Renewal Assessment Report

beta-cyfluthrin

Montur Forte FS 230

Volume 3 – B.9 Ecotoxicology data and assessment of risks for non-target species

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Rapporteur Member State: Germany

Co-Rapporteur Member State: Hungary

Version history

When	What

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B.9 Ecotoxicology data and assessment of risks for non-target species

Table B.9.0-1 Use pattern considered in this risk assessment

Crop	Timing of application	Number of applications	Application interval [days]	Maximum label rate [L/unit] [B]	Maximum application rate, individual treatment [g as/ha] [C]	
					Beta-Cyfluthrin	Imidacloprid
Sugar beet	BBCH 0	1	n r. [A]	0.1	10.4	19.5

A n.r.: not relevant
B 1 unit = 100 000 seeds
C max unit/ha: 1.3

Relevant metabolites of beta-cyfluthrin in environmental compartments

Table B.9.0-2 Relevant metabolites of beta-cyfluthrin

Compartment	Compound / Code
Soil	DCVA (Permethric acid) (AE 0433590) FPB-acid (4-fluoro-3-phenoxy-benzoic acid) (AE F105561)
Groundwater	DCVA (Permethric acid) (AE 0433590) FPB-acid (4-fluoro-3-phenoxy-benzoic acid) (AE F105561)
Surface water	DCVA (Permethric acid) (AE 0433590) FPB-acid (4-fluoro-3-phenoxy-benzoic acid) (AE F105561) FPB-aldehyde (AE B101880)

Compounds addressed in this document

The representative formulation Montur Forte FS 230 comprises beside the substance under evaluation, beta-cyfluthrin the active substance Imidacloprid.
The submitted dossier for Montur Forte FS 230, however, included only an assessment of exposure and risk for beta-cyfluthrin. Therefore, the dossier is considered as incomplete.
As a safe use has to be demonstrated for the representative formulation as a whole, the RMS amended the risk assessment for the second active ingredient imidacloprid and (where necessary) for the mixture toxicity of both active substances.
To address the risk for imidacloprid, reference is made to the assessment report as well as the addenda for imidacloprid.

Nevertheless, the following data gaps were defined due to missing data about toxicity to non-target organisms:

Effects to / risk assessment for non-target arthropods other than bees
As the dossier did not include an exposure- and risk assessment for non-target arthropods in off-field areas, the RMS calculated the off-field exposure via dust drift deposition according to SANCO/10553/2012; January 2014. However, due to missing data (laboratory studies) about the toxicity of the formulation Montur Forte FS230 to leaf dwelling arthropods (*Aphidius rhopalosiphi, Typhlodromus pyri*) the risk to non-target arthropods in off-field areas cannot be addressed.
Thus, a data gap is identified. Laboratory studies investigating the toxicity of the formulation Montur Forte FS 230 to the leaf-dwelling arthropods *Aphidius rhopalosiphi, Typhlodromus pyri* are required.

B.9.1 Effects on birds and other terrestrial vertebrates

B.9.1.1 Effects on birds

B.9.1.1.1 Effects of beta-cyfluthrin on birds

Table B.9.1-1: Acute toxicity of beta-cyfluthrin, cyfluthrin, Bulldock EC 25 to birds

Species	LD_{50} (mg as/kg bw)	NOEL	(mg as/kg bw) Reference	reliability
Beta-Cyfluthrin				
Bobwhite quail *Colinus virginianus*	> **2000**	2000	KIIA8.1.1/01 VB-027 [redacted], 1994 M-025760-01-1 R-19071	valid
Japanese quail *Coturnix coturnix japonica*	> **2000**	< 250	KIIA8.1.1/02 VW-106 [redacted], 1985 M-053473-01-2	valid
Gallus domesticus	> **5000**	> 5000	KIIA 8.1.1/08 [redacted], 1985, T 1019902 (FCR 4545), 13689, M-064864-01-1	valid
Canary bird *Serinus canaria*	**170**	-	KIIIA 10.1.6/02 [redacted] 2011	valid
Shiny cowbird *Molothrus bonar-iensis*	**2234**	--	KIIIA 10.1.6/02 [redacted] 2011	valid
Cyfluthrin				
Bobwhite quail *Colinus virginianus*	> **2000**	2000	KIIA 8.1.1/03 426 [redacted], 1983 M-008638-01-1 R-19070	valid
Japanese quail *Coturnix coturnix japonica*	> **5000**	500	KIIA 8.1.1/09 V-80518 [redacted], 1980 M-030215-01-3 **R-19069**	valid
Gallus domesticus	> **3000**[1] < 5000	< 3000	KIIA 8.1.1/05 [redacted], 1985 R3622 **M-039453-01-1**	valid
Canary bird *Serinus canaria*	> 125[3]	**50**	KIIA 8.1.1/06 [redacted], 1985 VK-137 AV 94-213 **M-030284-01-1**	valid
geometric mean LD_{50} = 2939.3 mg /kg bw; value used in the risk assessment : LD_{50} (geomean canary bird) = 92.2 mg/kg bw; with a safety factor of 1				

Reasoning: The overall geomean LD_{50}/10 is 293.3 mg/kg bw . This value is smaller than the endpoint of the most sensitive species *Serinus canaria* (92.2 mg//kg bw).

[1]Relevant for risk assessment; value lower than geomean-LD_{50}/10 of 183 mg/kg bw for 4 tested species.

Table B.9.1-2: Long-term toxicity of cyfluthrin to birds

Species	Endpoint	NOEC/ NOAEC [mg as/kg feed]	NOEL/ NOAEL [mg as/kg bw/day]	Reference	Reliability
Cyfluthrin					
Mallard duck *Anas platyrhynchos*	Reproduction one generation, 21 weeks	250	**37.74**	KIIA8.1.4/05 100359 [redacted], 1990 M-030237-01-1 R-19078	valid

Studies shaded in grey have been reviewed as part of the 2002 EU evaluation.
Values in bold: Endpoints used for risk assessment
1 Calculation described in CA 8.1.1.3
2 eggshell quality, no full one-generation

B.9.1.1.2 Effects of imidacloprid to birds

Table B.9.1-3: Toxicity of imidacloprid to birds with reference to agreed endpoints

Species	Substance	Exposure Duration System	Results Toxicity	Reference Author Date Report No.
Japanese quail Coturnix coturnix jap.	Imidacloprid	acute, oral	LD50 = 31 mg as/kg bw	[redacted] (1988) VW-123
Bobwhite quail Colinus virginianus	Imidacloprid	acute, oral	LD50 = 152 mg as/kg bw	[redacted] (1990) 100059
Mallard duck Anas platyrhynchos	Imidacloprid	acute, oral	LD50 = 283 mg as/kg bw	[redacted] (1996) 107354
Grey partridge Perdix perdix	Imidacloprid	acute, oral	LD50 = 13.9 mg as/kg bw	[redacted] (1991) V-908144
'Bird'	Imidacloprid	acute	L**D50 = 66 mg as/kg bw**	Risk assessment endpoint based on the geometric mean of above studies 1)
Bobwhite quail Colinus virginianus	Imidacloprid	20-week dietary chronic, reproduction	NOEC = 126 mg as/kg diet **NOEL = 9.3 mg as/kg bw/d 2)**	[redacted] (1991) 101203
Mallard duck Anas platyrhynchos	Imidacloprid	20-week feeding chronic, reproduction	NOEC = 128 mg as/kg diet NOEL = 11.7 mg as/kg bw/d 2)	[redacted] (1992) 103813-1

Mixture toxicity
According to Appendix B to the Guidance Document on the Risk assessment for birds and mammals (EFSA, 1438/2009), the basic concept of the risk assessment is that animals are exposed to residues of the active substances in the environment. Thus, the assessment for Montur Forte FS 230 does not evaluate the formulation toxicity as such, but the effects of an exposure to a mixture of active substances in the environment, resulting from the use of the formulation. Toxicity studies for birds with formulated products are typically not available. For the assessment of acute effects, a surrogate LD_{50} is calculated. Sublethal effects and effects on reproduction are assessed on a case-by-case basis. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney 1948 and 1971).
The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(as *i*) = fraction of active substance (i) in the mixture expressed as e.g.:
beta-cyfluthrin = 0,348
imidacloprid = 0,652

LD_{50}(as *i*) = acute toxicity value for active substance (*i*)

The acute toxicity for the mixture of both active substances is:

LD_{50} (mix – as) = 97.5 mg as (total)/kg bw

B.9.1.2Effects on terrestrial vertebrates other than birds

B.9.1.2.1 Effects of beta-cyfluthrin on terrestrial vertebrates other than birds

Acute oral toxicity to mammals
Acute oral toxicity studies with rodents that have already been evaluated for the Annex I inclusion of beta-cyfluthrin as well as a new study are summarised in the table below. For details please refer to document Vol3_CA_B 5.2.1

Table B.9.1-4: Acute toxicity of beta-cyfluthrin to mammals

Animal	species	Sex Formulation agent LD50	(mg as/kg bw)	References
rat	male*	PEG 400 #	380	[redacted], 1987b
	female*	PEG 400	651	[redacted], 1987b
	male	PEG 400	655	[redacted], 1987b
	female	PEG 400	1369	[redacted], 1987b
	male*	xylene	211	[redacted], 1987c
	female*	xylene	336	[redacted], 1987c
	male	xylene	307	[redacted], 1987c
	female	xylene	343	[redacted], 1987c
	male*	acetone/oil 1:10	84	[redacted], 1987d
	female*	acetone/oil 1:10	77	[redacted], 1987d
	male	acetone/oil 1:10	141	[redacted], 1987d
	female	acetone/oil 1:10	108	[redacted], 1987d
	female*	acetone/oil 1:10	200	[redacted], 2005a
	male*	water/Cremophor EL	11	[redacted], 1986a

mouse	male*	PEG 400	91	[redacted], 1987e
	female*	PEG 400	165	[redacted], 1987e

* = fasted animals
# = PEG 400: polyethylene glycol 400 (Lutrol)

The acute oral toxicity of beta-cyfluthrin depends on the vehicle used. Beta-Cyfluthrin was found to be very toxic to mammals via the oral route when administered using Cremophor as vehicle. However, Cremophor leads to unrealistically high bioavailability which does not correspond to bioavailability of beta-cyfluthrin from either formulated plant protection products or as residues on/in feed items. This is supported by a series of other studies using different vehicles such as PEG, xylene or acetone/oil.
Therefore, it is concluded that all endpoints obtained excluding the data generated with Cremophor are most appropriate for risk assessment. Further, for the calculation of the geometric mean those end-points were excluded where animals were not fasted.

Species	Rat		Mouse	
Gender	female	male	female	male
Individual LD_{50} in mg/kg bw	651	380	165	91
	336	211	-	-
	77	84	-	-
	200	-	-	-
Geomean for gender	240.9	**188.8**	165.0	**91.0**
Overall geometric mean LD_{50} in mg/kg bw (based on LD_{50} male)	**131.1**			

The overall geometric mean LD_{50} is based on the geometric mean LD_{50} derived for male rats and the LD_{50} value derived for male mice. This approach was chosen as the sensitivity to males appears to be higher than to females. The difference of the geometric means for gender (rats) is 52.1 mg/kg bw. This is 27.6 % of the lower LD_{50} (male) and 21.6 % of the higher LD_{50} (female). The difference between LD_{50} values for male and female mice is 74 mg/kg bw. This is 81.3 % of the lower LD_{50} (male) and 44.9 % of the higher LD_{50} (female). According to the EFSA GD 2009 chapter 2.1.1 the calculating of a geometric mean of the endpoints of genders should be abandoned when "the difference in the LD_{50} value is > 25 %".
The assumption of a higher sensitivity of male mammals is supported by the ADME study of Bernard (2013b) described in Vol. 3 B.6. Results show that the absorption in male animals is 1.5 fold higher than in female (in case of the highest test concentration – 10.1 mg as/kg bw). Thus, the higher sensitivity is based on a higher absorption rate of male rats/mice.

Table B.9.1-5: Acute toxicity of imidacloprid to mammals with reference to agreed endpoints

Species	**Substance**	**Exposure Duration System**	**Results Toxicity**	**Reference Author Date Report No.**
Rat	Imidacloprid	Acute oral toxicity	LD_{50} = 443 mg as/kg bw [1)]	[redacted] (1989) 18594
Mouse	Imidacloprid	Acute oral toxicity	LD_{50} = 148 mg as/kg bw [2)]	[redacted] (1989) 18593
'Mammal'	Imidacloprid	Acute oral toxicity	**LD_{50} = 256 mg as/kg bw**	Risk assessment endpoint based on the geometric mean of above studies

Long-term and reproduction toxicity to mammals

Table B.9.1-6: Chronic toxicity of beta-cyfluthrin to mammals

Species	Substance	Exposure Duration System	Results Toxicity	Reference Author Date
Rat	Beta-Cyfluthrin	3-generation	**NOAEL = 3.3 mg as/kg bw/d***	[redacted] (1983)
Rat	Beta-Cyfluthrin	2-generation	**NOAEL = 3.3 mg as/kg bw/d***	[redacted] (1996)

* addendum on the monograph of beta-cyfluthrin (7 May 2002)

Table B.9.1-7: Chronic toxicity of imidacloprid to mammals with reference to agreed endpoints

Species	Substance	Exposure Duration System	Results Toxicity	Reference Author Date Report No.
Rat	Imidacloprid	multi-generation	NOAEC = 250 mg as/kg food **NOAEL = 17 mg as/kg bw/d**	[redacted] (1990) R5097

Bold print: Values considered relevant for risk assessment

1) Geometric mean of 424 mg as/kg bw (LD_{50} of males) and 462 mg as/kg bw (LD_{50} of females; there 0 % mortality at 450 mg as/kg bw and 100 % mortality at 475 mg as/kg bw)

2) Geometric mean of LD_{50} values for males (LD_{50} = 131 mg as/kg bw) and females (LD_{50} = 168 mg as/kg bw)

Mixture toxicity

According to Appendix B to the Guidance Document on the Risk assessment for birds and mammals (EFSA, 1438/2009), the basic concept of the risk assessment is that animals are exposed to residues of the active substances in the environment. Thus, the assessment for Montur Forte FS 230 does not evaluate the formulation toxicity as such, but the effects of an exposure to a mixture of active substances in the environment, resulting from the use of the formulation. Toxicity studies for birds with formulated products are typically not available. For the assessment of acute effects, a surrogate LD_{50} is calculated. Sublethal effects and effects on reproduction are assessed on a case-by-case basis. A model often used to estimate the toxicity of mixtures is the assumption of dose/concentration additivity of toxicity (Finney approach of concentration additivity of toxicity; Finney 1948 and 1971).

The following formula is used to derive a surrogate LD_{50} for the mixture of active substances with known toxicity assuming dose additivity:

$$LD_{50}(mix) = \left(\sum_i \frac{X(a.s._i)}{LC_{50}(a.s._i)} \right)^{-1}$$

where:

X(as *i*) = fraction of active substance (i) in the mixture expressed as e.g.:
beta-cyfluthrin = 0,342
imidacloprid = 0,642

LD_{50} (mix – as) = 195.6 mg as (total)/kg bw

B.9.2 Risk assessment for birds and other terrestrial vertebrates

B.9.2.1 Risk assessment for birds

B.9.2.1.1 Exposure

Sugar beet seeds

In EFSA GD, the principle for the Tier 1 risk assessment for pelleted seeds is laid out in the scheme presented in section 5.1.2. The underlying assumption is that birds may ingest pelleted seeds by mistake as grit. In this context beet pills belong to the category of large granules (2-6 mm).
For the acute risk assessment the daily grit doses per bird (DGritD-bird$_{acute}$ and DGritD-bird$_{repro}$) are calculated according to the following formulas as given in the EFSA GD. Please note that, other than indicated in the GD, these figures do not refer to the body weight of a model species, but to one individual bird of that model species

$$DGritD\text{-}bird_{acute}\ (large\ granules) = 2453 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

$$DGritD\text{-}bird_{repro}\ (large\ granules) = 1306 \times \frac{G_{density}}{(71 + G_{density})} \times G_{loading}$$

where
$G_{density}$ = number of granules per m² on soil surface
$G_{loading}$ = the amount of the active substance in one granule
The amount (mg) of the active substance in one granule ($G_{loading}$) is:

beta-cyfluthrin + imidacloprid	0.240
beta-cyfluthrin	0.082
imidacloprid	0.154

On overall average, only 0.11 % (Barfknecht, 2000; KIIIA1 10.1.2; BAR/FS 003 (M-019632-01-1)[1]) to 0.17 % (de Leeuw et al., 1995[2]) remain on the surface according to inspections of freshly drilled sugar beet fields in the Netherlands and Germany, respectively. The value of 0.17 % is used for the reproductive risk assessment. At a drilling rate of 130 000 seeds per ha (see Table B.9.1-1), the average number of beet seed pills per m² is calculated to be 0.022. The acute risk assessment is based on the highest average value observed within the study by de Leeuw et al. (1995), which amounted to 0.6 %. At a drilling rate of 130 000 seeds per ha, the maximum number of beet seed pills per m² is calculated to be 0.078.
Taking these two parameters into account the daily grit doses per bird for the acute and reproductive risk assessment (DGritD-bird$_{acute}$ and DGritD-bird$_{repro}$) are calculated as:

[1] for detailed description of this study please refer to the assessment report for imidacloprid Vol3B_B9.1.4.1.
[2] de Leeuw J, Gorree M, de Snoo GR, Jamis WLM, van der Poll RJ, Luttik R (1995). Risks of granules on treated seeds to birds on arable fields. GML report No. 118. Centre of Environmental Science, Leiden University, Leiden, The Netherlands. ISSN 1381-1703.

	$DGritD_{acute}$ [mg as/kg bw]	$DGritD_{repro}$[mg as/kg bw]
beta-cyfluthrin + imidacloprid	0.6446	0.0096
beta-cyfluthrin	0.2207	0.0033
imidacloprid	0.4141	0.0062

However, as mentioned before, an error has been detected in the EFSA GD with regard to the unit of the daily grit dose (DGritD). Other than stated in the GD, the tabled figures do not refer to a number of grit particles taken up per kg body weight of a model bird species, but represent number of grit particles taken up per bird. Hence, recalculation of DGritD-birdacute and DGritD-birdrepro from mg/bird/d to DGritDacute and DGritDrepro in mg/kg bw/d is required to achieve a meaningful basis for TER calculations.

Since the assessment scheme for grit ingestion by birds in the EFSA GD is basically identical to the previous EPPO scheme, the background data in the respective EPPO document were re-analysed to obtain estimates for a recalculation of grit intake. As shown in Table B.9.2-1 the grit numbers per bird for large grit particles of 2451 (90th percentile) and 1307 (geom. mean) correspond to grit numbers per kg bw of 6195 (90th percentile) and 2337 (geom. mean) as averaged over the three species under investigation.

Table B.9.2-1: Data on grit ingestion by birds, taken from: OEPP/EPPO (2003): Environmental risk assessment scheme for plant protection products, Chapter 11: Terrestrial vertebrates. Bulletin OEPP/EPPO Bulletin 33, 147–149

species	**scientific name**	**mean bw (Dunning, 1993)**	**grit no. in gizzard**	**grit no. per bird/d**	**grit no. per kg bw/d**
small grit particles					
greenfinch	*Carduelis chloris*	27.8	95	399	14353
chaffinch	*Fringilla coelebs*	21.0	65	273	13000
linnet	*Carduelis cannabina*	15.3	100	420	27451
twite	*Carduelis flavirostris*	16.9	122	512	30296
brambling	*Fringilla montifringilla*	24.0	188	790	32917
goldfinch	*Carduelis carduelis*	15.6	43	181	11603
geom. mean			92	387	19746
90th %-ile			155	651	31607
large grit particles					
grey partridge	*Perdix perdix*	390	676	2839	7279
wood pigeon	*Columba palumbus*	470	208	874	1860
pheasant	*Phasianus colchicus*	953 (mean ♀)	214	899	943
geom. mean			311	1307	2337
90th %-ile			584	2451	6195

With the adjusted grit intake values, the daily grit doses per kg body weight of birds for the acute and reproductive risk assessment ($DGritD_{acute}$ and $DGritD_{repro}$) are calculated as:

	$DGritD_{acute}$ [mg as/kg bw]	$DGritD_{repro}$[mg as/kg bw]
beta-cyfluthrin + imidacloprid	1.6279	0.0173
beta-cyfluthrin	0.5574	0.0059
imidacloprid	1.04589	0.0111

Sugar beet seedlings

Beta-Cyfluthrin:
Beta-cyfluthrin is a non-systemic insecticide (please refer to Volume3CA_B3).
When comparing the calculated NAR (30000 – 36000 mg as/kg)/5 [for a loading rate of 0.9 mg/seed) with the measured residues (15.5 mg/kg seedlings) for the systemic, water soluble insecticide imidacloprid, it can be definitely assumed that actual residues for the non-systemic, water-insoluble insecticide beta-cyfluthrin were even much lower than for imidacloprid.
Therefore, the exposure of birds and mammals by beta-cyfluthrin via seedlings of the treated sugar beet seeds is considered to be negligible. Thus, a calculation of a theoretical exposure is dispensable.

Imidacloprid:
In section 5.2.1 of the EFSA GD, a generic approach is presented for estimating concentrations of an as in seedlings germinating from treated seeds. For a 'small omnivorous bird', the shortcut value is determined from the nominal loading application rate in mg/kg seed as follows:
shortcut = 0.5 × NAR / 5
With a thousand-grain weight of about 25-30 g for pelleted sugar beet seeds (taken from http://www.saatzuchtgleisdorf.at/index.php?seite=aussaatinformationen) and a loading of 0.154 mg as/granule, the NAR would amount to 5133-6 160 mg as/kg and the shortcut thus to 513-616.

