Inhibition to microbial activity (terrestrial)

Section A7.5.1.1/01

BPD Data Set IIIA /
Annex Point IIA. VII.7.4

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2006) Cyfluthrin tech.: Determination of effects on carbon transformation in soil [redacted] Report No.: LKC-C-54/06, BES Ref: M-265819-01-1 Report date: 08 February 2006 unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	OECD Guideline N°217	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Cyfluthrin technical	
3.1.1	Lot/Batch number	SC21163S81	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	98,8%	
3.1.4	Composition of Product	Not relevant	
3.1.5	Further relevant properties	none	
3.1.6	Method of analysis	Analytical certificate of December 02, 2005 approved until December 02, 2006	
3.2	**Reference substance**	Sodium chloride	
3.2.1	Method of analysis for reference substance	none	
3.3	**Testing procedure**		
3.3.1	Soil sample /	The soil was collected on October 28, 2005 at a depth of 0 – 20 cm in the from Field plot F on the Bayer CropScience AG's experimental farm Laacherhof, Germany Soil characteristic are given in table A7.5.1.1/01-1	
3.3.2	Test system	see table A7.5.1.1/01-2	
3.3.3	Application of TS	see table A7.5.1.1/01-3	

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Section A7.5.1.1/01

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3.3.4	Test conditions	see table A7.5.1.1/01-4	
3.3.5	Test parameter	Inhibition of microbial carbon transformation	
3.3.6	Analytical parameter	CO_2 measurement	
3.3.7	Duration of the test	28 days	
3.3.8	Sampling	Samples were taken on day 0 and after 28 days of incubation	
3.3.9	Monitoring of TS concentration	No	
3.3.10	Controls	Control : sieved soil treated with 10 g ground quartz sand/kg dry weight soil Solvent control : sieved soil treated with 10 g ground quartz sand/kg dry weight soil with acetone (0.63 ml acetone was mixed with 9 g quartz sand)	X
3.3.11	Statistics	Williams-Test for homogeneous variances (two-sided, $\alpha = 0.05$) was chosen to determine NOEC and LOEC values. Probit Analysis (95 % confidence limit) was used to determine LC10 and LC25 values. The software used to perform the statistical analysis was ToxRat Pro 2.09 (released October 30, 2005):(Ratte, 2002)	
		4 RESULTS	
4.1	**Range finding test**	Not performed	
4.1.1	Concentration	Not relevant	
4.1.2	Effect data	Not relevant	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	3, 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry weight soil.	
4.2.2	Actual concentrations of test substance	no measurements conducted during test	
4.2.3	Growth curves	Not applicable	
4.2.4	Cell concentration data	Not applicable	
4.2.5	Concentration/ response curve	See fig A7.5.1.1/01-1 and A7.5.1.1/01-2	
4.2.6	Effect data	Statistically significant differences (Williams - test, $\alpha = 0.05$, two-sided) concerning the CO2 production/hour/kg dry wt. soil 28 days after application were found in the soil samples treated with 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry wt. soil. See table A7.5.1.1/01-5	
4.2.7	Other observed effects	None	

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4.3	**Results of controls**	No effect
4.4	**Test with reference substance**	Performed separately
4.4.1	Concentrations	16 g NaCl/kg dry weight soil
4.4.2	Results	distinct and long-term (> 28 days) influences on microbial mineralization of carbon
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The influence of Cyfluthrin technical on carbon transformation in soil was investigated.. A loamy sand soil (1.2 % org. C) was exposed for 28 d to concentrations of 3, 11, 30, 90 and 300 mg cyfluthrin tech./kg dry weight soil. An additional solvent control was prepared. Glucose was added to the soil samples (2 g/kg dry weight soil) to induce maximum respiration rate.
5.2	**Results and discussion**	Statistically significant differences (Williams - test, $\alpha = 0.05$, two-sided) concerning the CO_2 production/hour/kg dry wt. soil 28 days after application were found in the soil samples treated with 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry wt. soil.
5.2.1	NOEC	3 mg Cyfluthrin tech./kg dry weight soil
5.2.2	EC_{10}	11 mg Cyfluthrin tech. /kg dry weight soil. (95% confidence limit: 3 – 23 mg/kg)
5.2.3	EC_{50}	EC50 : Not determinedue to mathematical reasons. EC25 : 157 mg Cyfluthrin tech. /kg dry weight soil. (95% confidence limit: 71 – 749 mg/kg)
5.3	**Conclusion**	
5.3.1	Reliability	1
5.3.2	Deficiencies	None

X

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/11/04
Materials and Methods	Applicant's version is acceptable with some amendments: **3.3.10 controls**: Test item was solved in acetone. To check possibly occurring damage to the microflora, a solvent control (ground quartz sand and acetone) has been performed and was considered at evaluation of the results.
Results and discussion	Applicant´s version is acceptable with following amendments: **5.2** See Annex 2: Evaluation by Rapporteur Member State, Ch1 –Tables CA table 1: modified A7.5.1.1/01-5: Effects on non-target soil micro-organisms after 28 days **5.2.3** EC 50: > 300 mg/kg
Conclusion	Significant effects on process of carbon transformation by the soil microflora (respiration inhibition) could be observed at treatment levels of 11, 30, 90 and 300 mg cyfluthrin tech./kg dry weight soil. Detected NOEC of cyfluthrin tech. is 3 mg/kg dry weight soil.
Reliability	1
Acceptability	Acceptable
Remarks	None
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.1/01-1: Soil characteristics

Criteria	Details
Nature	soil sample
Sampling site:	
Geographical reference on the sampling site	latitude of 51°4' north and a longitude of 6°55' east.
Data on the history of the site	Plant protection chemicals have not been used on this field since 1981. The plot has been under grass and has not been treated with fertilizers since 1996. On March 07, 2000 the plot was plowed and then freshly planted with grass.
Depth of sampling [cm]	0-20 cm
Sand / Silt / Clay content [% dry weight]	Loamy sand soil
pH	5.6 (KCl)
Organic carbon content [% dry weight]	1.2%
Nitrogen content [% dry weight]	0.1%
Cation exchange capacity	5.9 mep/100 g dry weight soil
Initial microbial biomass	461 mg microbial C/kg dry weight soil 3.8% of soil organic (c) content
Reference of methods	The carbon content of the metabolically active microbial biomass in the soil was determined at the start of the test as described by Anderson and Domsch (1978).
Collection / storage of samples	The soil was collected on October 28, 2005 and stored at 4 ± 2 °C until used, as described in the BBA Guideline (1990), ISO/DIS 10381-6 (1993) and OECD/OCDE Guideline No. 217 (2000).
Pretreatment	Soil samples were passed through a 2 mm sieve

Table A7.5.1.1/01-2: Test system

Criteria	Details
Culturing apparatus	Brown glass bottles closed with parafilm
Number of vessels / concentration	Three replicates per concentration
Aeration device	none
Measuring equipment	gas analyzer (Wösthoff Co., Bochum, Germany
Test performed in closed vessels	closed with parafilm

Table A7.5.1.1/01-3: Application of test substance

Criteria	Details
Application procedure	Sieved soil (2 mm) was treated with either 10 g ground quartz sand/kg dry weight soil (control), 10 g ground quartz sand/kg dry weight soil with acetone (solvent control) or a mixture of quartz sand and Cyfluthrin tech. (3, 11, 30, 90 and 300 mg/kg dry weight soil).
Carrier	ground quartz sand
Concentration of liquid carrier [% v/v]	Not relevant
Liquid carrier control	Not relevant
Other procedures	none

Table A7.5.1.1/01-4: Test conditions

Criteria	Details
Organic substrate	-
Incubation temperature	20±2°C
Soil moisture	45% of the maximum water holding capacity
Method of soil incubation	individual subsamples
Aeration	no

Table A7.5.1.1/01-5: Effects on non-target soil micro-organisms

Test item Test object	Cyfluthrin tech. Soil micro-organism, carbon-transformation (loamy sand soil)	
Mg test item/ hg dry weight soil	Mg CO2/h/kg dry st soil after 28 d (mean value)	% of pooled-control
Control	258.3	-
Solvent control	273.0	-
Pooled control	265.7	100
3.0	248.5	94
11.0	238.2	90*
30.0	235.4	89*
90.0	212.2	80*
300.0	177.1	67*

* Statistically significant difference to the pooled control (Williams - test, α = 0.05, two-sided)

