):
Kinetics:
Field or Lab:

Application data

Application rate assumed: maximum occurrence in soil
40.5 %

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.0047	
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	n. a.			

Metabolite FPB-acid
Method of calculation

Molecular weight relative to the parent: 232.2
DT₅₀ (d):
Kinetics:
Field or Lab:

Application data

Application rate assumed: maximum occurrence in soil
12.7 %

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

PEC _(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.0016	
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				
Plateau concentration	n. a.			

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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 v4.4.4
Crop: potato

Active substance:
Crop uptake factor: 0.0
Water solubility (mg/L): 0.00185 at pH 7 and 20°C
Vapour pressure: 1.33×10^{-6} Pa at 20°C
Geometric mean parent DT_{50 lab/field} x 32.2 d (not normalised)
K_{OC}: parent, arithmetic mean 112000 mL/g, arithmetic mean $1/n = 1$.

Metabolites:

FPB-acid

Crop uptake factor: 0
Water solubility (mg/L): 24000 at pH 7 and 20°C
Vapour pressure: 4.2×10^{-5} Pa at 20°C
Geometric mean parent DT_{50 lab/field} x 1.3 d (not normalised)
K_{OC}: parent, arithmetic mean 136 mL/g, arithmetic mean $1/n = 0.664$
Transformation fraction (from as): 0.812

DCVA

Crop uptake factor: 0
Water solubility (mg/L): 42000 at pH 7 and 20°C
Vapour pressure: 1.3×10^{-2} Pa at 20°C
Geometric mean parent DT_{50 lab/field} x 4.1 d (not normalised)
K_{OC}: parent, arithmetic mean 9 mL/g, arithmetic mean $1/n = 0.888$
Transformation fraction (from as): 0.872

Application rate

Gross application rate: 2 x 12.5 g as/ha.
Crop growth stage: BBCH 10 - 49
Canopy interception %: 15
Application rate net of interception: 10.63 g as/ha.
No. of applications: 2

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

Time of application (absolute or relative application dates): emergence

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

FOCUS PEARL 4.4.4 / Potato	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			FPB-acid	DCVA	Met III
	Chateaudun	< 0.001	< 0.001		
	Hamburg	< 0.001	< 0.001	0.001	
	Jokioinen	< 0.001	< 0.001		
	Kremsmunster	< 0.001	< 0.001		
	Okehampton	< 0.001	< 0.001		
	Piacenza	< 0.001	< 0.001		
	Porto	< 0.001	< 0.001		
	Sevilla	< 0.001	< 0.001		
	Thiva	< 0.001	< 0.001		

PEC_(gw) From lysimeter / field studies

No data

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

Parent

Parameters used in FOCUSsw step 1 and 2

Parameters used in FOCUSsw step 3 (if performed)

Application rate

FOCUSsw step 1 and 2 calculations not conducted.

Version control no.'s of FOCUS software:
 Water solubility (mg/L): 2.1 µg/L
 Vapour pressure: 2.2×10^{-6} Pa at 20°C
 Koc (mL/g): 112004
 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) 1.0
 Q10=2.58, Walker equation coefficient 0.7
 Crop uptake factor: 0

Crop and growth stage: wheat BBCH 10 - 49
 Number of applications: 2
 Interval (d): 14
 Application rate(s): 7.5 g as/ha
 Application window:

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg)	
			Actual	TWA	Actual	TWA
D 3	ditch	0 h	0.0314		0.114	
		24 h	0.00949	0.0162	0.0945	0.110
		2 d	0.00344	0.0112	0.0766	0.103
		4 d	0.000889	0.00648	0.0576	0.0878
		7 d	0.000309	0.00393	0.0439	0.0731
		14 d	0.000087	0.00205	0.0291	0.0551
		21 d	0.00004	0.00139	0.0212	0.0453
		28 d	0.000021	0.00105	0.0161	0.0388
		42 d	0.000116	0.00131	0.114	0.0403
D4	pond	0 h	0.00143		0.0252	
		24 h	0.00114	0.00123	0.0251	0.0252
		2 d	0.00103	0.00115	0.0250	0.0252
		4 d	0.000892	0.00105	0.0246	0.0252
		7 d	0.000761	0.000955	0.0238	0.0250
		14 d	0.000559	0.000805	0.0217	0.0246
		21 d	0.000429	0.000700	0.0194	0.0240
		28 d	0.000332	0.000620	0.0172	0.0232
		42 d	0.000208	0.000571	0.0135	0.0215
D4	stream	0 h	0.0264		0.0323	
		24 h	0.000025	0.00214	0.00789	0.0148
		2 d	0.000008	0.00108	0.00552	0.0108
		4 d	0.000003	0.000541	0.00383	0.00768
		7 d	0.000001	0.000310	0.00279	0.00579
		14 d	0.000000	0.000155	0.00179	0.00401
		21 d	0.000000	0.000104	0.00132	0.00319
		28 d	0.000000	0.000078	0.00103	0.00268
		42 d	0.000000	0.000077	0.00155	0.00264

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 4 Environmental fate and behaviour

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

Method of calculation

Not performed.

PEC

Maximum concentration

dust drift in sugar beet at sowing:

PEC 2 D (1 m) 0.007 g/ha beta-cyfluthrin

PEC 3 D 0.09 g/ha beta-cyfluthrin

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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				
<i>Serinus canaria</i> ,	as	Acute	LD ₅₀	92.2 ¹
<i>Colinus virginianus</i>	Preparation Bulldock EC 25	Acute	LD ₅₀	>2000
<i>Anas platyrhynchos</i>	as	Long-term	NOEC/NOAEL	269 ppm/ 37.74
Mammals				
(geometric mean of male rats and mice)	as	Acute	LD ₅₀	131.1
rat (<i>Rattus rattus</i>)	Preparation Bulldock EC 25	Acute	LD ₅₀	> 300 (as: 8.79) < 2000 (as:54.8)
rat (<i>Rattus rattus</i>) based on effects on reproduction in a 2- generation study	as	Long-term	NOAEL	3.3 mg/kg bw/d
<p>Endocrine disrupting properties (Annex Part A, points 8.1.5)</p> <p>Mammals: A detailed analysis of all the apical toxicological studies (developmental toxicity studies in rats and rabbits, reproductive toxicity study in rats, developmental neurotoxicity study in rats and long-term toxicity/carcinogenicity in mice and rats) on beta-cyfluthrin revealed no evidence of any reproducible endocrine effect. Therefore, based on a complete toxicological data set, there is no evidence of any endocrine disrupting potential of beta-cyfluthrin in mammals.</p> <p>Birds: The effects observed in the long-term studies with birds are not considered related to endocrine toxicity.</p>				
<p>Additional higher tier studies (Annex Part A, points 10.1.1.2):</p> <p><i>no studies submitted</i></p>				
<p>Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3):</p> <p><i>A study testing the acute toxicity of a Bulldock formulation to wild birds (Addy-Orduna, L et. al 2011) was found via literature research. Results are implemented in the geometric mean LD₅₀ for acute toxicity.</i></p>				

¹ Relevant for risk assessment; value lower than geometric mean-LD₅₀/10 of 183 mg/kg bw for [4] tested species.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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