However, residue studies submitted for the EU evaluation of imidacloprid and assessed in Addendum 7 (January 2014, Gaucho FS 600 - seed treatment in sugar beets, loading rate = 0.9 mg/seed) show a maximum concentration of 15.5 mg as/kg seedlings and a mean concentration of 10.28 mg as/kg seedlings. As the loading rate is 0.154 mg as imidacloprid/granule for the representative application of Montur Forte FS 230, the resulting actual concentration of imidacloprid in sugar beet seedlings should be lower. Thus, the exposure of birds to imidacloprid by seedlings of sugar beet seed treated Montur Forte FS 230 is covered by the representative application of Gaucho FS 600 described in Addendum 7.

B.9.2.2 Toxicity to exposure ratio for birds

Sugar beet seeds

Based on the toxicity and exposure data presented above, TER values for the acute and reproductive risk can be derived as the quotient of ecotoxicological endpoint (LD_{50} or NOEL) and exposure estimate (DGritD).

Beta-Cyfluthrin:

TER_{acute} = LD_{50} / $DGritD_{acute}$ = 92.2 mg as/kg bw / 0.557 mg as/kg bw = 175 (adjusted acceptability criterion = 1 please refer to Volume 1 section 2.9.1)
TER_{repro} = NOEL / $DGritD_{repro}$ = 37.7 mg as/kg bw/d / 0.006 mg as/kg bw = 6363

Imidacloprid:
TER_{acute} = LD_{50} / $DGritD_{acute}$ = 66 mg as/kg bw / 1.046 mg as/kg bw = 63.1
TER_{repro} = NOEL / $DGritD_{repro}$ = 9.3 mg as/kg bw/d / 0.011 mg as/kg bw = 836

Mixture toxicity:

$TER_{acute} = LD_{50} / DGritD_{acute}$ = 97.5 mg as/kg bw / 1.628 mg as/kg bw = 59.9

TER values for beta-cyfluthrin, imidacloprid and the mixture toxicity of both active substances are above the criterion of 10 and 5 for acute and reproductive risk, respectively, indicating an acceptable risk for birds ingesting pelleted sugar beet seeds as grit.

Sugar beet seedlings

Beta-Cyfluthrin:
The exposure of birds to beta-cyfluthrin is regarded as negligible. (please refer to B.9.2.1.1). Therefore, the acute and reproductive risk for birds feeding from seedlings of Montur Forte FS 230 treated sugar beet seeds is acceptable in terms of beta-cyfluthrin.

Imidacloprid:
Residue studies submitted for the EU evaluation of imidacloprid and assessed in Addendum 7(Gaucho FS 600 - seed treatment in sugar beets, loading rate = 0.9 mg/seed) show a maximum concentration of 15.5 mg as/kg seedlings and a mean concentration of 10.28 mg as/kg seedlings. Since the loading rate of imidacloprid in the representative use of Montur Forte FS 230 is lower (0.154 mg as/seed), results of the residue studies as well as the subsequent risk assessment described in Addendum 7 for imidacloprid cover the acute and reproductive risk for birds feeding from seedlings of Montur Forte FS 230 in terms of imidacloprid. The acute and reproductive risk for birds was concluded to be acceptable. Please refer to addendum 7 for imidacloprid for details!

Bioaccumulation and food chain behavior / secondary poisoning

According to the EC Guidance Document on Risk Assessment for Birds and Mammals, substances with a log P_{OW} greater than 3 have potential for bioaccumulation and should be assessed for the risk of biomagnification in terrestrial food chains.

Beta-cyfluthrin has a log P_{OW} value of 5.9 and therefore the risk of biomagnification in terrestrial food chains has to be assessed.

Imidacloprid has a log P_{OW} value of 0.57 and therefore no formal risk assessment from secondary poisoning is therefore required.

Food chain from earthworm to earthworm-eating birds

The risk due to secondary poisoning via earthworms is based on a 100-g bird consuming 104.6 g worms per day. The concentration in earthworms is derived from the bioconcentration in earthworms, which is calculated from the K_{ow}, and the concentrations in soil.

The bioconcentration via the dry soil is calculated in accordance with the 'dry soil approach' in EFSA GD 2009. The calculations below are based on the worst case 21 day TWA PEC in soil from the representative use as sugar beet seed treatment.

Application rate of beta-cyfluthrin (g as/ha)	10.4	
PEC_{soil} 21 d TWA (mg as/kg)	0,011	DT_{50} (soil) = 32,2 d
Kow	794,328	Log Pow = 5.9
Foc	0.02	default
Koc	112,004	Mean (n =)
BCF earthworm	4.26	BCF-worm/soil = (PEC-worm,ww / PEC-soil,dw)

PEC earthworm (mg as/kg)	0,099	PEC-worm = PEC-soil × BCF-worm
DDD birds (mg/kg bw/day)	0.050	DDD = PEC-worm × 1.05
NOEL (mg/kg bw/d)	37.74	Mallard duck
TER birds	**711.6**	**≥ 5, acceptable risk**

In this worst case scenario the TER value is above the trigger of 5, indicating an acceptable risk to birds regarding secondary poisoning via earthworms. No further assessment is needed.

Food chain from fish to fish-eating birds

The risk due to secondary poisoning via fish to fish-eating vertebrates is based on a 1000-g bird consuming 159 g fish per day. The calculations risk from secondary poisoning to **fish-eating birds** was conducted in accordance with EFSA GD 2009.

Application rate of beta-cyfluthrin (g as/ha)	10.4	
RAC- aq (mg/L)	0.000000067	RAC tier 3 invertebrates
BCF fish	2295	Whole fish
BMF	2	Biomagnfication factor (relevant for BCF ≥ 2000)
PEC fish (mg as/kg)	0.000308	PECfish = PECsw*BCFfish*BMF
DDD birds (mg/kg bw/day)	0.000049	DDD = PECfish × 0.159
NOEL (mg/kg bw/d)	37.74	Mallard duck
TER birds	**771822**	**≥ 5, acceptable risk**

In all scenarios the TER value is above the trigger of 5, indicating an acceptable risk to birds regarding secondary poisoning via fish. No further assessment is needed.

B.9.2.3 Risk assessment for mammals

B.9.2.3.1 Exposure

Sugar beet seeds

According to the EFSA GD (2009) chapter 5.2.1 a risk assessment for mammals is not required in case of pelleted seeds.

Sugar beet seedlings

Beta-Cyfluthrin:
Beta-cyfluthrin is a non-systemic insecticide (please refer to Volume3CA_B3).
When comparing the calculated NAR (30000 – 36000 mg as/kg)/5 [for a loading rate of 0.9 mg/seed) with the measured residues (15.5 mg/kg seedlings) for the systemic, water soluble insecticide imidacloprid, it can be definitely assumed that actual residues for the non-systemic, water-insoluble insecticide beta-cyfluthrin were even much lower than for imidacloprid.
Therefore, the exposure of mammals and mammals by beta-cyfluthrin via seedlings of the treated sugar beet seeds is considered to be negligible. Thus, a calculation of a theoretical exposure is dispensable.

Imidacloprid:
In section 5.2.1 of the EFSA GD, a generic approach is presented for estimating concentrations of an as in seedlings germinating from treated seeds. For a ‘small omnivorous bird’, the shortcut value is determined from the nominal loading application rate in mg/kg seed as follows:

shortcut = 0.25 × NAR / 5

With a thousand-grain weight of about 25-30 g for pelleted sugar beet seeds (taken from http://www.saatzuchtgleisdorf.at/index.php?seite=aussaatinformationen) and a loading of 0.154 mg as/granule, the NAR would amount to 5133-6 160 mg as/kg and the shortcut thus to 256-308.

However, residue studies submitted for the EU evaluation of imidacloprid and assessed in Addendum 7 (Gaucho FS 600 - seed treatment in sugar beets, loading rate = 0.9 mg/seed) show a maximum concentration of 15.5 mg as/kg seedlings and a mean concentration of 10.28 mg as/kg seedlings. As the loading rate is 0.154 mg as imidacloprid/granule for the representative application of Montur Forte FS 230, the resulting actual concentration of imidacloprid in sugar beet seedlings should be lower. Thus, the exposure of mammals to imidacloprid by seedlings of sugar beet seed treated Montur Forte FS 230 is covered by the representative application of Gaucho FS 600 described in Addendum 7.

B.9.2.4 Toxicity to exposure ratio for mammals

Sugar beet seeds

According to the EFSA GD (2009) chapter 5.2.1 an risk assessment for mammals is not required in case of pelleted seeds.

Sugar beet seedlings

Beta-Cyfluthrin:
The exposure of mammals to beta-cyfluthrin is regarded as negligible. (please refer to B.9.2.1.1). Therefore, the acute and reproductive risk for mammals feeding from seedlings of Montur Forte FS 230 treated sugar beet seeds is acceptable in terms of beta-cyfluthrin.

Imidacloprid:
Residue studies submitted for the EU evaluation of imidacloprid and assessed in Addendum 7(Gaucho FS 600 - seed treatment in sugar beets, loading rate = 0.9 mg/seed) show a maximum concentration of 15.5 mg as/kg seedlings and a mean concentration of 10.28 mg as/kg seedlings. Since the loading rate of imidacloprid in the representative use of Montur Forte FS 230 is lower (0.154 mg as/seed), results of the residue studies as well as the subsequent risk assessment described in Addendum 7 for imidacloprid cover the acute and reproductive risk for mammals feeding from seedlings of Montur Forte FS 230 in terms of imidacloprid. The acute and reproductive risk for mammals was concluded to be acceptable. Please refer to addendum 7 for imidacloprid (January, 2014) for details!

Bioaccumulation and food chain behaviour / secondary poisoning

According to the EC Guidance Document on Risk Assessment for Birds and Mammals, substances with a log P_{OW} greater than 3 have potential for bioaccumulation and should be assessed for the risk of biomagnification in terrestrial food chains.

Beta-cyfluthrin has a log P_{OW} value of 5.9 and therefore the risk of biomagnification in terrestrial food chains has to be assessed.

Imidacloprid has a log P_{OW} value of 0.57 and therefore no formal risk assessment from secondary poisoning is therefore required.

Food chain from earthworm to earthworm-eating mammals

The risk due to secondary poisoning via earthworms is based 10 g mammal consuming 12.8 g worms/day. The concentration in earthworms is derived from the bioconcentration in earthworms,

which is calculated from the K_{ow}, and the concentrations in soil.

The bioconcentration via the dry soil is calculated in accordance with the 'dry soil approach' in EFSA GD 2009. The calculations below are based on the worst case 21 day TWA PEC in soil from the representative use as sugar beet seed treatment.

Application rate of beta-cyfluthrin (g as/ha)	10.4	
PEC_{soil} 21 d TWA (mg as/kg)	0,011	DT_{50} (soil) = 32,2 d
Kow	794,328	Log Pow = 5.9
Foc	0.02	default
Koc	112,004	Mean (n =)
BCF earthworm	4.26	BCF-worm/soil = (PEC-worm,ww / PEC-soil,dw)
PEC earthworm (mg as/kg)	0,047	PEC-worm = PEC-soil × BCF-worm
DDD mammals (mg/kg bw/day)	0.061	DDD = PEC-worm × 1.28
NOEL (mg/kg bw/d)	3.3	rat
TER mammals	**54.3**	**≥ 5, acceptable risk**

In this worst case scenario the TER value is above the trigger of 5, indicating an acceptable risk to mammals regarding secondary poisoning via earthworms. No further assessment is needed.

Food chain from fish to fish-eating mammals

The risk due to secondary poisoning via fish to fish-eating vertebrates is based on a 3000-g bird consuming 425 g fish per day. The calculations risk from secondary poisoning to **fish-eating mammals** was conducted in accordance with EFSA GD 2009.

Application rate of beta-cyfluthrin (g as/ha)	10.4	
RAC- aq (mg/L)	0.000000067	RAC tier 3 invertebrates
BCFfish	1822	Whole fish
BMF	2	Biomagnification factor (relevant for BCF ≥ 2000)
PEC fish (mg as/kg)	0.000308	PECfish = PECsw*BCFfish*BMF
DDD mammals (mg/kg bw/day)	0.000044	DDD = PECfish × 0.142
NOEL (mg/kg bw/d)	3.3	Mallard duck
TER mammals	**190372**	**≥ 5, acceptable risk**

In all scenarios the TER value is above the trigger of 5, indicating an acceptable risk to mammals regarding secondary poisoning via fish. No further assessment is needed.

B.9.3 Effects on aquatic organisms

B.9.3.1 Approaches and endpoints used for risk assessment for aquatic organisms

The following risk assessment was performed according to the recommendations of the aquatic GD (EFSA 2014) as well as according to the draft guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014).

Aquatic studies were conducted with the representative formulation Beta-cyfluthrin + Imidacloprid FS 230.

Summaries of these studies are provided under section B.9.3.2 and B.9.3.3, while Table B.9.3-1 gives

an overview of the resulting endpoints.

Table B.9.3-1: Toxicity of the formulated product Beta-Cyfluthrin + Imidacloprid FS 230 to aquatic organisms

Test substance	Test species		Endpoint	Reference
Beta-Cyfluthrin + Imidacloprid FS 230	Invertebrate, acute, *D. magna*	LC_{50}	4.2 µg form/L	Riebschlaeger (2012) M-425443-01-1 KIIIA1 10.2.2.2
	Invertebrate, chronic, *C. riparius*	NOEC EC_{15}	15.5 µg form/L 19.9 µg form/L	Bruns (2012) M-432814-01-1 KIIIA1 10.2.2.3
	Algae, *P. subcapitata*	ErC_{50}	> 100 mg form/L	Bruns (2012) M-426620-01-1 KIIIA1 10.2.6

Endpoints from aquatic studies with the active substance beta-cyfluthrin, and its metabolites DCVA, FPB-acid and FPB-aldehyde, which are considered relevant for the risk assessment, are summarised in **Fehler! Verweisquelle konnte nicht gefunden werden.**. For a complete overview of all aquatic endpoints, reference is made to the Volume_3 CA_B-9.3.

Table B.9.3-2: Further endpoints for beta-cyfluthrin used by the RMS for the lower tier acute and long term aquatic risk assessment of Montur Forte FS 230

Group/Species	Test substance	Time-scale/test design	End point	Toxicity (µg/L)	Reference
Laboratory tests ‡					
Fish					
Oncorynchus mykiss	Beta-Cyfluthrin	96 h/ flow-trough	LC_{50}	0.068 (mm)	KIIA8.2.1/02 103231 [redacted], 1994 M-056053-01-1 R-19086
Oncorynchus mykiss	FPB – acid (metabolite)	96 h/static	LC_{50}	4060 (nom)	KIIA 8.2.1/13 EBFRL003 [redacted], 2010 M-364414-01-1 R-27962
Oncorynchus mykiss	DCVA (metabolite)	96 h/static	LC_{50}	>14700 (nom)	KIIA8.2.1/05 515 [redacted], 1984 M-034724-01-1 R-19097
Oncorynchus mykiss	FPB – aldehyd (metabolite)	96 h/static	LC_{50}	792	KIIA8.2.1/06 502 [redacted], 1984 M-034806-01-1 R-19096
Oncorynchus mykiss	Cyfluthrin	58 d ELS / flow-through	NOEC	0.01 (mm)	KIIA 8.2.4 683 [redacted], 1985 M-008695-01-1 R-19088
	Beta-Cyfluthrin adjustment*		NOEC	0.0042 (mm)	
Aquatic invertebrates					
Hyalella azteca [a)]	Cyfluthrin	96 h / flow-through	EC_{50}	0.00055	KIIA 8.3.1.3/04 M-458228-01-1 Bradley, 2013
	Beta-Cyfluthrin adjustment*			0.000231	

Daphnia magna	Beta-Cyfluthrin	48 h/static-renewal	EC_{50}	0.105 (mm)	KIIA 8.3.1.1/03 D58707 Kimmel, 2014a M-481046
Gammarus pulex	Cyfluthrin formulation	21 d/static	EC_{50} (2 d) EC_{50} (7 d) EC_{50} (21d) $NOEC_{be-haviour}$ (21d) Adjusted values*	0.0075 (mm) 0.0021 (mm) 0.000378 (mm) 0.000109 (mm)	KIIA 8.3.1.3/05; KIIA 8.3.2.1/06 (KIIIA110.2.6/01) HBF/SP 01-99 Heimbach, 2000 M-020399-01-1 R-19104 Please refer to Volume 3CP_Bulldock EC 25_B-9.3.2 /KIIIA110.2.6/01
Americamysis bahia	Cyfluthrin	96 h/flow-through	EC_{50} (4d) adjusted value*	0.00082 (mm)	KIIA 8.3.1.3/03 808 Surprenant, 1987 M-027941-01-1
Americamysis bahia	Beta-Cyfluthrin	96 h/flow-through	EC_{50} (4d)	0,0022	KIIA 8.3.1.3/01 106797 Machado, 1994a M-056044-01-1 R-34702)
Americamysis bahia	Beta-Cyfluthrin	96 h/flow-through	EC_{50} (4d)	0,0023	KIIA 8.3.1.3/02 106588 Machado, 1994b M-056064
Daphnia magna	FPB – acid (metabolite)	48 h/ static	EC_{50}	39300 (nom)	KIIA8.2.4.8/07 09 EBFRL002 Bruns, 2010 M-363182-01-1 R-27963
Daphnia magna	DCVA (metab-olite)	48 h/static	EC_{50}	25000 (nom)	KIIA 8.3.1.1/04 505 Forbis and Burgess, 1984 M-034747-01-1 R-19099
Daphnia magna	FPB – aldehyd (metabolite)	48 h/static	EC_{50}	1300 (nom)	KIIA 8.3.1.1/05 504 Forbis and Burgess, 1984 M-034810-01-1 R-19098
Americamysis bahia	Beta-Cyfluthrin	28 d/ flow-through	NOEC	0.00041 (mm)	KIIA 8.3.2.1/04 EBFRL028 M-465880-01-1 Schwader, 2013

Daphnia magna	Beta-Cyfluthrin	21 d/ static-renewal	EC10	**0,023 (mm)**	KIIA 8.3.2.1/03 D58718 Kimmel, 2014 M-480965-01-1 R-30152
Sediment dwelling organisms					
Chironomus riparius	Beta-Cyfluthrin	28 d/ static/water – sediment system/spiked water	NOEC	0.4 (nom)	KIIA 8.5.2/02 D58720 Kimmel, 2014c M-481015-01-1 R-30154
Chironomus riparius	Beta-Cyfluthrin	28 d/ static/water – sediment system/spiked sediment	EC10	170 µg/kg	KIIA 8.5.2/03 D58731 Kimmel, 2014d M-481037-01-1 R-30153
Chironomus riparius	FBC-acid	Toxicity is addressed by the study with the active substance.			
Chironomus riparius	FPB-aldehyde	Toxicity is addressed by the study with the active substance.			
Chironomus riparius	DCVA	Toxicity is addressed by alternative information replacing experimental studies according EFSA GD (2013).) (KIIA 8.2.5.4/04)			
Algae					
Scenedesmus subspicatus	Beta-Cyfluthrin	96 h static	E_rC_{50} E_bC_{50}	> 2 > 2	KIIA 8.4/01 HBF/AL 40 Heimbach, 1987 M-056512-01-1 R-19109
Higher plant [*Not required in compliance with Reg (EU) 544/2011 article 8(2:8)]*					
Lemna gibba	Cyfluthrin	7 d static-renewal	E_rC_{50}	> 840 (mean measured)	KIIA 8.6 M-437708-02-1 Banman et al. 2012

*regarding to the adjustment please refer to Vol. 3CA B.9.2.2 and B.9.2.4

[a)] The acute toxicity endpoint in aquatic invertebrates reported by the notifier was based on a study on *D. magna* (Kimmel 2014a). Since *H. azteca* has proven to be more sensitive the RMS considers this better suitable for (first tier)-risk assessment (first tier).

[b)] The chronic toxicity endpoint in aquatic invertebrates reported by the notifier was based on a study on *D. magna* (Kimmel,2014b). Since *Americamysis bahia* has proven to be more sensitive the RMS considers this better suitable for (first –tier) risk assessment.

Active substance imidacloprid:

Endpoints from aquatic studies with the active substance beta-cyfluthrin, and its metabolites, which are considered relevant for the risk assessment, are summarised in Table B.9.3-3. For a complete overview of all aquatic endpoints, reference is made to the assessment report for the inclusion of imidacloprid into annex I as well as to its addenda.