Fig A7.5.1.1/01 Carbon transformation on day 0, just after treatment

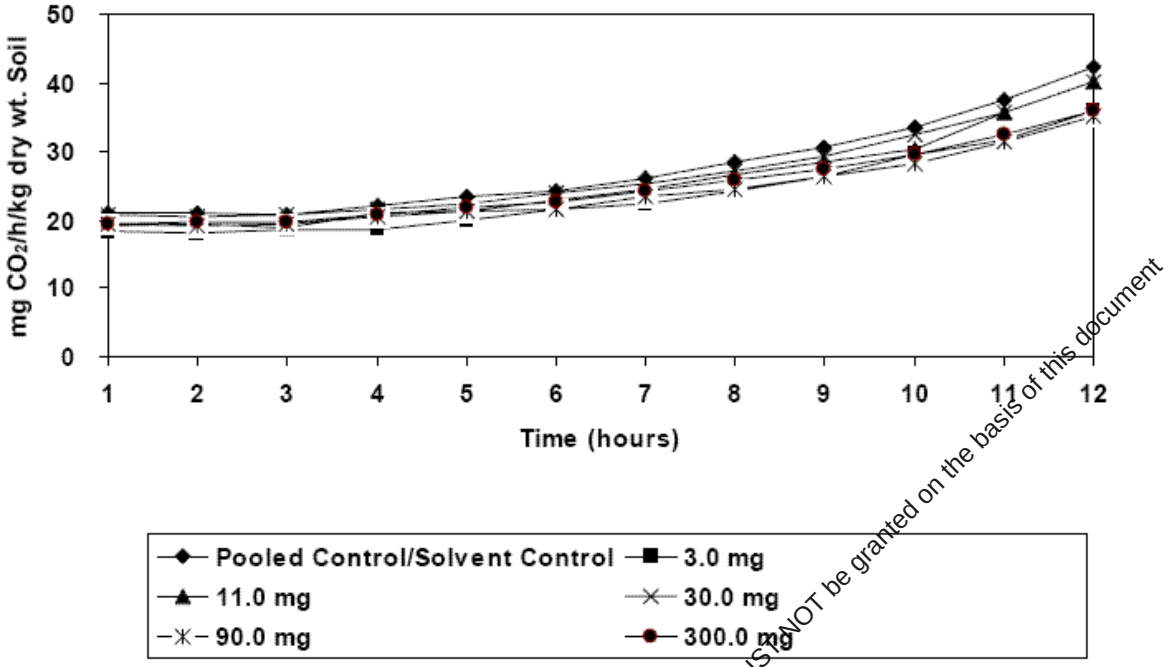
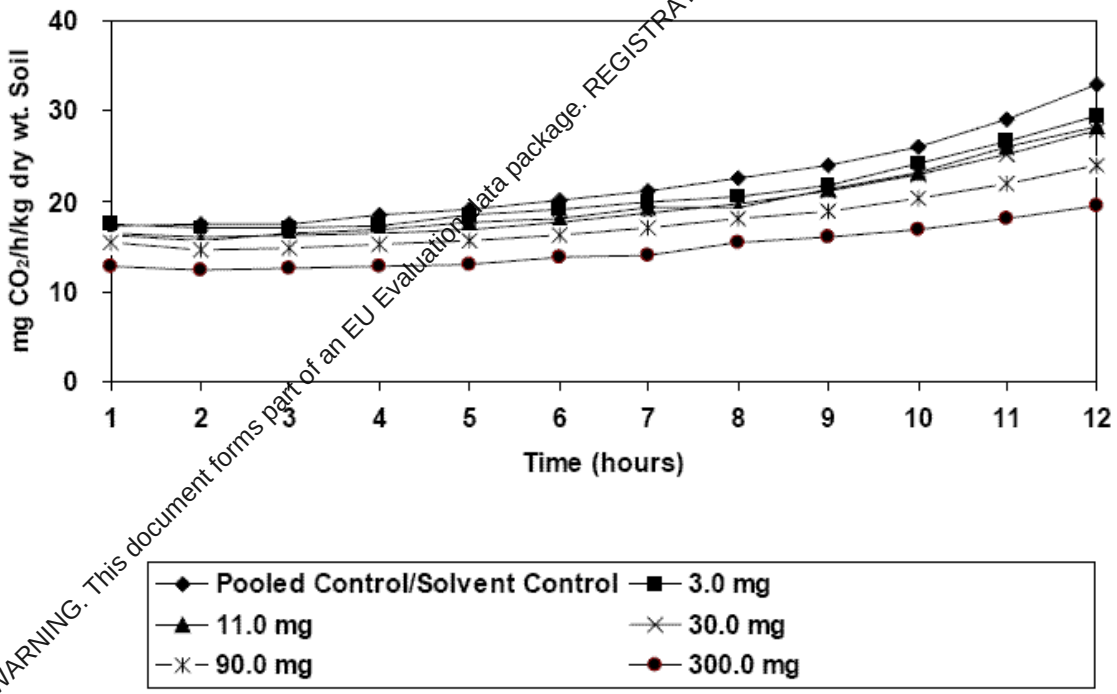


Fig A7.5.1.1/02 Carbon transformation on day 28, just after treatment



Annex 2: Evaluation by Rapporteur Member State, CA –Tables

CA Table 1 – modified Table A7.5.1.1/01-5: Effects on non-target soil micro-organisms after 28 days

Test item Test object	Cyfluthrin tech. Soil micro-organism, carbon-transformation (loamy sand soil)		
Mg test item/kg dry	Mg CO_2/h/kg dry	% of pooled-	% difference

weight soil	wt soil after 28 d (mean value)	control	in respiration rate
Control	258.3	-	-
Solvent control	273.0	-	-
Pooled control	265.7	100	0
3.0	248.5	94	6
11.0	238.2	90*	10
30.0	235.4	89*	11
90.0	212.2	80*	20
300.0	177.1	67*	33

* Statistically significant difference to the pooled control (Williams - test, $\alpha = 0.05$, two-sided)

Inhibition to microbial activity (terrestrial)

Section A7.5.1.1/02

BPD Data Set IIIA /
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			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2006) Cyfluthrin tech.: Determination of effects on nitrogen transformation in soil, [redacted] Report No.: LKC-N-62/06, BES Ref: M-265333-01-1 Report date: 08.02.2006 unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	OECD Guideline N°216	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Cyfluthrin technical	
3.1.1	Lot/Batch number	SC21163S81	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	98,8%	
3.1.4	Composition of Product	Not relevant	
3.1.5	Further relevant properties	none	
3.1.6	Method of analysis	Analytical certificate of December 02, 2005 approved until December 02, 2006	
3.2	**Reference substance**	Sodium chloride	
3.2.1	Method of analysis for reference substance	none	
3.3	**Testing procedure**		
3.3.1	Soil sample /	The soil was collected on October 28, 2005 at a depth of 0 – 20 cm in the from Field plot F1 on the Bayer CropScience AG's experimental farm Laacherhof, Germany Soil characteristic are given in table A7.5.1.1/02-1	
3.3.2	Test system	see table A7.5.1.1/02-2	
3.3.3	Application of TS	Sieved soil (2 mm) was treated with a mixture of quartz sand and	

Inhibition to microbial activity (terrestrial)

Section A7.5.1.1/02

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		Cyfluthrin tech. See table A7.5.1.1/02-3.	
3.3.4	Test conditions	Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation. See table A7.5.1.1/02-4	
3.3.5	Test parameter	Inhibition of microbial nitrogen transformation	
3.3.6	Analytical parameter	Ammonium, nitrite and nitrate measurement	
3.3.7	Duration of the test	28 days	
3.3.8	Sampling	Samples were taken on day0 and after 28 days of incubation	
3.3.9	Monitoring of TS concentration	No	
3.3.10	Controls	Control : sieved soil treated with 10 g ground quartz sand/kg dry weight soil Solvent control : sieved soil treated with 10 g ground quartz sand/kg dry weight soil with acetone (0.54 mL acetone was mixed with 9 g quartz sand)	X
3.3.11	Statistics	The software used to perform the statistical analysis was ToxRat Pro 2.09 (released October 30, 2005); (Ratte, 2002). For the determination of the NOEC/LOEC the control and the solvent control were pooled, because there was no statistically significant difference (Student t-Test for homogeneous variances, a = 0.05, one-sided smaller). Data (amount of nitrate in mg/kg at day 28) were tested for normal distribution and homogeneity of variance using R/S Test and Cochran-Test (a = 0.05) respectively. Data were not normally distributed even after transformation but homogeneity of variances was given. Therefore Bonferroni-Welch-Test for non homogeneous variances (two-sided, a = 0.05) was used to determine NOEC and LOEC values. Since the NOEC is the highest test concentration an ECX calculation could not be performed.	
		4 RESULTS	
4.1	**Range finding test**	Not performed	
4.1.1	Concentration	Not relevant	
4.1.2	Effect data	Not relevant	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	3, 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry weight soil.	
4.2.2	Actual concentrations of test substance	no measurements conducted during test	
4.2.3	Growth curves	Not applicable	
4.2.4	Cell concentration data	Not applicable	
4.2.5	Concentration/ response curve	See fig A7.5.1.1/02-1	

Inhibition to microbial activity (terrestrial)

Section A7.5.1.1/02

BPD Data Set IIIA / Annex Point IIA. VII.7.4

4.2.6	Effect data	No statistically significant differences were seen in quantities of Nitrate-N in the soil samples 28 days after treatment between the pooled control and all treatment groups. .See table A7.5.1.1/02-5	
4.2.7	Other observed effects	None	
4.3	**Results of controls**	No effect	
4.4	**Test with reference substance**	Performed separately	
4.4.1	Concentrations	16 g NaCl/kg dry weight soil	
4.4.2	Results	distinct and long-term (> 28 days) influences on microbial mineralization of carbon	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The influence of Cyfluthrin technical on nitrogen transformation in soil was investigated.. A loamy sand soil (1.2 % org. C) was exposed for 28 d to concentrations of 3, 11, 30, 90 and 300 mg cyfluthrin tech./kg dry weight soil. An additional solvent control was prepared. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.	
5.2	**Results and discussion**	No statistically significant differences were seen in quantities of Nitrate-N in the soil samples 28 days after treatment between the pooled control and all treatment groups.	X
5.2.1	NOEC	≥ 300 mg Cyfluthrin tech./kg dry weight soil	X
5.2.2	EC_{10}	> 300 mg Cyfluthrin tech. /kg dry weight soil.	X
5.2.3	EC_{50}	> 300 mg Cyfluthrin tech. /kg dry weight soil.	
5.3	**Conclusion**		
5.3.1	Reliability	1	
5.3.2	Deficiencies	None	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/11/04
Materials and Methods	Applicant's version is acceptable with some amendments: **3.3.10 controls**: Test item was solved in acetone. To check possibly occurring damage to the microflora, a solvent control (ground quartz sand and acetone) has been performed and was considered at evaluation of the results.
Results and discussion	Applicant´s version is acceptable with following amendments: **5.2** No clear dose-effect relationship can be identified. See Annex 2: Evaluation by Rapporteur Member State, Cat –Tables CA table 1: modified A7.5.1.1/02-5: Effects on non-target soil micro-organisms after 28 days
Conclusion	Significant effects on process of nitrogen transformation by the soil microflora could not be observed at all treatment levels (3, 11, 30, 90 and 300 mg) of cyfluthrin tech./kg dry weight soil. Hence detected NOEC of cyfluthrin tech. is > 300 mg/kg dry weight soil.
Reliability	1
Acceptability	Acceptable
Remarks	None
	Comments from ...
Date	**GIVE DATE OF COMMENTS SUBMITTED**
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.1/02-1: Soil characteristics