Spray application of Bulldock EC 25 in wheat/potato at 7.5 g as/ha [x 2 (14 d)]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	1.43	62.4	1
All	Small omnivorous bird	Long-term	0.36	105	5
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	1.07	122.5	10
All	Small herbivorous mammal	Acute	1.07	> 8.2 ¹	10
All	Small herbivorous mammal	Long-term	0.27	12.2	5
Tier 1 in winter/spring wheat ¹					
BBCH 10-19	Small insectivorous mammal "shrew"	Acute	0.070	125.0	10
BBCH ≥ 20	Small insectivorous mammal "shrew"	Acute	0.050	175.9	10
BBCH ≥ 40	Small herbivorous mammal "vole"	Acute	0.378	23.2	10
BBCH 10-29	Small omnivorous mammal "mouse"	Acute	0.159	33.1	10
BBCH 30-39	Small omnivorous mammal "mouse"	Acute	0.034	66.3	10
BBCH ≥ 40	Small omnivorous mammal "mouse"	Acute	0.048	109.6	10
Tier 1 in potatoes ¹					
BBCH 10-19	Small insectivorous mammal "shrew"	Acute	0.070	0.070	10
BBCH ≥ 20	Small insectivorous mammal "shrew"	Acute	0.050	0.050	10
BBCH ≥ 40	Small herbivorous mammal "vole"	Acute	0.378	0.378	10
BBCH 10-40	Large herbivorous mammal "lagomorph"	Acute	0.156	0.156	10
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	Acute	0.097	0.097	10
BBCH 10-39	Small omnivorous mammal "mouse"	Acute	0.068	0.068	10

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH ≥ 40	Small omnivorous mammal "mouse"	Acute	0.048	0.048	10
Risk from bioaccumulation and food chain behaviour					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.104	362.1	5
Earthworm-eating mammals		Long-term	0.127	26	5
Fish-eating birds		Long-term	0.000049	771822	5
Fish-eating mammals		Long-term	0.000044	75568	5
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} xDWR	TER	Trigger
Leaf scenario	Since none of the representative crop uses falls into these categories, the leaf scenario does not apply to the use of Bulldock EC 25.				
Puddle scenario, Screening step					
Application rate (g as/ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					

¹ RA based on the toxicity endpoint of the formulation Bulldock. LD₅₀ > 300 mg/kg bw (>8.79 mg as/kg bw)

Spray application of Bulldock EC 25 in wheat/potato at 12.5 g as/ha [x 2 (14 d)]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	2.38	38.5	1
All	Small omnivorous bird	Long-term	0.60	63	5
Screening Step (Mammals)					
All	Small omnivorous bird	Acute	1.78	73.7	10
All	Small omnivorous bird	Acute	1.78	>4.93 ¹	10
All	Small omnivorous bird	Long-term	0.45	7.3	5
Tier 1 in winter/spring wheat¹					
BBCH 10-19	Small insectivorous mammal "shrew"	Acute	0.117	75.0	10
BBCH \geq 20	Small insectivorous mammal "shrew"	Acute	0.083	105.5	10

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
BBCH \geq 40	Small herbivorous mammal "vole"	Acute	0.631	13.9	10
BBCH 10-29	Small omnivorous mammal "mouse"	Acute	0.265	33.1	10
BBCH 30-39	Small omnivorous mammal "mouse"	Acute	0.133	66.3	10
BBCH \geq 40	Small omnivorous mammal "mouse"	Acute	0.080	109.6	10
Tier 1 in potatoes ¹					
BBCH 10-19	Small insectivorous mammal "shrew"	Acute	0.117	75.0	10
BBCH \geq 20	Small insectivorous mammal "shrew"	Acute	0.083	105.5	10
BBCH \geq 40	Small herbivorous mammal "vole"	Acute	0.631	13.9	10
BBCH 10-40	Large herbivorous mammal "lagomorph"	Acute	0.541	33.8	10
BBCH \geq 40	Large herbivorous mammal "lagomorph"	Acute	0.162	54.3	10
BBCH 10-39	Small omnivorous mammal "mouse"	Acute	0.113	77.6	10
BBCH \geq 40	Small omnivorous mammal "mouse"	Acute	0.080	109.6	10
Risk from bioaccumulation and food chain behaviour					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.063	603	5
Earthworm-eating mammals		Long-term	0.076	43	5
Fish-eating birds		Long-term	0.000049	771822	5
Fish-eating mammals		Long-term	0.000044	75568	5
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} xDWR	TER	Trigger
Leaf scenario	Since none of the representative crop uses falls into these categories, the leaf scenario does not apply to the use of Bulldock EC 25.				

¹ RA based on the toxicity endpoint of the formulation Bulldock. LD₅₀ > 300 mg/kg bw (>8.79 mg as/kg bw)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Application of Montur Forte FS 230 as seed treatment in sugar beet seeds at 10.4 g as/ha (beta-cyfluthrin) and 19.5 g as/ha (imidacloprid)

Growth stage	Indicator or focal species	Time scale	DGirtD-bird (mg/kg bw per day)	TER	Trigger
Screening Step (Birds) ingestion as grit					
BBCH0	medium granivorous bird	Acute	0.557 ¹	166	1
BBCH0	medium granivorous bird	Acute	1.628 ²	59.9	10
BBCH0	medium granivorous bird	Long-term	0.0033 ¹	6363	5
(Birds) ingestion of sugar beet seedlings					
A TER-calculation was not made. Referring to risk assessment for application of Gaucho as a seed treatment in sugar beet seeds [Imidacloprid Addendum 7 (January 2014)] the risk to birds is considered acceptable.					
Screening Step (Mammals) ingestion as grit					
According to the EFSA GD (2009) chapter 5.2.1 a risk assessment for mammals is not required in case of pelleted seeds.					
(Mammals) ingestion of sugar beet seedlings					
A TER-calculation was not made. Referring to risk assessment for application of Gaucho as a seed treatment in sugar beet seeds [Imidacloprid Addendum 7 (January 2014)] the risk to mammals is considered acceptable.					
Risk from bioaccumulation and food chain behaviour					
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	0.05	711.6	5
Earthworm-eating mammals		Long-term	0.061	54.3	5
Fish-eating birds		Long-term	0.000049	771822	5
Fish-eating mammals		Long-term	0.000044	75568	5
Risk from consumption of contaminated water					
Scenarios	Indicator or focal species	Time scale	PEC _{dw} xDWR	TER	Trigger
Leaf scenario	Since the representative crop use does not fall into these categories, the leaf scenario does not apply to the use of Montur Forte FS 230.				
Puddle scenario, Screening step					
Application rate (g as/ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed.					