Table B.9.3-3: Endpoints for imidacloprid used by the RMS for the lower tier acute and long term aquatic risk assessment of Montur Forte FS 230

Test sub-stance	**Test species**	**EU agreed endpoints [2)]**	**References: Author Date Report-No.**
Acute toxicity to fish			
Imidacloprid (NTN 33893)	*Cyprinodon variegatus*	96 h LC_{50} = 161.0 mg/L	[redacted] 1990 100354
Chronic toxicity to fish			
Imidacloprid (NTN 33893)	*Oncorhynchus mykiss* (ELS)	31 d NOEC = 9.02 mg as/L	[redacted] 2002 1022.016.321
Acute toxicity to aquatic invertebrates			
Imidacloprid (NTN 33893)	*Americamysis bahia*	96 h EC_{50} = 0.0341 mg as/L	Ward, G.S. 1990 100355
Imidacloprid	*Daphnia magna*	48 h EC_{50} = 85 mg as/L	Young, B.M. and Hicks, S.L. 1990 100245
Imidacloprid	*Caenis horaria*	EC_{50} = 6.68 µg/L	EFSA Journal 2014;12(10):3835/.Roessink et al. (2013)[2)]
	SSD	RAC_{sw} = 0.098 µg/L	EFSA Journal 2014;12(10):3835[2)]
Imidacloprid-desnitro (M09)	*Hyalella azteca*	96 h LC_{50} = 51.8 mg as/L 96 h EC_{50} = 29 mg as/L	Roney, D. J. and Bowers, L. M. 1996 107315
Imidacloprid-urea (M12)	*Hyalella azteca*	96 h LC_{50} > 94.83 mg/L 96 h EC_{50} > 94.83 mg/L	Dobbs, M. G. and Frank, J. T. 1996 107148
Chronic toxicity to aquatic invertebrates			
Imidacloprid (NTN 33893)	*Daphnia magna*	21 d NOEC = 1.8 mg as/L	Young, B. M. and Blake-more, G. C. 1990 100247
Imidacloprid	*Caenis horaria*	NOEC = 24 ng/L	Roessink et al. (2013)[2)]
Sediment dwellers			
Imidacloprid (NTN 33893)	*Chironomus riparius*	28 d EC_5 = 0,00186 mg as/L 28 d EC_{50} = 0,00311 mg as/L	Dorgerloh, M. and Sommer, H. 2001 DOM 21035

Imidacloprid-5-hydroxy (M01)	*Chironomus riparius*	24 h LC_{50} = 0.668 mg as/L	Dorgerloh, M. and Sommer, H. 2002 DOM 22033
Imidacloprid-nitrosimine (M07)	*Chironomus riparius*	24 h LC_{50} = 0.283 mg/L	Dorgerloh, M. and Sommer, H. 2002 DOM 22032
Imidacloprid-6-CAN (M14) (6-chloro-nicotinic acid)	*Chironomus riparius*	96 h LC_{50} >1.0 mg/L	Bowers, L. M. and Lam, C. V. 1998 108127
Imidacloprid-desnitro (M09)	*Chironomus riparius*	28 d EC_{50} = 45.99 mg as/L emergence	Dorgerloh, M. and Sommer, H. 2001 DOM 21039
Imidacloprid-urea (M12)	*Chironomus riparius*	28 d EC_{50} = 248.7 mg as/L emergence	Hendel, B. 2001 HDB/Ch 48
Imidacloprid-AMCP (M16)	*Chironomus riparius*	28 d EC_{50} >105 mg as/L emergence/development	Hendel, B. 2001 HDB/Ch 49
Imidacloprid-desnitro-olefine (M23)	*Chironomus riparius*	28 d EC_{50} = 21.3 mg as/L emergence	Hendel, B. and Sommer, H. 2001 HDB/Ch 51
Toxicity to algae			
Imidacloprid (NTN 33893)	*Scenedesmus subspicatus*	96 h E_rC_{50} > 10 mg as/L 96 h $NOE_rC \geq$ 10 mg as/L	Heimbach, F. 1986 HBF/Al 27
Mesocosm/Microcosm			
Imidacloprid SL 200	Aquatic community	182 d NOEC = 0.0006 mg as/L	Ratte H.T. and Memmert U. 2003 811776
Nuprid 200 SC (200 g/L Imidacloprid)	Aquatic community	77 d NOEC = 0.0006 mg as/L (2-fold application with 21-d interval)	Hammers-Wirtz, M., Strauss, T., Memmert, U. 2009 B07683[2)]
Imidacloprid	Several aquatic invertebrate species (chronic endpoints): A. aquaticus* G. pulex* C. obscuripes* S. lutaria* P. minutissima* C. dipterum* C. horaria* C. riparius** C. tentans*** H. azteca***	HC5 (EC10) of SSD analysis = 0.027 µg/L(+ AF of 3) RAC = 0.009 µg/L2)	EFSA Journal 2014;12(10):3835[2)] * from Roessink et al. (2013) ** from Pestana et al. (2009) *** from Stoughton et al. (2008)

ELS = early life stage; NO(E)AEC = No observed (ecologically) adverse effect concentration

1) EFSA Scientific Report (2008) 148, 1-120, Conclusion on the peer review of imidacloprid; Appendix 1 – List of endpoints

2) (EFSA Journal 2014;12(10):3835):

Acute: Nevertheless, as it was agreed at the meeting, in the absence of further data, EFSA considered that the endpoints

from Roessink *et al*., (2013) can be used for risk assessment as a conservative approach. The experts also agreed to use the lowest endpoint where several studies on the same species were available.
The HC5 value (and 95 % confidence interval) on the basis of acute toxicity **data for insects** (n=15, values in bold in Table B1 of Appendix B) was 0.49 (0.098 – 1.38) µg/L. Consequently, for insect taxa the **median HC5 was 0.49 µg/L** and the **lower limit HC5 was 0.098 µg/L**.
The experts discussed the AF by taking into account the criteria in the EFSA PPR Panel (2013). Most of the criteria in the guidance indicate that the appropriate AF should be 6. However, the experts considered that an AF of 5 could be suitable because some criteria triggered the lowest AF recommended in the guidance document and the most sensitive tested species were considered in the SSD.
Therefore, applying an AF of 5 to the median HC5 of 0.49 µg/L, the resulting tier-2B RACsw;ac was 0.098 µg as/L. However, it has to be noted that this **tier-2B RACsw;ac** may only be used as provisional for risk assessment, due to the limitations related to the data set.

Chronic:„ A SSD approach was carried out by the Netherlands (NL) based on some literature data (n=10, values in bold in Tables B3 and B4 in Appendix B). EFSA evaluated the NL approach in the **study evaluation notes** (see section 3; EFSA, 2014b). The chronic SSD and the endpoints used to construct this curve were discussed at the Pesticides Peer Review Experts' Meeting 116 (June 2014). The chronic SSD curve provided by the NL and agreed at the meeting has been included in Appendix C of this Conclusion. The **HC5 value** (and 95 % confidence interval) was **0.027** (0.0031 – 0.092) **µg as/L**. The experts agreed to apply an AF of 3 to the median HC5, as recommended by the EFSA PPR Panel (2013). Therefore, the **tier-2B RACsw;ch** was **0.009 µg as/L**. This RAC is more relevant than the **tier-2A,** above. However, as already mentioned, it is noted that this **tier-2B RACsw;ch** may only be used as provisional for risk assessment, due to the limitations related to the data set used to construct the SSD." A data gap concerning the chronic toxicity to aquatic invertebrates was defined. Until now, reliable data addressing these data have not been provided. Thus, in this report, the provisional tier-2B $RAC_{sw;ch}$ of 0.009 µg as/L will be used for risk assessment..

Toxicity of the Montur Forte FS 230 in comparison with the estimated additive toxicity of beta-cyfluthrin and imidacloprid

Surface water bodies are exposed by both active substances of Montur Forte FS 230 via run-off/drainage and dust drift deposition.
In case of the entry via run-off/drainage, imidacloprid and beta-cyfluthrin are likely to enter water bodies at different points of time and in different proportions than initially in the formulation, due to the distinct characteristics of the substances. Thus, endpoints of active substances are used for the risk assessment without considering mixture toxicity.
By contrast, via dust drift deposition, the toxicity of the formulation in comparison with the estimated additive toxicity of beta-cyfluthrin and imidacloprid was considered for the risk assessment.

Fish:
No study investigating the toxicity of the representative formulation Montur Forte FS 230 is available.
The most sensitive acute endpoint determined for beta-cyfluthrin is 96 h LC_{50} = 0.068µg/L (*Oncorynchus mykiss)*. As the most sensitive acute endpoint of imidacloprid is 96 h LC_{50} = 161.0 mg/L (*Cyprinodon variegates*), the toxicity of beta-cyfluthrin to fish is seven orders of magnitude higher than toxicity of imidacloprid.
Therefore, it can be assumed that toxic effects of Montur Forte FS 230 are mainly caused by its active ingredient beta-cyfluthrin.
For this reason and because of animal welfare, the acute study with the representative formulation is considered as not necessary.
Thus, risk assessment is based on the RACs derived for beta-cyfluthrin:

Tier 1 RAC acute = 0.00068 µg/L
Tier 1 RAC chronic = **0.00042µg/L**

Tier 2 RAC acute = **0.0346 µg/L**

Aquatic invertebrates:
The endpoint of Montur Forte FS 230 derived from the acute study with *D. magna* is 48 h –EC_{50} = 4.2 µg/L. The test system was semi-static. The measured recovery rate was > 80 %.
The 48 h –EC_{50} of beta-cyfluthrin and imidacloprid to *D. magna* are 0.105 µg/L and 850 µg/L, respectively.
The additive toxicity is estimated by the formula:

$$\frac{1}{EC50\ formulation} = \frac{n1}{EC501} + \frac{n2}{EC502}$$

n1 = portion of beta-cyfluthrin (m/m) = 0.074*
n2 = portion of imidacloprid (m/m) = 0.138*
*density of the preparation = 1.12

Calculated EC_{50} (formulation) = 1.42 µg/L

Hence, the formulation is slightly less toxic than when calculated through combined toxicity (assuming additive toxicity) (i.e. 4.20 versus 1.42 µg/L for measured and calculated toxicity, respectively).
According to the EFSA Aquatic GD (2013), the model deviation ration (MDR) is derived from the quotient of EC_{50} (calculated mixture toxicity) and EC_{50} (measured mixture toxicity).
Thus, the MDR for acute endpoint for *Daphnia magna* is 0.34 and therefore within the range between 0.2 and 5. Consequently, it is considered that the measured EC_{50} value for the formulation should be used for the risk assessment.
However, it was shown that other aquatic invertebrate species were more sensitive than *Daphnia magna* to the active ingredients of the formulation.
The most sensitive acute laboratory endpoint for beta-cyfluthrin was determined for *Hyalella azteca* with an acute (beta-cyfluthrin adjusted)[3] 96h EC_{50} of 0.000231µg/L. Hence, *Hyalella azteca* is 455 fold more sensitive to beta-cyfluthrin than *Daphnia magna*.

According to the EFSA Conclusion 2014 (EFSA Journal 2014;12(10):3835), the most sensitive acute laboratory endpoint for imidacloprid was determined for the aquatic insect *Caenis horaria* EC_{50} = 6.68 µg/L (These data are just used for discussing the toxicity of imidacloprid in comparison to the toxicity of beta-Cyfluthrin. According EFSA Journal 2014;12(10):3835, these data have limitations. Therefore they were not used for a tier I risk assessment. However, a data gap was defined concerning tier 3 data on aquatic invertebrates. Therefore, the *Caenis horaria* EC_{50} = 6.68 µg/L was used to derive a provisional tier-2B $RAC_{sw;ch}$ based on a SSD approach. As *Caenis horaria is the most sensitive species in this SSD, it was used for comparing the toxicity of* both active substances in the formulation Montur Forte FS 230. Refering to these data, *Caenis horaria* is 270 fold more sensitive to imidacloprid than *Daphnia magna*.).

However, by comparing the acute toxicity of both active substances to the crustaceans (*Daphnia magna*, *Americamysis bahia* and *Hyalella azteca),* it is shown that beta-cyfluthrin is 4 to 5 orders of magnitude more toxic than imidacloprid.

Moreover,when comparing available data on the toxicity of both active substances to the most sensitive organisms *Caenis horaria* (imidacloprid) and *Hyalella azteca* (beta-cyfluthrin), it is also shown that beta-cyfluthrin is 5 orders of magnitude more toxic than imidacloprid.

Therefore, the acute risk assessment for the formulation beta-cyfluthrin + Imidacloprid FS 230 (Montur Forte FS 230) is based on the RACs derived for beta-cyfluthrin.

For the chronic risk assessment of aquatic invertebrates, the toxicity values for beta-cyfluthrin led to a RAC (tier 3) of 0.067 ng/L while for imidacloprid the provisional tier-2B $RAC_{sw;ch}$ is of 9 ng/L [HC5 (EC_{10}) of SSD analysis = 0.027 µg/L; AF of 3: see EFSA conclusions on aquatic risk assessment of imidacloprid of Sept2014], i.e. about 4 orders of magnitude lower for beta-cyfluthrin. Therefore, the chronic risk assessment for the formulation beta-cyfluthrin + Imidacloprid FS 230 (Montur Forte FS 230) is also based on the RACs derived for beta-cyfluthrin.

[3] regarding to the adjustment please refer to Vol. 3CA B.9.1 and B.9.2.4

Tier 1 RAC acute = 0.0023 ng/L
Tier 1 RAC chronic = 0.041 ng/L

Tier 2 RAC acute = 0.0354 ng/L*
Tier 2 RAC chronic = 0.068 ng/L*

Tier 3 RAC = 0.105 ng/L[4]

Sediment dwellers:

The endpoint for *C. riparius* derived from the study with Montur Forte FS 230 is a measured NOEC = 15.5 µg/L.
The 28 d endpoints for the active ingredients are:
Beta-Cyfluthrin: NOEC = 0.4 µg/L (nom)
Imidacloprid: EC5 = 1.86 µg/L

The calculated additive toxicity for the formulation is: NOEC = 3.86 µg/L.

Hence, the formulation is less toxic than predicted. However, the MDR is 0.25 and therefore in the range of 0.2 to 5.

Algae:

The representative formulation Montur forte FS 230 as well as beta-cyfluthrin and imidacloprid show no toxicity to algae in the conducted laboratory tests:

Montur forte FS 230: 96 h ErC50 > 100 mg form/L *P. subcapitata*
beta-cyfluthrin: 96 h E_rC_{50} > 10 mg as/L *Scenedesmus subspicatus*

Imidacloprid: 96 h E_rC_{50} > 10 mg as/L *Scenedesmus subspicatus*

B.9.3.2 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

KIIIA1 10.2.2.2 (newly submitted with the dossier)

Author:	Riebschläger T.
Title:	Acute toxicity of beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G to the waterflea *Daphnia magna* in a static renewal laboratory test system
Date:	2004
Doc ID:	M-425443-01-1
Guidelines:	OECD Guideline 202, (2004) U.S. EPA Pesticide Assessment Guidelines, Subdivision E, § 72-2 (1982) EC Council Regulation No 440/2008, Method C.2 (2008) OPPTS Guideline 850.1010 Draft (1996), modified JMAFF 12 Nousan No. 8147 (2000)
GLP:	yes
Validity:	valid

[4] for details please refer to Vol1 section 2.9.2.2

Objectives:
The study was performed, to detect possible effects of the test item on mobility of *Daphnia magna* caused by 48 hours of exposure in a static renewal laboratory test system, expressed as EC_{50} for immobilisation.

Materials and Methods:
Beta-cyfluthrin + Imidacloprid FS 230 (80+150) G ,batch 2011-001451, specification No.: 102000010926-04, content: 7.25 % w/w beta-cyfluthrin, 13.6 % w/w imidacloprid (TOX 09324-00); *Daphnia magna* (1_{st} instars < 24 h old, 6 x 5 animals per concentration), exposed in a static renewal test system for 2 × 24 hours to nominal concentrations of 0, 0.8, 2.0, 5.0, 12.5, and 31.3 µg form./L without feeding.
The content of beta-cyfluthrin and imidacloprid in exposure media was measured for verification of the test item concentrations.

Dates of experimental work: September 12 2011 to November 07 2011

Results:
Validity of the study
To be a valid test, a maximum control mortality of 0.0 % is allowed. In the present test 0.0 % of the introduced animals died. Thus the test is valid.

Analytical results
The accompanying chemical analysis of beta-cyfluthrin in the freshly prepared test solutions at test initiation ranged between 96 % and 114 % (mean: 107 %) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 75 % and 100 % (mean: 83 %) of nominal.
The accompanying chemical analysis of imidacloprid in the freshly prepared test solutions at test initiation ranged between 96 % and 103 % (mean: 101 %) of the corresponding nominal concentrations.
The corresponding concentrations of the aged test solutions at the end of the 48 hours exposure period ranged between 101 % and 111 % (mean: 103 %) of nominal.
None of the measured active ingredients was detected in samples from untreated water control.
As the toxicity has to be attributed to the tested formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

Biological results
Acute immobilisation of *Daphnia magna*:

Nominal test concentration (µg form./L)	**Exposed daphnids (=100 %)**	**Immobilised daphnids**			
		48 h.		**48 h.**	
		%	%	n	%
control	30	0	0.0	0	0.0
0.8	30	0	0.0	2	6.7
2.0	30	0	0.0	8	26.7
5.0	30	4	13.3	15	50.0
12.5	30	6	20.0	26	86.7
31.3	30	17	56.7	29	96.7

No immobility or other effects on behaviour occurred in untreated control within 48 hours of exposure.

Conclusions:
Based on nominal concentrations of beta-cyfluthrin + Imidacloprid FS 230 (80+150) G, the following EC_{50} values for immobilisation after 24 and 48 hours of static exposure were assessed:

Statistical results of probit analysis conducted for determination of EC_{50} values:

Probit analysis for data obtained after	EC_{50} µg form./L (nominally)	Lower 95 % cl µg form./L (nominally)	Upper 95 % cl µg form./L (nominally)
24 hours	26.9	17.5	41.6
48 hours	4.2	3.2	5.6

KIIIA1 10.2.1 /02 (newly submitted with the dossier)

Author:	Bruns E.
Title:	*Pseudokirchneriella subcapitata g*rowth inhibition test with beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150) G
Date:	2012
Doc ID:	M-426620-01-1
Guidelines:	OECD Guideline 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test (March 23, 2006)
GLP:	yes
Validity:	valid

Objectives:
The aim of the study was to determine the influence of the test item on exponentially growing *Pseudokirchneriella subcapitata* expressed as NOEC, LOEC and EC_x for growth rate of algal biomass (cells per volume).
Materials and Methods:
Beta - Cyfluthrin + Imidacloprid FS 230 (80 + 150) G analysed content: 7.25 % w/w beta – cyfluthrin and 13.6 % w/w imidacloprid was tested, specified by batch ID: 2011-001451, sample description: TOX09324-00 and specification no.: 102000010926-04.
Pseudokirchneriella subcapitata (freshwater microalgae, formerly known as *Selenastrum capricornutum*) were exposed in a chronic multi-generation test for 3 days under static exposure conditions to nominal concentrations of 0.960, 3.07, 9.80, 31.3 and 100 mg formulation/L in comparison to a control. The pH values ranged from 8.0 to 8.5 in the controls and the incubation temperature ranged from 21.6 °C to 22.2 °C (measured in an additional incubated glass vessel) over the whole period of testing at a continuous illumination of 8447 lux.
Quantitative amounts of beta - cyfluthrin and imidacloprid were measured in all treatment groups and in the control on day 0 and day 3 of the exposure period.

Dates of experimental work: June 10 2011 to November 15 2011

Results:
Test conditions met all validity criteria, given by the mentioned guideline(s).
The analytical findings of beta - cyfluthrin in the treatment levels found on day 0 were 26 % to 79 % of nominal (average 49.6 %). On day 3 analytical findings of 34 % to 43 % of nominal (average 38.8 %) were found.
The analytical findings of imidacloprid in the treatment levels found on day 0 were 110 % to 114 % of nominal (average 112 %). On day 3 analytical findings of 109 % to 113 % of nominal (average 111 %) were found.
Beta-cyfluthrin is highly adsorptive. Therefore the recoveries observed for beta-cyfluthrin are related to its physico-chemical properties. The results for imidacloprid demonstrate that the test item has been applied correctly and that the results of the study are reliable.
Given that the toxicity cannot be attributed to any of the as compounds but to the formulation as a whole, all results are based on nominal test concentrations of the formulation.

Table B.9.3-4: The static 72 hour algae growth inhibition test provided the following effects:

Nominal concentration [mg form./L]	Cell number after 72 h (means) per mL	(0-72h)-average specific growth rates [days^{-1}]	Inhibition of average specific growth rate [%]
control	664 000	1.396	--
0.960	700 000	1.414	-1.3
3.07	625 000	1.375	1.6
9.80	654 000	1.393	0.3
31.3	656 000	1.394	0.2
100	682 000	1.406	-0.7

test initiation with 10,000 cells/mL
-% inhibition: increase in growth relative to the control

Conclusions:
The (0 - 72h)-ErC_{50} for beta - Cyfluthrin + Imidacloprid FS 230 (80 + 150) G is > 100 mg form./L, the (0 - 72h)-ErC_{10} is > 100 mg form./L and the (0 - 72h) - NOErC is ≥ 100 mg form./L.

B.9.3.3 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

KIIIA110.2.6 (newly submitted with the dossier)

Author:	Bruns E.
Title:	*Chironomus riparius* 28-day chronic toxicity test with beta-Cyfluthrin & Imidacloprid FS 230 (80 + 150) G in a water-sediment system using spiked water
Date:	2012
Doc ID:	M-432814-01-1
Guidelines:	OECD Guideline 219: Sediment-Water Chironomid Toxicity Test Using Spiked Water (adopted 13 April 2004)
GLP:	yes
Validity:	valid

Objectives:
The aim of the study was to determine the influence of the test item on emergence and development of *Chironomus riparius* for 28-days in a static water-sediment-system (spiked water exposure), expressed as NOEC, LOEC and ECx for emergence rate and development rate, if possible.

