

# **Renewal Assessment Report**

**beta-cyfluthrin**

**Montur Forte FS 230**

**Volume 3 – B.8 Environmental fate and behaviour  
and environmental exposure assessment**

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## Version history

When	What

## Table of contents

<b>B.8</b>	<b>Environmental fate and behaviour and environmental exposure assessment.....</b>	<b>4</b>
B.8.1	Fate and behaviour in soil.....	4
B.8.1.1	Rate of degradation in soil .....	4
B.8.1.2	Mobility in soil.....	4
B.8.2	Predicted environmental concentrations in soil (PEC <sub>S</sub> ).....	4
B.8.3	Predicted environmental concentrations in ground water (PEC <sub>GW</sub> ) .....	7
B.8.4	Fate and behaviour in water and sediment.....	9
B.8.4.1	Aerobic mineralisation in surface water .....	9
B.8.4.2	Water/sediment study.....	9
B.8.4.3	Irradiated water/sediment study.....	9
B.8.5	Predicted environmental concentrations in surface water and sediment (PEC <sub>SW</sub> , PEC <sub>SD</sub> ).....	9
B.8.6	Fate and behaviour in air.....	11
B.8.6.1	Route and rate of degradation in air and transport via air.....	11
B.8.6.2	Predicted environmental concentrations from airborne transport.....	12
B.8.7	Predicted environmental concentrations from other routes of exposure .....	12
B.8.8	References relied on.....	13

## B.8 Environmental fate and behaviour and environmental exposure assessment

### Introduction

Montur Forte FS 230 is a formulation supporting the renewal of approval of beta-cyfluthrin. Montur Forte FS 230 contains 80 g/L beta-cyfluthrin and 150 g/L imidacloprid and is formulated as a flowable suspension for insecticidal seed treatment (FS) of sugar beet.

Concentrations of beta-cyfluthrin in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC) in soil, surface water, sediment, and groundwater following the proposed use pattern are provided.

The GAP of the representative uses of Montur Forte FS 230 are given in the following table:

Crop	Region	Formulation	Application	Maximum number of applications	Application rate (g/ha active substance)	Application rate (L/ha product)
sugar beet	all zones	FS, 80 g/L beta-cyfluthrin, 150 g/L imidacloprid	seed treatment	1	10.4 beta-cyfluthrin	0.1 L per unit *, maximum seeding density 1.3 units/ha

\* 1 unit = 100000 seeds

### B.8.1 Fate and behaviour in soil

#### B.8.1.1 Rate of degradation in soil

The rate of degradation of Montur Forte FS 230 relies on the information given for the active substance beta-cyfluthrin.

#### B.8.1.2 Mobility in soil

The data on mobility of Montur Forte FS 230 in soil rely on the information given for the active substance beta-cyfluthrin.

### B.8.2 Predicted environmental concentrations in soil (PECs)

The  $PEC_{soil}$  estimation for beta-cyfluthrin and its metabolites was provided by the study of Kreschnak 2014 using a  $DT_{50}$  of 71.5 days from the field trial in S-France, SFO-kinetic. Another  $PEC_{soil}$  calculation is provided in the following by the RMS including an estimation of  $PEC_{accu}$ . The PEC is calculated on the basis of the degradation kinetic of a field trial in Germany (HS-kinetic,  $DT_{50\ fast}$  27.8 days,  $DT_{50\ slow}$  142.9 days,  $t_b$  28 days).

#### B.8.2/1 (Hammel & Porschewski 2013a)

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Reference	: Hammel, K. and Porschewski, R
Title	: Beta-cyfluthrin and metabolites: PEC soil EUR, Use in sugarbeets in Europe
Year of execution	: 12. 12. 2013

GLP statement	: not relevant
Guideline	: not relevant; calculation according FOCUS guidance
Test substance	: beta-Cyfluthrin
Test system	: PEC in soil under field conditions

## Methods and Materials

The predicted environmental concentrations in soil ( $PEC_{soil}$ ) of beta-cyfluthrin and its metabolites were estimated. The parameters used in the  $PEC_{soil}$  calculation are given in Table B.8.2-1. For the active substance beta-cyfluthrin a  $DT_{50}$  of 101.7 days is assumed (worst case of laboratory studies, 20 °C, pH 2). The application pattern and the calculated PEC are given in Table B.8.2-2. Only the initial maximum values are presented.