¹based on beta-cyfluthrin only

²based on the total amount of both active substances and mixture toxicity

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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				
<i>Oncorhynchus mykiss</i>	as	Acute 96 hr (flow-through)	Mortality, LC ₅₀	0.068 µg as/L _(mm)
<i>Oncorhynchus mykiss</i>	Bulldock EC25	Acute 96 hr (flow-through)	Mortality, LC ₅₀	2.6 µg prep./L _(nom) 0.08 µg as/L _(mm)
<i>Oncorhynchus mykiss</i>	as	Chronic (58d ELS flow-through)	Growth, development, and behaviour NOEC	0.0042 µg as/L _(mm)
<i>Oncorhynchus mykiss</i>	FPB-acid	96 hr (static)	Mortality, LC ₅₀	4060 µg /L _(mm)
<i>Oncorhynchus mykiss</i>	DCVA	96 hr (static)	Mortality, LC ₅₀	>14700 (nom)
<i>Oncorhynchus mykiss</i>	FPB-aldehyde	96 hr (static)	Mortality, LC ₅₀	792 (nom)
Aquatic invertebrates				
<i>Hyaella azteca</i>	as	96 h (flow-through)	Mortality, EC ₅₀	0.000231 µg as/L _(mm)
<i>Daphnia magna</i>	Bulldock EC 25	48 h (semi-static)	Mortality, EC ₅₀	2.9 µg prep./L _(nom) 0.055 µg as/L _(mm)
<i>Daphnia magna</i>	Montur Forte FS 230	48 h (semi-static)	Mortality, EC ₅₀	4.2 µg prep./L _(nom)
<i>Americamysis bahia</i>	as	28 d (flow-through)	Development, NOEC	0.00041 µg as/L _(mm)
<i>Daphnia magna</i>	FPB-acid	48 h (static)	Mortality, EC ₅₀	39300 µg/L _(nom)
<i>Daphnia magna</i>	DCVA	48 h (static)	Mortality, EC ₅₀	25000 µg/L _(nom)
<i>Daphnia magna</i>	FPB-aldehyde	48 h (static)	Mortality, EC ₅₀	1300 µg/L _(nom)
Sediment-dwelling organisms				
<i>Chironomus riparius</i>	as	28 d (static, spiked water)	NOEC	0.4 µg as/L _(nom)
<i>Chironomus riparius</i>	as	28 d (static, spiked-	NOEC	< 0.125 µg as/kg dry sediment _(nom)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
		sediment)	EC ₁₀	0.17 µg as/kg dry sediment _(nom)
<i>Chironomus riparius</i>	Montur Forte	28 d (static)	NOEC	15.5 µg form/L _(nom)
<i>Chironomus riparius</i>	FPB-acid	Toxicity is addressed by the study with the active substance.		
<i>Chironomus riparius</i>	DCVA	Toxicity is addressed by alternative information replacing experimental studies according EFSA GD (2013).). (KIIA 8.2.5.4/04)		
<i>Chironomus riparius</i>	FPB-aldehyde	Toxicity is addressed by the study with the active substance.		
Algae				
<i>Scenedesmus subspicatus</i>	as	72 h (static)	Growth rate: E _r C ₅₀ (NOEC)	> 2 µg as/L _(nom)
<i>Pseudokirchneriella subcapitata</i>	Montur Forte FS 230	72 h (static)	Growth rate: E _r C ₅₀ (NOEC)	> 100 mg form./L _(nom)
Higher plant				
<i>Lemna gibba</i>	as	7d (semi-static)	E _r C ₅₀	> 0.84 µg as/L _(nom)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
Further testing on aquatic organisms				
<u>Fish acute:</u>				
tier 2: SSD median HC ₅ LC ₅₀ = 0.312 µg/L				
AF (assessment factor) = 9				
RAC _{acute} = 34.6 ng/L				
<u>Aquatic invertebrates:</u>				
tier	acute	chronic		
2	Geometric mean calculated on the basis of 4 species of invertebrates effect values [based on mean measured concentrations (ng/L)] <u>Daphnia magna:</u> 2d LC ₅₀ = 75.9 ng/L (geomean of LC ₅₀ = 55 ng/L and 105 ng/L) <u>Americamysis bahia:</u> 4d LC ₅₀ = 2.25 ng/L (geomean of values: 2,22 ng/L; 2,23 ng/L) <u>Gammarus pulex:</u> 4d LC 50 = 4,0 ng/L (mean of values for 2 and 7d) <u>Hyallela azteca:</u> 4d LC 50 = 0,23 ng/L Geomean LC ₅₀ : 3.54 ng/L AF = 100 RAC _{acute} = 0.0354	In a weight of evidence approach the selection of the lowest endpoint from the three invertebrate species tested is possible. Accounting for the part of the species sensitivity and a reduced AF of 6 is applied: <u>Daphnia magna:</u> NOEC (21 d) = 25 ng/L <u>A. bahia:</u> NOEC (21 d) = 0,41 ng/L <u>Gammarus pulex:</u> NOEC (21 d) = 0,43 ng/L AF = 6 RAC _{chronic} = 0.068 ng/L		
3	Based on an overall assessment taking into account the outcome of microcosm studies (Heimbach (2000; KIIIA1 10.2.3/03); Jenkins, W.R.(2014; KIIIA1 10.2.3/05) as well as results from laboratory studies ETO-RAC is 0.105 ng/L** ERO-RAC is 1.05 ng/L (** recommended, for details please refer to Volume 1 section 2.9.2.2)			

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity ¹
<p>Potential endocrine disrupting properties (Annex Part A, point 8.2.3)</p> <p>Based on the absence of any indication of relevant effects to fish up to 0.14 µg/L (adjusted² 0.0059 µg/L) in the FLC testing with <i>Pimephales promelas</i>, it is concluded that beta-cyfluthrin has no potential endocrine disrupting properties.</p>				

¹ (nom) nominal concentration; (mm) mean measured concentration; prep.: preparation; as: active substance

² As the study was conducted with cyfluthrin instead with beta-cyfluthrin the endpoint was multiplied with the factor 0.42.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	beta-Cyfluthrin	FPB-acid	DCVA	FPB-aldehyde
logP _{O/W}	5.9	2.6	2.5	2.6 (surrogate based on FPB-acid data)
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5 % lipid content)	2295	-	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5 % lipid content)	1822	-	-	-
Annex VI Trigger for the bioconcentration factor	2000	-	-	-
Clearance time (days) (CT ₅₀)	8.66 d			
(CT ₉₀)	26.5 d			
Level and nature of residues (%) in organisms after the 28 day depuration phase	0.017 µg/g			