Materials and Methods:
Beta-cyfluthrin & Imidacloprid FS 230 (80 + 150) G, as contents: 7.25 % w/w (81.93 g/L) & 13.6 % w/w (153.7 g/L), density: 1.130 g/mL was tested, specified by batch-no.: 2011-001451, TOX-No.: 09324-00 and specification-no.: 102000010926-04). First instar of *Chironomus riparius* larvae, 4 beakers per test concentration and control with 20 animals each) were exposed in a static water-sediment system for 28 days to nominal concentrations in the overlying medium (spiked water application) of 6.90, 10.3, 15.5, 23.3 and 34.9 µg formulation./L.
Measurements of the water temperature were done continuously in one negative control vessel and recorded hourly by a data logger. Additionally the temperature was measured once a week in the overlying water of the additional test vessels of each test concentration incl. control(s).
Dissolved oxygen was measured twice per week in the overlying water of the additional test vessels of each test concentration incl. control(s) and additionally in all test vessels at the end of the test (day 28).
The pH was measured once per week in the overlying water of the additional test vessels of each test concentration incl. control(s) and additionally in all test vessels at the end of the test (day 28).
For verification of the aspired exposure concentrations, the content of both active substances beta-Cyfluthrin and imidacloprid were analytically determined.

Recoveries of beta-cyfluthrin and imidacloprid were measured four times during the study: 1 hour, 3, 7 and 28 days after application in one additional test container of each nominal initial test concentration of 6.90, 10.3, 15.5, 23.3 and 34.9 µg formulation/L and control of the overlying water and the pore water of the sediment.

Dates of experimental work: November 15 2011 to January 27 2012

Results:

Test system

Dissolved oxygen concentrations ranged in the water phase from 7.0 to 7.6 mg O2/L (7.0 mg O2/L= 85 % O_2 - saturation), the water pH values ranged from 8.4 to 8.6 and the water temperature ranged from 20.5 °C to 20.6 °C measured from parallel beakers of each test concentration over the whole period of testing, fulfilling the guideline requirements.

Analytical findings

Chemical analyses of beta-cyfluthrin and imidacloprid were performed for overlying water and pore water samples over time.

Analysis of the overlying water

Beta-cyfluthrin and imidacloprid were analysed in the overlying water at the beginning of the exposure period (nearly one hour after spiking) and reflect high recoveries of 89.6 % to 97.0 % (mean 92.1 %) for beta-cyfluthrin and 99.3 % to 105 % (mean 102 %) for imidacloprid of nominal concentrations in all test levels.

As the toxicity has to be attributed to the test formulation as a whole, all results submitted by this report are related to nominal test concentrations of the formulated product.

After 3 days of exposure no recoveries of beta-cyfluthrin higher than 0.0627 µg/L (LOQ) were found in the overlying water of the test concentrations from 0.50 to 1.69 µg beta-cyfluthrin /L (corresponding to 6.90 to 23.3 µg form./L), only at the highest concentration of 2.53 µg beta-cyfluthrin /L (corresponding to 34.9 µg form./L) 4.3 % of nominal was found. The analysis of beta-cyfluthrin on day 7 and day 28 showed no recoveries higher than 0.0627 µg/L.

Recoveries of imidacloprid on day 3 ranged from 71.0 % to 80.9 % (mean 76.6 %), on day 7 from 58.8 % to 61.3 % (mean 60.1 %) and 32.4 % to 40.2 (mean 36.3 %) of nominal test concentrations were found on day 28.

Analysis of the pore water

No recoveries of beta-cyfluthrin higher than 0.0627 µg/L (LOQ) were found in the pore water samples of all test levels over the whole test duration.

Chemical analysis of imidacloprid in the pore water (averages) over time yield 0.7 % of nominal on day 0, 2.5 % on day 3, 2.3 % on day 7 and 2.3 %, on day 28.

	Analytical results of beta-cyfluthrin and imidacloprid: average % of all nominal test concentrations			
Overlying water	**1 hour / day 0**	**day 3**	**day 7**	**day 28**
Beta-Cyfluthrin	92.1	0.9	0	0
Imidacloprid	102	76.6	60.1	36.3
Pore water				
Beta-Cyfluthrin	0	0	0	0
Imidacloprid	0.7	2.5	2.3	2.3

Biological findings

Start of emergence was on day 14 for the control and test concentration of 6.90 µg form./L. The start of emergence was postponed for one day at test concentrations of 10.3 and 15.5 µg form./L. At test concentration of 23.3 µg form./L the start of emergence was delayed for 2 days and at the highest test concentration of 34.9 µg form./L only one female midge emerged on day 24.

90.0 % of the inserted (n = 80) larvae maturated to adults in the control after 28 days, fulfilling the guideline requirements.

Influence on emergence and development rate after 28 days (based on initial nominal concentrations of the formulation in the overlying water):

Nominal test concentration µg form./L			Number of emerged midges (introduced midges)	Emergence of inserted larvae (pooled sex)			Development rate (1/d)
µg form./L	µg CYB/L	µg IMD/L		total (%)	male (%)	female (%)	pooled sex
Control	0	0	72 (80)	90.0	43.75	46.25	0.065
6.90	0.50	0.94	76 (80)	95.0	50.00	45.00	0.061*
10.3	0.75	1.41	73 (80)	91.25	48.75	42.50	0.060*
15.5	1.13	2.11	76 (80)	95.0	47.50	47.50	0.060*
23.3	1.69	3.17	51 (80)	63.75*	42.50	21.25	0.056*
34.9	2.53	4.75	1 (80)	1.25*	0	1.25	0.043*

*statistical significance (Williams Multiple Sequential t-test Procedure, □ = 0.05, one-sided smaller)

The Chi2-Test indicates no statistically different distribution between sexes compared to the assumption of 50 % females and 50 % males. Therefore male and female results were pooled for further statistical analyses to increase the statistical power.
Statistical significance (α = 0.05) on emergence rate for male and female midges (pooled) was evaluated for initial nominal test concentration of 23.3 µg form./L (= LOEC) and higher test concentrations, resulting in an NOEC of 15.5 µg form./L.
For development rate of male and female midges (pooled) statistical significance was evaluated for all nominal test concentrations, resulting in an NOEC of < 6.90 µg form./L.

Conclusions:
Test conditions met all validity criteria, given by the mentioned guideline.
Results are based on initial nominal concentrations in µg form./L of the test item in the overlying water:

Endpoints	NOEC	LOEC	EC_{15}	EC_{50}
Emergence rate (pooled sex) (95 % confidence limits)	15.5	23.3	19.9 (15.1 – 23.2)	25.0 (21.3 – 30.3)
Development rate (pooled sex) (95 % confidence limits)	< 6.90	<= 6.90	21.5 (5.60 – 27.8)	> 34.9

B.9.3.4 Further testing on aquatic organisms

No further studies submitted.

B.9.4 Risk assessment for aquatic organisms

B.9.4.1 Predicted environmental concentrations used in risk assessment

Entry via Run-off/Drainage

The exposure to surface water due to run-off and drainage is covered by FOCUS SW (FOCUS 2001).

Predicted environmental concentrations of beta-cyfluthrin and its metabolites in surface water were calculated according to FOCUS for the uses of beta-cyfluthrin + Imidacloprid FS 230 as seed treatment for sugar beet. PEC_{sw} values that are relevant for the aquatic risk assessment are summarised in the following tables. For details of PEC calculations refer to Volume_3CP_Montur Forte FS 230_B-8.

Table B.9.4-1: Maximum PEC_{sw} values – FOCUS Step 1 & 2

Compound	FOCUS scenario	$PEC_{sw, max}$ [µg/L]
Beta-Cyfluthrin	Step 1	0.021
	Step 2 - North	0.004
	Step 2 - South	0.008

Table B.9.4-2: Maximum PEC_{sw} values – FOCUS Step 3

Compound	FOCUS Scenario	$PEC_{sw, max}$ [µg/L]
Beta-Cyfluthrin	D3 (ditch, 1st)	0
	D4 (pond, 1st)	2.76×10^{-10}
	D4 (stream, 1st)	4.01×10^{-9}
	R1 (pond, 1st)	0
	R1 (stream, 1st)	0
	R3 (stream, 1st)	0

Bold value was considered in risk assessment as a worst case, covering all other scenarios.

Entry via Dust drift deposition

Furthermore, PEC_{sw} values due to dust drift deposition are calculated according the draft guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014) chapter 10.5.6[5]

Since no agreed scenario in FOCUS SW (FOCUS 2001) addresses water bodies in different distances from field edge regarding dust drift generated at sowing of treated seeds, concentrations in surface water from dust drift deposition can be calculated in a first approximation by using the PEC *2D dust ground deposition*.

The predicted environmental concentrations in a water body located 1 m from field edge can be calculated via the PEC *2D dust ground deposition* deposited in the non-target area (in g as/ha) converted into a PEC *surface water dust* (µg as/L) in a standard water body as follows:

$$PEC_{surface\ water\ dust}\ (\mu g\ a.s./L) = \frac{PEC_{2D\ dust\ ground\ deposition}\ (g\ a.s./ha) \times 100}{water\ volume\ (L/m^2)}$$

Where:

PEC= Predicted Environmental Concentration
as = active substance
water volume= 300 L/m² surface area in a ditch of 1 m width, 0.3 m depth at a 1 m distance from the field edge

The PEC *2D dust ground deposition* for sugar beets (according table 9-1) is defined as 0.02 g as/ha as a generic approach.
Therefore, the PEC $_{surface\ water\ dust}$ (µg as/L) = 0.0067 µg as/L. As the term active substance refers to

[5] Although the guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014) has not been finalised or entered into force within the EU, it is used for addressing the exposure of surface water bodies via drift of abraded dust. As there is evidence that off-field areas including surface water bodies are exposed by pesticides from abraded dust. In the absences of other reliable data, values given in SANCO/10553/2012 (January 2014) are used for predicting the environmental concentration in surface water bodies.

the total concentration of all active substances in the seed treatment formulation and the risk assessment for Montur Forte FS 230 is based on beta-cyfluthrin only, the value has to be adjusted according the portion of beta-cyfluthrin. The ratio between beta-cyfluthrin and the sum of beta-cyfluthrin and imidacloprid is 0.35. Consequently, the adjusted **$PEC_{surface\ water\ dust}$ (µg as/L) = 0.002345 µg beta-cyfluthrin/L and 0.00435 µg imidacloprid/L.**

B.9.4.2 Risk assessment based on exposure to surface water due to run-off and drainage

Table B.9.4-3: TER calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER	Trigger
Sugar beet					
Beta-Cyfluthrin	Fish, acute *Oncorynchus mykiss* (Tier-1)	LC_{50} 0.068	0.008	8.5	100
	Invertebrate, acute *D. magna*	EC_{50} 0.105	0.008	13	100
	Invertebrate, acute *Hyalella azteca* (tier 1)	LC_{50} 0.000231	0.008	0.029	100
	Fish, chronic *Oncorynchus mykiss*	NOEC 0.0042	0.008	0.525	10
	Invertebrate, chronic *Americamysis bahia* (tier 1)	NOEC 0.000172	0.008	0.022	10
	Sediment dweller, chronic	NOEC = 0.4	0.008	50	10
	Green algae, chronic	ErC_{50} > 10	0.008	>1250	10

The required triggers are not met for surface water organisms such as fish and invertebrates for beta-cyfluthrin when based on worst-case FOCUS Step 2 PEC_{sw} values. Therefore, TER calculations based on FOCUS Step 3 PEC_{sw} values are provided in the following.

Table B.9.4-4: TER calculations for beta-cyfluthrin based on FOCUS Step 3

Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER	Trigger
Beta-Cyfluthrin, sugar beet					
Fish, acute Oncorynchus mykiss	LC_{50} 0.068	4.01 × 10-9	D4 (stream, 1st)	16957606	100
Invertebrate, acute *Hyalella azteca*	LC_{50} 0.000231	4.01 × 10-9	D4 (stream, 1st)	57606	100
Fish, chronic *Oncorynchus mykiss*	NOEC 0.0042	4.01 × 10-9	D4 (stream, 1st)	1050000	10

Invertebrate, chronic *Americamysis bahia*	NOEC 0.00041	4.01 × 10-9	D4 (stream, 1st)	102244	10

Based on FOCUS Step 3 PEC_{sw} values, the TER_{acute} and TER_{lt} values for the active substance beta-cyfluthrin exceed the required trigger of 100 and 10, respectively.
This indicates an acceptable risk to aquatic organisms by exposure with beta-cyfluthrin via run-off and drainage. The calculations for the worst-case scenario D4 (stream, 1st) cover all other FOCUS scenarios which are relevant for sugar beet.

The PECsw,max step3 for Imidacloprid for Montur Forte FS 230 were not provided by the notifier. Therefore, they were estimated on the basis of values calculated from the formulation Gaucho (Focus step 3):
(please refer to EFSA Journal 2014;12(10):3835)
PEC_{sw} max of imidacloprid based on the application of Gaucho:
Maximum run-off scenario: < 0.0005 µg/L
Maximum drainage Scenario:
FOCUS Step 3: PEC_{sw} = 0.01 µg/L; PEC_{sed} = 0.01 µg/kg

These values correspond with an application rate of 117 g as/ha.
The application rate (imidacloprid) of Montur Forte 230 is 19.5 g as/ha, i.e. 6 fold lower.
Thus, the roughly estimated PECsw values of imidacloprid by the application of Montur Forte FS 230 are::
Maximum run-off scenario: < 0.000083 µg/L
Maximum drainage Scenario:
FOCUS Step 3: PEC_{sw} = 0.0017 µg/L; PEC_{sed} = 0.0017 µg/kg

Table B.9.4-5: TER calculations for imidacloprid based on FOCUS Step 3 (estimated)

Scenario	**PEC global max (µg/L)**	**Fish acute**	**Fish chronic**	**Invertebrates acute**	**Invertebrates prolonged**
		C. variegatus	***Oncorhynchus mykiss***	***SSD***	***Tier II RACsw***
		LC_{50} (µg/L)	**NOEC (µg/L)**	***Tier II RACsw*[2] (µg/L)**	***Tier II RACsw*[1] (µg/L)**
		161 000	9020	0.098	**0.009**
run-off max	< 0.000083	1939759036	108674699	1180.7	108.4
TER criterion		100	10	1	1

[1] EFSA Journal 2014;12(10):3835: Nevertheless, as it was agreed at the meeting, in the absence of further data, EFSA considered that the endpoints from Roessink *et al*., (2013) can be used for risk assessment as a conservative approach. The experts also agreed to use the lowest endpoint where several studies on the same species were available.
The HC5 value (and 95 % confidence interval) on the basis of acute toxicity **data for insects** (n=15, values in bold in Table B1 of Appendix B) was 0.49 (0.098 – 1.38) µg/L. Consequently, for insect taxa the **median HC5 was 0.49 µg/L** and the **lower limit HC5 was 0.098 µg/L**.
The experts discussed the AF by taking into account the criteria in the EFSA PPR Panel (2013). Most of the criteria in the guidance indicate that the appropriate AF should be 6. However, the experts considered that an AF of 5 could be suitable because some criteria triggered the lowest AF recommended in the guidance document and the most sensitive tested species were considered in the SSD.
Therefore, applying an AF of 5 to the median HC5 of 0.49 µg/L, the resulting tier-2B RACsw;ac was 0.098 µg as/L. However, it has to be noted that this **tier-2B RACsw;ac** may only be used as provisional for risk assessment, due to the limitations related to the data set.
[2] EFSA Journal 2014;12(10):3835 :„ A SSD approach was carried out by the Netherlands (NL) based on some literature data (n=10, values in bold in Tables B3 and B4 in Appendix B). EFSA evaluated the NL approach in the **study evaluation notes** (see section 3; EFSA, 2014b). The chronic SSD and the endpoints used to construct this curve were discussed at the

Pesticides Peer Review Experts' Meeting 116 (June 2014). The chronic SSD curve provided by the NL and agreed at the meeting has been included in Appendix C of this Conclusion. The **HC5 value** (and 95 % confidence interval) was **0.027** (0.0031 – 0.092) **µg as/L**. The experts agreed to apply an AF of 3 to the median HC5, as recommended by the EFSA PPR Panel (2013). Therefore, the **tier-2B RACsw;ch** was **0.009 µg as/L**. This RAC is more relevant than the **tier-2A,** above. However, as already mentioned, it is noted that this **tier-2B RACsw;ch** may only be used as provisional for risk assessment, due to the limitations related to the data set used to construct the SSD." A data gap concerning the chronic toxicity to aquatic invertebrates was defined. Until now, reliable data addressing these data have not been provided. Thus, in this report, the provisional tier-2B $RAC_{sw;ch}$ of 0.009 µg as/L will be used for risk assessment.

Based on these estimated PEC_{sw} values, the acceptability criteria are met. Thus, the risk to aquatic organisms is considered to be acceptable.

B.9.4.3 Risk assessment based on exposure via dust drift deposition

The TER calculations are based on exposure values given by SANCO/10553/2012 (2014) and adjusted to the portion of beta-cyfluthrin:

Species	**RAC [ng/L]**	**$PEC_{sw,max}$ [ng/L]**	**TER**
Fish, acute Tier 2	34.6	**2.345**	14.9
Fish, chronic Tier 1	**0.42**	**2.345**	**0.17**
Invertebrate Tier 3	**0.067**	**2.345**	**0.03**
Sediment dweller Chronic Tier 1	40	**2.345**	16.9

TER values indicate an unacceptable risk for fish (chronic) and aquatic invertebrates due to exposure of beta-cyfluthrin and therefore with Montur Forte FS230 via dust drift deposition.

B.9.5 Effects on arthropods

B.9.5.1 Effects on bees (KCP 10.3.1)

Montur forte 230 FS (150 g imidacloprid/L, 80 g beta-cyfluthrin/L) is a flowable concentrate seed treatment. Effects on bees of Montur forte 230 FS are not evaluated as part of the first EU review of beta-cyfluthrin. Therefore all relevant data and assessments are provided here and are considered adequate.

B.9.5.1.1 Acute toxicity (KCP 10.3.1.1)

Acute oral (KCA 10.3.1.1.1) and contact (KCA 10.3.1.1.2) toxicity

Report: CP 9.5.1.1/1
Schmitzer, S., 2011
Effects of beta-cyfluthrin + imidacloprid FS 230 (80+150) G (acute contact and oral) on honey bees (*Apis mellifera* L.) in the laboratory, study no. 64111035

Guidelines: OECD 213 and 214 (1998)

GLP: yes

Objectives:
The purpose of this study was to determine the acute contact and oral toxicity of beta-cyfluthrin + imidacloprid FS 230 (80+150) G to the honey bee (*A. mellifera* L.).
Mortality of the bees was used as the toxic endpoint. Sub-lethal effects, such as changes in behaviour, were also assessed.

Material and Methods:
- Beta-cyfluthrin + imidacloprid FS 230 (80+150) G: beta-cyfluthrin (FCR 4545): 7.25 % w/w, 81.93 g/L; imidacloprid (NTN 33893): 13.6 % w/w, 153.7 g/L (all values analytical)
- Batch ID.: 2011-001451, Sample Description: TOX 09324-00
- Material No.: 06519113
- Specification No.: 102000010926 - 04
- Density: 1.130 g/mL (20 °C).

Under laboratory conditions 30 worker bees (*Apis mellifera*) per treatment level were exposed for 96 hours to doses of 5.0, 2.5, 1.3, 0.63, 0.31, 0.16 and 0.078 µg product per bee by topical application (contact dose response test) and 30 worker bees/treatment were exposed for 96 hours to doses of 1.5, 0.62, 0.47, 0.25, 0.14, 0.068 and 0.035 µg product/bee by feeding (oral dose response test, value based on the actual intake of the test item).
Due to increasing mortality between 24 and 72 hours the contact and oral tests were prolonged for a further 48 hours up to 96 hours

Findings:

Table B.9.5-1: Toxicity to honey bees in laboratory tests

Test item	**Beta-cyfluthrin + imidacloprid FS 230 (80+150) G**	
Test object	***Apis mellifera***	
Exposure	contact (solution in Adhäsit(0.5 %)/water)	oral (sugar solution)
Dose rate µg product/bee	5.0, 2.5, 1.3, 0.63, 0.31, 0.16, 0.078	1.5, 0.62, 0.47, 0.25, 0.14, 0.068, 0.035
LD_{50} µg product/bee	24 hours: n.d. 48 hours: 0.603 72 hours: 0.279 **96 hours: 0.201**	24 hours: 0.476 48 hours: 0.311 72 hours: 0.270 **96 hours: 0.277**
LD_{20} µg product/bee	24 hours: 0.654 48 hours: 0.076 72 hours: 0.060 **96 hours: 0.082**	24 hours: 0.177 48 hours: 0.132 72 hours: 0.125 **96 hours: 0.148**
LD_{10} µg product/bee	24 hours: n.d. 48 hours: n.d. 72 hours: n.d. **96 hours: 0.051**	24 hours: 0.105 48 hours: 0.085 72 hours: 0.084 **96 hours: 0.107**
NOED µg product/bee*	24 hours: 0.31 48 hours: 0.08 72 hours: 0.08 **96 hours: < 0.08**	24 hours: 0.14 48 hours: 0.14 72 hours: 0.14 **96 hours: 0.14**

n.d. = not determined
* The NOED was estimated using Fisher Exact Test (pairwise comparison, one-sided greater, $\alpha = 0.05$).

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.18 and 0.14 µg as/bee, respectively.