**Table B.8.2-1: Parameters for  $PEC_{soil}$  calculation by Hammel & Porschewski 2013**

Parameter	beta-cyfluthrin	FPB-acid	DCVA
molecular mass	434.3	232.2	209
$DT_{50}$	101.7	2.9	8.5
maximum occurrence in soil %	-	13.4	42.7

**Table B.8.2-2:  $PEC_{soil}$  for beta-cyfluthrin and its metabolites after single application**

Crop	rate (g/ha as)	BBCH code	interception %	$PEC_{soil}$ max (mg/kg)		
				beta-cyfluthrin	FPB-acid	DCVA
sugar beet	10.4	00	0	0.014	< 0.001	0.003

## Comment

In the study of Hammel & Porschewski (2013a) a laboratory  $DT_{50}$  was used for calculation of  $PEC_{soil}$ . The RMS prefers the use of field data instead of laboratory data for calculation of soil PEC values.

According to the kinetic re-evaluation of the field studies by the RMS, the trial in Germany with two applications in October 2012 is seen as the worst case situation for soil degradation in the field (Robinson 2014d, HS-kinetic,  $DT_{50 \text{ fast}}$  27.8 days,  $DT_{50 \text{ slow}}$  142.9 days,  $t_b$  28 days). The RMS is aware of the difference between the sowing season of sugar beet (spring) and the applications in the field trial (October). The kinetic data from the study by Robinson 2014d are used anyway as a worst case for any climatic or soil condition.

A new  $PEC_{soil}$  calculation is provided in the following by the RMS including an estimation of  $PEC_{accu}$ . The estimation of a  $PEC_{accumulation}$  is seen necessary as the  $DT_{90}$  = 359 days in the field study conducted by Robinson 2014d in Germany is > 1 year.

## PEC soil calculation conducted by the RMS

$PEC_{soil}$  calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm<sup>3</sup>, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop) were assumed. The  $PEC_{soil}$  calculations were performed with ESCAPE 2.0 based on the input parameters for beta-cyfluthrin and its metabolites FPB-acid and DCVA given in Table B.8.2-3.

**Table B.8.2-3: Parameters for PEC<sub>soil</sub> calculation by RMS**

Parameter	beta-cyfluthrin	FPB-acid	DCVA
molecular mass	434.3	232.2	209.1
degradation kinetic for active substance	HS-kinetic, k <sub>1</sub> = 0.0249 (DT <sub>50</sub> 27.8 d), k <sub>2</sub> = 0.00485 (DT <sub>50</sub> 143 d), t <sub>b</sub> = 28 d (maximum field, Robinson 2014d)		
maximum occurrence of metabolites in soil %		12.7	40.5

Due to the slow degradation of beta-cyfluthrin in soil (DT<sub>90</sub> > 365 d, field data) the accumulation potential of beta-cyfluthrin needs to be considered. Therefore an accumulated soil concentration (PEC<sub>soil,accu</sub>) is used for risk assessment which comprises background concentration in soil (PEC<sub>soil,bkgd</sub>) considering a tillage depth of 20 cm (arable crop) and the maximum annual soil concentration PEC<sub>soil,act</sub> for a soil depth of 5 cm:

$$PEC_{soil,accu} = PEC_{soil,act} + PEC_{soil,bkgd} \text{ [mg/kg]}$$

where:

PEC<sub>soil,act</sub> = maximum annual soil concentration

PEC<sub>soil,bkgd</sub> = Plateau concentration in soil after many years considering a tillage depth of 20 cm (arable crop)

Beside PEC<sub>soil,act</sub> values PEC<sub>soil,twa</sub> values are also required for risk assessment. PEC<sub>soil,act</sub> and PEC<sub>soil,twa</sub> values are estimated after application of 10.5 g/ha as seed treatment in sugar beet. The results are given in Table B.8.2-4 and Table B.8.2-5.