Criteria	Details
Nature	soil sample
Sampling site:	
Geographical reference on the sampling site	latitude of 51°4' north and a longitude of 6°55' east.
Data on the history of the site	Plant protection chemicals have not been used on this field since 1981. The plot has been under grass and has not been treated with fertilizers since 1996. On March 07, 2000 the plot was plowed and then freshly planted with grass.
Depth of sampling [cm]	0-20 cm
Sand / Silt / Clay content [% dry weight]	Loamy sand soil
pH	5.6 (KCl)
Organic carbon content [% dry weight]	1.2%
Nitrogen content [% dry weight]	0.1%
Cation exchange capacity	5.9 mep/100 g dry weight soil
Initial microbial biomass	461 mg microbial C/kg dry weight soil 3.8% of soil organic (c) content
Reference of methods	The carbon content of the metabolically active microbial biomass in the soil was determined at the start of the test as described by Anderson and Domsch (1978).
Collection / storage of samples	The soil was collected on October 28, 2005 and stored at 4 ± 2 °C until used
Pretreatment	Soil samples were passed through a 2 mm sieve

Table A7.5.1.1/02-2: Test system

Criteria	Details
Culturing apparatus	Brown glass bottles closed with parafilm
Number of vessels / concentration	Three replicates per concentration
Aeration device	none
Measuring equipment	Methods of Bran + Lubbe were used for the determination of ammonium (Bran + Lubbe, G-102-93 Rev.1), nitrate plus nitrite and nitrite (Bran + Lubbe, G-109-94Rev.1).
Test performed in closed vessels	closed with parafilm

Table A7.5.1.1/02-3: Application of test substance

Criteria	Details
Application procedure	Sieved soil (2 mm) was treated with either 10 g ground quartz sand/kg dry weight soil (control), 10 g ground quartz sand/kg dry weight soil with acetone (solvent control) or a mixture of quartz sand and Cyfluthrin tech. (3, 11, 30, 90 and 300 mg/kg dry weight soil).
Carrier	ground quartz sand
Concentration of liquid carrier [% v/v]	Not relevant
Liquid carrier control	Not relevant
Other procedures	none

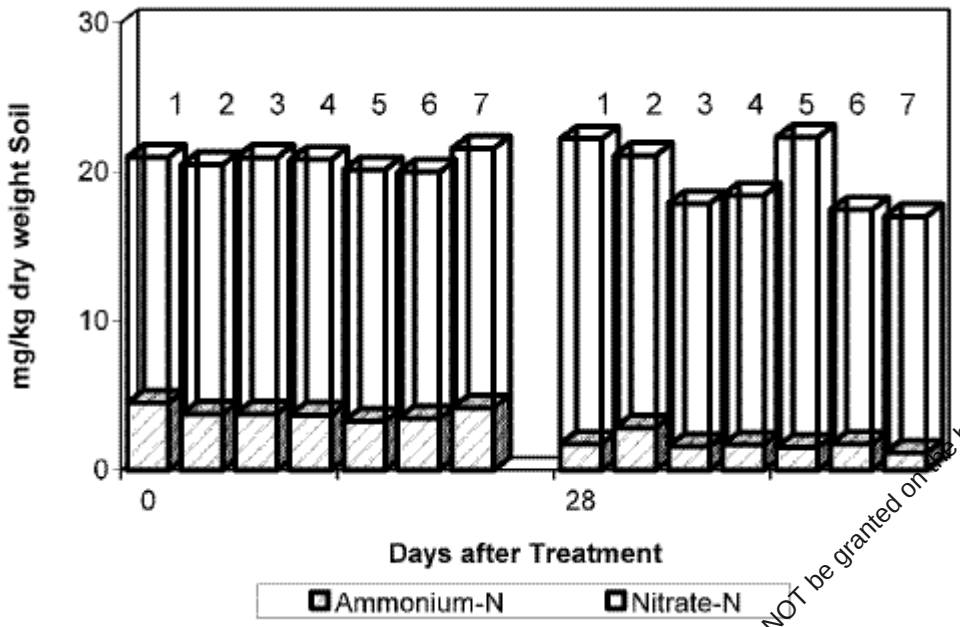
Table A7.5.1.1/02-4: Test conditions

Criteria	Details
Organic substrate	Lucerne-grass-green meal Hoeveler Kraftfutter, 40764 Langenfeld 40.6 % Ctotal, 0.05 % Cinorg, 2.5 % N
Incubation temperature	20±2°C
Soil moisture	45% of the maximum water holding capacity
Method of soil incubation	individual subsamples
Aeration	No

Table A7.5.1.1/02-5: Effects on non-target soil micro-organisms

Test item Test object	Cyfluthrin tech. Soil micro-organism, (loamy sand soil)	
mg test item/ hg dry weight soil	mg CO2/h/kg dry st soil after 28 d (mean value)	% of pooled-control
Control	20.46 ± 1.89	-
Solvent control	18.29 ± 1.57	-
Pooled control	19.38 ± 1.96	100
3.0	16.29 ± 1.58	84
11.0	16.74 ± 1.93	86
30.0	20.81 ± 0.99	107
90.0	15.72 ± 3.67	81
300.0	15.87 ± 2.92	82

Fig A7.5.1.1/02-1 Nitrogen transformation: mean values



1 = Control
2 =Solvent Control
3 = 3 mg Cyfluthrin tech./kg dry weight Soil
4 = 11 mg Cyfluthrin tech./kg dry weight Soil
5 = 30 mg Cyfluthrin tech./kg dry weight Soil
6 = 90 mg Cyfluthrin tech./kg dry weight Soil
7 = 300 mg Cyfluthrin tech./kg dry weight Soil

Annex 2: Evaluation by Rapporteur Member State, CA –Tables

CA Table 1 – modified Table A7.5.1.1/02-5: Effects on non-target soil micro-organisms (28 d)

Test item Test object	Cyfluthrin tech. Soil micro-organism, (loamy sand soil)		
mg test item/ kg dry weight soil	mg Nitrate-N/kg dry wt soil after 28 d (mean value)	% of pooled-control	% deviation from control after 28 d (nitrate transformation)
Control	20.46 ± 1.89	-	-
Solvent control	18.29 ± 1.57	-	-
Pooled control	19.38 ± 1.96	100	-
3.0	16.29 ± 1.58	84	16
11.0	16.74 ± 1.93	86	14
30.0	20.81 ± 0.99	107	-7
90.0	15.72 ± 3.67	81	19
300.0	15.87 ± 2.92	82	18

Document IIIA / Section A7.5.1.2/01 — Earthworm, acute toxicity test

BPD Data Set IIIA / Annex Point IIIA XIII 3.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1985). Acute toxicity of Cyfluthrin (Tech.) to Earthworms. [redacted] Report No. HBF/Rg 54. BES Ref M-008890-01-1 Report date: Dates of study May to November 1985. Unpublished.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I (included in Revision Nov 2001, Annex II)	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes. OECD 207	
2.2	**GLP**	No, (not required, as study started before June 30 1988).	
2.3	**Deviations**	Number of replicates was reduced.	
		3 METHOD	
3.1	**Test material**	Cyfluthrin tech	
3.1.1	Lot/Batch number	Pt. 233 490 583.	
3.1.2	Specification	as given in Section 2	
3.1.3	Description	Sticky yellowish substance	
3.1.4	Purity	92.0%	
3.1.5	Stability	released until: 25.12.85	
3.2	**Reference substance**	Chloracetamide	
3.2.1	Method of analysis for reference substance	None.	
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	See table A7.5.1.2/01-1	
3.3.2	Application of the test substance	The test substance was dissolved in acetone, added to finely ground quartz sand and evaporated to dryness before being distributed in the test substrate using a domestic mixer.	
3.3.3	Test organisms	Earthworm (*Eisenia foetida*). See table A7.5.1.2/01-2	
3.3.4	Test system	The worms were exposed to different concentrations of cyfluthrin in an artificial soil consisting of 69% sand, 20% clay mineral and 10% peat. See table A7.5.1.2/01-3	x
3.3.5	Test conditions	22 ± 2°C, 70-90% RH, constant light (400-800 lux). See table	x

Document IIIA / Section A7.5.1.2/01 — **Earthworm, acute toxicity test**

BPD Data Set IIIA / Annex Point IIIA XIII 3.2

		A7.5.1.2/01-4
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality and body weight changes were recorded.
3.3.8	Examination	After 14 days exposure the number of surviving animals and their weight alteration during the test was determined.
3.3.9	Monitoring of test substance concentration	Not required according OECD 207
3.3.10	Statistics	No details are presented in the report.
		4 RESULTS
4.1	**Filter paper test**	Not performed .
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	10, 100, 1000 mg/kg dry weight artificial soil.
4.2.2	Effect data (Mortality)	See tables A7.5.1.2/01-5, A7.5.1.2/01-6
4.2.3	Concentration / effect curve	none
4.2.4	Other effects	Weight alterations in the earthworms in comparison to the control were observed for cyfluthrin at 10 mg a.i./kg dry weight substrate and above.
4.3	**Results of controls**	
4.3.1	Mortality	The mortality rate in the control was below 10% which is regarded as the limit for natural mortality. For detailed mortality results see table A7.5.1.2-5
4.3.2	Number/ percentage of earthworms showing adverse effects	See table A7.5.1.2/01-5
4.3.3	Nature of adverse effects	Weight alterations in the earthworms in comparison to the control were observed for cyfluthrin at 10 mg a.i./kg dry weight substrate and above
4.4	**Test with reference substance**	Chloracetamide
4.4.1	Concentrations	10, 18, 24, 32 and 56 mg a.i./kg.
4.4.2	Results	LC_{50} at 14 days = 19.7 mg/kg dry weight substrate (95% confidence limits 18.3 – 21.2 mg/kg). This result is within the usual range and therefore validates the study.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The acute toxicity of cyfluthrin technical to earthworms was determined in a 14-day laboratory study according to the test guideline OECD 207.