Contact test:
The contact test was prolonged for a further 48 hours up to 96 hours due to increasing mortality between 24 and 72 hours. Dose levels of 5.0, 2.5, 1.3, 0.63, 0.31, 0.16 and 0.078 µg product/bee resulted in mortality of 100.0, 96.7, 96.7, 86.7, 76.7, 30.0 and 20.0 % at test termination (96 hours). No mortality occurred in the control group (water + 0.5 % Adhäsit).
Throughout the entire time of the experiment, strong behavioural abnormalities (*e.g.* movement coordination problems, apathy, cramps etc.) were observed amongst the test item treated dose groups. These behavioural impairments were increasing with increasing dose levels and decreasing with time.

Oral test:
The oral test was also prolonged for a further 48 hours up to 96 hours due to increasing mortality between 24 and 72 hours. In the oral test, the maximum nominal dose levels of the test item (2.0, 1.0 and 0.50 µg product/bee) could not be achieved, because the bees did not ingest the full volume of treated sugar solution, even when offered over a period of 6 hours. Actual oral doses of 1.5, 0.62, 0.47, 0.25, 0.14, 0.068 and 0.035 µg product/bee resulted in mortality ranging from 100.0 % to 6.7 % at the end of the test (96 hours after application). 3.3 % mortality occurred in the control group. Like in the contact test, behavioural abnormalities (*e.g.* movement coordination problems and/or apathy, cramps) were observed amongst the test item treated dose groups. These behavioural impairments were increasing with increasing dose levels and decreasing with time.

Conclusions:
The toxicity of beta-cyfluthrin + imidacloprid FS 230 (80+150) G was tested in both, an acute contact and an acute oral toxicity test on honey bees. The contact and oral LD_{50} values (96 h) of beta-cyfluthrin + imidacloprid FS 230 (80+150) G were determined to be 0.201 µg and 0.277 µg product/bee, respectively.

RMS's comments:
This study is considered valid and acceptable for the risk assessment.

Report: CP 9.5.1.1/2
Schmitzer, S., 2010
Effects of beta-cyfluthrin EC 025 G (Acute Contact and Oral) on Honey Bees (*Apis mellifera L.*) in the laboratory, study no.: 52601035
Guidelines: OECD 213 and 214 (1998)

GLP: yes

Objectives:
The purpose of this study was to determine the acute contact and oral toxicity of beta-cyfluthrin EC 025 G to the honey bee (*A. mellifera* L.).
Mortality of the bees was used as the toxic endpoint. Sub-lethal effects, such as changes in behaviour, were also assessed.

Material and Methods:

- Beta-cyfluthrin EC 025 G= beta-cyfluthrin (FCR 4545): 2.93 % w/w, 26.11 g/L analytical
- Specification No.: 102000006581-02
- Batch ID.: PF90225222
- Sample Description: TOX08742-00
- Density: 0.891 g/mL (20 °C)

Under laboratory conditions 30 worker bees (*Apis mellifera*) per treatment were exposed for 96 hours to doses of 100.0, 50.0, 25.0, 12.5, 6.3 and 3.1 ng as/ bee for topical application (contact) and for 48 hours to doses of 43.2, 41.5, 20.0, 11.9, 6.8 and 3.5 ng as/bee for feeding (oral, value based on the actual intake of the test item).
Due to increasing mortality between 24 and 72 hours the contact test was prolonged for further 48 hours up to 96 hours.

Findings:

Table B.9.5-2: Toxicity to Honey Bees in laboratory tests

Test item	Beta-cyfluthrin EC 025 G	
Test object	*Apis mellifera*	
Dose rate [ng as/bee]	100.0, 50.0, 25.0, 12.5, 6.3, 3.1	43.2, 41.5, 20.0, 11.9, 6.8, 3.5
Exposure	contact (solution in Adhäsit (0.5 %)/water)	oral (sugar solution)
LD_{50} [ng as/bee]	24 hours: 61.3 48 hours: 37.5 72 hours: 32.4 **96 hours: 33.7**	24 hours: 17.3 **48 hours: 16.4**

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.19 and 0.14 µg as/bee, respectively.

Contact test:
Due to increasing mortality between 24 and 72 hours the contact test was prolonged for further 48 hours up to 96 hours.
Dose levels of 100.0, 50.0, 25.0, and 3.1 ng as/bee led to mortality of 100.0, 83.3, 30.0 and 6.7 % at the end of the test (96 hours), respectively. No mortality occurred in the 12.5 and 6.3 ng as/bee dose levels.
There was 6.7 % mortality in the control group (water + 0.5 % Adhäsit). During the first 4 hours, behavioural abnormalities (e.g. movement coordination problems and apathy) were observed in all test treatment groups except for the 3.1 ng as/bee dose level group. 24 and 48 hours following the application, behavioural abnormalities (e.g. movement coordination problems and/or apathy) occurred in the 100.0, 50.0 and 25.0 ng as/bee dose levels. At the 72 hour assessment, no behavioural abnormalities were found any more. After 96 hours following the application one single bee in the 50.0 and 25.0 ng as/bee dose groups each showed moving coordination problems.

Oral test:
The maximum nominal dose levels of the test item (100.0, 50.0, 25.0 and 12.5 ng as/bee) could not be achieved, maximum because the bees did not ingest the full volume of treated sugar solution even when offered over a period of 6 hours. Mortality occurred in the 43.2, 41.5, 20.0, 11.9 and 6.8 ng as/bee dose levels. Oral doses of 43.2, 41.5, 20.0, 11.9 and 6.8 ng as/bee resulted in mortality ranging from 96.7 % to 10.0 % at the end of the test (48 hours after application). No mortality occurred in the 3.5 ng as/bee group and the control group. During the 4 hours assessment movement coordination problems and/or apathy were observed in the five highest groups (43.2, 41.5, 20.0, 11.9 and 6.8 ng as/bee). After 24 hours only one single bee in the 41.5 ng as/bee dose level showed dis-coordinated movement. 48 hours following the application, no behavioural abnormalities occurred any more.

Conclusions:
The toxicity of beta-cyfluthrin EC 025 G was tested in both an acute contact and oral toxicity test on honey bees. The LD_{50} (96 h) of beta-cyfluthrin EC 025 G was determined to be 33.7 ng as/bee (0.0337 µg as/bee) in the contact toxicity test. The LD_{50} (48 h) was determined to be 16.4 ng as/bee (0.0164 µg as/bee) in the oral toxicity test.

RMS's comments:
This study is considered valid and acceptable for the risk assessment.

B.9.5.1.2 Chronic toxicity (KCP 10.3.1.2)

No tests on chronic toxicity of Montur forte 230 FS were submitted. However, a chronic toxicity of Bulldock 25 EC (25 g/L beta- cyfluthrin), to adult honey bees was assessed in a 10-day chronic feeding test (please refer to Sandrock C., 2014a, CP 9.5.1.2/1).

B.9.5.1.3 Effects on honeybee brood (KCP 10.3.1.3)

No tests regarding the effects of Montur forte 230 FS on honeybee brood were submitted. However, the acute toxicity of Bulldock 25 EC (25 g/L beta- cyfluthrin), to bee larvae was assessed in a laboratory study (please refer to Sandrock C., 2014b, CP 9.5.1.3/1).

B.9.5.1.4 Sublethal effects (KCP 10.3.1.4)

Sub-lethal effects on honey bees were assessed in cage, tunnel and field tests already available for the EU evaluation of beta-cyfluthrin (2002).

In addition two new field studies with Bulldock 25 EC were conducted considering repeated applications. The studies investigated potential long-term effects and are summarised in the CP part of Bulldock 25 EC under points CP B 9.5.1.6/1 and CP 9.5.1.6/2.

B.9.5.1.5 Cage and tunnel tests (KCP 10.3.1.5)

No semi-field studies in accordance with PP 1/170 or other appropriate test guidelines and GLP requirements were submitted.

B.9.5.1.6 Field tests (KCP 10.3.1.6)

No field studies in accordance with PP 1/170 or other appropriate test guidelines and GLP requirements were submitted.

B.9.5.1.7 Summary of effects on honeybees

Due to the results of laboratory tests Montur forte 230 FS is considered to be highly toxic to bees for oral and contact exposure, respectively. However as bees are not exposed to relevant residues

- via nectar and pollen (sugar beets do not flower in commercial sugar beet production, beta-cyfluthrin is virtually non-systemic),
- via seed-treatment dust during the sugar-beet-pill sowing operation (sugar beet pills are very resistant to mechanical abrasion and are predominately sown with mechanical, non-air assisted sowing machines),
- via guttation liquid (beta-cyfluthrin is virtually non-systemic, moreover, sugar beet shows guttation only very rarely [e.g. Joachimsmeier *et. al.*, 2011; M-481776-01-1; MCP 10.3.1; DOI 10.5073 / jki. 2012.437.020]),

it can be concluded that beta-cyfluthrin, when used for the preparation of sugar beet pills, does not pose an unacceptable risk for honey bees.

B.9.5.1.8 Risk assessment for honeybees

Toxicity

Table B.9.5-3 presents a summary of all studies submitted for the risk assessment. Further details regarding studies with Montur forte 230 FS are providing in section B.9.5.1.1.

Table B.9.5-3: Endpoints for the beta-cyfluthrin containing seed-treatment product Montur forte 230 FS

Test substance	Test species	Endpoint	Value	Reference
Montur forte 230 FS	adult honeybees	72 h acute oral LD_{50}	0.270 µg product/bee (0.072 µg as/bee)	Schmitzer, S. (2011) Study no.: 64111035 CP 9.5.1.1./01
		96 h acute contact LD_{50}	0.201 µg product/bee (0.054 µg as/bee)	

Details of the honeybee testing with the active substance beta-cyfluthrin are presented in MCA, Section 9, Point B.9.3.1.

Exposure

The recommended use pattern for Montur forte 230 FS includes application in sugar beets as seed treatment at a maximum application rate of up to 29.9 g active substance/ha.

Due to the low water solubility (≈ 2 µg/L) beta-cyfluthrin is virtually non-systemic and in commercial beet production, the root is harvested before flowering. Thus, no bee exposure via potential residues of beta-cyfluthrin in nectar and pollen is expected. In addition, no exposure through dust is expected since sugar beet pills are very resistant to mechanical abrasion and sowing occurs predominately via mechanical, non-air assisted sowing machines.

Risk assessment

Due to the results of laboratory tests Montur forte 230 FS is considered to be highly toxic to bees for oral and contact exposure, respectively. However as bees are not exposed to relevant residues via nectar and pollen, dust during sowing and guttation liquid it can be concluded that beta-cyfluthrin, when used for the preparation of sugar beet pills, does not pose an unacceptable risk for honey bees.

B.9.5.2 Effects on non-target arthropods other than bees

B.9.5.2.1 Standard laboratory tests

No studies submitted/available.

B.9.5.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

KIIIA1 10.5.2/01

Author:	Neumann, P
Title:	Acute effects of Beta-cyfluthrin (techn.) & Imidacloprid (techn.) on larvae of carabid beetles (*Poecilus cupreus*) under extended laboratory test conditions
Date:	1999
Doc ID:	M-024650-01-1
Report no.:	NNP/PC008
Guidelines:	Internal testing method, Bayer AG
GLP:	yes
Validity:	n.a. (no official guideline); control mortality of 20 % is deemed to be high

Material and methods:
The effect of a mixture of imidacloprid (techn.) (content of as: 98.6 %, TOX 4941-00, specification: article No.:04145852, batch No.: 230824088) and of beta-cyfluthrin (techn.) (content of as: 98.5 %, TOX 5102-00 specification: article No.:04000838, batch No.: 380866077) on larvae of *Poecilus cupreus* was assessed under extended laboratory conditions. Twenty larvae per treatment (1 per test cup) were exposed to soil residues of the test substance. The soil substrate (Lufa 2.1) was moistened to about 40 % of its water holding capacity. Test application rates were 0.005 mg beta-cyfluthrin /kg soil & 0.010 mg imidacloprid /kg soil, 0.010 mg beta-cyfluthrin /kg soil & 0.010 mg imidacloprid /kg soil

and 0.010 mg beta-cyfluthrin /kg soil & 0.020 mg imidacloprid /kg soil (dry weight). The whole study duration was 55 days. Endpoints were mortality (individuals which fail to hatch successfully), development time (time to metamorphosis), and adult body weight. The reference treatment caused a mortality rate of 100 %.

Findings:

***Poecilus cupreus*, extended laboratory testing**

Test species	*Poecilus cupreus* (larval stages)			
Exposure	natural standard soil (Lufa 2.1)			
Test formulation	Control	Beta-Cyfluthrin (techn.) & Imidacloprid (techn.)		
Application rate	---	0.005 mg/kg & 0.010 mg/kg	0.010 mg/kg & 0.010 mg/kg	0.010 mg/kg & 0.020 mg/kg
Mortality rate [%]	20	0	20	5
Development time [d]	43.0	42.2	42.3	43.8
Mean adult body mass [mg]	89.4	81.6	82.6	80.5*
Effect on body mass [%]	-	8.7	7.6	10.0 %

*statistically significant different from the control treatment ($p < 0.05$).

Conclusion:
An exposure to Imidacloprid (techn.) & Beta-cyfluthrin at 0.005 & 0.010, 0.010 & 0.010 and 0.010 & 0.020 mg/kg had no adverse effect on ground beetle larvae compared to the control treatment. Only at 0.010 & 0.020 mg/kg the body weight was statistically reduced by 10 % compared to the control.

Findings:

Test species	*Poecilus cupreus* (larval stages)			
Exposure	natural standard soil (Lufa 2.1)			
Test formulation	Control	Beta-Cyfluthrin EC 025		
Application rate	-	0.04 mg as/kg	0.40 mg as/kg	4.00 mg as/kg
Mortality rate [%]	10	0	100*	100*
Time to metamorphosis [d]	41.0	49.1*	-	-
Mean adult body mass [mg]	80.3	73.7*	-	-
Effect on body mass [%]	-	8.2	-	-

*statistically significant different from the control treatment ($p < 0.05$).

Conclusion:
An exposure to beta-cyfluthrin at 0.40 and at 4.0 mg as/kg resulted in a mortality of 100 %. The mortality at 0.04 mg as/kg was not increased but the time to metamorphosis was significantly prolonged and the mean adult body mass was significantly reduced in statistical comparison to the control treatment.

KIIIA1 10.5.2/02 (newly submitted with the dossier)

Author:	Jans, D.
Title:	Determination of the effects of sugar beet seeds treated with Beta- Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L) on larvae of *Poecilus cupreus* L. (Carabidae) in an aged residue extended
Date:	2013
Doc ID:	M-453475-01-1

Report no.:	EBNTL078
Guidelines:	CANDOLFI ET AL. (2001)
GLP:	yes
Validity:	valid

Material and methods:
Sugar beet pills coated with Beta-cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L), specified by sample description: TOX 09312-00; specification no.: 102000010926-04; batch ID: 2011-000793 (analysed content of active ingredient: beta-cyfluthrin: 8.45 g/unit; imidacloprid: 14.43 g/unit [1 unit = 100000 seeds]).
The formulation used for the seed treatment was a flowable concentrate for seed treatment of Beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L), specified by sample description: TOX 09062-00; specification no.: 102000010926-04; batch ID: 2010-003825 [analysed content of active ingredient: beta-cyfluthrin: 79.55 g/L, imidacloprid: 151.4 g/L]; density: 1.130 g/mL.
To establish a plateau concentration for imidacloprid in the soil of the test item group, untreated soil was mixed with a water dispersible powder for slurry seed treatment of imidacloprid WS 70 % w/w, specified by sample description: TOX 09095-00; specification no.: 102000006811 - 03; batch ID: EDFL005274 [analysed content of active ingredient: imidacloprid: 69.0 % w/w].
For that untreated soil was mixed with Imidacloprid WS 70 % w/w to achieve a nominal imidacloprid concentration of 0.2 mg as/kg dry soil. Then the treated soil was stored under controlled environment conditions for three month (at a temperature range of 15.0 - 21.0 °C and a relative humidity range of 45 - 70 %). After that period, this treated soil was mixed with untreated soil again to achieve an imidacloprid concentration of 0.02 mg as/kg dry soil.
Finally the treated soil was filled in plastic boxes (surface area 38 x 24 cm) and one sugar beet pill coated with Beta-cyfluthrin + Imidacloprid FS 230 was put into each box which is equivalent to a seed density of 1.1 unit/ha. One sugar beet pill without seed treatment was put into each box for the control and the reference item treatment.
The boxes for the first bioassay were used directly in the laboratory to conduct the extended laboratory test with larvae of the carabid beetle *Poecilus cupreus.*
All other boxes were embedded in a field and were exposed this way to field conditions to allow the development of the sugar beets plants and the aging of the residues. The boxes for the second bioassay were transferred after six weeks from the field to the laboratory and the second extended laboratory test with *Poecilus* larvae was performed.
The effects on the development of the test organisms were compared to those of a control group in boxes which were filled with untreated soil and one untreated sugar beet pill.
A toxic reference (active substance: dimethoate) applied on the first day of each bioassay at 250 g as/ha in 400 L deionised water on exposure units with untreated soil and one untreated sugar beet pill was included to indicate the relative susceptibility of the test organisms and the test system.
For the second bioassay the boxes for the control as well as for the reference item group were kept under the same field conditions as boxes of the test item group.
In the extended laboratory test of each bioassay, one larva of *Poecilus cupreus*, one to two days old, was transferred on the respective box and the development, adult body weight and sex were assessed over a period of 56 days. The test organisms were fed with deep frozen larvae of *Tenebrio molitor*. For each bioassay, 20 boxes each for the control and test item group and 10 boxes for the reference item group were used as replicates.

Start of experimental work: 24 MAR 2011
Completion of experimental work: 13 JUL 2011

Findings:

Test item:	**Sugar beet pills coated with Beta-Cyfluthrin + Imidacloprid FS 230 g/L**					
Test organism:	*Poecilus cupreus*					
Exposure to:	**Soil containing aged residues of imidacloprid and sugar beet pills coated with Beta-Cyfluthrin + Imidacloprid FS 230 g/L**					
	Bioassay 1			Bioassay 2		
	Control group	Test item group	Reference item group	Control group	Test item group	Reference item group
No. of beetles found alive	18	20	0	15	15	0
No. of beetles found dead	0	0	0	0	0	0
No. of beetles not found	2	0	10	5	5	10
Successfully hatched beetles (in %)	**90**	**100**	**0**	**75**	**75**	**0**
No. of females	10	10	n.a.	6	4	n.a.
No. of males	8	10	n.a.	9	11	n.a.
Mean weight of beetles found (in g)	**0.0972 (S.d. 0.0119)**	**0.0986 (S.d. 0.0115) not sign.#**	**n.a.**	**0.0787 (S.d. 0.0130)**	**0.0778 (S.d. 0.0171) not sign.#**	**n.a.**

Mann-Whitney-Wilcoxon test (two-sided)
S.d.: Standard deviation; n.a.: not assessed; not sign.: not significant

Conclusions:
In this extended laboratory test the effects of sugar beet pills coated with beta-cyfluthrin + Imidacloprid FS 230 g/L on the carabid beetle *Poecilus cupreus* using soil containing aged residues of imidacloprid were determined.
In the first bioassay using exposure units filled with treated soil and one sugar beet pill directly sown in the laboratory, no impact on the successful metamorphosis of *Poecilus cupreus* has been detected.
In the second bioassay using exposure units filled with treated soil in which a sugar beet plant had been grown under field conditions for six weeks, no effects on the development or the body weight of the carabid beetles occurred.

KIIIA1 10.5.2/03 (newly submitted with the dossier)

Author:	Jans, D.
Title:	Determination of the effects of sugar beet seeds treated with Beta- Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L) on Aleochara bilineata GYLL. (Coleoptera) beetles in an aged residue extended laboratory test
Date:	2013
Doc ID:	M-465184-01-1
Report no.:	CW11/008
Guidelines:	CANDOLFI ET AL. (2001)
GLP:	yes
Validity:	due to the low parasitation rate in the control group the second bioassay (aged residues) is classified as invalid; the first bioassay is valid

Material and methods:
Sugar beet pills coated with beta-cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L), specified by sample description: TOX 09312-00; specification no.: 102000010926-04; batch ID: 2011-000793 (analysed

content of active ingredient: beta-cyfluthrin: 8.45 g/unit; imidacloprid: 14.43 g/unit [1 unit = 100000 seeds]).
The formulation used for the seed treatment was a flowable concentrate for seed treatment of Beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L), specified by sample description: TOX 09062-00; specification no.: 102000010926-04; batch ID: 2010-003825 [analysed content of active ingredient: beta-cyfluthrin: 79.55 g/L, imidacloprid: 151.4 g/L]; density: 1.130 g/mL.
To establish a plateau concentration for imidacloprid in the soil of the test item group, untreated soil was mixed with a water dispersible powder for slurry seed treatment of Imidacloprid WS 70 % w/w, specified by sample description: TOX 09095-00; specification no.: 102000006811 - 03; batch ID: EDFL005274 [analysed content of active ingredient: imidacloprid: 69.0 % w/w].
For that untreated soil was mixed with Imidacloprid WS 70 % w/w to achieve a nominal imidacloprid concentration of 0.2 mg as/kg dry soil. Then the treated soil was stored under controlled environment conditions for three month (at a temperature range of 15.0 - 21.0 °C and a relative humidity range of 45 - 70 %). After that period, this treated soil was mixed with untreated soil again to achieve an imidacloprid concentration of 0.02 mg as/kg dry soil.
Finally the treated soil was filled in plastic boxes (surface area 38 x 24 cm) and one sugar beet pill coated with beta-cyfluthrin + Imidacloprid FS 230 was put into each box which is equivalent to a seed density of 1.1 unit/ha. One sugar beet pill without seed treatment was put into each box for the control and the reference item treatment.
The boxes for the first bioassay were used directly in the laboratory to conduct the extended laboratory test with adults of the rove beetle *Aleochara bilineata*.
All other boxes were embedded in a field and were exposed this way to field conditions to allow the development of the sugar beets plants and the aging of the residues. The boxes for the second bioassay were transferred after four weeks from the field to the laboratory and the second extended laboratory test with *Aleochara* beetles was performed.
The effects on the development of the test organisms were compared to those of a control group in boxes which were filled with untreated soil and one untreated sugar beet pill.
A toxic reference (active substance: dimethoate) applied on the first day of each bioassay at 1800 g as/ha in 400 L deionised water on exposure units with untreated soil and one untreated sugar beet pill was included to indicate the relative susceptibility of the test organisms and the test system.
For the second bioassay the boxes for the control as well as for the reference item group were kept under the same field conditions as boxes of the test item group.
In the extended laboratory test of each bioassay, 10 male and 10 female adults of *Aleochara bilineata* (1 - 7 days old) were transferred on the respective box. At day 7, 14 and 21 after the start of each bioassay, approximately 1000 onion fly pupae (*Delia antiqua*) were added to allow parasitation and the number of hatched *Aleochara* beetles of the F_1 generation was recorded over a period of 47 days in the first and 40 days in the second bioassay. From these data the endpoint reproductive capacity was calculated for each bioassay.