**Table B.8.2-4: Results of PEC<sub>soil</sub> calculation after applications of 10.5 g/ha active substance as seed treatment in sugar beet (soil bulk density 1.5 g/cm<sup>3</sup>, soil depth 5 cm)**

<b>Plant protection product:</b>			Montur Forte FS 230 (80 g/L beta-cyfluthrin)		
<b>Use:</b>			sugar beet		
<b>Number of applications</b>			1		
<b>Application rate:</b>			10.5 g/ha as		
<b>Crop interception:</b>			0		
active substance	application	soil relevant application rate (g/ha)	PEC <sub>act</sub> (mg/kg)	tillage depth (cm)	PEC <sub>bkgd</sub> (mg/kg)
beta-cyfluthrin	every year	10.5	0.0140	20	0.0004
DCVA			0.0027	-	-
FPB-acid			0.0010	-	-

\* a tillage depth of 20 cm was considered for calculating the background concentration

**Table B.8.2-5: Results of PEC<sub>soil, twa</sub> calculation after applications of 10.5 g/ha as in sugar beet**

Time (d)	PEC <sub>act</sub> * (mg/kg)	PEC <sub>twa</sub> (mg/kg)	Begin TWA-frame (d)	End TWA-frame (d)
1	0.014	0.0142	0	1
2	0.0137	0.014	0	2
4	0.013	0.0137	0	4
7	0.0121	0.0132	0	7
14	0.0103	0.0122	0	14
21	0.0087	0.0113	0	21
28	0.0073	0.0105	0	28
42	0.0069	0.0093	0	42
50	0.0066	0.0089	0	50
100	0.0053	0.0074	0	100

\* PEC<sub>soil,act</sub> values are related to the time after the second application after many years

### B.8.3 Predicted environmental concentrations in ground water (PEC<sub>gw</sub>)

The PEC<sub>gw</sub> was calculated by Hammel&Porschewski 2013b.

#### B.8.3/1 (Hammel & Porschewski 2013b)

Reference	: Hammel, K. and Porschewski, R
Title	: Beta-cyfluthrin and metabolites: PEC gw FOCUS PEARL, use in sugar beets in Europe
Date of execution	: 12. 12. 2013
Report no.	: EnSa-13-1002
GLP statement	: not relevant
Guideline	: not relevant; calculation according FOCUS guidance
Test substance	: beta-Cyfluthrin
Test system	: PEC in groundwater under field conditions

### Materials and Methods

The predicted environmental concentrations in groundwater (PEC<sub>gw</sub>) for beta-cyfluthrin were calculated using the simulation model FOCUS PEARL (version 4.4.4). Detailed application data used for simulation of PEC<sub>gw</sub> are given in Table.

**Table B.8.3-1: First application dates and related information for beta-cyfluthrin as used for the simulation runs**

<b>Crop</b>	Sugar beet
<b>Repeat interval for app. events</b>	Every Year
<b>Application technique</b>	Incorporation (3 cm)
<b>Absolute / Relative to</b>	Planting
<b>Scenario</b>	1 <sup>st</sup> App. Date (Julian day)
Chateaudun	25 Mar (84)
Hamburg	01 Apr (91)
Jokioinen	10 May (130)
Kremsmuenster	01 Apr (91)
Okehampton	10 Apr (100)
Piacenza	01 Mar (60)
Porto	28 Feb (59)
Sevilla	31 Oct (304)
Thiva	15 Apr (105)

Further input parameters for PEC<sub>gw</sub> modelling of beta-cyfluthrin and its metabolites are summarised in Table B.8.3-3. Water solubility and vapour pressure of beta-cyfluthrin refer to isomer II. Water solubility and vapour pressure of metabolites were calculated with the program EPIWIN v.3.10. The DT<sub>50</sub> for soil degradation was derived from the laboratory studies by Hiler 2013 a+b and normalised by Hammel & Porschewski 2013b, see Table B.8.3-2.