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		The test animals were exposed to different concentrations of cyfluthrin in an artificial soil consisting of sand, clay mineral and peat. The test compound was thoroughly mixed into the artificial soil. After 14 days, the number of surviving animals and their weight alteration during the test period was determined.	
5.2	**Results and discussion**	The no-observed-effect-concentration for *Eisenia fetida* exposed to cyfluthrin was 1 mg/kg dry weight soil based on weight losses and the lowest-observed-effect-concentration was 10 mg/kg. The LC_{50} was greater than 1000 mg/kg dry weight soil, the highest concentration tested.	
5.2.1	LC_0		
5.2.2	LC_{50}	LC_{50} >1000 mg/kg.	x
5.2.3	LC_{100}		
5.3	**Conclusion**	The LC_{50} (test duration: 14 days, test species: *Eisenia foetida*) is greater than 1000 mg a.i./kg dry weight substrate.	
		The No Observed Effect Concentration (NOEC) is 1 mg a.i./kg dry weight substance.	x
5.3.1	Other Conclusions		
5.3.2	Reliability	1	
5.3.3	Deficiencies	None	

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	2006/09/06
Materials and Methods	Applicant's version is acceptable with the following comment: To 3.3.4, table A7.5.1.2/01-3: According OECD Guideline 207 the test should be conducted with 5 concentrations in a geometric series. And furthermore, 4 replicates with 10 worms instead of 3 replicates with 10 worms per concentration should be used. To 3.3.5: The test temperature is 20 ± 1°C.
Results and discussion	Applicant's version can be adopted.
Conclusion	Applicant's version can be adopted with the following comment: LC_0: not determinable LC_{50}: >1000 mg/kg dry weight substrate , (see above 5.2.2) LC_{100}: not determinable Other conclusions: The NOEC is derivated by preliminary range finding test with nominal concentrations of 0.1, 1, 10, 100 and 1000 mg a.i./ kg dw substrate (see above 5.3).
Reliability	2
Acceptability	acceptable

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Remarks	Number of replicates and concentrations was reduced and the concentrations are not in a geometric series.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2/01-1: Preparation of TS solution

Criteria	Details
Dispersion	Yes. The solution was added to ground quartz sand and pounded until the acetone had evaporated. The treated sand was then distributed in the test substrate by mixing using a domestic mixer.
Vehicle	Acetone.
Concentration of vehicle	2172 mg of the active ingredient was made up to 20 ml acetone and evaporated to dryness before the worms were exposed
Vehicle control performed	Yes
Other procedures	Glass lids were placed over the test vessels to prevent evaporation.

Table A7.5.1.2/01-2: Test organisms

Criteria	Details
Species/strain	Earthworm *(Eisenia foetida andrei).*
Source of the initial stock	[redacted]
Culturing techniques	Temperature 22 ± 2°C, 70 – 90 % relative humidity, 12:12 hour light dark cycle.
Age/weight	More than 2 months old/Pre-test mean weight 403 mg, 422 mg in first main study, 311 mg in second main study.
Pre-treatment	On day prior to start of study, removed from breeding substrate and kept in test substrate under test conditions until study start.

Table A7.5.1.2/01-3: Test system

Criteria	Details
Artificial soil test substrate	69% fine quartz sand (84% with particle size 0.06 – 0.2 mm), 10% dried, finely ground peat (sphagnum peat; pH 2 – 4), 20% kaolin (kaolinite content of approximately 36%, pH ~7, "Kaolin W" from Erbsloh/Geisenheim) and approximately 1% $CaCO_3$ (pure) to adjust the pH to 6 ± 0.5.
Test mixture	See above
Size, volume and material of test container	1.5 L glass preserving jars
Amount of artificial soil (kg)/ container	500 g dry weight.
Nominal levels of test concentrations	10, 100, 1000 mg/kg artificial soil.
Number of replicates/concentration	3.
Number of earthworms/test concentration	30.
Number of earthworms/container	10.
Light source	Not stated.
Test performed in closed vessels due to significant volatility of test substrate	Yes. 1.5 L preserving jars covered with glass lid.

Table A7.5.1.2/01-4: Test conditions

Criteria	Details
Test temperature	Temperature 20 ± 1°C, 70 – 90% relative humidity,
Moisture content	Water content as a % of the maximum water capacity: Pre-test: 65.4%; Main study: 57.5 – 81.1%
pH	Pre-test: 6.6 – 6.7; Main study: 6.4 – 6.9
Adjustment of pH	1% calcium carbonate added at test initiation to adjust the pH to 6 ± 0.5
Light intensity / photoperiod	Constant light 400 – 800 lux.
Relevant degradation products	None.

Table A7.5.1.2/01-5: Mortality data

Test Substance Concentration (nominal/measured)[1] [mg/kg artificial soil]	Mortality			
	Number		Percentage	
	7 d	14 d	7 d	14 d
Main study 1				
Control	0	0	0	0
1000	2	2	6.7	6.7
Main study 2				
Control	0	0	0	0
10	0	0	0	0
100	0	0	0	0
1000	1	3	6.7	10
Temperature [°C]	20 ± 1°C	20 ± 1°C		
pH	6.4 ± 0.01 6.9 ± 0.02	6.4 ± 0.08 6.5 ± 0.02		
Moisture content	25.3 ± 0.4 24.4 ± 0.7	33.7 ± 0.2 33.6 ± 1.2		

[1] specify, if TS concentrations were nominal or measured

Table A7.5.1.2/01-6: Effect data (mg/kg soil)

	14 d [mg/kg soil][1]	95 % c l.
LC_0	-	-
LC_{50}	>1000 mg	
LC_{100}	-	-

[1] effect data are based on nominal concentrations

Table A7.5.1.2/01-7: Validity criteria for acute earthworm test according to OECD 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	Yes	

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BPD Data Set IIIA / Annex Point IIIA XIII 3.2

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1985). Acute toxicity of Cyfluthrin (Tech.) to Springtails (*Folsomia Candida*). [redacted]. Bayer Report No. HBF Co 03. BES Ref. M-032023-01-1 Report date: 9 December 1985. Unpublished.
1.2	**Data protection**	Yes.
1.2.1	Data owner	Bayer CropScience AG
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No, however based upon OECD 207.
2.2	**GLP**	No, (not required, as study started before June 30 1988).
2.3	**Deviations**	Not applicable.

3 METHOD

3.1	**Test material**	Cyfluthrin tech.
3.1.1	Lot/Batch number	Pt. 233 490 583
3.1.2	Specification	as given in section 2
3.1.3	Purity	92.1%
3.1.4	Composition of Product	as given in Section 2
3.1.5	Further relevant properties	Sticky yellowish substance.
3.1.6	Method of analysis	None.
3.2	**Reference substance**	None.
3.2.1	Method of analysis for reference substance	Not applicable
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	See table A7.5.1.2/02-1
3.3.2	Application of the test substance	The test substance was dissolved in acetone, added to finely ground quartz sand and evaporated to dryness before being distributed in the test substrate using a domestic mixer.
3.3.3	Test organisms	Springtails (*Folsomia candida*) See table A7.5.1.2/02-2
3.3.4	Test system	The springtails were exposed to different concentrations of cyfluthrin in an artificial soil consisting of 69% quartz sand, 20% clay mineral and

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		10% peat. See table A7.5.1.2/02-3
3.3.5	Test conditions	20 ± 1°C, 70-90% RH, constant light (400-800 lux) See table A7.5.1.2/02-4
3.3.6	Test duration	14 days
3.3.7	Test parameter	Mortality was recorded.
3.3.8	Examination	After 14 days exposure the number of surviving animals was determined.
3.3.9	Monitoring of test substance concentration	Not required according OECD 207
3.3.10	Statistics	Probit analysis using the "Maximum-Likelihood" method.
		4 RESULTS
4.1	**Filter paper test**	Not performed.
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	1.0, 5.6, 10, 56, 100, 178, 316, 562 and 1000 mg/kg dry weight artificial soil.
4.2.2	Effect data (Mortality)	See tables A7.5.1.2/02-5, A7.5.1.2/02-6
4.2.3	Concentration / effect curve	See figure 1
4.2.4	Other effects	none
4.3	**Results of controls**	
4.3.1	Mortality	The mortality rate in the control was lower than 10% in the main test and at 10% in the pretest which is below the validity criteria of 20% of the currently established test guideline ISO 11267 for Testing effects on *Folsomia*. For detailed mortality results see table A7.5.1.2/02-5
4.3.2	Number/ percentage of organisms showing adverse effects	See table A7.5.1.2/02-5
4.3.3	Nature of adverse effects	mortality
4.4	**Test with reference substance**	None, as test guidelines at the time of test performance was established for acute effects on earthworm.
4.4.1	Concentrations	Not applicable.
4.4.2	Results	Not applicable.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The acute toxicity of cyfluthrin technical to springtails was determined in a 14-day acute toxicity study following the test guideline OECD 207 for effects on earthworm with adaptations. The test animals were exposed to a range of concentration from 1.0 to

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		1000 mg cyfluthrin /kg of artificial soil consisting of 84% sand, 20% clay mineral and 10% peat. The test compound was thoroughly mixed into the artificial soil. After 14 days, the number of surviving animals during the test period was determined.	x
5.2	**Results and discussion**	The LC_{50} was 599 mg/kg dry weight soil. The acute no-observed-effect-concentration (NOEC) for *Folsomia candida* exposed to cyfluthrin was 10 mg/kg dry weight soil and the lowest-observed-effect-concentration was 56 mg/kg.	
5.2.1	LC_0		
5.2.2	LC_{50}	599 mg/kg (95% confidence interval 234-5639 mg as/kg dw)	
5.2.3	LC_{100}		
5.3	**Conclusion**	The LC_{50} (test duration: 14 days, test species: *Folsomia candida*) is 599 mg a.i./kg dry weight substrate.	
5.3.1	Other Conclusions	The acute No Observed Effect Concentration (NOEC) is 10 mg a.i./kg dry weight substance.	
5.3.2	Reliability	1, the study complies with an acute toxicity test for soil macroorganisms as established in OECD 207 for earthworms. The currently valid ISO 11267 method for testing of effects on collembola, the appropriate soil test organism for an insecticide, evaluates in addition the chronic effects on reproduction, resulting in a long term realistic NOEC.	
5.3.3	Deficiencies	None	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/06
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted.
Conclusion	Applicant's version can be adopted with the following comment: LC_0: not determinable LC_{50}: 599 mg/kg dry weight substrate LC_{100}: not determinable To 5.1: The artificial soil consisting of 69% sand instead of 84%.
Reliability	2
Acceptability	acceptable
Remarks	Number of replicates per concentrations and controls must be at least 5 instead of 3, furthermore the concentrations are not in a geometric series.