* based on measured concentration of the parent substance

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spring spray application of Bulldock EC 25 at 7.5 g as/ha in winter wheat [x2 (14 d)]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyaella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
		0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D1/ditch	0.03350	2.03	0.125	0.00690	0.0122	59.7	11.9
D1/stream	0.04170	1.63	0.101	0.00554	0.00983	48.0	9.59
D2/ditch	0.03880	1.75	0.108	0.00595	0.0106	51.5	10.3
D2/stream	0.03410	1.99	0.123	0.00677	0.0120	58.7	11.7
D3/ditch	0.03830	1.78	0.110	0.00603	0.0107	52.2	10.4
D4/pond	0.00154	44.2	2.73	0.15	0.266	1300	260
D4/stream	0.03000	2.27	0.14	0.0077	0.0137	66.7	13.3
D5/pond	0.00168	40.5	2.5	0.138	0.244	1190	238
D5/stream	0.03320	2.05	0.127	0.00696	0.0123	60.2	12.0
D6/ditch	0.03850	1.77	0.109	0.006	0.0106	51.9	10.4
R1/pond	0.02500	2.72	0.168	0.00924	0.0164	80.0	16.0
R1/stream	0.00147	46.3	2.86	0.157	0.279	1360	272
R3/stream	0.03520	1.93	0.119	0.00657	0.0116	56.8	11.4
R4/stream	0.02500	2.72	0.168	0.00924	0.0164	80.0	16.0
Trigger**		100	10	100	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – autumn spray application of Bulldock EC 25 at 7.5 g as/ha in winter wheat [x2 (14 d)]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
		0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D1/ditch	0.03350	2.03	0.0290	0.00690	0.0122	59.7	11.9
D1/stream	0.04320	1.57	0.00929	0.00535	0.00949	46.3	9.26
D2/ditch	0.03860	1.76	0.0190	0.00598	0.0106	51.8	10.4
D2/stream	0.03290	2.07	0.0463	0.00702	0.0125	60.8	12.2
D3/ditch	0.03810	1.78	0.0298	0.00606	0.0108	52.5	10.5
D4/pond	0.03270	2.08	0.0494	0.00706	0.0125	61.2	12.2
D4/stream	0.00152	44.7	0.124	0.152	0.270	1320	263
D5/pond	0.03530	1.93	0.0408	0.00654	0.0116	56.7	11.3
D5/stream	0.001610	42.2	0.119	0.143	0.255	1240	248
D6/ditch	0.03850	1.77	0.0215	0.006	0.0106	51.9	10.4
R1/pond	0.02490	2.73	0.0121	0.00928	0.0165	80.3	16.1
R1/stream	0.00170	40.0	0.0879	0.136	0.241	1180	235
R3/stream	0.0350	1.94	0.00135	0.0066	0.0117	57.1	11.4
R4/stream	0.0250	2.72	0.0136	0.00924	0.0164	80.0	16.0
Trigger**		100	10	100	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spray application of Bulldock EC 25 at 7.5 g as/ha in spring wheat [x2 (14 d)]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
		LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
		0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D1/ditch	0.03910	1.74	0.0171	0.00591	0.0105	51.2	10.2
D1/stream	0.03350	2.03	0.035	0.00690	0.0122	59.7	11.9
D3/ditch	0.03830	1.78	0.0263	0.00603	0.0107	52.2	10.4
D4/pond	0.00150	45.3	0.152	0.154	0.273	1330	267
D4/stream	0.03130	2.17	0.0888	0.00738	0.0131	63.9	12.8
D5/pond	0.00170	40	0.135	0.136	0.2412	1180	235
D5/stream	0.03240	2.10	0.115	0.00713	0.0127	61.7	12.3
R4/stream	0.02500	2.72	0.133	0.00924	0.0164	80.0	16.0
Trigger**		100	10	100	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spray application of Bulldock EC 25 at 12.5 g as/ha in spring wheat [x2 (14 d)]

Scenario	PEC global	fish acute	fish chronic	Aquatic	Aquatic	Algae	Sed. dweller
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

max (µg/L)	invertebrates		invertebrates prolonged		prolonged	
	<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
	LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
	0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D1/ditch	0.065100	1.045	0.0103	0.00355	0.00630	30.7	6.14
D1/stream	0.055800	1.22	0.021	0.00414	0.00735	35.8	7.17
D3/ditch	0.063800	1.07	0.0158	0.00362	0.00643	31.3	6.27
D4/pond	0.002490	27.3	0.0909	0.0928	0.165	803	161
D4/stream	0.052200	1.30	0.0533	0.00443	0.00785	38.3	7.66
D5/pond	0.002830	24.0	0.0809	0.0816	0.145	707	141
D5/stream	0.054000	1.26	0.0691	0.00428	0.00759	37.0	7.41
R4/stream	0.041600	1.63	0.00798	0.00555	0.00986	48.1	9.62
Trigger**	100	10	100	10	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spring spray application of Bulldock EC 25 at 12.5 g as/ha in winter wheat [x2 (14 d)]

Scenario	PEC global	fish acute	fish chronic	Aquatic	Aquatic	Algae	Sed. dweller
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

max (µg L)	invertebrates		invertebrates prolonged		prolonged	
	<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
	LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
	0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D1/ditch	0.05580	1.22	0.0753	0.00414	0.00735	35.8	7.17
D1/stream	0.06950	0.978	0.0604	0.00332	0.00590	28.8	5.76
D2/ditch	0.06460	1.05	0.0650	0.00358	0.00635	31.0	6.19
D2/stream	0.05680	1.20	0.07392	0.00407	0.00722	35.2	7.04
D3/ditch	0.06380	1.07	0.0658	0.00362	0.00643	31.3	6.27
D4/pond	0.002560	26.6	1.64	0.0902	0.1605	781	156
D4/stream	0.050	1.36	0.084	0.00462	0.0082	40.0	8.0
D5/pond	0.00280	24.3	1.50	0.0825	0.146	714	143
D5/stream	0.05530	1.232	0.0759	0.00418	0.00741	36.2	7.23
D6/ditch	0.06410	1.063	0.0655	0.00360	0.00640	31.2	6.24
R1/pond	0.04160	1.63	0.101	0.00555	0.00986	48.1	9.62
R1/stream	0.002450	27.8	1.71	0.0943	0.167	816	163
R3/stream	0.05870	1.16	0.0716	0.00394	0.00698	34.1	6.81
R4/stream	0.04170	1.63	0.101	0.00554	0.00983	48.0	9.59
Trigger**	100	10	100	10	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – autumn spray application of Bulldock EC 25 at 12.5 g as/ha in winter wheat [x2 (14 d)]

Scenario	PEC global max	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates	Algae	Sed. dweller prolonged
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

(µg L)	prolonged					
	<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
	LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
	0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D3/ditch	0.03140	1.22	0.0174	0.00416	0.00738	36.0	7.20
D4/pond	0.00141	0.946	0.00558	0.00321	0.00570	27.8	5.56
D4/stream	0.02640	1.06	0.0114	0.00359	0.00638	31.1	6.22
D6/ditch	0.03110	1.24	0.0278	0.00422	0.00748	36.5	7.30
D6/ditch	0.03120	1.07	0.0179	0.00364	0.00646	31.5	6.30
R1/pond	0.00141	1.25	0.0296	0.00424	0.00752	36.7	7.34
R1/stream	0.02160	26.8	0.0741	0.0909	0.161	787	157
R2/stream	0.02850	1.16	0.0244	0.00393	0.00697	34.0	6.80
R3/stream	0.03040	25.3	0.0714	0.0859	0.152	743	149
D6/ditch	0.06410	1.06	0.0129	0.00360	0.00640	31.2	6.24
R1/pond	0.04140	1.64	0.00724	0.00558	0.00990	48.3	9.66
R1/stream	0.002840	24.0	0.0527	0.0813	0.144	704	141
R3/stream	0.05830	1.17	0.000808	0.00396	0.00703	34.3	6.86
R4/stream	0.04170	1.63	0.00816	0.00554	0.00983	48.0	9.59
Trigger**	100	10	100	10	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spray application of Bulldock EC 25 at 7.5 g as/ha in potatoes [x2 (14 d)]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