**Table B.8.3-2: Normalisation of experimental DT<sub>50</sub> for soil degradation by Hammel & Porschewski 2013b (experimental data from studies by Hiler 2013 a+b)**

Soil texture	DT <sub>50</sub> experimental	experimental moisture	reference moisture	moisture correction	DT <sub>50</sub> normalised
sandy clay loam	101.7	30.85	37.1	0.88	89.4
silt loam	19.9	26.25	30.9	0.89	17.8
sandy loam	20.1	11.15	14.6	0.83	16.6
sandy loam	26.5	30.15	15.7	0.88	23.4
geomean	<b>32.2</b>				<b>28.0</b>

**Table B.8.3-3: Substance specific and model related input parameters for PEC<sub>gw</sub> calculation of beta-cyfluthrin and its metabolites**

Parameter	Unit	Beta-cyfluthrin	DCVA	FPB-acid
Molar mass	[g/mol]	434.4	209.0	232.2
Water solubility	[mg/L]	0.002	128	45.8
Vapour Pressure	[Pa]	$1.40 \times 10^{-8}$	$2.60 \times 10^{-1}$	$8.00 \times 10^{-4}$
Freundlich Exponent	[-]	1.000	0.888	0.664
Plant uptake factor	[-]	0.0	0.0	0.0
Walker Exponent	[-]	0.7	0.7	0.7
DT <sub>50</sub>	[days]	28.0	3.5	1.2
Molar activ. energy	[kJ/mol]	65.4	65.4	65.4
K <sub>om</sub>	[mL/g]	71885.0	5.2	78.8
K <sub>f</sub>	[mL/g]	-	-	-

## Results

PEC<sub>gw</sub> were evaluated as the 80<sup>th</sup> percentile of the mean annual leachate concentration at 1 m soil depth. PEC<sub>gw</sub> values for beta-cyfluthrin and its metabolites are given in the following Table B.8.3-4.

**Table B.8.3-4: PEC<sub>gw</sub> (PEARL) of beta-cyfluthrin and its metabolites for the intended use in sugar beet (1 × 10.4 g as/ha)**

FOCUS Scenario	Beta-cyfluthrin	DCVA	FPB-acid
	PEC <sub>gw</sub> [µg/L]	PEC <sub>gw</sub> [µg/L]	PEC <sub>gw</sub> [µg/L]
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Jokioinen	<0.001	<0.001	<0.001
Kremsmuenster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001
Sevilla	<0.001	<0.001	<0.001
Thiva	<0.001	<0.001	<0.001

## Conclusion

The RMS does not agree in all cases with the input parameters for PEC<sub>gw</sub> calculation. For vapour pressure of beta-cyfluthrin  $4.5 \times 10^{-7}$  Pa should be used (isomer II at 20 °C, see document M-CA, Section 2).

The high sorption of parent and the fast degradation of metabolites have the main influence on modelling of leaching of beta-cyfluthrin and its metabolites into groundwater. The calculated PEC<sub>gw</sub> are in all cases <0.001 µg/L, and it can be expected that the slight deviation in vapour pressure is of no relevant influence on results.

The RMS does therefore not conduct a new PEC<sub>gw</sub> calculation.



## B.8.4 Fate and behaviour in water and sediment

### B.8.4.1 Aerobic mineralisation in surface water

The data on aerobic mineralisation of Montur Forte FS 230 in soil rely on the information given for the active substance beta-cyfluthrin.

### B.8.4.2 Water/sediment study

The data on water/sediment study of Montur Forte FS 230 in soil rely on the information given for the active substance beta-cyfluthrin.

### B.8.4.3 Irradiated water/sediment study

The data on irradiated water/sediment study of Montur Forte FS 230 in soil rely on the information given for the active substance beta-cyfluthrin.

## B.8.5 Predicted environmental concentrations in surface water and sediment (PEC<sub>sw</sub>, PEC<sub>sd</sub>)

The PEC<sub>gw</sub> was calculated by Hammel&Porschewski 2013c.