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2/02-1: Preparation of TS solution

Criteria	Details
Dispersion	Yes. The solution was added to ground quartz sand and pounded until the acetone had evaporated. The treated sand was then distributed in the test substrate by mixing using a domestic mixer.
Vehicle	Acetone.
Concentration of vehicle	2172 mg of the active ingredient was made up to 20 ml acetone, further diluted to meet a total volume of 5 ml to be applied to the test substrate of 500 g. The solvent was evaporated to dryness before the springtails were exposed.
Vehicle control performed	Yes
Other procedures	Glass lids were placed over the test vessels to prevent evaporation.

Table A7.5.1.2/02-2: Test organisms

Criteria	Details
Species/strain	Springtails *(Folsomia candida).*
Source of the initial stock	[redacted].
Culturing techniques	Temperature 20 ± 1°C, 70 – 90 % relative humidity, constant light. The breeding method is based on methods by Spahr (1981) (Anzeiger Schadlingskunde, Pflanzenschutz, Umweltschutz 54, 27 - 29), and Wolf-Roskosch (1983) (Chemikaliengesetz Heft 3, Teste 27/83, Umweltbundesamt, 83 - 109).
Age/weight	Adult, 2 – 3 mm length.
Pre-treatment	Cultivation on activated carbon mixed with gypsum, feeding in 14 days and change to fresh substrate in 8 weeks interval, respectively.

Table A7.5.1.2/02-3: Test system

Criteria	Details
Artificial soil test substrate	69% fine quartz sand (84% with particle size 0.06 – 0.2 mm), 10% dried, finely ground peat (sphagnum peat; pH 2 – 4), 20% kaolin (kaolinite content of approximately 36%, pH ~7, "Kaolin W" from Erbsloh/Geisenheim) and approximately 1% $CaCO_3$ (pure) to adjust the pH to 6 ± 0.5.
Test mixture	See above
Size, volume and material of test container	100 ml glass beakers
Amount of artificial soil (kg)/ container	50 g dry weight.
Nominal levels of test concentrations	1.0, 5.6, 10, 56, 100, 178, 316, 562 and 1000 mg/kg dry weight artificial soil.
Number of replicates/concentration	3
Number of Springtails/test concentration	30
Number of Springtails/container	10
Light source	Not stated.
Test performed in closed vessels due to significant volatility of test substrate	Yes. 100 ml glass beakers with glass lid.

Table A7.5.1.2/02-4: Test conditions

Criteria	Details
Test temperature	Temperature 20 ± 1°C, 70 – 90% relative humidity,
Moisture content	Water content as a % of the maximum water capacity: Pre-test: 41.6%; Main study: 47.4%
pH	Pre-test: 6.6 – 6.8; Main study: 6.2
Adjustment of pH	1% calcium carbonate added at test initiation to adjust the pH to 6 ± 0.5
Light intensity / photoperiod	Constant light 400 – 800 lux.
Relevant degradation products	None.

Table A7.5.1.2/02-5: Mortality data

Test Substance Concentration (nominal) mg/kg artificial soil		Mortality	
Pre-test		**Number 14 d**	**Percentage 14 d**
Control		-	10
Cyfluthrin	0.1	-	17
	1	-	40
	10	-	27
	100	-	40
	1000	-	73
Main study			
Control		1	3
Cyfluthrin	1	2	7
	5.6	1	3
	10	0	0
	56	4	13
	100	6	20
	178	5	17
	316	13	43
	562	15	50
	1000	22	73
Temperature [°C]		20 ± 1°C	
pH		6.6 ± 0.01 6.2 ± 0.06	
Moisture content (main test)		at start at end	ca. 24%* 24.7%

* corresponding to 47.4 % of maximum water holding capacity

Table A7.5.1.2/02-6: Effect data (mg/kg soil)

	14 d [mg/kg soil][1]	95 % c.l.
LC_0	-	-
LC_{50}	599	234 - >1000 mg a.i./kg
LC_{100}	-	-

[1] effect data are based on nominal concentrations

Table A7.5.1.2/02-7: Validity criteria for acute test according to OECD 207

	fulfilled	Not fulfilled
Mortality of control animals < 10%	**Yes**	

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Effects on beneficial arthropods other than bees

X

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1 REFERENCE

1.1	**Reference**	[redacted] (2005) Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1). [redacted]. Bayer AG, Report No. P14HR BES Ref M-258697-01-1 12 October 2005 Unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience AG
1.2.2	Companies with letter of access	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).
2.2	**GLP**	Yes
2.3	**Deviations**	None.

3 METHOD

3.1	**Test material**	4-Fluoro-3-phenoxybenzoic acid
3.1.1	Lot/Batch number	M23458, AE F105561 001C94 0001
3.1.2	Specification	Not relevant, metabolite testing
3.1.3	Purity	94% w/w
3.1.4	Composition of Product	Not relevant, metabolite testing
3.1.5	Further relevant properties	Stability under correct storage conditions: April 19,2007
3.1.6	Method of analysis	Identity of the test material confirmed by MS and NMR
3.2	**Toxic standard**	Yes, Dimethoate
3.2.1	Method of analysis for reference substance	N/A
3.3	**Test methods**	

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Effects on beneficial arthropods other than bees

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3.3.1	Test organisms	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.1.2/03-1
3.3.2	Test system	See table A7.5.1.2/03-2
3.3.3	Test conditions	See table A7.5.1.2/03-3
3.3.4	Test duration	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	14 days after test initiation mortality was assessed. Reproduction was tested on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	Monitoring of test substance concentration	No
3.3.8	Statistics	Mortality : The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) Reproduction: Welch t-test; 1-sided, $p \leq 0.05$

4 RESULTS

4.1 Soil test

4.1.1	Initial concentrations of test substance	9.4, 30.1, 94, 297 and 940 mg /kg dry soil
4.1.2	Effects data Mortality/ Reproduction	Mortality: There was no concentration dependent mortality after 14 days. Mortality ranged from 5.00 - 16.25% in the treated samples corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%. The ANOVA and Dunnett's t-test showed not significant difference in the mortality compared to the control. The LC50 was hence > 940 mg test item/kg soil. Reproduction : Statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed a significant difference concerning the cumulative number of juveniles per female after 7 days between the control and the concentration of 940.0 mg test item/kg soil (dw).At 297.0 mg/kg soil effects were not statistically significant, the NOEC was determined to be 297.0 mg test item/kg soil. See table A7.5.1.2/03-4 and table A7.5.1.2/03-5

4.2 Results of controls

4.2.1	Mortality	In the control groups 3% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 21.95% (fertile eggs/female/7 days). Both control parameters are within acceptable guideline limits.
4.2.3	Number/ percentage of predator mites showing adverse effects	Not stated except reproduction and mortality see 4.2.2
4.2.4	Nature of adverse effects	see 4.2.1 and 4.2.2., based upon initial number of test organisms and the number of mites retrieved.

4.3 Test with toxic

Performed

	standard	
4.3.1	Concentrations	5.0 mg/kg dry soil
4.3.2	Results	The toxic reference, dimethoate, caused 96.56% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed on 4-Fluoro-3-phenoxybenzoic acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett *et al.* 1994).

The test compound was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content 1.27 ± 0.27) at five nominal rates of 9.4, 30.1, 94, 297 and 940 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation.

Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of two highest concentrations of the test item which caused less than 50% corrected mortality. After 7 days in an untreated mating unit, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days.

Mortality and egg production in the treatment groups was evaluated for statistical significance in comparison to the water control group.

5.2 Results and discussion

After 14 days of exposure, three percent of adult mites died in the control. Mortality in the treatment ranged from 5.00 - 16.25% m (corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%).

Since the mortality observed with the test item was not higher than 16.25%, the LC50 value could not be calculated and was estimated as being > 940.0 mg test item/kg soil (dw).

The ANOVA and the Dunnett's t-test (1-sided, $p < 0.05$) showed no significant difference in the mortality after 14 days between the control and all concentrations of the test item tested.

Therefore, the $NOEC_{Mortality}$ was determined as > 940 mg test item/kg soil (dw). The $LOEC_{Mortality}$ could not be determined and was assumed to be > 940.0 mg test item/kg soil (dw).

A statistical significant difference (Welch t-test; 1-sided, $p < 0.05$) concerning the cumulative number of juveniles per female after 7 days between the control females and the females of the concentration of 940.0 mg/kg soil (dw) was evident. Analysis of the reproduction success in the next lower concentration of 297.0 mg/kg soil revealed no

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		statistical difference to the untreated control Thus the $NOEC_{Reproduction}$ was determined as 297 mg/kg soil.
5.2.1	LR_{50}	>940 mg/kg dry soil
5.3	**Conclusion**	-Fluoro-3-phenoxybenzoic acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of > 940 mg/kg dry soil. A statistical significant difference in reproductive potential (cumulative number of juveniles per female after 7 days) was observed between the control females and the females of the concentration of 940 mg/kg soil (dw). The NOEC reproduction was determined with 297.0 mg test item/kg soil.
5.3.1	Other Conclusions	Validity criteria were fulfilled
5.3.2	Reliability	1
5.3.3	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/29
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted with the following comments: To 3.1, 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and therefore it is beta-cyfluthrin-4-Fluoro-3-phenoxybenzoic acid. To 5.3.1: The endpoint of mortality is LC_{50} instead of LR_{50}.
Conclusion	LC_{50}: > 940 mg/kg soil dw Other conclusions: $NOEC_{Mortality}$ > 940 mg /kg soil dw $NOEC_{Reproduction}$ = 297 mg/kg soil dw Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	The test was conducted at continual darkness, but this is not relevant for this species. This study summary is the same as A 7.5.2.1/02.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*

Document IIIA/ Section 7.5.1.2/03 **Effects on beneficial arthropods other than bees** **X**

BPD Data set IIIA/ Annex Point XIII.3

Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2/03-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* Canestrini (Acari: Laelapidae)
Source of the initial stock	[redacted]
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.1.2/03-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0.01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 32.7
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameters. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 9.4, 30.1, 94, 297 and 940 mg/kg dry soil, toxic standard
Number of replicates/concentration	4 (5 for water control), 3 for toxic standard
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.1.2/03-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.1.2/03-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	3%		21.95
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
9.4	8.5%	P>0.05	Not assessed
30.1	3.4%	P>0.05	Not assessed
94	2.1%	P>0.05	Not assessed
297	13.7%	P>0.05	8.4%
940	9.8%	P>0.05	29.4%*

* Statistically significantly different from deionised water control.