Start of experimental work: 24 MAR 2011
Completion of experimental work: 19 JUL 2011

Findings:

Test item:	**Sugar beet pills coated with Beta-Cyfluthrin + Imidacloprid FS 230 g/L**
Test organism:	*Aleochara bilineata*
Exposure to:	**Soil containing aged residues of imidacloprid and Sugar beet pills coated with Beta- Cyfluthrin + Imidacloprid FS 230 g/L**

Bioas-say	Treatment	Mean number of hatched beetles of the F_1-generation per replicate	Hatched beetles per introduced female (mean ± s.d.)	No. of hatched beetles per host pupae (mean ± s.d.)	Parasitation rate (%)	Reduction of reproductive capacity R (%)
1	Control	1001	100.1 ± 19.55	0.334 ± 0.065	33.38	
	Test item	920	92.0 ± 17.00	0.307 ± 0.057	30.66	8.1 not sign.#
	Reference item	20	2.0 ± 1.24	0.007 ± 0.004	0.66	98.0
2	Control	745	74.5 ± 18.68	0.248 ± 0.062	24.83	
	Test item	555	55.5 ± 20.44	0.185 ± 0.068	18.51	25.5 not sign. ##
	Reference item	60	6.0 ± 2.70	0.020 ± 0.009	1.99	92.0

Wilcoxon test (one-sided);
one-way ANOVA, Williams test (one-sided)
n.sign. not significant

Conclusion:
In this extended laboratory test the effects of sugar beet pills coated with beta-cyfluthrin + Imidacloprid FS 230 g/L on the reproductive capacity of the rove beetle *Aleochara bilineata* using soil containing aged residues of imidacloprid were determined.
In the first bioassay using exposure units filled with treated soil and one sugar beet pill directly sown in the laboratory, a reduction of reproductive capacity of 8.1 % occurred.
In the second bioassay using exposure units filled with treated soil in which a sugar beet plant had been grown under field conditions for four weeks, the reduction of reproductive capacity was 25.5 %.
Due to the low parasitation rate in the control group the second bioassay (aged residues) is classified as invalid. The first bioassay is valid.

B.9.5.3 Semi-field studies with non-target arthropods

No studies submitted.

B.9.5.4 Field studies with non-target arthropods

No studies submitted.

B.9.5.5 Other routes of exposure for non-target arthropods

No studies submitted. No other routes of exposure are to be considered if the product is used according to good agricultural practice.

B.9.6 Risk assessment for arthropods

B.9.6.1 Risk assessment for non-target arthropods other than bees

The risk assessment was performed according to Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002), to the Guidance Document on regulatory testing and risk assessment proce-

dures for plant protection products with non-target arthropods (ESCORT 2, Candolfi et al. 2000[2]) as well as according to the draft guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014).

Studies with the soil dwelling arthropods, *Aleochara bilineata*, *Pardosa* spp., *Poecilus cupreus*, (adult), *Poecilus cupreus* (larvae) were conducted with the representative formulation beta-cyfluthrin + Imidacloprid FS 230. Summaries of these studies are provided under point B.9.5.2.1 and B.9.5.2.2, while Table B.9.6-1 gives an overview of the resulting endpoints.

Table B.9.6-1: Ecotoxicological endpoints for ground dwelling arthropods exposed to beta-cyfluthrin (CYB: beta-cyfluthrin; IMD: imidacloprid)

Test species	Tested Formulation, study type, exposure	Ecotoxicological Endpoint				Author (Year) Reference	
Poecilus cupreus, larvae	CYB tech. Extended Lab., mixed into soil Control 0.005 mg CYB / kg dry soil 0.010 mg CYB / kg dry soil 0.015 mg CYB / kg dry soil	treat. (mg as/kg dry soil) control 0.005 0.010 0.015	Mortality [%] 20 25 0 0	Effect on body weight [%] - 9.2 8.6 10.9	Development time [d] 43.0 42.7 42.9 45.1	KIIA 8.8.1.3 Neumann (2002) M-079000-02-1 (amended)	valid
Poecilus cupreus, larvae	CYB tech. + IMD tech. Extended Lab., test item mixed into soil (LUFA 2.1)	treat. CYP/IMD(mg as/kg dry soil) 0.005/0.01 0.01/0.01 0.01/0.02	corr. Mortality [%] -25[1] 0 -18.8[1]	Effect on body weight [%] 8.7 7.6 10.0	Development time [d] 42.2 42.3 43.8	KIIIA1 10.5.2/01 Neumann (1999) M-024650-01-1	valid
Poecilus cupreus, larvae	CYB EC 025 Extended Lab., formulation mixed into soil	treat. CYP/IMD(mg as/kg dry soil) control 0.040 0.40 4.0	corr. Mortality [%] 10 0 100 100	Effect on body weight [%] - 8.2 - -	Development time [d] 41.0 49.1 - -	Neumann, 2001; M-080415-01-1 KIIIA1 10.5.2./02; please refer to Volume_3CP_Bulldock EC 25_B-9.5.2.2[2]	valid
Poecilus cupreus, larvae	CYB+IMD FS 230 (80+150) Aged residue extended lab, sugar beet pills ($1.1x10^5$ pills /ha) in soil, (9.3g CYB + 15.8g IMD / ha)		Effect on hatching rate [%] 1st bioassay (day of drilling) -11.1[1] 2nd bioassay (6 weeks aging in the field) 0	Effect on body weight [%] -1.4[1] 1.1		Jans (2013) M-453475-01-1 KIIIA1 10.5.2/02	valid

Aleochara bilineata,	CYB+IMD FS 230 (80+150) Aged residue extended lab, sugar beet pills ($1.1x10^5$ pills /ha) in soil, (9.3g CYB + 15.8g IMD / ha)	1st bioassay (day of drilling)	Effect on Re-production [%] 8.1	Jans (2013) M-465184-01-1 KIIIA1 10.5.2/03	valid (1. Bioas-say)
		2nd bioassay (4 weeks aging in the field)	25.5		

[1] A negative value indicates a higher feeding rate, higher body weight or lower mortality in the treatment than in the control
[2] This study was submitted with the dossier of Montur Forte FS230. However, the test substance is identical with Bulldock EC25. Therefore, this study is documented in Volume_3CP_Bulldock EC 25_B-9.5.2.2.
*CYB+IMD FS 500 (80+420): studies have been originally submitted, evaluated and are cited in Addendum 1 to the Monograph of 01 October 1996 (starting page 153-155)

In-field risk assessment

Assessment of exposure via coated seeds only

A study that was conducted with larvae of *Poecilus cupreus* by mixing beta-cyfluthrin (tech.) and imidacloprid (tech.) into Lufa 2.1 soil (Neumann, P., 1999, KIIIA1 10.5.2/01).
The exposure to imidacloprid (techn.) & Beta-cyfluthrin at 0.005 & 0.010, 0.010 & 0.010 and 0.010 & 0.020 mg/kg had no adverse effect on ground beetle larvae compared to the control treatment. Only at 0.010 & 0.020 mg/kg the body weight was statistically reduced by 10 % compared to the control.

These test rates were about 29 % below the maximum PEC_{soil} value that is expected for beta-cyfluthrin from the use of beta-cyfluthrin + Imidacloprid FS230 according to the proposed use pattern ($PEC_{soil, max}$ 0.014 mg beta-cyfluthrin/kg soil).
Further studies that were conducted with larvae of *Poecilus cupreus* with application rates of beta-cyfluthrin at 0.015 mg as/kg soil (Neumann, 2002, KIIA 8.8.1.3) and 0.040 mg as/kg soil (Neumann, 2001; KIIIA1 10.5.2./02; please refer to Volume_3CP_Bulldock EC 25_B-9.5.2.2) resulted in no increased mortality indicating that the exposure to beta-cyfluthrin following the application of beta-cyfluthrin + Imidacloprid FS 230 will not result in unacceptable adverse effects on larvae of *Poecilus cupreus*.
To confirm the conclusions for *Poecilus cupreus* and to address the risk to a second soil dwelling arthropod *Aleochara bilineata*, aged residue studies were conducted with *Aleochara bilineata* and larvae of *Poecilus cupreus* (Jans, 2013, KIIIA1 10.5.2/02 and Jans, 2013, KIIIA1 10.5.2/03)
. For these studies sugar beet seeds were treated with the representative formulation beta-cyfluthrin + Imidacloprid FS 230 (80+150) at a treatment rate of 0.1 L/Unit (1 Unit = 10^5 seeds). In addition a plateau concentration of 0.02 mg imidacloprid/kg dry soil was established in the test soil before introducing the treated sugar beet pills into the soil. The sugar beet pills were introduced into the test containers with a seeding rate of 1.1 $x10^5$ seeds/ha. A first bioassay was started at the day when the seeds were introduced and a second bioassay was started 4 weeks (for *Aleochara bilineata*) and 6 weeks (for *Poecilus cupreus*) later. The study results confirmed already in the first bioassay that even initial effects will be clearly below 50 %.

Species	ER_{50} (g/ha)	In-field rate
Poecilus cupreus (larvae)	$1.1x10^5$ Montur Forte FS 230 coated sugar beet pills[1]	1.3×10^5 Montur Forte FS 230 coated sugar beet pills
Aleochara bilineata	$1.1x10^5$ Montur Forte FS 230 coated sugar beet pills[1]	1.3×10^5 Montur Forte FS 230 coated sugar beet pills

[1] The seed rate in the testing was only 84.6 % of the maximum seed rate in field (accoriding the gap table).The a exposure was 1 treaded pill/912 cm^2. To achieve the maximum seed of 1.3×10^5 pills/ha, the testing area should have been one seed only 769 cm^2. However, as effects measrued in the test swere far below 50 % for both species, the risk is regarded as ac-

ceptable

It can be concluded that the use beta-cyfluthrin + Imidacloprid FS 230 according to the proposed use pattern will not result in unacceptable adverse effects on non-target arthropod species in the in-field area.

Off-field risk assessment

The off-field is exposed by dust abraded and drifted during the drilling.

Risk has to be assessed according the draft guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014) chapter 11.5[6]:

Non-target arthropods outside the field sown with treated seeds will be exposed to the active substance through the deposition of abraded dust. Foliar dwelling non-target arthropods have to be considered particularly at risk. It is considered that the realistic worst case exposure for terrestrial invertebrates – especially pollinators – will not be found on the ground but in 3 dimensional spatial structures (e.g. trees, hedges, adjacent crops). Thus, the predicted 3-D exposure data (as listed in chapter 10.5.4 of the draft GD SANCO/10553/2012) will be employed in the assessment of the risk for foliar-dwelling non-target arthropods exposed to contaminated dust. As long as no generic factors are available for every crop, a worst case extrapolation factor of 13 is used to derive 3-D exposure data from 2-D ground deposition data.

Because of the attractiveness of flowers to pollinators, a vegetation dilution factor is deemed to underestimate the risk for species e.g. foraging in the outer part of a flowering hedge. Moreover, pollinators like bees or butterflies will forage from one flower to the next and accumulate high amount of dust. Thus, no vegetation distribution factor should be used to assess the realistic environmental risk for non-target arthropods exposed to contaminated dust deposited in 3-dimensional structures.

The TER-ratio can be calculated as follows:

$$TER_{3D\,dust} = \frac{Ecotoxicological\,Endpoint_{liquid\ formulation}\ (g\ a.s./ha)}{PEC_{3D\,dust\,deposition}\ (g\ a.s./ha)}$$

where

TER	=	Toxicity to Exposure Ratio
as	=	active substance
PEC *3D dust deposition*	=	Predicted Environmental Concentration after deposition of abraded dust in adjacent 3-dimensional structures

A TER trigger value of 10 or 5 (Uniform principles; Regulation (EU) No 546/2011) is proposed. These triggers are in line with the ESCORT 2 safety factors of 10 or 5 in the off-field risk assessment based on resp. first tier and extended laboratory tests.

The PEC *3D dust deposition* can be calculated as follows (chapter 10.5.4 of SANCO/10553/2012):

[6] Although the guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014) has not been finalised or entered into force within the EU, it is used for addressing the exposure of off-field areas via drift of abraded dust. As there is evidence that off-field areas are exposed by pesticides from abraded dust. In the absences of other reliable data, values given in SANCO/10553/2012 (January 2014) are used for predicting the environmental exposure of off-field areas.

$$PEC_{3D\,dust\,deposition}\,(g\,a.s./ha) = PEC_{2D\,ground\,dust\,deposition}\,(g\,a.s./ha) \times 3D\,extrapolation\,factor$$

where

PEC	=	Predicted Environmental Concentration
as	=	active substance
3D factor	=	extrapolation factor was determined in field studies with different crop types to be **13**.

The 3D extrapolation factor describes the ratio between dust deposition in 3D structures (measured in gauze netting) and 2D structures (measured in Petri dishes).

According to chapter 10.5.4 (of SANCO/10553/2012) the PEC 3-D is **0.26 g as*/ha.**

However, studies testing the toxicity of Montur Forte FS 230 on leaf dwelling arthropods (*Aphidius rhopalosiphi, Typhlodromus pyri*) were not submitted.

Therefore, a risk assessment referring exposure in the off-field area cannot be carried out.
A data gap is defined.

B.9.7 Effects on non-target soil meso- and macrofauna

B.9.7.1 Earthworms

Earthworm studies with the formulation Montur Forte FS 230 were conducted in artificial soil with a peat content of 5 %.
For this reason, the resulting endpoints for the formulation containing beta-cyfluthrin (log P_{OW} = 5.9) is not divided by 2.
Rational:
RMS acknowledges the decision by EFSA during the peer review 91 of penflufen from April 2012 regarding the division of endpoints for lipophilic substances conducted with 5 % organic matter (peat) in the test soil. However, RMS would not support the decision to divide the endpoint of the earthworms studies performed in a standard soil with an OM content of 5 % by 2. The approach of dividing endpoints is published in the old Guidance document (GD) for terrestrial ecotoxicology (SANCO/10329/2002). By the time the old GD was discussed, tests for soil organisms were conducted with testing soils containing 10 % peat only. Therefore, a division of endpoints was necessary to address the bioavailability of chemicals for soil organisms in test soils. Assuming a linear correlation between the OM-content and the bioavailability of chemicals for test organisms, it would be inconsistent to divide endpoints by 2 from tests conducted with soils containing 5 % OM.
A linear correlation between OM-content and bioavailability for soil organisms provided, tests conducted with soils containing 10 % OM had to be divided by 4 if tests conducted with soils containing 5 % OM are divided by two.
Moreover, if the division of endpoints by two is used for both OM-contents (5 % + 10 %), there would not be an incentive for applicants to submit new studies on soil organisms with soils containing 5 % OM anymore.
This question should urgently be clarified by an eligible committee on EU-level, independently from the evaluation of active substances according to regulation EC No 1107/2009.
Unless the further approach how to handle tests with different OM-content in testing soils is not clear, tests on soil organisms with 5 % OM in testing soils should not be divided by two.

Table B.9.7-1: Toxicity of beta-cyfluthrin, metabolites FPB-acid and DCVA and beta-Cyfluthrin FS 230 (Montur Forte FS 230) to earthworms

Species	Test design	LC_{50} (mg as/kg dw soil)	NOEC (mg./kg dw soil)	Reference	reliability
Beta-Cyfluthrin					
Eisenia fetida	14 d acute	>1000 >500 [A]	10 5 [A](as)	KIIA 8.9.1/01 HBF/RG 83 Heimbach, 1987 M-053564-01-1 R-19143	valid
FPB-acid					
Eisenia fetida	14 d acute	> 63 > 31.5 [1]	1 < 63 <31.5	KIIA 8.9.1/02 09P11RA Moser and Scheffczyk, 2009 M-354192-01-1 R-27979	valid
Eisenia fetida	56 d chronic	-	5.2 (reproduc-tion) **2.6 (reproduc-tion)** [A]	KIIA 8.9.2/01 kra/Rg-R-143/13 Kratz, 2013a M-468873-01-1 R-34697	valid
DCVA					
Eisenia fetida	14 d acute	122.7 61.35 [1]	< 63 <31.5 [1]	KIIA 8.9.1/03 09P10RA Moser, 2009 M-356435-01-1 R-27978	valid
Eisenia fetida	56 d chronic	184.76 92.38 [1]	5.2 (reproduc-tion) **2.6 (reproduc-tion)** [A]	KIIA 8.9.2/02 kra/Rg-R-157/13 Kratz, 2013b M-468552-01-1 R-34696	valid
Montur Forte FS 230					
Eisenia fetida	56 d chronic, test item mixed into soil	-	1.78 (reproduction)	Leicher (2011) M-407796-01-1 KIIIA1 10.6.3/02	valid
Eisenia fetida	56 d chronic, expo-sure via treated sugar beet pills	-	>1,300, 000 treated sugar beet pills	Luehrs (2003) M-110969-01-1 KIIIA1 10.6.3/01	valid

[A] corrected by factor of 2 due to lipophilic substance (log P_{ow} > 2) and 10 % peat content in test soils

B.9.7.1.1 Earthworm sub-lethal effects

KIIIA1 10.6.3/01 (newly submitted with the dossier)

Author:	**Luehrs, U.**
Title:	Imidacloprid & β-Cyfluthrin FS 230: Effects on Reproduction and Growth of Earthworms *Eisenia fetida* in Artificial Soil with 5 % Peat in the Test Substrate

Date:	2003
Doc ID:	M-110969-01-1
Guidelines:	ISO 11268-2, 1998 and BBA VI 2-2, 1994
GLP:	yes
Validity:	valid

Objectives:
The purpose of this study was to investigate the effects of Imidacloprid & β-Cyfluthrin FS 230 on the mortality, body weight, feeding activity and reproduction of adult Eisenia fetida.

Material and Methods:
Imidacloprid & β-Cyfluthrin FS 230
Sample No.: TOX06257-00
Development No.: 30-00266429,
Batch No.: 06200/0214(0193)
Sugar Beet Pills treated with the Test Item:
Content of as: FCR 4545 (β-Cyfluthrin): 7.89 g/unit, NTN 33893 (Imidacloprid): 14.60 g/unit
toxic standard: Derosal SC 360 (active ingredient carbendazim) is tested at least once a year in a dose response study;
control: 1 untreated sugar beet pill
artificial soil with 5 % peat
Sugar beet pills treated with Imidacloprid & β-Cyfluthrin FS 230 were placed in the soil at a depth of approximately 2.5 cm in test containers with a soil surface of approximately 707 cm² at the 1-fold, 2-fold, 5-fold and 10-fold rate corresponding to 1, 2, 5 and 10 seed pills per test unit.
Earthworms *Eisenia fetida* (80 worms per treatment group) were exposed at 18 - 20 °C, light 520 - 800 lux, 16 h light : 8 h dark, fed weekly with dried cattle manure, initial soil water content 22.5 % - 22.7 %, water content at experimental termination 22.1 % - 25.9 %; initial pH 5.9, pH 6.0 - 6.2 at experimental termination;
Endpoints were mortality, body weight change, feeding activity and reproduction (counted in 4 sub samples per test unit).

Dates of experimental work: April 16 2003 – June 13 2003

Test item:	**Imidacloprid & beta-Cyfluthrin FS 230**				
Test species:	Eisenia fetida				
Exposure:	Test item treated pills placed in ca. 2.5 cm depth in soil				
Test duration:	57 days				
	Control	**Imidacloprid & beta-Cyfluthrin FS 230**			
		1-fold rate	**2-fold rate**	**5-fold rate**	**10-fold rate**
mortality [%] [1]	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	1.3 n.s2 ± 1.8
body weight change [%] [1]	22.5 ± 4.0	13.9 n.s.3 ± 4.0	21.7 n.s. 3 ± 6.9	17.4 n.s. 3 ± 5.1	13.3 n.s. 3 ± 0.9
reproduction of juveniles [1]	305 ± 87	307 n.s.4* ± 87	423 * 4 ± 84	410 n.s. 4 ± 76	286 n.s. 4± 78
% of control	-	100.8	138.8	134.5	93.9
amount of food added [g] [1]	100.0± 0.0	100.0± 0.0	100.0± 0.0	100.0± 0.0	100.0± 0.0

1 mean ± SD = mean ± Standard Deviation from 2 replicates (8 sub samples for reproduction); the results represent rounded values calculated on the exact raw data
2 = Fisher-exact test, $\alpha = 0.05$, two-sided
3 = Bonferroni t-test, $\alpha = 0.05$, two-sided
4 = Dunnett test, $\alpha = 0.05$, two-sided
n.s. = not significantly different compared to the control
* = significantly higher compared to the control
- = not relevant

Reference Test:
The most recent toxic standard test showed statistically significant effects on reproduction at a concentration of 1.6 mg carbendazim/kg artificial soil (dry weight); the EC_{50} for reproduction was calculated as 1.9 mg carbendazim/kg soil dry weight.