### B.8.2/1 (Hammel & Porschewski 2013c)

Reference	: Hammel, K. and Porschewski, R
Title	: Cyb PEC sw FOCUS EUR: Predicted environmental concentrations in surface water and sediment. Use in sugarbeets in Europe. Beta-cyfluthrin (FCR4545), DCVA, FPB-acid, FPB-aldehyd
Date of execution	: 12. 12. 2013
Report no.	: EnSa-13-1003
GLP statement	: not relevant
Guideline	: not relevant; calculation according FOCUS guidance
Test substance	: beta-Cyfluthrin and metabolites
Test system	: PEC in surface water under field conditions

## Materials and Methods

Predicted environmental concentrations in surface water and sediment (PEC<sub>sw</sub> and PEC<sub>sed</sub>) of beta-cyfluthrin were calculated for the use in sugar beet in Europe. Details of the parameters and the application dates used in the calculations are summarised in Table B.8.5-1 and Table B.8.5-2.

**Table B.8.5-1: Application dates of beta-cyfluthrin for the FOCUS Step 3 calculations**

Crop: sugar beets 1 x 10.4 g/ha		
	application start date (Julian Day)	appl. date
D3 (1st)	29-Apr (119)	04-May

D4 (1st)	01-May (121)	30-May
R1 (1st)	24-Apr (114)	26-Apr
R3 (1st)	22-Apr (112)	22-Apr

**Table B.8.5-2: Substance specific and model related input parameter for PEC<sub>sw</sub> calculation of beta- cyfluthrin (Hammel & Porschewski 2013c)**

Parameter	Unit	Beta-cyfluthrin
molar mass	[g/mol]	434.3
water Solubility	[mg/L]	0.0021
vapour pressure	[Pa]	$1.4 \times 10^{-8}$
plant uptake factor	[-]	0.0
wash-off Factor PRZM	[1/cm]	0.5
wash-off factor MACRO	[1/mm]	0.05
Koc	[mL/g]	123930
Freundlich exponent	[-]	1
degradation		
soil	[days]	28.0
water	[days]	27.6
sediment	[days]	1000
Walker exponent	[-]	0.7
effect of temperature		
activation energy	[J/mol]	65400
exponent	[1/K]	0.095
Q <sub>10</sub>	[-]	2.58

## Results

The maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> values for relevant FOCUS Step 3 scenarios are given in Table B.8.5-3. Time dependent PEC values or time-weighted average concentrations are not included in this summary because they were not used in the risk assessment.

**Table B.8.5-3: Maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> of beta-cyfluthrin at Step 3 after seed treatment in sugar beet (10.4 g/ha as)**

FOCUS scenario	PEC <sub>sw</sub> [µg/L]	PEC <sub>sed</sub> [µg/kg]
D3 (ditch, 1st)	< 0.000001	< 0.000001
D4 (pond, 1st)	$2.76 \times 10^{-10}$	$3.23 \times 10^{-7}$
D4 (stream, 1st)	$4.01 \times 10^{-9}$	$3.09 \times 10^{-7}$

R1 (pond, 1st)	< 0.000001	< 0.000001
R1 (stream, 1st)	< 0.000001	< 0.000001
R3 (stream, 1st)	< 0.000001	< 0.000001

## Conclusion

The RMS does not fully agree with the input parameter used in the study by Hammel & Porschewski 1013c (Table B.8.5-2).

For vapour pressure of beta-cyfluthrin  $4.5 \times 10^{-7}$  Pa should be used (isomer II at 20 °C, see document M-CA, Section 2).

For the  $K_{oc}$  the mean (= 112000 mL/g) of the five soils from the studies by Gronberg 1987 and Burhenne 1996 should be used (see Vol. 3 B.8.1.2, Adsorption of cyfluthrin).

Due to the very low water solubility of beta-cyfluthrin, the wash-off factors of 0.02 for PRZM and 0.002 for MACRO are used instead of default values that are only appropriate for water solubility > 8 g/L (see Generic guidance for FOCUS surface water scenarios, ver. 1.2, December 2012).

From the water-sediment study, it is clear that beta-cyfluthrin is transferred very quickly from water to sediment ( $\text{DissT}_{50} = 0.5$  days). It can be assumed the degradation most probably happens in the sediment or at the sediment-water-interface. The  $\text{DegT}_{50}$  for whole system (27.6 days) is attributed to the sediment and a conservative  $\text{DegT}_{50}$  of 1000 days as default is attributed to the water phase.