Table A7.5.1.2/03-5: Effect data

	28 d [mg/kg soil dry weight][1]
LC_{50}	>940

[1] effect data are based on nominal (n) concentrations

Table A7.5.1.2/03-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	**Not fulfilled**
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥ 10 (fertile eggs/female/7 days)	**Yes**	

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Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2005); Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)., [redacted]. Report No. P15HR BES N° M-259607-01-1 27 October 2005 unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience AG
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).
2.2	**GLP**	Yes
2.3	**Deviations**	None.

3 METHOD

3.1	**Test material**	cis and trans -3-(2,2-dichlorovinyl)2,2-dimethylcylopropane carboxylic acid (Beta-Cyfluthrin Permethric-acid) (1:1 mixture of the cis- and trans- isomer)
3.1.1	Lot/Batch number	a. (cis-isomer) 920622ELB03 b. (trans-isomer) 920622ELB04
3.1.2	Specification	Not relevant, metabolite testing
3.1.3	Purity	99.8% w/w
3.1.4	Composition of Product	1:1 mixture of the cis- and trans- isomer
3.1.5	Further relevant properties	Stability under correct storage conditions: June 02, 2010
3.1.6	Method of analysis	The test item was identified by MS and NMR,
3.2	**Toxic standard**	Yes, Dimethoate
3.2.1	Method of analysis for reference substance	N/A
3.3	**Test methods**	

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3.3.1	Test organisms	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.1.2/04-1
3.3.2	Test system	See table A7.5.1.2/04-2
3.3.3	Test conditions	See table A7.5.1.2/04-3
3.3.4	Test duration	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	14 days after test initiation mortality was assessed; Reproduction was examined on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	Monitoring of test substance concentration	No
3.3.8	Statistics	Mortality: A One-Way Analysis of Variance (ANOVA), followed by a Dunnett's t-test (1-sided, $p \leq 0.05$) was used to determine whether or not there were significant differences. The LC50 value was calculated by Probit analysis using Linear Max. Likelihood Regression. Reproduction: The Welch t-test for inhomogeneous variances (1-sided, $p \leq 0.05$) was used to determine significant differences The statistical software package ToxRat Professional 2.09 was used for these calculations.

4 RESULTS

4.1 Soil test

4.1.1	Initial concentrations of test substance	10, 32, 100, 316 and 1000 mg/kg dry soil
4.1.2	Effects data Mortality/ Reproduction	Mortality: After 14 days of exposure, mortality ranged from 6.3-13.8% in the samples treated with up to 100 mg/kg soil (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed respectively (corrected mortality 24.7 and 93.3%). Reproduction: Statistical analysis (Welch t-test; 1-sided, $p \leq 0.05$) showed no significant difference concerning the cumulative number of juveniles per female over a total period of 7 days between the control and the concentrations of 100 and 316 mg test item/kg soil (dw). See table A7.5.1.2/04-4 and table A7.5.1.2/04-5

4.2 Results of controls

4.2.1	Mortality	In the control groups 7% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 24.1 (no of juvenile/emale/7 days). Both control parameters are within acceptable guideline limits.
4.2.2	Number/ percentage of predator mites showing adverse effects	Not stated except reproduction and mortality see 4.2.2

4.2.3	Nature of adverse effects	no other endpoints than mortality and reproduction success reported
4.3	**Test with toxic standard**	Performed
4.3.1	Concentrations	5.0 mg/kg dry soil
4.3.2	Results	The toxic reference, dimethoate, caused 96.4% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed with permethric-acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett et al. 1994). Validity criteria were fulfilled and no major deviations were noted.

Permethric-acid was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content of 1.21 ± 0.27) at five nominal rates of 10, 32, 100, 316 and 1000 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation.

Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of the two highest concentrations of the test item which caused less than 50% corrected mortality (i.e. 100 and 316 mg test item/kg soil (dw)). After 7 days in an untreated mating units, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days.

Mortality and reproduction success in the treatment groups was statistically compared to the water control group.

5.2 Results and discussion

After 14 days of exposure, seven percent of adult mites died in the control. Mortality in the concentrations of 10, 32 and 100 mg test item/kg soil (dw) ranged from 6.3 – 13.8% mortality (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed, respectively (corrected mortality 24.7 and 93.3%). The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) showed a significant difference in the mortality after 14 days between the control and these concentrations.
The LC50 value calculated by Probit analysis using Linear Max. Likelihood Regression was determined as 400.9 mg test item/kg soil (dw) (95% confidence limits could not be calculated due to

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		mathematical reasons). Based upon the statistically significant different at 316 mg/kg soil (dw), the $NOEC_{Mortality}$ was determined to be 100 mg test item/kg soil (dw) and the $LOEC_{Mortality}$ was determined to be 316 mg test item/kg soil (dw). Reproduction in both the 100 and 316 mg/kg dry soil treatments were 23.7 and 26.4 juveniles per female over the 7-day reproduction period, with the control having produced 24.1 juveniles per female. The statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed no significant difference, thus the $NOEC_{Reproduction}$ was determined as 316 mg/kg soil.
5.2.1	LC_{50}	400.9 mg/kg dry soil
5.3	**Conclusion**	Permethric-acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of <100 mg/kg dry soil (NOEC) and theLC_{50} was 400.9 mg/kg dry soil. There were no adverse effects on reproduction at concentrations of >316 mg/kg dry soil.
5.3.1	Other Conclusions	Validity criteria were fulfilled
5.3.2	Reliability	1
5.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/29
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted with the following comment: To 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and therefore it is beta-cyfluthrin-permetric-acid.
Conclusion	LC_{50} : 400.9 mg /kg soil dw Other conclusions: $NOEC_{Mortality}$ = 100 mg /kg soil dw $NOEC_{Reproduction}$ > 316 mg/kg soil dw Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	The test was conducted at continual darkness, but this is not relevant for this species. This study summary is the same as A 7.5.2.1/03.

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.1.2/04-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae)
Source of the initial stock	[redacted]
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.1.2/04-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0,01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 36.6
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameter. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 10, 32, 100, 316 and 1000 mg/kg dry soil
Number of replicates/concentration	4 (5 for water control)
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.1.2/04-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.1.2/04-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	7%		24.1
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
10	5.9%	P>0.05	Not assessed
32	-0.8%	P>0.05	Not assessed
100	7.3	P>0.05	1.9%
316	24.7	P<0.05*	-9.3%
1000	93.3	P<0.05*	Not assessed

* Statistically significantly different from deionised water control.

Table A7.5.1.2/04-5: Effect data

	28 d [mg/kg soil dry weight]
LC_{50}	400.9

Table A7.5.1.2/04-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)	**Yes**	

Document IIIA/ Sections 7.5.1.3 **BPD Data Set IIA/ Annex Point XIII.3.2**	**Acute toxicity to plant.**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Cyfluthrin is a general insecticide used worldwide as broadcast and seed treatment application on a wide variety of crops without phytotoxic effects. Therefore a study on toxicity to plants was not considered as necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is not comprehensible, because there are no data from PPP available, which justify this statement.	
Conclusion	The non-submission of data is acceptable because it is only data requirement on PT18 if products used outside buildings as well as products to be used by gassing, fogging or fumigation, release to soil is possible.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.2.1/01 — Reproduction study with other soil non-target macro-organism

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			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2006) Cyfluthrin tech.: Influence on the reproduction of the Collembola species, Folsomia Candida tested in artificial soil., [redacted], Report No.: FRM-coll-45/06, BES Ref: M-265191-01-1 Report date: 02 February 2006 unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2			
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	ISO 11267 (1999) Soil quality - Inhibition of reproduction of Collembola (Folsomia Candida) by soil pollutants	
2.2	**GLP**	Yes	
2.3	**Deviations**	None	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Cyfluthrin technical	
3.1.1	Lot/Batch number	SC21163S8i	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	98.8%	
3.1.4	Composition of Product	Not relevant	
3.1.5	Further relevant properties	none	
3.1.6	Method of analysis	Analytical certificate of December 02, 2005 approved until December 02, 2006	
3.2	**Reference substance**	Betosip, active ingredient: Phenmedipham.	
3.2.1	Method of analysis for reference substance	none	
3.3	**Testing procedure**		
3.3.1	Preparation of the test substance	Cyfluthrin was dissolved in acetone and then mixed with quartz to prepare stock solution. See table A7.5.2.1/01-1	
3.3.2	Application of the test substance	At the test start water and stock solution were mixed into the artificial soil. See table A7.5.2.1/01-1	
3.3.3	Test organisms	Springtails *Folsomia candida* (collembola, Isotomidae) see table	

Section A7.5.2.1/01 — Reproduction study with other soil non-target macro-organism

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		A7.5.2.1/01-2
3.3.4	Test system	Test soil : Artificial soil consisting of 10 % peat, 20 % Kaolin clay and 70 % quartz sand adjusted to pH 6 ± 0.5 with 0.45 % Calcium carbonate. See table A7.5.2.1/01-3
3.3.5	Test conditions	See table A7.5.2.1/01-4
3.3.6	Duration of the test	28 days
3.3.7	Test parameter(s)	Mortality and reproduction
3.3.8	Examination / Sampling	After 28 days
3.3.9	Monitoring of TS concentration	No
3.3.10	Controls	Control : artificial soil mixed with ground quartz sand Solvent control artificial soil mixed with ground quartz sand with acetone (3 ml acetone for 5g quartz sand; acetone is evaporated for 45 min under a fume hood)
3.3.11	Statistics	Toxrat Pro 2.09 (released October 30, 2005)
		4 RESULTS
4.1	**Range finding test**	Not performed
4.1.1	Concentrations	Not relevant
4.1.2	Number/ percentage of animals showing adverse effects	Not relevant
4.1.3	Nature of adverse effects	Not relevant
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	3,11, 30, 90 and 300 mg test item/kg artificial soil dry weight
4.2.2	Actual concentrations of test substance	No measured
4.2.3	Effect data	The values for mortality are shown in tale A7.5.2.1/01-5. The highest mortality rate of 24% was found in the item concentration of 90 and 300 mg cyfluthrin/kg artificial soil dry weight. A statistically significant effect was found in the highest treatment group with 300 mg cyfluthrin/kg artificial soil dry weight. Results of reproduction performance are shown in Table A7.5.2.1/01-5
4.2.4	Concentration / response curve	See fig A7.5.2.1/01-1
4.2.5	Other effects	none
4.3	**Results of controls**	