	<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
	LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
	0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D3/ditch	0.03140	2.17	0.0344	0.00736	0.0131	63.7	12.7
D4/pond	0.00141	48.2	0.15	0.164	0.291	1420	284
D4/stream	0.02640	2.58	0.130	0.00875	0.0155	75.8	15.2
D6/ditch	0.03110	2.19	0.0459	0.00743	0.0132	64.3	12.9
D6/ditch	0.03120	2.18	0.0423	0.00740	0.0131	64.1	12.8
R1/pond	0.00141	48.2	0.112	0.164	0.291	1420	284
R1/stream	0.02160	3.15	0.00816	0.0107	0.0189	92.6	18.5
R2/stream	0.02850	2.39	0.0084	0.00811	0.0144	70.2	14.0
R3/stream	0.03040	2.27	0.0166	0.00760	0.0135	65.8	13.2
Trigger**	100	10	100	10	10	10	10

*[Only scenarios where the trigger is not met at FOCUS_{sw} step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

FOCUS_{sw} step 3 - TERs for beta-cyfluthrin – spray application of Bulldock EC 25 at 12.5 g as/ha in potatoes [x2 (14 d)]

Scenario	PEC global max (µg L)	fish acute	fish chronic	Aquatic invertebrates	Aquatic invertebrates prolonged	Algae	Sed. dweller prolonged
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List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

	<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Hyalella azteca</i>	<i>Americamysis bahia</i>	<i>Pseudokirchn. subcapitata</i>	<i>Chironomus riparius</i>
	LC ₅₀	NOEC	EC ₅₀	NOEC	EC ₅₀	NOEC
	0.068 µg/L	0.0042 µg/L	0.000231 µg/L	0.00041 µg/L	>2 µg/L	0.4 µg/L

2FOCUS Step 3*

D3/ditch	0.05230	1.30	0.0206	0.00442	0.00784	38.2	7.65
D4/pond	0.002360	28.9	0.0901	0.0979	0.174	847	169
D4/stream	0.0440	1.55	0.0781	0.00525	0.00932	45.5	9.09
D6/ditch	0.05180	1.31	0.0275	0.00446	0.00792	38.6	7.72
D6/ditch	0.05190	1.31	0.0253	0.00445	0.00790	38.5	7.71
R1/pond	0.002360	28.8	0.0673	0.0979	0.174	847	169
R1/stream	0.0360	1.89	0.00489	0.00642	0.0114	55.6	11.1
R2/stream	0.04750	1.43	0.00504	0.00486	0.00863	42.1	8.42
R3/stream	0.05070	1.34	0.00996	0.00456	0.00809	39.4	7.89
Trigger**	100	10	100	10	10	10	10

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

FOCUSsw step 4 - TER values for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in winter wheat, application in spring] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 % drift reduction	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	<i>Overall assessment/microcosm</i>
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.0003010	1040	14.0	0.349
D1/stream	0.00030	1040	14.0	0.350
D2/ditch	0.0003070	1020	13.7	0.342
D2/stream	0.0003060	1020	13.7	0.343
D3/ditch	0.0003030	1030	13.9	0.347
D4/pond	0.0001140	2740	36.8	0.921
D4/stream	0.0002690	1160	15.6	0.390
D5/pond	0.0001250	2500	33.6	0.840
D5/stream	0.0002980	1050	14.1	0.352
D6/ditch	0.0003050	1020	13.8	0.345
R1/pond	0.0002240	1390	18.8	0.469
R1/stream	0.000110	2840	38.2	0.955
R3/stream	0.0003170	984	13.2	0.331
R4/stream	0.0002830	1100	14.8	0.371
TER criterion		9	10	1

FOCUSsw step 4 - TER values for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in winter wheat, application in autumn] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 % drift reduction	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	<i>Overall assessment/microcosm</i>
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.0003010	1040	14.0	0.349
D1/stream	0.0003420	912	12.3	0.307
D2/ditch	0.0003060	1020	13.7	0.343
D2/stream	0.0002950	1060	14.2	0.356
D3/ditch	0.0003020	1030	13.9	0.348
D4/pond	0.0002940	1060	14.3	0.357

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

D4/stream	0.0001130	2760	37.2	0.929
D5/pond	0.0003170	984	13.2	0.331
D5/stream	0.0001200	2600	35.0	0.875
D6/ditch	0.0003050	1020	13.8	0.344
R1/pond	0.0003360	929	12.5	0.312
R1/stream	0.0001270	2460	33.1	0.827
R3/stream	0.0003600	867	11.7	0.292
R4/stream	0.0004890	638	8.59	0.215
TER criterion		9	10	1

FOCUSsw step 4 - TER values for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in spring wheat (20 m + 90 % drift reduction measures)]

Focus scenario	Step 4 20m + 90 % drift reduction	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	Overall assessment/microcosm
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.000309	1010	13.6	0.340
D1/stream	0.000301	1040	14.0	0.349
D2/ditch	0.000303	1030	13.9	0.347
D2/stream	0.000111	2810	37.8	0.946
D3/ditch	0.000281	1110	14.9	0.374
D4/pond	0.0001270	2460	33.1	0.827
D4/stream	0.000291	1070	14.4	0.361
D5/pond	0.0002820	1110	14.9	0.372
TER criterion		9	10	1

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

FOCUSsw step 4 - TER values for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in winter wheat, application in spring] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 %	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	<i>Overall assessment/microcosm</i>
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.0006010	519	6.99	0.175
D1/stream	0.000330	945	12.7	0.318
D2/ditch	0.0003070	020	13.7	0.342
D2/stream	0.0006120	510	6.86	0.172
D3/ditch	0.0003030	1030	13.9	0.347
D4/pond	0.0001140	2740	36.8	0.921
D4/stream	0.0005390	579	7.79	0.195
D5/pond	0.0001250	2500	33.6	0.840
D5/stream	0.0005960	523	7.05	0.176
D6/ditch	0.0003050	1020	13.8	0.344
R1/pond	0.0004490	695	9.35	0.234
R1/stream	0.000110	2840	38.2	0.955
R3/stream	0.0006330	493	6.64	0.166
R4/stream	0.0004710	662	8.92	0.223
TER criterion		9	10	1

FOCUSsw step 4- TER values for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in winter wheat, application in autumn] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 %	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	<i>Overall assessment/microcosm</i>
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.0006020	518	6.98	0.174
D1/stream	0.0003420	912	12.3	0.307
D2/ditch	0.000306	1020	13.7	0.343
D2/stream	0.0005910	528	7.11	0.178
D3/ditch	0.0003020	1030	13.9	0.348

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

D4/pond	0.0005870	532	7.16	0.179
D4/stream	0.0001130	2760	37.2	0.929
D5/pond	0.0006340	492	6.62	0.166
D5/stream	0.0001200	2600	35.0	0.875
D6/ditch	0.0003050	1020	13.8	0.344
R1/pond	0.0005610	556	7.49	0.187
R1/stream	0.0001280	2440	32.8	0.820
R3/stream	0.000638	489	6.58	0.165
R4/stream	0.0008140	383	5.16	0.129
TER criterion		9	10	1

FOCUSsw step 4- TER values for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in spring wheat (20 m + 90 % drift reduction measures)]