The PEC given in Table are very low ( $< 10^{-6}$  µg/L, kg). It can be assumed that the changes of input data mentioned above are of no relevant influence on the maximum PEC values. The RMS therefore does not conduct a new  $\text{PEC}_{\text{sw}}$  calculation.

In this evaluation the  $\text{PEC}_{\text{sw}}$  for beta-cyfluthrin are calculated. But the plant protection product Montur Forte FS 230 contains beta-cyfluthrin and imidacloprid. The  $\text{PEC}_{\text{sw,max}}$  step 3 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)

$\text{PEC}_{\text{sw}}$  max of imidacloprid based on the application of Gaucho:

Maximum run-off scenario: < 0.0005 µg/L

Maximum drainage scenario:

FOCUS Step 3:  $\text{PEC}_{\text{sw}} = 0.01$  µg/L;  $\text{PEC}_{\text{sed}} = 0.01$  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  $\text{PEC}_{\text{sw}}$  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:  $\text{PEC}_{\text{sw}} = 0.0017$  µg/L;  $\text{PEC}_{\text{sed}} = 0.0017$  µg/kg

## B.8.6 Fate and behaviour in air

### B.8.6.1 Route and rate of degradation in air and transport via air

The data on degradation and transport of Montur Forte FS 230 in air rely on the information given for the active substance beta-cyfluthrin.

### **B.8.6.2 Predicted environmental concentrations from airborne transport**

The data on airborne transport of Montur Forte FS 230 rely on the information given for the active substance beta-cyfluthrin.

### **B.8.7 Predicted environmental concentrations from other routes of exposure**

During sowing of sugar beet an active substance containing dust abraded from the surface of the seed might deposit outside the field. The drift deposition is calculated according to the draft guidance document “Authorisation of Plant Protection Products for Seed Treatment” (SANCO/10553/2012, January 2014) chapter 10.5.6.

A PEC 2 D dust ground deposition of active substances from sugar beet seeds in off-crop areas at 1 m distance from field edge is expected to be 0.02 g/ha active substances as a generic approach. The term active substances refers to the total content of both beta-cyfluthrin and imidacloprid. The percentage of beta-cyfluthrin in the product Montur Forte FS 230 is 35 % (80 g/L beta-cyfluthrin + 150 g/L imidacloprid). Therefore the PEC 2 D dust ground deposition of beta-cyfluthrin is 0.007 g/ha.

A PEC 3 D dust deposition (for three-dimensional structures like hedges or trees) of active substances from sugar beet seeds in off-crop areas is expected to be 0.26 g/ha active substances as a generic approach. This corresponds to 0.09 g/ha beta-cyfluthrin.

Detailed information about the derivation of the drift deposition values are given in the draft guidance document mentioned above.

## B.8.8 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
KCP 9.1.3 /01	Hammel, K.; Porschewski, R.	2013	Beta-cyfluthrin (CYB) and metabolites: PECsoil EUR - Use in sugarbeets in Europe Bayer CropScience, Report No.: EnSa-13-1042, Edition Number: <a href="#">M-473659-01-1</a> Date: 2013-12-12 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCP 9.2.4.1 /01	Hammel, K.; Porschewski, R.	2013	Beta-cyfluthrin (CYB) and metabolites: PECgw FOCUS PEARL, PELMO EUR - Tier 1 - Use in sugarbeets in Europe Bayer CropScience, Report No.: EnSa-13-1002, Edition Number: <a href="#">M-473652-01-1</a> Date: 2013-12-12 GLP/GEP: no, unpublished	N	N		Bayer CropScience
KCP 9.2.5 /01	Hammel, K.; Porschewski, R.	2013	CYB PECsw FOCUS EUR: Predicted environmental concentrations in surface water and sediment - Use in sugarbeets in Europe Bayer CropScience, Report No.: EnSa-13-1003, Edition Number: <a href="#">M-473660-01-1</a> Date: 2013-12-12 GLP/GEP: no, unpublished	N	N		Bayer CropScience

Grey shaded Studies indicate Baseline Dossier Studies  
Black Studies indicate Supplementary Dossier Studies