Section A7.5.2.1/01 — Reproduction study with other soil non-target macro-organism

BPD Data Set IIIA / Annex Point IIIA.XIII.3.2

4.3.1	Number/ percentage of animals showing adverse effects	In the control 8% and in the solvent group 12% of the adults collembola died which is within the tolerated range of 20% mortality recommended by the guideline.
4.3.2	Nature of adverse effects	mortality
4.4	**Test with reference substance**	Performed once a year
4.4.1	Concentrations	89, 133, 200, 300 and 450 mg Betosip/kg artificial soil dry weight
4.4.2	Results	The mortality rate of adult collembolan was 8%, 15%, 20%, 88% and 98% at 89, 133, 200, 300 and 450 mg Betosip/kg artificial soil dry weight, respectively With 200, 300 and 450 mg Betosip/kg artificial soil dry weight, the number of juveniles was statistically significantly reduced.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Influence of cyfluthrin technical on the reproduction of the Collembola species *Folsomia Candida* was tested in artificial soil. 10 collembola per replicate were exposed to control, control solvent, 3, 11, 30, 90 and 300 mg cyfluthrin/kg artificial soil dry weight at 18-22°C. Mortality and reproduction were determined after 28 days.
5.2	**Results and discussion**	The highest mortality rate of 24% was found in the item concentration of 90 and 300 mg cyfluthrin/kg artificial soil dry weight. The LC50 was estimated to be > 300 mg cyfluthrin/kg artificial soil dry weight. A statistically significant effect was found in the highest treatment group with 300 mg cyfluthrin/kg artificial soil dry weight.
5.2.1	NOEC	90 mg cyfluthrin/kg artificial soil dry weight
5.2.2	LOEC	300 mg cyfluthrin/kg artificial soil dry weight
5.3	**Conclusion**	The NOEC and LOEC reproduction was 90 and 300 mg cyfluthrin/kg artificial soil dry weight, respectively
5.3.1	Other Conclusions	The validity criteria have been fulfilled (See table A7.5.2.1/01-6)
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/29
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted.
Conclusion	Applicant's version can be adopted.
Reliability	1

Section A7.5.2.1/01 — Reproduction study with other soil non-target macro-organism

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Acceptability	acceptable
Remarks	A statistically significant effect was found in comparison between the untreated control and the solvent control. Therefore, for the statistical evaluation the solvent control was chosen.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.2.1/01-1: Preparation and application of the test substance

Dispersion	Yes
Vehicle	Yes, quartz sand
Concentration of vehicle	0.9994 g test item was solved in 2 ml acetone and mixed with 9 g quartz sand. The acetone was evaporated for 45 minutes under a fume hood (stock mixture I). 1.0003 g of stock mixture I was mixed with 9 g Quartz sand (stock mixture II). For the solvent control 3 ml acetone was mixed with 5 g quartz sand, corresponding to the amount of acetone in the highest test item concentration. It was evaporated in the same way as the stock mixture I (45 minutes under the fume hood). Then, from these stock mixtures the appropriate amounts were mixed with quartz sand to realise the demanded test concentrations. The exact data were documented in the following table. At test start water and the test item quartz sand mixture was mixed into the artificial soil.
Vehicle control performed	Yes
Other procedures	none

Actual amount of stock solution in g	Mixed with quartz sand (g)	Corresponding nominal concentration (mg cyfluthrin/kg artificial soil dry weight)
0.1517 (stock II)	4.85	36
0.0543 (stock I)	4.95	11
0.1526 (stock I)	4.85	30
0.4520 (stock I)	4.55	90
1.5033 (stock I)	3.50	300

Table A7.5.1.1-2: Test organisms

Criteria	Details
Species/strain	Springtails *Folsomia candida* (collembola, Isotomidae)
Source of the initial stock	[redacted]
Culturing techniques	The Collembola were bred in a mixture of Plaster of Paris, activated charcoal and demineralised water (11:1:10 w/w). Bellaplast vessels (9.5 cm 0) were filled up to a height of 1 cm with this mixture. The vessels, closed with perforated plastic lids, were moistened, fed and aerated regularly once a week. The breeding culture was kept at 20 - 24 °C in permanent dark. Collembola were fed once a week with bakers dry yeast
Age/weight	10-12 days
Pre-treatment	Twelve days before starting the test, egg clusters from the breeding containers were transferred to fresh breeding substrate to obtain Collembola of a uniform age (10-12 days old at test start).

Table A7.5.1.1-3: Test system

Criteria	Details
Artificial soil test substrate	Sphagnum peat(Air dried and finely ground): 10% • Kaolin clay: 20% (Content of Kaolin (AI2Si205(OH)4) = 56 % • Industrial quartz sand (Sort: F 36): 70% (Particle size: 0.20 mm - 0.05 mm = 68.2 %) • Calcium carbonate (CaC03): 0.45% (For adjustment of pH to 6.0 ± 0.5) Maximum water holding capacity (WHCmax): 77.3 g water per 100 g artificial soil.
Test mixture	See table A7.5.2.1/01
Size, volume and material of test container	Glass vessels (volume: 140 ml, diameter: 5 cm) covered with glass lids which allow aeration.
Amount of artificial soil (kg)/ container	
Nominal levels of test concentrations	3,11, 30, 90 and 300 mg test item/kg artificial soil dry weight
Number of replicates/concentration	5 (+1 without Collembola for measurement of soil moisture during the test and pH and soil moisture at the end of the test)
Number of collembola/test concentration	50
Number of collembola/container	10
Light source	source: artificial light, intensity : start: 555 Lx 14 days: 585 Lx end: 575 LX (Integrated luxmeter of the climatic chamber)
Test performed in closed vessels due to significant volatility of test substrate	No

Table A7.5.2.1/01-4: Test conditions

Criteria	Details
Test temperature	20 + 2 °C (continuously recorded by a thermo hydrograph integrated in the climatic chamber)
Moisture content	Start : 25.59% to 27.50% End : 23.89% to 25.59%
pH	Start : 6.41 to 6.46 End : 5.72 to 5.76
Adjustment of pH	No
Light intensity / photoperiod	duration: light/dark = 16/8 h
Relevant degradation products	none

Table A7.5.2.1/01-5: Effects data

Test item Test object Exposure	Cyfluthrin technical Folsomia candida Artificial soil		
mg test item/kg artificial soil dry weight nominal concentration	Adult mortality (%)	Mean number of juveniles ±SD	Reproduction (% of solvent control)
Control	8	1139 159	-
Solvent control	12	920 139	-
3	16	1102 136	120
11	12	981 98	107
30	12	863 150	94
90	24	789 61	86
300	24	626 122	68

*) statistically significant difference to the solvent control (Dunnett's Test one-sided-smaller, a = 0.05)

Fig A7.5.2.1/01-1: Mean Reproduction of Collembola after 4 weeks

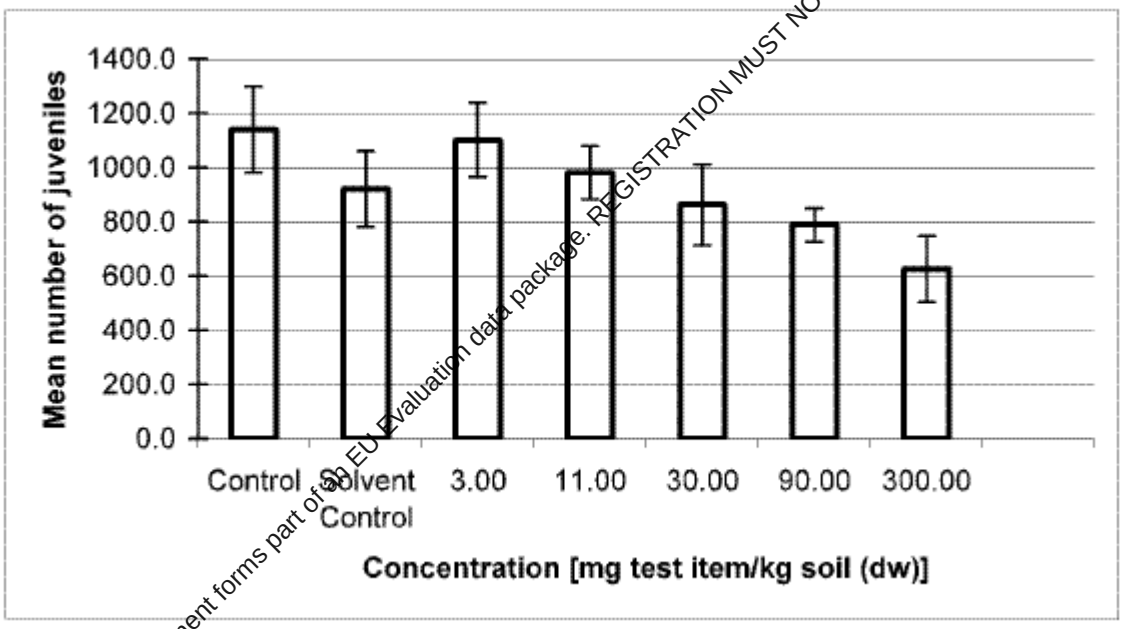

Table A7.5.2.1/01-6: Validity criteria for *reproduction of Collembola (Folsomia Candida)ISO 11267 (1999)*

	fulfilled	Not fulfilled
Average mortality of the adults in the control after 28 days: (<20%)	**Yes**	
Average reproduction rate in the control after 28 days: > 100 juveniles/control vessel	**Yes**	
Coefficient of variation of reproduction in the control after 28 days: < 30 %	**Yes**	