Conclusions:
Imidacloprid & β-Cyfluthrin FS 230 did not show significant adverse effects on mortality, body weight change, reproduction or feeding activity of the earthworm *Eisenia fetida* in artificial soil up to the 10-fold field rate (1 300 000 pills/ha), i.e. the highest rate test tested. The number of juvenile earthworms was not significantly different compared to the control at any test item concentration except at the 2-fold field rate (260 000 pills/ha), where the number of juveniles was statistically significantly increased (Dunnett-test, a = 0.05, two-sided). However, an increased number of earthworms is not considered to be an adverse effect and the statistical significance was not considered to be treatment related, since in the higher rates no effect could be observed.

Therefore, the No-observed-effect-concentration (NOEC) for reproduction was determined to be the 10-fold field rate (1 300 000 pills/ha).

KIIIA1 10.6.3/02 (newly submitted with the dossier)

Author:	Leicher, T.
Title:	Beta-cyfluthrin + Imidacloprid FS 230 (80+150) G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat
Date:	2003
Doc ID:	M-407796-01-1
Guidelines:	ISO 11268-2: 1998 (E); OECD 222: April 13, 2004
GLP:	yes
Validity:	valid

Objectives:
The purpose of this study was to assess the effect of beta-cyfluthrin + Imidacloprid FS 230 (80+150) G on survival, growth, and reproduction on the earthworm *Eisenia fetida* during an exposure in an artificial soil with 5 different test concentrations.

Material and methods:
Test item: Beta-cyfluthrin + Imidacloprid FS 230 (80+150) G; (Sample description: TOX09062-00; Batch ID: 2010-003825; Material No. 06519113; Specification No. 102000010926 - 04; content: 79.55 g beta-cyfluthrin/L and 151.4 g imidacloprid/L; density: 1.130 g/mL).
Adult *Eisenia fetida* (approx. 6 months old, 8 × 10 animals for the control group and 4 x 10 animals per test concentration of the treatment group) were exposed in an artificial soil (with 5 % peat content) to the nominal test concentrations of 1.00, 1.78, 3.17, 5.64, and 10.04 mg test item/kg dry weight artificial soil. The test item was mixed into the soil. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Dates of experimental work: February 18 2011- April 26, 2011

Findings:
The validity criteria of the test according to the guideline were fulfilled:

Validity criteria	Recommended	Obtained
Mortality of the adults in the control	≤ 10 %	0.0 %
Rate of reproduction of juveniles (earthworms per	≥ 30	236, 260, 234, 199, 203, 198, 154, 257

control vessel)		
Coefficient of variance of reproduction in the control	≤ 30 %	16.4 %

No worms died after 28 days of exposure at the control group and all treatment groups.

Growth:
Statistically significant different values for the growth relative to the control were not observed at any test concentration.

Reproduction:
No statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the test concentrations of 1.00 and 1.78 mg test item/kg dry weight artificial soil. Statistically significant different values for the number of juveniles per test vessel relative to the control were observed at the three highest test concentrations (3.17, 5.64 and 10.04 mg test item/kg dry weight artificial soil).

Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days are summarised below:

Test object	***Eisenia fetida***					
Test item	**Control**	**CYB+IMD FS 230 (80+150) G**				
mg test item/kg dry weight artificial soil	-	1.00	1.78	3.17	5.64	10.04
5Mortality of adult earthworms [%] after 28 days	0	0	0	0	0	0
Mean change of body weight of the adults from day 0 to day 28 [%]	18.02	18.51	19.74	22.57	18.60	12.41
Standard Deviation	5.28	1.90	62.8	8.07	4.88	8.67
Mean number of offspring per test vessel after 56 days	217.6	222.0	197.3	165.5 *	174.8 *	137.8 *
Standard Deviation	35.7	12.8	20.7	34.9	17.0	16.7

(Values in this table are rounded values)
* statistically significant different to the control (Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$)

The table below shows the results of the most recent toxic reference test which indicate that the test organisms are sufficiently sensitive.

Test object	***Eisenia fetida***			
Reference test item	**Control**	**Carbendazim 360 g as/L**		
Test concentration (mg as/kg dry weight artificial soil)	-	1.25	2.5	5.0
Mortality of adult earthworms [%] after 28 days	0	0	0	0
Mean change of body weight of the adults from day 0 to day 28 [%]	+44.6	+55.4 *	+ 44.2	+ 32.2 *
Standard Deviation	± 8.9	±4.6	± 6.6	± 2.8
Mean number of offspring per test vessel after 56 days	220.0	247.5	157.5 **	20.8 **
Standard Deviation	± 22.7	± 24.3	± 5.4	± 15.6

(values in this table are rounded values)
* statistically significant different to the control (Williams Multiple Sequential t-test, two-sided, $\alpha = 0.05$)
** statistically significant different to the control (Williams Multiple Sequential t-test, one-sided smaller, $\alpha = 0.05$)

Conclusions:
Based on biological and statistical significance:

NOEC related to growth: ≥ 10.04 mg test item/kg dry weight artificial soil
LOEC related to growth: > 10.04 mg test item/kg dry weight artificial soil

NOEC related to reproduction: 1.78 mg test item/kg dry weight artificial soil
LOEC related to reproduction: 3.17 mg test item/kg dry weight artificial soil
An EC_{50} could not be calculated.

B.9.7.2 Other non-target soil meso- and macrofauna – sublethal effects

All studies summarised below were conducted in artificial soil with a peat content of 5 % or in LUFA 2.1. soil with an assumed peat content of < 5 %.
For this reason, the resulting endpoints for beta-cyfluthrin (log P_{OW} = 5.9) and its metabolites FPB-acid (log Pow = 2.6) and DCVA (log Pow = 2.5) are not divided by 2.
Rational:
RMS acknowledges the decision by EFSA during the peer review 91 of penflufen from April 2012 regarding the division of endpoints for lipophilic substances conducted with 5 % organic matter (peat) in the test soil. However, RMS would not support the decision to divide the endpoint of the soil macro-organisms studies performed in a standard soil with an OM content of 5 % by 2. The approach of dividing endpoints is published in the old Guidance document (GD) for terrestrial ecotoxicology (SANCO/10329/2002). By the time the old GD was discussed, tests for soil organisms were conducted with testing soils containing 10 % peat only. Therefore, a division of endpoints was necessary to address the bioavailability of chemicals for soil organisms in test soils. Assuming a linear correlation between the OM-content and the bioavailability of chemicals for test organisms, it would be inconsistent to divide endpoints by 2 from tests conducted with soils containing 5 % OM.
A linear correlation between OM-content and bioavailability for soil organisms provided, tests conducted with soils containing 10 % OM had to be divided by 4 if tests conducted with soils containing 5 % OM are divided by two.
Moreover, if the division of endpoints by two is used for both OM-contents (5 % + 10 %), there would not be an incentive for applicants to submit new studies on soil organisms with soils containing 5 % OM anymore.
This question should urgently be clarified by an eligible committee on EU-level, independently from the evaluation of active substances according to regulation EC No 1107/2009.
Unless the further approach how to handle tests with different OM-content in testing soils is not clear, tests on soil organisms with 5 % OM in testing soils should not be divided by two.

New studies have been conducted exposing *Hypoaspis aculeifer* and *Folsomia candida* to beta-cyfluthrin and Montur Forte FS 230.
In addition, studies on *Hypoaspis aculeifer* and *Folsomia candida* with the metabolites FPB-acid and DCVA (permethric-acid) are available and summarised below.

Table B.9.7-2: Effect of beta-cyfluthrin, metabolites FBP-acid and DCVA and the representative formulation beta-Cyfluthrin FS 230 (Montur Forte FS 230) to soil macro-organisms other than earthworms

Species	Test design	NOEC (reproduction) (mg as/kg dry soil)	Reference	reliability
Beta-Cyfluthrin				
Hypoaspis aculeifer	14 d chronic	**0.97**	KIIA 8.9.2/03 74501089 Pavic, 2012	valid

			M-476271-01-1; R-30149	
Folsomia candida	28 d chronic	**56**	KIIA 8.9.2/04 FRM-Coll-172/14 Frommholz, 2014 M-475305-01-1; R-34698	valid
FPB-acid				
Hypoaspis aculeifer	14 d chronic	**297**	KIIA 8.9.2/05 P14HR Moser and Scheffczyk, 2005a M-258697-01-1; R-23564	valid
Folsomia candida	28 d chronic	**28**	KIIA 8.9.2/06 FRM-Coll-144/12 Frommholz, 2012a M-440962-01-1; R-34695	valid
DCVA				
Hypoaspis aculeifer	14 d chronic	**≥ 316** **100 (mortality)**	KIIA 8.9.2/07 P15HR Moser and Scheffczyk, 2005b M-259607-01-1; R-23565	valid
Folsomia candida	28 d chronic	**18**	KIIA 8.9.2/08 FRM-Coll-143/12 Frommholz, 2012b M-440379-01-1; R-34694	valid
beta-Cyfluthrin+ imdidacloprid FS 230 (Montur Forte FS 230)				
Hypoaspis aculeifer	14 d chronic, test item mixed into soil	**≥32 mg product/kg dws**	Moser & Scheffczyk (2003) M-103032-01-1 KIIIA1 10.6.6 /01	valid
Folsomia candida	28 d chronic, test item mixed into soil	**4.6 mg product/kg dws**	Frommholz (2011) M-407864-01-1 KIIIA1 10.6.6 /03	valid
Folsomia candida	28 d, treated pills placed in ca. 2.5 cm depth in the soil	**1 seed/vessel (5-fold field rate) or 714 mL product/ha**[1]	Lechelt-Kunze (2003) M-111565-01-1 KIIIA1 10.6.6 /02	valid

Values in bold: Endpoints used for risk assessment

KIIIA1 10.6.6 /01 (newly submitted with the dossier)

Author:	Moser, T.; Scheffczyk, A. (2003)
Title:	Imidacloprid & Beta-Cyfluthrin FS 230: Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)
Date:	2003
Doc ID:	M-103032-01-1
Guidelines:	SECOFASE, Final Report, improvement and standardisation of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996) and Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett et al. 1994)
GLP:	yes
Validity:	valid

Objectives:
The purpose of this study was to determine lethal and sublethal effects of the test item on the mite species *Hypoaspis aculeifer* (Laelapidae). Test parameters were the mortality/escape rate after a 14-day exposure period and the reproduction over a 7-day period for surviving females. The $NOEC_{Mortality}$ and the $NOEC_{Reproduction}$ were determined.

Material and methods:
Test item: Imidacloprid & beta-cyfluthrin FS 230;
batch no.: 06200/0214(0193);
Development No.:30-00266429;
TOX No.: 06257-00 mixed with deionised water;
toxic standard dimethoate 5 mg/kg soil (dw), formulation Perfekthion;
control: water treated;
solvent control: none.
Test soil: LUFA 2.1 (A peat content < 5 % assumed.)
20 Hypoaspis ac.uleifer (maximum 2 day old protonymphs) per replicate were exposed to 0.32, 1.00, 3.20, 10.00 and 32.00 mg test item/kg LUFA 2.1 (dw). The mites were exposed to the test item at 25 °C and permanent dark. They were fed with prey mites and enchytraeids. Mortality was determined after 14 days. Thereafter, survived mites were transferred to uncontaminated substrate and the reproduction was observed after a total duration of 28, 29, 30 and 32, 33, 34 days.

Dates of work: June 23, 2003 – July 27, 2003.
Findings:
All data show evidence that the validity criteria have been fulfilled:

Mortality/escape rate of the adults in the control after 14 days of exposure (demanded ≤ 25 %):	14 %
Mean reproduction rate in the control after the 7-day reproduction period (demanded ≥ 10 fertile eggs (=juveniles) per female):	17.2 ± 8.3
Mortality/escape (corrected according to Abbott (1925)) rate of the adults in the reference item after 14 days of exposure (demanded 50 – 99.5 %):	78.7 %

Fourteen percent of adult mites died in the control. At all concentrations of the test item tested 11.3 – 18.8 % mortality were observed (corresponding to a corrected mortality according to Abbott (1925) from –3.2 to 5.5 %). Since the mortality observed with the test item was not higher than 18.8 % the LC_{50} value could not be calculated and was estimated to be > 32.00 mg test item/kg soil (dw).
At all concentrations of the test item tested, mortality rates remained below the maximum control mortality of 25 % as validity criterion.
Thus the $NOEC_{mortality}$ has to be regarded as ≥ 32.00 mg Imidacloprid & beta-cyfluthrin FS 230/kg soil (dw).
Reproduction was examined only for the two highest concentrations of the test item which caused less than 50 % mortality (i.e. 10.00 and 32.00 mg test item/kg soil (dw)). Statistical analysis (Dunnett's

test;1-sided smaller, $p \leq 0.05$) showed no significant difference concerning the cumulative number of juveniles per female after 7 days between the control and all concentrations of the test item tested. Therefore, the $NOEC_{reproduction}$ has to be regarded as ≥ 32.00 mg Imidacloprid & beta-cyfluthrin FS 230/kg soil (dw).

Effects on Mortality and reproduction of *Hypoaspis aculeifer* are summarised below:

Concentration (mg test item/kg soil (dw))	**Average mortality [%]**	**Corrected mortality [%]**	**Mean cumulative number of juveniles/female after 7 days**	**Reduction of juveniles [%]**
Control	14.0	0.0	17.2 ± 8.3	0.0
Reference	81.7	78.8		
0.32	12.5	-1.7		
1.00	18.8	5.5		
3.20	15.0	1.2		
10.00	11.3	-3.2	15.7 ± 4.7	8.6
32.00	18.8	5.5	17.7 ± 6.9	-2.8
			Adult mortality	**Reproduction**
LOEC (mg test item/kg soil (dw))			-	-
LC_{50}/EC_{50} (mg test item/kg soil (dw))			-	-
NOEC (mg test item/kg soil (dw))			≥ 32.00	≥ 32.00

- could not be calculated

After 14 days of exposure, 78.7 % corrected mortality according to Abbott (1925) of the adult mites was observed with the reference item group which was within the recommended range of 50 – 99.5 %.

Conclusions:
Both the $NOEC_{Mortality}$ and $NOEC_{Reproduction}$ have to be regarded as ≥ 32.00 mg Imidacloprid & beta-cyfluthrin FS 230/kg soil (dw).

KIIIA1 10.6.6 /02 (newly submitted with the dossier)

Author:	Lechelt-Kunze, C.
Title:	Imidacloprid & Beta-Cyfluthrin FS 230 dressed sugar beet seed (sort Achat): Influence on the Reproduction of the Collembola Folsomia candida with 5 % Peat in Artificial Soil
Date:	2003
Doc ID:	M-111565-01-1
Guidelines:	ISO 11267 (1999) Soil quality – Inhibition of reproduction of Collembola (Folsomia candida) by soil pollutants
GLP:	yes
Validity:	valid

Deviations:
The test was performed with dressed sugar beet seeds which were inserted directly into the soil at a depth of 2.5 cm. Instead of 30 g soil per test vessel 610 g artificial soil (fresh weight) were used (corresponding to 500 g artificial soil (dry weight)). The height of the soil layer within the test vessel was 5 cm. The surface of the vessel was 140 cm^2.

Objectives:
The purpose of the study was to provide data for the registration of plant protection products on the lethal and sublethal effects of the test item on the Collembola species Folsomia candida as a

representative of the soil fauna.

Material and methods:
Imidacloprid & beta-cyfluthrin FS 230 dressed sugar beet seed (sort Achat), Batch No.: Rübenpillen (Tox 6257), TOX No.: 06298-00, Development No.: 30-00266429, Content: imidacloprid: 14.60 g/Unit, beta-cyfluthrin: 7.89 g/Unit, Toxic standard: Betosip, active ingredient: Phenmedipham, test concentrations 50, 100 and 200 mg Betosip/kg artificial soil (dw), tested once a year, Report Coll-R2/02, October 29, 2002, non-GLP.
20 Collembola (10-12 days old) per replicate were exposed to control (1 undressed sugar beet seed) and 1 sugar beet seed dressed with Imidacloprid & beta-cyfluthrin FS 230/vessel (140 cm2), representing a 5 fold field rate, corresponding to 714 mL product/ha at 18 – 22 °C, 400 – 800 Lux, 16h light : 8h dark, 5 % peat in artificial soil. During the test they were fed with granulated dry yeast. Mortality and reproduction were determined after 28 days.

Dates of work: April 23, 2003 – May 21, 2003

Findings:

Test item	Imidacloprid & Beta-Cyfluthrin FS 230 dressed sugar beet seed		
Test object	*Folsomia candida*		
Exposure	Artificial soil		
Dressed seeds/vessel	**Adult mortality (%)**	**Mean number of juveniles±SD**	**Reproduction (% of control)**
1 untreated control seed	15	1483±356	
1 treated seed	14	1485±222	100
	Adult mortality		**Reproduction**
NOEC (seed/vessel)			**1**
LOEC (seed/vessel)			**>1**

In the control group 15 % of the adult Collembola died which is within the tolerated range of 20 % mortality demanded by the guideline. With 1 seed/vessel (140 cm^2), representing a 5 fold field rate, corresponding to 714 mL product/ha 14 % of the adult Collembola died.
Concerning the number of juveniles statistical analysis (Student-T Test, one sided-smaller, $\alpha = 0.05$) reveals no significant difference between the control and the treatment group.

Conclusions:
For reproduction a NOEC of 1 Imidacloprid & beta-cyfluthrin FS 230 dressed sugar beet seed /vessel (140 cm2) and a LOEC of >1 Imidacloprid & beta-cyfluthrin FS 230 dressed sugar beet seed /vessel (140cm^2) representing a 5 fold field rate, corresponding to 714 mL product/ha was determined.

KIIIA1 10.6.6 /03 (newly submitted with the dossier)

Author:	Frommholz, U.
Title:	Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil.
Date:	2011
Doc ID:	M-407864-01-1
Guidelines:	OECD 232 adopted, September 07, 2009: Collembolan Reproduction Test in Soil
GLP:	yes
Validity:	valid

Objectives:
The purpose of this study was to assess the effect of beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G on survival and reproduction of the collembolan species *Folsomia candida* during an exposure of 28 days in an artificial soil comparing control and treatment.

Material and methods:
Beta-cyfluthrin + Imidacloprid FS 230 (80+150) G
(analytical findings: 7.04 % w/w beta-cyfluthrin (FCR 4545) equivalent to 79.55 g/L; 13.4 % w/w imidacloprid (NTN 33893) equivalent to 151.4 g/L;
density: 1.130 g/mL (20 °C),
batch ID: 2010-003825,
customer order no.: TOX09062-00,
specification no.: 102000010962-04,
master recipe ID: 0033090-001.
Artificial soil:
74.8 % fine quartz sand
5 % Sphagnum peat
20 % Kaolin clay
10 collembolans (10-12 days old) per replicate (8 replicates for the control group and 4 replicates for each treatment group) were exposed to control (water treated), 1.5, 2.6, 4.6, 8.1 and 14.4 mg test item/kg artificial soil dry weight at 20 ± 2 °C, 400 – 800 lux, 16h light : 8h dark. During the study, they
were fed with granulated dry yeast.
Mortality and reproduction were determined after 28 days.

Dates of work: March 28, 2011 - May 03, 2011

Test item	**Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G**		
Test object	***Folsomia candida***		
Exposure	**Artificial soil**		
mg test item/kg soil dry weight nominal concentration	**Adult mortality (%)**	**Mean number of juveniles±SD**	**Reproduction (% of control)**
Control	7.1	1287.7 ± 336.4	**-**
1.2	17.5.	1389.3 ± 122.0	**107.9** n.s.
2.6	30.0	1066.3 ± 219.5	**82.8** n.s.
4.6	32.5	1107.8 ± 145.0	**86.0** n.s.
8.1	27.5	705.3 ± 89.0	**54.8 ***
14.4	52.5	217.5 ± 94.4	**16.9 ***
		Adult mortality	**Reproduction**
LC_{50}/EC_{50} (mg test item/kg soil dry weight)		>14.4 2)	**8.4** 1)
$NOEC_{reproduction}$ (mg test item/kg soil dry weight)			**4.6**
$LOEC_{reproduction}$ (mg test item/kg soil dry weight)			**8.1**

The calculations were performed with un-rounded values
1) Probit analysis
2) estimated value
* = statistically significant (William's-t test one-sided-smaller, a = 0.05)
n.s. = statistically not significant (William's-t test one-sided-smaller, a = 0.05)

Observations:

Mortality:
In the control group 7.1 % of the adult Folsomia candida died which is below the allowed maximum of ≤ 20 % mortality. A LC_{50} could not be calculated and is considered to be > 14.4 mg test item/kg artificial soil dry weight.
Reproduction:
Concerning the number of juveniles statistical analysis (William's-t test, one-sided smaller, α = 0.05)

revealed a statistically significant difference between control and the treatment groups with 8.1 and 14.4 mg test item/kg artificial soil dry weight.
Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is 4.6 mg test item/kg artificial soil dry weight. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is 8.1 mg test item/kg artificial soil dry weight. The EC_{50} determined by Probit analysis is 8.4 mg test item/kg artificial soil dry weight.