Focus scenario	Step 4 20m + 90 % drift reduction	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	<i>Overall assessment/microcosm</i>
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D1/ditch	0.000309	1010	13.6	0.340
D1/stream	0.000601	519	6.99	0.175
D3/ditch	0.000303	1030	13.9	0.347
D4/pond	0.000111	2810	37.8	0.946
D4/stream	0.000563	554	7.46	0.187
D5/pond	0.000127	2460	33.1	0.827
D5/stream	0.000582	536	7.22	0.180
R4/stream	0.000470	664	8.94	0.223
TER criterion		9	10	1

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

FOCUSsw step 4- TER values for beta-cyfluthrin [2 x 7.5 g as/ha (14 d) in potatoes] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 %	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	Overall assessment/microcosm
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D3/ditch	0.0003020	1030	13.9	0.348
D4/pond	0.0001090	2860	38.5	0.963
D4/stream	0.0002750	1130	15.3	0.382
D6/ditch	0.0002990	1040	14.0	0.351
D6/ditch	0.0003000	1040	14.0	0.350
R1/pond	0.0001120	2790	37.5	0.938
R1/stream	0.0002250	1390	18.7	0.467
R2/stream	0.0002970	1050	14.1	0.354
R3/stream	0.0003180	981	13.2	0.330
TER criterion		9	10	1

FOCUSsw step 4- TER values for beta-cyfluthrin [2 x 12.5 g as/ha (14 d) in potatoes] (20 m + 90 % drift reduction measures)

Focus scenario	Step 4 20m + 90 %	Fish acute	Fish chronic	Invertebrates
		SSD	<i>Oncorhynchus mykiss</i>	Overall assessment/microcosm
		median HC5 LC50 (µg/L)	NOEC (µg/L)	RAC (µg/L)
		PEC (µg/L)	0.0042	0.000105
D3/ditch	0.0003020	1030	13.9	0.348
D4/pond	0.0001090	2860	38.5	0.963
D4/stream	0.0005490	568	7.65	0.191
D6/ditch	0.0002990	1040	14.0	0.351
D6/ditch	0.00030	1040	14.0	0.350
R1/pond	0.0001150	2710	36.5	0.913
R1/stream	0.0004490	695	9.35	0.234
R2/stream	0.0005930	526	7.08	0.177
R3/stream	0.0006360	491	6.60	0.165
TER criterion		9	10	1

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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 PART REFLECTS THE NEW EFSA GD ON BEES WHICH HAS NOT YET BEEN TAKEN NOTE BY EC. THIS WAS BECAUSE OF DIFFERENCES BETWEEN THE DATA REQUIREMENTS AND THE MORE DETAILED APPROCHES PROPOSED BY THE NEW EFSA GD ON BEES.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
<i>Apis mellifera</i> L.	beta-cyfluthrin	acute	Oral toxicity (LD ₅₀)	0.05 µg/bee
<i>Apis mellifera</i> L.	beta-cyfluthrin	acute	Contact toxicity (LD ₅₀)	0.012 µg/bee
<i>Apis mellifera</i> L.	Bulldock 25 EC	chronic	10 d-LD ₅₀	0.019 µg/bee/day
<i>Apis mellifera</i> L.	Bulldock 25 EC	bee brood development	NOEC larvae	0.02 µg/larva (single oral exposure)
no data	no data	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	no data

Potential for accumulative toxicity: no data
<p>Semi-field test (Cage and tunnel test)</p> <p>Available tent studies indicate that beta-cyfluthrin has adverse effects on bee mortality when applied on flowering crops during daily bee flight. In addition, behavioural effects and slightly increased mortality rates were observed during the first 2 days following the evening application. There are no indications that beta-cyfluthrin has an effect on the overall colony or brood development.</p>
<p>Field tests</p> <p>In the two studies conducted during bee flight for the application rate of 7.5 g as/ha flight intensity was reduced and mortality was slightly increased for one day. At 15 g as/ha effects lasted over 3 days after application. In two new field studies with application after daily bee flight at 17.5 g as/ha the foraging activity was reduced for 1 day and adult mortality slightly increased for 2 days. Furthermore, effects on brood development and brood termination rate were observed in the test item treatment.</p>

Risk assessment for spray application in tomato (17.5 g as/ha), potato and wheat (12.5 g as/ha)

Species	Crop	Test substance	Risk quotient	HQ	Trigger
<i>Apis mellifera</i> L.	tomatoes	beta-cyfluthrin	HQ oral	519	50
<i>Apis mellifera</i> L.	tomatoes	beta-cyfluthrin	HQ contact	1067	50
<i>Apis mellifera</i> L.	wheat, potatoes	beta-cyfluthrin	HQ oral	371	50
<i>Apis mellifera</i> L.	wheat, potatoes	beta-cyfluthrin	HQ contact	762	50

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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
<i>Typhlodromus pyri</i>	Bulldock EC 25	Mortality, LR ₅₀	0.0025 g as/ha
		Reproduction, ER ₅₀	not tested
<i>Aphidius rhopalosiphi</i>	Bulldock EC 25	Mortality, LR ₅₀	0.163 g as/ha
		Reproduction, ER ₅₀	not tested
Additional species			
<i>Poecilus cupreus</i> (adult)	Bulldock EC 25	Mortality, LR ₅₀	>7.7 g as/ha

First tier risk assessment for – Spray application in wheat and potato at 2 x 7.5 g as/ha and 2 x 12.5 g as/ha

Test substance	Intended use	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
Bulldock EC 25	Wheat, potato 7.5 g as/ha	<i>Typhlodromus pyri</i>	0.0025 g as/ha	5100	4.76	2
Bulldock EC 25		<i>Aphidius rhopalosiphi</i>	0.163 g as/ha	78	0.07	2
Bulldock EC 25	Wheat, potato 12.5 g as/ha	<i>Typhlodromus pyri</i>	0.0025 g as/ha	8500	7.99	2
Bulldock EC 25		<i>Aphidius rhopalosiphi</i>	0.163 g as/ha	130	0.12	2

¹PER off –field with risk mitigation: 5 m + 90 % drift reduction (drift factor = 0.00047)

For the use of Montur Forte FS, a risk assessment (off-field) based on laboratory studies is not possible due to the lack of appropriate toxicity data.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha) ^{1,2}	End point	% effect ³	ER ₅₀
extended laboratory tests							
<i>Poecilus cupreus</i>	larvae	Bulldock EC 25 LUFA 2.1	65 days	0.04 mg as/kg dw (initial)	Mortality	0 % effect on mortality	>0.04 mg as/kg dw (initial)
				0.4 mg as/kg dw (initial)	Mortality	100 %	
<i>Poecilus cupreus</i>	larvae	beta-cyfluthrin LUFA 2.1	55 days	0.014 mg as/kg dw	Mortality	0 % (corrected)	> 0.014 mg/kg dw
aged residue tests							
<i>Coccinella septempunctata</i>	larvae	Bulldock EC 25	0-7d	0.3 as(initial)	Mortality	91 - 87	< 0.3 g as/ha
			14 d	1.2 as (initial)	Mortality	19	> 1.2 g as/ha
			28 d	25 as (initial)	Mortality	46	25 g as/ha
<i>Poecilus cupreus</i>	larvae	Montur Forte FS 230 (Imidacloprid Beta-cyfluthrin + Imidacloprid FS230) coated sugar beet pills	on day 1	1.1x10 ⁵ pills /ha 9.3g beta-cyfluthrin + 15.8g imidacloprid / ha	Mortality /Effect on hatching rate body weight	- 11.1 -1.4	>1.1x10 ⁵ Montur Forte FS 230 coated sugar beet pills
			after 6 weeks aging in field		Mortality /Effect on hatching rate body weight	0 1.1	
<i>Aleochara bilineata</i>	adult	Montur Forte FS 230 (Imidacloprid Beta-cyfluthrin + Imidacloprid FS230) coated sugar beet pills	on day 1	1.1x10 ⁵ pills /ha 9.3g beta-cyfluthrin + 15.8 g imidacloprid / ha	Reproduction	8.1	1.1x10 ⁵ Montur Forte FS 230 coated sugar beet pills

¹ indicate whether initial or aged residues

² for preparations indicate whether dose is expressed in units of as or preparation

³ indicate if positive percentages relate to adverse effects or not

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Risk assessment (infield) for – Montur Forte FS 230, sugar beet seed treatment at 10.4 g beta-cyfluthrin and 19.5 g as imidacloprid/ha based aged residue tests

Species	ER ₅₀ (g/ha)	In-field rate	Off-field rate ¹
<i>Poecilus cupreus</i> (larvae)	1.1x10 ⁵ Montur Forte FS 230 coated sugar beet pills ²	1.3 x 10 ⁵ Montur Forte FS 230 coated sugar beet pills	-
<i>Aleochara bilineata</i>	1.1x10 ⁵ Montur Forte FS 230 coated sugar beet pills	1.3 x 10 ⁵ Montur Forte FS 230 coated sugar beet pills	

¹Indicate distance assumed to calculate the drift rate and if 3D or 2D.

²The seed rate in the testing was only 84.6 % of the maximum seed rate in field (according the gap table). The a exposure was 1 treaded pill/912 cm². To achieve the maximum seed of 1.3 x 10⁵ pills/ha, the testing area should have been one seed only 769 cm². However, as effects measured in the test were far below 50 % for both species, the risk is regarded as acceptable

For the use of Bulldock EC25, a risk assessment (in-field and off-field) based on extended or aged residues studies is not possible due to the lack of appropriate toxicity data.

For the use of Montur Forte FS, a risk assessment (off-field) based on extended or aged residues studies is not possible due to the lack of appropriate toxicity data.

Semi-field tests
<u>Semi-field test with <i>Poecilus cupreus</i>:</u> The results show that in a field situation (winter wheat after harvest), under normal management conditions, a spray application of Bulldock EC 25 applied at 300 ml/ha (8 g as/ha) poses no risk to carabid beetles, represented by <i>Poecilus cupreus</i> , active at ground level.
Field studies
-
Additional specific test
-

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 as/ OM ¹	Time scale	End point	Toxicity
Earthworms					
<i>Eisenia fetida</i>	Bulldock EC 25	test item was mixed into soil/ 10 % OM	Chronic	reproduction,	NOEC = 30 mg/kg d.w. soil (0.83 mg as/kg dw soil) ²

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Test organism	Test substance	Application method of test as/ OM ¹	Time scale	End point	Toxicity
<i>Eisenia fetida</i>	Montur Forte FS230	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 1.78 mg/kg dw soil
<i>Eisenia fetida</i>	Montur Forte FS230	exposure via treated sugar beet pills	Chronic	reproduction	NOEC > 1,300, 000 treated sugar beet pills
<i>Eisenia fetida</i>	FPB-acid	test item was mixed into soil/ 10 % OM	Chronic	reproduction	NOEC = 2.6 mg/kg dw soil ²
<i>Eisenia fetida</i>	DCVA	test item was mixed into soil/ 10 % OM	Chronic	reproduction	NOEC = 2.6 mg/kg dw soil ²
Other soil macroorganisms					
<i>Folsomia candida</i>	beta-cyfluthrin	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 56 mg/kg dw soil
<i>Folsomia candida</i>	Bulldock EC 25	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 55.6 mg/kg soil dw (1.592 mg as/kg soil dw)
<i>Folsomia candida</i>	Montur Forte FS 230	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 55.6 mg/kg dw soil
<i>Folsomia candida</i>	FPB-acid	test item was mixed into LUFA 2.1 soil/ < 5 % OM	Chronic	reproduction	NOEC = 28 mg/kg dw soil
<i>Folsomia candida</i>	DCVA	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 18 mg/kg dw soil

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Test organism	Test substance	Application method of test as/ OM ¹	Time scale	End point	Toxicity
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC = 0.97 mg/kg dw soil
<i>Hypoaspis aculeifer</i>	Montur Forte FS 230	test item was mixed into soil/ 5 % OM	Chronic	reproduction	NOEC ≥ 32 mg/product/kg soil dw
<i>Hypoaspis aculeifer</i>	FPB-acid	test item was mixed into LUFA 2.1 soil/ < 5 % OM assumed	Chronic	reproduction	NOEC = 297 mg/kg soil
<i>Hypoaspis aculeifer</i>	DCVA	test item was mixed into soil/ 5 % OM	Chronic	mortality	NOEC = 100 mg/kg soil dw

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

² corrected by factor of 2 due to lipophilic substance (log Pow > 2) and 10 % peat content in test soil

Higher tier testing (e.g. modelling or field studies) no studies
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Nitrogen transformation	beta-cyfluthrin	max. field rate/soil concentration:	at 180 g/ha < 25 % effect at day 0-28
Nitrogen transformation	Bulldock EC 25	max. field rate/soil concentration: 2 x 0.5 Lprod./ha (2x 12.5 gas/ha)	at 9.61 mg/kg dry soil. corresponding to 8.0 L test item/ha (200 mg as/ha) < 25 % effect at day 0-28 [In line with the OECD test guideline the endpoint should be based on nitrogen transformation rate and not nitrogen levels]
Nitrogen transformation	Montur Forte	max. field rate/soil concentration: 0.196 mg product/kg dry soil	at 0.98 mg/kg dry soil < 25 % effect at day 0-28

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Nitrogen transformation	FPB-acid	max. field rate/soil concentration: 0.0016 mg/kg soil (max. value for Bulldock EC 25) 0.003 mg/kg dry soil (Montur Forte FS 230)	at 0.125 mg/kg dry soil corresponding to 94 g/ha < 25 % at day 0-28
Nitrogen transformation	DCVA	max. field rate/soil concentration: 0.0047 mg/kg dry soil (max. value for Bulldock EC 25) 0.001 mg/kg dry soil (Montur Forte FS 230)	0.112 mg/kg dry soil < 25 % at day 0-28