Conclusions:

$NOEC_{reproduction}$: 4.6 mg test item/kg artificial soil dry weight.
$LOEC_{reproduction}$: 8.1 mg test item/kg artificial soil dry weight.
LC_{50} (adult mortality): >14.4 mg test item/kg artificial soil dry weight (estimated value)
EC_{50} (reproduction): 8.4 mg test item/kg artificial soil dry weight.
(95 % confidence limit 5.4 – 14.1 mg test item/kg artificial soil dry weight)

B.9.8 Risk assessment for non-target soil meso- and macrofauna

Exposure
The maximum PEC_{soil} values were calculated following the recommendations of the FOCUS soil working group (FOCUS, 1997) assuming a soil depth of 5 cm, a bulk density of 1.5 g/cm3 and application rates. For details please refer to Volume_3CP_Montur Forte FS 230_B-8.2.
Nevertheless, the RMS wants to allude to an alternative approach of calculating PEC_{soil} that is still under discussion. In the draft guidance document "Authorisation of Plant Protection Products for Seed Treatment" (SANCO/10553/2012; January 2014) it is proposed to calculate PEC_{sphere}. PEC_{sphere} is the concentration of active substances forms concentrically around the treated seed in a distance of 5 cm.

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breakdown resulting from an exposure to Montur Forte FS 230 / beta-cyfluthrin and imidacloprid as well as the major soil degradation products of beta-cyfluthrin and imidacloprid was assessed by comparing the maximum PEC_{SOIL} with the NOEC value to generate chronic TER values. The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC\,(mg/kg)}{PEC_{soil}\,(mg/kg)}$$

The results of the risk assessment are summarised in the following table.

Table B.9.8-1: TER values for earthworms and other soil macro- and mesofauna (Tier-1), seed treatment sugar beets

Species	Test item	Time scale	Endpoint [mg/kg soil dw]	Max. PEC_{SOIL} [mg/kg soil dw]	TER
Eisenia fetida	beta-Cyfluthrin + Imidacloprid FS 230	Chronic	1.78	0.196[A]	9.08
	FBP-acid	Chronic	2.6[1]	0.003	866.67
	DCVA (permethric acid)	Chronic	2.6[1]	< 0.001	>2600.00
Folsomia candida	beta-Cyfluthrin		56	0.014	4000.00
	beta-cylfuthrin + Imidacloprid FS 230		4.6	0.196[A]	23.47
	FBP-acid		28	0.003	9333.33
	DCVA (permethric		18	< 0.001	18000

	acid)				
Hypoaspis aculeifer	beta-Cyfluthrin		0.97	0.014	69.29
	Beta-Cyfluthrin + Imidacloprid FS 230		≥ 32	0.196[A]	163.27
	FBP-acid		297	< 0.001	297000
	DCVA (permethric acid)		100	0.003	33333.33

1 corrected by factor of 2 due to lipophilic substance (log P_{ow} > 2) and 10 % peat content in test soils
[A] Product PECsoil 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)

TER_{LT} values for earthworms and other soil macro- and mesofauna exceed the trigger of 5.

Therefore, it can be concluded that chronic risk for earthworms and other soil macro- and mesofauna than earthworm from the use of Montur Forte FS 230 as treatment of sugar beet seeds according to the proposed good agricultural practice will be acceptable.

The risk assessment for earthworms is confirmed by the chronic earthworm study with treated sugar beet seeds in soil representing the 10 fold seed rate for sugar beet seed according the GAP table.

Table B.9.8-2: Refined TER calculations for earthworms

substance	Test species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Beta-Cyfluthrin + Imidacloprid FS 230	Earthworm, reproduction	NOEC >1300000 seeds/ha (10-fold field rate)	130000 seeds/ha (1-fold field rate)	> 10	5

B.9.9 Effects on soil nitrogen transformation

Toxicity

Table B.9.9-1: Effects on soil micro-organisms

Test design	NOEC (reproduction) (mg as/kg dry soil)	Reference	reliability
Cyfluthrin			
Nitrogen mineralisation 28-day study (Cyfluthrin techn.)	No significant effects (>25 %) on nitrogen mineralisation by day 28 at 0.018 and **0.18 kg/ha**	KIIA 8.10.1/02 BSI/47987 Blumenstock, 1987 M-054489-01-2 R-19148	valid
Carbon mineralisation 28-day study (Cyfluthrin techn.)	No significant effects (>25 %) on microbial respiration by day 28 at 0.018 and **0.18 kg/ha**	KIIA 8.10.1/01 AJO/46887 Anderson, 1987 M-054544-01-2 R-19147	valid
FPB-acid			
Nitrogen mineralisation 28-day study	No significant effects (>25 %) on nitrogen mineralisation at 0.012 mg/kg dry soil and 0.125 mg/kg dry soil, corre-	KIIA 8.10.1/03 13 10 48 016 N Schulz, 2013a M-454537-01-1	valid

	sponding to 0.009 kg and 0.094 kg test item/ha, respectively	R-34704	
DCVA			
Nitrogen - mineralisation 28-day study	No significant effects (>25 %) on nitrogen mineralisation at 0.011 mg/kg dry soil and 0.112 mg/kg dry soil, corresponding to 0.008 kg and 0.084 kg test item/ha, respectively	KIIA 8.10.1/04 13 10 48 017 N Schulz, 2013b M-454538-01-1 R-34705	valid
Beta-Cyfluthrin + Imidacloprid FS 230			
Nitrogen - mineralisation 28-day study	No significant effects (>25 %) on nitrogen mineralisation at 0.98 mg prod./kg dry soil	Schulz (2011) M-416194-01-1 KIIIA1 10.7.1	valid

dws = dry weight soil; as = active substance; prod. = product
Studies shaded in grey have been reviewed as part of the first EU evaluation.
Values in bold: Endpoints used for risk assessment

KIIIA1 10.7.1 (newly submitted with the dossier)

Author:	Schulz, L.
Title:	Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G: Effects on the activity of soil microflora (Nitrogen transformation test)
Date:	2011
Doc ID:	M-416194-01-1
Guidelines:	OECD 216 (2000)
GLP:	yes
Validity:	valid

Objectives:
The purpose of this study was to determine the effects of the test item on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

Materials and Methods: Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G (analytical findings: 7.25 % w/w Beta-cyfluthrin (FCR 4545) is equivalent to 81.93 g/L, 13.6 % w/w imidacloprid (NTN 33893) is equivalent to 153.7 g/L); Density (20 °C): 1.130 g/mL, Specification No.: 102000010926- 04, Batch ID: 2011-001451, Master recipe ID: 0033090-001, Sample description: TOX09324-00, Material No. 06519113) was used in the test. A loamy sand soil (DIN 4220) was exposed for 28 days to 0.20 and 0.98 mg test item/kg soil dry weight. Application rates were equivalent to 0.13 and 0.65 L test item/ha. Determination of the nitrogen transformation (NO3-nitrogen production) in soil enriched with Lucerne meal (concentration in soil 0.5 %). NH4-nitrogen, NO3- and NO2-nitrogen were determined using the Autoanalyser II (BRAN+LUEBBE) at different sampling intervals (0, 7, 14 and 28 days after treatment).
The coefficients of variation in the control (NO3-N) were maximum 7.3 % and thus fulfilled the demanded range (≤15 %).

Dates of work: August 05, 2011 – September 02, 2011

Findings:

Effects on nitrogen transformation in soil after treatment with beta-cyfluthrin + Imidacloprid FS 230 (80+150) G are summarised below:

Time Interval (days)	**Application rates**				
		[CYB+IMD FS 230 (80+150) G]			
	Control	**0.20 mg/kg dry weight soil**		**0.98 mg/kg dry weight soil**	
	Nitrate-N1)	Nitrate-N[1)]	% difference to control	Nitrate-N[1)]	% difference to control
0-7	1.77±0.18	1.62±0.10	-8.1 n s	1.75±0.08	-0.8 n s
7-14	0.84±0.47	1.05±0.11	+24.9 n s	0.71±0.25	-15.3 n s
14-28	0.86±0.13	0.85±0.00	-1.7 n s	0.98±0.10	+12.9 n s

The calculations were performed with unrounded values
1) Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation
n.s. = No statistically significant difference to the control (Student-t-test for homogeneous variances, 2-sided, $p \leq 0.05$ Welch-t-test for inhomogeneous variances, 2-sided, $p \leq 0.05$)

In a separate study the reference item dinoterb caused a stimulation of nitrogen transformation of +42.0 %, +68.1 % and +92.3 % at 6.80 mg, 16.00 mg and 27.00 mg dinoterb per kg soil dry weight, respectively, 28 days after application.

Observations:
No adverse effects of beta-cyfluthrin + Imidacloprid FS 230 (80+150) G on nitrogen transformation in soil could be observed in both test concentrations (0.20 mg/kg dry soil and 0.98 mg/kg dry soil) after 28 days. Only negligible differences from the control of -1.7 % (test concentration 0.20 mg/kg dry soil) and +12.9 % (test concentration 0.98 mg/kg dry soil) were measured at the end of the 28-day incubation period. (time interval 14-28).

Conclusions:
Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G caused no adverse effects (difference to control < 25 %, OECD 216) on the soil nitrogen transformation (measured as NO_3-N production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 0.98 mg test item/kg soil, which is equivalent up to an application rate of 0.65 L test item/ha.
Risk assessment for soil nitrogen transformation

B.9.9.1 Risk assessment for soil nitrogen transformation

Table B.9.9-2: Risk assessment for soil micro-organisms

Test substance	**Endpoint**	**Value**	**$PEC_{soil,max}$ [mg/kg]**
Beta-Cyfluthrin + Imidacloprid FS 230	Nitrogen transformation	No negative effects up to 0.98 mg test item/kg dry soil after 28 days	0.916[A]

A worst-case PEC_{soil} for the product taking into account the maximum application rate of 10.4 g as/ha, a product density of 1.13 kg/L, a soil bulk density of 1.5 g/cm³ and a distribution at soil layer of 0-5 cm

According to regulatory requirements the risk is acceptable, if the effect on nitrogen transformation at the maximum PEC_{soil} values is < 25 % after 100 days.
In no case, deviations from the control exceeded 25 % after 28 days, indicating low risk to soil micro-organisms.

B.9.10 Effects on terrestrial non-target higher plants

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

B.9.10.1 Summary of screening data

No studies are necessary.

B.9.10.2 Testing on non-target plants

No studies are necessary.

B.9.10.3 Extended laboratory studies on non-target plants

No studies are necessary.

B.9.10.4 Semi-field and field tests on non-target plants

No studies are necessary.

B.9.11 Risk assessment for terrestrial non-target higher plants

For non-target terrestrial plants no direct exposure via the soil as a result of treated seeds is expected. For insecticides used for seed treatment a risk assessment for non-target plants via dust is not considered necessary.

B.9.12 Effects on other terrestrial organisms (flora and fauna)

The spectrum of the biological activity of the product is well represented by the results and the risk assessments in Point 10.2 to 10.8 of this dossier. Therefore, further data from biological primary screening or other preliminary tests are not considered relevant for the risk assessment.

B.9.13 Risk assessment for other terrestrial organisms (flora and fauna)

Not applicable.

B.9.14 References relied on

Annex point / reference number	Author(s)	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP status *(where relevant)*, published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KIIIA1 10.2	Grace. Nillos Mae. Qin Sujie. Larive Cynthia. Schlenk Daniel. Gan Jay.	2009	Epimerisation of cypermethrin stereoisomers in alcohols. Journal of agricultural and food chemistry 57 (15): 6938-43. doi:10.1021/jf900921g. published	N	N		LIT
KIIIA1 10.2	Perschke. H.; Hussain. M.	1992	Chemical isomerisation of deltamethrin in alcohols. J. Agric. Food Chem. 1992. 40. 686–690. published	N	N		LIT
KIIIA1 10.1.2 (OECD)	Barfknecht, R.	2000	Exposure of sugar beet pills in the Netherlands Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: BAR/FS 003, Edition Number: M-019632-01-1 Date: 2000-09-12 GLP/GEP: yes, unpublished	Y	Y	data submitted on EU level (for the evaluation of Imidacloprid)	Bayer CropScience
KIIIA1 10.2.2.2 (OECD)	Riebschlaeger, T.	2012	Acute toxicity of beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G to the waterflea Daphnia magna in a static renewal laboratory test system Bayer CropScience, Report No.: EBNTL072, Edition Number: M-425443-01-1 Date: 2012-02-21 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience

Annex point / reference number	**Author(s)**	**Year**	**Title** **Source** ***(where different from company)*** **Company name, Report No., Date, GLP status** ***(where relevant)*****, published or not**	**Vertebrate study Y/N**	**Data protection claimed Y/N**	**Justification if data protection is claimed**	**Owner**
KIIIA1 10.2.2.3 (OECD)	Bruns, E.	2012	Pseudokirchneriella subcapitata growth inhibition test with beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150) G Bayer CropScience, Report No.: EBNTL073, Edition Number: M-426620-01-1 Date: 2012-03-06 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience
KIIIA1 10.2.6 (OECD)	Bruns, E.	2012	Chironomus riparius 28-day chronic toxicity test with beta-Cyfluthrin & Imidacloprid FS 230 (80 + 150) G in a water-sediment system using spiked water Bayer CropScience, Report No.: EBNTL074, Edition Number: M-432814-01-1 Date: 2012-05-25 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience
KCP 10.3.1 /01	Joachimsmeier, I.; Pistorius, J.; Heimbach, U.; Schenke, D.; Kirchner, W.; Zwerger, P.	2011	Frequency and intensity of guttation events in different crops in Germany Publisher:11th International Symposium of the ICP-BR Bee Protection Gr, Location:Julius-Kuhn-Archiv, Volume:437, Pages:87-90, Year:2012, Report No.: M-481776-01-1, Edition Number: M-481776-01-1 GLP/GEP: n.a., published	N	N		

Annex point / reference number	Author(s)	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP status *(where relevant)*, published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 10.3.1.1 /01	Schmitzer, S.	2011	Effects of beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 64111035, Edition Number: M-421688-01-1 Date: 2011-12-15 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience
KCP 10.3.1.1 /02	Schmitzer, S.; Sekine, T.	2010	Effects of beta-Cyfluthrin EC 025 G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory IBACON GmbH, Rossdorf, Germany TF- BCS-Irvita, Report No.: 52601035, Edition Number: M-363013-01-1 Date: 2010-02-05 GLP/GEP: yes, unpublished	N	Y	to complete the risk assessment for bees using the current representative formulation	TF- BCS-Irvita
KCP 10.3.1.2 /01	Sandrock, C.	2014	Bulldock 25 EC: Toxicity effects to honey bee (Apis mellifera L.) worker adults after oral chronic exposure under laboratory conditions Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland TF- BCS-Irvita, Report No.: 20120186, Edition Number: M-479053-01-1 Date: 2014-02-06 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	TF- BCS-Irvita

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KCP 10.3.1.3 /01	Sandrock, C.	2014	Bulldock 25 EC: Toxicity effects to honeybee (Apis mellifera L.) larvae after single exposure under laboratory conditions Innovative Environmental Services (IES) Ltd, Witterswil, Switzerland TF- BCS-Irvita, Report No.: 20120187, Edition Number: M-479050-01-1 Date: 2014-02-20 GLP/GEP: yes, unpublished	N	Y	new data requirement under Reg. 1107/2009	TF- BCS-Irvita
KIIIA1 10.5.2/01 (OECD)	Neumann, P.	1999	Acute effects of beta-Cyfluthrin (techn.) & Imidacloprid (techn.) on larvae of carabid beetle (Poecilus cupreus) under extended laboratory test conditions Bayer AG, Leverkusen, Germany Bayer CropScience, Report No.: NNP/PC008, Edition Number: M-024650-01-1 Date: 1999-12-13 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience
KIIIA1 10.5.2/02 (OECD)	Jans, D.	2013	Determination of the effects of sugar beet seeds treated with beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L) on larvae of Poecilus cupreus L. (Carabidae) in an aged residue extended laboratory test Bayer CropScience, Report No.: CW11/007, Edition Number: M-453475-01-1 Date: 2013-02-15 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience

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KIIIA1 10.5.2/03 (OECD)	Jans, D.	2013	Determination of the effects of sugar beet seeds treated with beta-Cyfluthrin + Imidacloprid FS 230 (80 + 150 g/L) on Aleochara bilineata GYLL. (Coleoptera) beetles in an aged residue extended laboratory test Bayer CropScience, Report No.: CW11/008, Edition Number: M-465184-01-1 Date: 2013-05-07 GLP/GEP: yes, unpublished	N	Y	data not submitted on EU level	Bayer CropScience
KIIIA1 10.6.3/01 (OECD)	Luehrs, U.	2003	Imidacloprid & ß-Cyfluthrin FS 230: Effects on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5 percent peat in the test substrate IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 16861022, Edition Number: M-110969-01-1 Date: 2003-07-02 GLP/GEP: yes, unpublished	N	Y	to complete the risk assessment for soil organisms	Bayer CropScience
KIIIA1 10.6.3/02 (OECD)	Leicher, T.	2011	Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat Bayer CropScience, Report No.: LRT-RG-R-103/11, Edition Number: M-407796-01-1 Date: 2011-05-13 GLP/GEP: yes, unpublished	N	Y	to complete the risk assessment for soil organisms	Bayer CropScience

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KIIIA1 10.6.6 /01 (OECD)	Moser, T.; Scheffczyk, A.	2003	Imidacloprid & beta-Cyfluthrin FS 230: effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1) ECT Oekotoxikologie GmbH, Floersheim, Germany Bayer CropScience, Report No.: P5HR, Edition Number: M-103032-01-1 Date: 2003-07-31 GLP/GEP: yes, unpublished	N	Y	new data requirement under Reg. 1107/2009	Bayer CropScience
KIIIA1 10.6.6 /02 (OECD)	Lechelt-Kunze, C.	2003	Imidacloprid & beta-Cyfluthrin FS 230 dressed sugar beet seed (sort Achat): Influence on the reproduction of the collembola Folsomia candida with 5 % peat in artificial soil Bayer CropScience, Report No.: LKC/COLL 12/03, Edition Number: M-111565-01-1 Date: 2003-07-08 GLP/GEP: yes, unpublished	N	Y	to complete the risk assessment for soil organisms	Bayer CropScience
KIIIA1 10.6.6 /03 (OECD)	Frommholz, U.	2011	Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil Bayer CropScience, Report No.: FRM-COLL-114/11, Edition Number: M-407864-01-1 Date: 2011-05-19 GLP/GEP: yes, unpublished	N	Y	to complete the risk assessment for soil organisms	Bayer CropScience

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KIIIA1 10.7.1 (OECD)	Schulz, L.	2011	Beta-Cyfluthrin + Imidacloprid FS 230 (80+150) G: Effects on the activity of soil microflora (nitrogen transformation test) BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 11 10 48 056 N, Edition Number: M-416194-01-1 Date: 2011-10-13 GLP/GEP: yes, unpublished	N	Y	new data requirement under Reg. 1107/2009	Bayer CropScience

B.9.15 References of Guidance documents and open literature:

References of Guidance documents and open literature:

Annex point / reference number	citation
KIIIA1 10.1	European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu
KIIIA1 10.2	Grace, Nillos Mae, Qin Sujie, Larive Cynthia, Schlenk Daniel, Gan Jay. 2009. "Epimerisation of cypermethrin stereoisomers in alcohols." Journal of agricultural and food chemistry 57 (15): 6938-43. doi:10.1021/jf900921g.
KIIIA1 10.2	Perschke, H.; Hussain, M. Chemical isomerisation of deltamethrin in alcohols. J. Agric. Food Chem. 1992, 40, 686–690.
KIIIA1 10.2	European Food Safety Authority; Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters on request from EFSA. EFSA Journal 2013;11(7):3290
KIIIA1 10.5	de Jong, F.M.W, Bakker, F.M., Brown, K., Jilesen, C.J.T.J., Posthuma-Doodeman, C.J.A.M., Smit, C.E., van der Steen, J.J.M, van Eekelen, G m.A. 2010. Guidance for summarising and evaluating field studies with non-target arthropods - A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies. Published by the National Institute for Public Health and the Environment. Available online: ww.rivm nl/bibliotheek/601712006/pdf
KIIIA1 10.5	Candolfi, M.P., Barrett, K.L.; Campbell, P.J., Forster, R., Grandy, N., Huet, M-C, Lewis, G. Oomen, P.A., Schmuck, R. and Vogt, H. 2000.".Guidance document on regulatory testing and risk assessment procedures for plant protectionproducts with non-target arthropods – From the ESCORT 2 workshop"
KIIIA1 10.5/ KIIIA1 10.6	Draft Guidance Document on the authorisation of plant protection products for seed treatment 2014 (SANCO/10553/2012 Rev. 1)
KIIIA1 10.6	J Boesten, A Helweg, M Businelli, L. Bergstrom, H Schaefer, A Delmas, R Kloskowski, A Walker, K Travis, L Smeets, R Jones,V Vanderbroeck, A Van Der Linden, S Broerse, M Klein, R Layton, O-S Jacobsen, D Yon. 1997. "Soil persistence models and EU registration - The final report of the work of the Soil Modelling Work group of FOCUS" Available online: http://ec.europa.eu/food/plant/protection/evaluation/guidance/soil_en.pdf
	Guidance document (GD) for terrestrial ecotoxicology (SANCO/10329/2002)