Toxicity/exposure ratios for soil organisms

Bulldock EC 25, wheat: 2x7.5 g as/ha, interception: 25 %, 14 d

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0128	64.8	5
	FPB-acid	Chronic	0.0009	2890	5
	DCVA	Chronic	0.0025	1040	5
<i>Folsomia candida</i>	beta-cyfluthrin	Chronic	0.0128	4380	5
	FPB-acid	Chronic	0.0009	31100	5
	DCVA	Chronic	0.0025	7200	5
	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0128	124	5
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	Chronic	0.0128	75.8	5
	FPB-acid	Chronic	0.0009	330000	5
	DCVA	Chronic	0.0025	40000	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

Bulldock EC 25: wheat. 2x12.5 g as/ha, interception: 25 %. 14 d

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0213	39.0	5
	FPB-acid	Chronic	0.0014	1860	5
	DCVA	Chronic	0.0042	619	5
<i>Folsomia candida</i>	beta-cyfluthrin	Chronic	0.0213	2630	5
	FPB-acid	Chronic	0.0014	20000	5
	DCVA	Chronic	0.0042	4290	5
	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0213	74.7	5
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	Chronic	0.0213	45.5	5
	FPB-acid	Chronic	0.0014	212000	5
	DCVA	Chronic	0.0042	23800	5

Bulldock EC 25: potatoes 2x7.5 g as/ha, interception: 15 %. 14 d

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0143	58.0	5
	FPB-acid	Chronic	0.001	2600	5
	DCVA	Chronic	0.0028	929	5
<i>Folsomia candida</i>	beta-cyfluthrin	Chronic	0.0143	3920	5
	FPB-acid	Chronic	0.001	28000	5
	DCVA	Chronic	0.0028	6430	5
	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0143	111	5
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	Chronic	0.0143	67.8	5
	FPB-acid	Chronic	0.001	297000	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

	DCVA	Chronic	0.0028	35700	5
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Bulldock EC 25: potatoes, 2x12.5 g as/ha interception: 15 %. 14 d

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0242	34.3	5
	FPB-acid	Chronic	0.0016	1630	5
	DCVA	Chronic	0.0047	553	5
<i>Folsomia candida</i>	beta-cyfluthrin	Chronic	0.0242	2310	5
	FPB-acid	Chronic	0.0016	17500	5
	DCVA	Chronic	0.0047	3830	5
	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0242	65.8	5
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	Chronic	0.0242	40.1	5
	FPB-acid	Chronic	0.0016	186000	5
	DCVA	Chronic	0.0047	21300	5

Bulldock EC 25: tomatoes greenhouse. 2 x 17.5 g as/ha, interception: 50 %. 14 d)

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0152	54.6	5
	FPB-acid	Chronic	0.0010	2600	5
	DCVA	Chronic	0.0030	867	5
<i>Folsomia candida</i>	beta-cyfluthrin	Chronic	0.0152	3680	5
	FPB-acid	Chronic	0.0010	28000	5
	DCVA	Chronic	0.0030	6000	5
	beta-cyfluthrin (Bulldock 25 EC)	Chronic	0.0152	105	5

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

<i>Hypoaspis aculeifer</i>	beta-cyfluthrin	Chronic	0.0152	63.8	5
	FPB-acid	Chronic	0.0010	297000	5
	DCVA	Chronic	0.0030	33300	5

Montur Forte FS 230: seed treatment sugar beets

Species	Test item	Time scale	Max. PEC _{soil} [mg/kg soil dw]	TER	Trigger
<i>Eisenia fetida</i>	beta-cyfluthrin + imidacloprid FS 230	Chronic	0.196 ^A	9.08	5
	FBP-acid	Chronic	0.003	867	5
	DCVA (permethric acid)	Chronic	< 0.001	>2600	5
<i>Folsomia candida</i>	beta-cyfluthrin		0.014	4000	5
	beta-cyfluthrin + imidacloprid FS 230		0.196 ^A	23.5	5
	FBP-acid		0.003	9330	5
	DCVA (permethric acid)		< 0.001	18000	5
<i>Hypoaspis aculeifer</i>	beta-cyfluthrin		0.014	69.3	5
	beta-cyfluthrin + imidacloprid FS 230		0.196 ^A	163	5
	FBP-acid		< 0.001	297000	5
	DCVA (permethric acid)		0.003	333000	5

^A Product PEC_{soil} based on a product density of 1.13 kg/L and standard soil parameters (soil layer of 5 cm with a bulk density of 1.5 g/cm³)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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 required for herbicides or plant growth regulators as ER ₅₀ tests should be provided

Laboratory dose response tests

Species	Test substance	ER ₅₀ (g as/ha) ² vegetative vigour	ER ₅₀ (g as/ha) emergence	Exposure ¹ (g as/ha)	TER	Trigger
Green cabbage (<i>Brassica oleracea</i> var. <i>sabellica</i>).	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Cucumber (<i>Cucumis sativa</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Carrot (<i>Daucus carota</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Lacy phacelia (<i>Phacelia tanacetifolia</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Sunflower (<i>Helianthus annuus</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Flax (<i>Linum usitatissimum</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Onion (<i>Allium cepa</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Rye grass (<i>Lolium multiflorum</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Barley (<i>Hordeum vulgare</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Erect brome (<i>Bromus erectus</i>)	Bulldock EC 25	> 60	> 60	0.346	> 173	5
Extended laboratory studies : Semi-field and field test:						

¹ explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data): drift rate: 2.77 % (1m distance), exposure for the maximum application rates (12.5 g as/ha) in wheat and potatoes

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Section 5 Ecotoxicology

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	30 min EC ₅₀ > 10000 mg/L

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)

Available monitoring data concerning adverse effect of the as: no data available
Available monitoring data concerning effect of the PPP: 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	beta-cyfluthrin
water	beta-cyfluthrin
sediment	beta-cyfluthrin
groundwater	beta-cyfluthrin

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	beta-cyfluthrin
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 :	GHS09 H400 Aquatic Acute 1 H410 Aquatic Chronic 1
Peer review proposal ⁸ for harmonised classification according to Regulation (EC) No 1272/2008:	GHS09 H400 Aquatic Acute 1 M-factor acute = 1000000 H410 Aquatic Chronic 1 M-factor chronic = 100000

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.

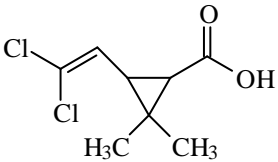
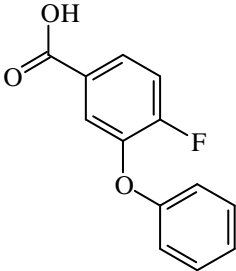
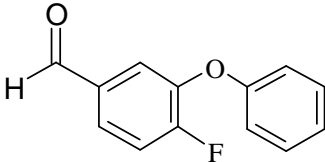
⁸ It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product (Name)
Germany	March 2017	beta-cyfluthrin Bulldock EC 25 Montur Forte FS 230

Appendix

Used compounds code(s)

Code/Trivial name*	Chemical name/SMILES notation	Structural formula
DCVA	3-(2',2'-Dichloroethen-1'-yl)-2,2-dimethylcyclopropanecarboxylic acid	
FPB-acid COE 538/78	4-Fluoro-3-phenoxybenzoic acid	
FPB-aldehyde FCR 1260	4-Fluoro-3-phenoxybenzaldehyde	

* The compound code / trivial name in bold is the name used in the list of endpoints.