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			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2005) Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1). [redacted] Bayer AG, Report No. P14HR BES Ref M-258697-01-1 12 October 2005 Unpublished	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).	
2.2	**GLP**	Yes	
2.3	**Deviations**	None.	
		3 METHOD	
3.1	**Test material**	4-Fluoro-3-phenoxybenzoic acid	x
3.1.1	Lot/Batch number	M23458, AE F105561 001C94 0001	
3.1.2	Specification	Not relevant, metabolite testing	
3.1.3	Purity	94% w/w	
3.1.4	Composition of Product	Not relevant, metabolite testing	
3.1.5	Further relevant properties	Stability under correct storage conditions: April 19,2007	
3.1.6	Method of analysis	Identity of the test material confirmed by MS and NMR	
3.2	**Toxic standard**	Yes, Dimethoate	
3.2.1	Method of analysis for reference substance	N/A	
3.3	**Test methods**		

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3.3.1	Test organisms	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.2.1/02-1
3.3.2	Test system	See table A7.5.2.1/02-2
3.3.3	Test conditions	See table A7.5.2.1/02-3
3.3.4	Test duration	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	14 days after test initiation mortality was assessed. Reproduction was tested on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	Monitoring of test substance concentration	No
3.3.8	Statistics	Mortality : The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) Reproduction: Welch t-test; 1-sided, $p \leq 0.05$

4 RESULTS

4.1	**Soil test**	
4.1.1	Initial concentrations of test substance	9.4, 30.1, 94, 297 and 940 mg /kg dry soil
4.1.2	Effects data Mortality/ Reproduction	Mortality: There was no concentration dependent mortality after 14 days. Mortality ranged from 5.00 - 16.25% in the treated samples corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%. The ANOVA and Dunnett's t-test showed not significant difference in the mortality compared to the control. The LC50 was hence > 940 mg test item/kg soil. Reproduction : Statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed a significant difference concerning the cumulative number of juveniles per female after 7 days between the control and the concentration of 940.0 mg test item/kg soil (dw).At 297.0 mg/kg soil effects were not statistically significant, the NOEC was determined to be 297.0 mg test item/kg soil. See table A7.5.2.1/02-4 and table A7.5.2.1/02-5
4.2	**Results of controls**	
4.2.1	Mortality	In the control groups 3% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 21.95% (fertile eggs/female/7 days). Both control parameters are within acceptable guideline limits.
4.2.3	Number/ percentage of predator mites showing adverse effects	Not stated except reproduction and mortality see 4.2.2
4.2.4	Nature of adverse effects	see 4.2.1 and 4.2.2., based upon initial number of test organisms and the number of mites retrieved.
4.3	**Test with toxic**	Performed

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	standard	
4.3.1	Concentrations	5.0 mg/kg dry soil
4.3.2	Results	The toxic reference, dimethoate, caused 96.56% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed on 4-Fluoro-3-phenoxybenzoic acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett *et al.* 1994). x The test compound was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content 1.27 ± 0.27) at five nominal rates of 9.4, 30.1, 94, 297 and 940 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation. Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of two highest concentrations of the test item which caused less than 50% corrected mortality. After 7 days in an untreated mating unit, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days. Mortality and egg production in the treatment groups was evaluated for statistical significance in comparison to the water control group.
5.2	**Results and discussion**	After 14 days of exposure, three percent of adult mites died in the control. Mortality in the treatment ranged from 5.00 - 16.25% m (corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.66%). Since the mortality observed with the test item was not higher than 16.25%, the LC50 value could not be calculated and was estimated as being > 940.0 mg test item/kg soil (dw). The ANOVA and the Dunnett's t-test (1-sided, $p < 0.05$) showed no significant difference in the mortality after 14 days between the control and all concentrations of the test item tested. Therefore, the $NOEC_{Mortality}$ was determined as > 940 mg test item/kg soil (dw). The $LOEC_{Mortality}$ could not be determined and was assumed to be > 940.0 mg test item/kg soil (dw). A statistical significant difference (Welch t-test; 1-sided, $p < 0.05$) concerning the cumulative number of juveniles per female after 7 days between the control females and the females of the concentration of 940.0 mg/kg soil (dw) was evident. Analysis of the reproduction success in the next lower concentration of 297.0 mg/kg soil revealed no

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		statistical difference to the untreated control Thus the $NOEC_{Reproduction}$ was determined as 297 mg/kg soil.	
5.2.1	LR_{50}	>940 mg/kg dry soil	x
5.3	**Conclusion**	4-Fluoro-3-phenoxybenzoic acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of > 940 mg/kg dry soil. A statistical significant difference in reproductive potential (cumulative number of juveniles per female after 7 days) was observed between the control females and the females of the concentration of 940 mg/kg soil (dw). The NOEC reproduction was determined with 297.0 mg test item/kg soil.	x
5.3.1	Other Conclusions	Validity criteria were fulfilled	
5.3.2	Reliability	1	
5.3.3	Deficiencies	No	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/29
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted with the following comments: To 3.1, 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and therefore it is beta-cyfluthrin-4-Fluoro-3-phenoxybenzoic acid. To 5.3.1: The endpoint of mortality is LC_{50} instead of LR_{50}.
Conclusion	LC_{50}: > 940 mg/kg soil dw Other conclusions: $NOEC_{Mortality}$ > 940 mg /kg soil dw $NOEC_{Reproduction}$ = 297 mg/kg soil dw Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	The test was conducted at continual darkness, but this is not relevant for this species.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*

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Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.2.1/02-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* Canestrini (Acari: Laelapidae)
Source of the initial stock	[redacted]
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.2.1/02-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0.01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 32.7
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameters. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 9.4, 30.1, 94, 297 and 940 mg/kg dry soil, toxic standard
Number of replicates/concentration	4 (5 for water control), 3 for toxic standard
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.2.1/02-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.2.1/02-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	3%		21.95
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
9.4	8.5%	P>0.05	Not assessed
30.1	3.4%	P>0.05	Not assessed
94	2.1%	P>0.05	Not assessed
297	13.7%	P>0.05	8.4%
940	9.8%	P>0.05	29.4%*

* Statistically significantly different from deionised water control.

Table A7.5.2.1/02-5: Effect data

	28 d [mg/kg soil dry weight][1]
LC_{50}	>940

[1] effect data are based on nominal (n) concentrations

Table A7.5.2.1/02-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥ 10 (fertile eggs/female/7 days)	**Yes**	

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1 REFERENCE

1.1	**Reference**	[redacted] (2005); Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite *Hypoaspis aculeifer* Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1)., [redacted] Report No. P15HR BES N° M-259607-01-1 27 October 2005 unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience AG
1.2.2		
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of the entry of the existing active substance into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes Guidance document on regulatory testing procedures for pesticides with non-target arthropods (Barrett *et al.* 1994). SECOFASE, Final Report. Development, improvement and standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).
2.2	**GLP**	Yes
2.3	**Deviations**	None.

3 METHOD

3.1	**Test material**	cis and trans -3-(2,2-dichlorovinyl)2,2-dimethylcylopropane carboxylic acid (Beta-Cyfluthrin Permethric-acid) (1:1 mixture of the cis- and trans- isomer)
3.1.1	Lot/Batch number	a. (cis-isomer) 920622ELB03 b. (trans-isomer) 920622ELB04
3.1.2	Specification	Not relevant, metabolite testing
3.1.3	Purity	99.8% w/w
3.1.4	Composition of Product	1:1 mixture of the cis- and trans- isomer
3.1.5	Further relevant properties	Stability under correct storage conditions: June 02, 2010
3.1.6	Method of analysis	The test item was identified by MS and NMR,
3.2	**Toxic standard**	Yes, Dimethoate
3.2.1	Method of analysis for reference substance	N/A
3.3	**Test methods**	

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3.3.1	Test organisms	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae) See table A7.5.2.1/03-1
3.3.2	Test system	See table A7.5.2.1/03-2
3.3.3	Test conditions	See table A7.5.2.1/03-3
3.3.4	Test duration	Mortality/escape rate was determined after 14 days of exposure, reproduction was determined after 34 days.
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	14 days after test initiation mortality was assessed; Reproduction was examined on test concentrations showing less than 50% mortality and the control by two reproduction sets, examined on day 28-30 and 32-34.
3.3.7	Monitoring of test substance concentration	No
3.3.8	Statistics	Mortality: A One-Way Analysis of Variance (ANOVA), followed by a Dunnett's t-test (1-sided, $p \leq 0.05$) was used to determine whether or not there were significant differences. The LC50 value was calculated by Probit analysis using Linear Max. Likelihood Regression. Reproduction: The Welch t-test for inhomogeneous variances (1-sided, $p \leq 0.05$) was used to determine significant differences The statistical software package ToxRat Professional 2.09 was used for these calculations.

4 RESULTS

4.1 Soil test

4.1.1	Initial concentrations of test substance	10, 32, 100, 316 and 1000 mg/kg dry soil
4.1.2	Effects data Mortality/ Reproduction	Mortality: After 14 days of exposure, mortality ranged from 6.3-13.8% in the samples treated with up to 100 mg/kg soil (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed respectively (corrected mortality 24.7 and 93.3%). Reproduction: Statistical analysis (Welch t-test; 1-sided, $p \leq 0.05$) showed no significant difference concerning the cumulative number of juveniles per female over a total period of 7 days between the control and the concentrations of 100 and 316 mg test item/kg soil (dw). See table A7.5.2.1/03-4 and table A7.5.2.1/03-5

4.2 Results of controls

4.2.1	Mortality	In the control groups 7% (mean value) mortality of *H. aculeifer* occurred.
4.2.2	Reproduction	The mean reproductive performance of the controls was 24.1 (no of juvenile/emale/7 days). Both control parameters are within acceptable guideline limits.
4.2.2	Number/ percentage of predator mites showing adverse effects	Not stated except reproduction and mortality see 4.2.2

4.2.3	Nature of adverse effects	no other endpoints than mortality and reproduction success reported
4.3	**Test with toxic standard**	Performed
4.3.1	Concentrations	5.0 mg/kg dry soil
4.3.2	Results	The toxic reference, dimethoate, caused 96.4% corrected mortality. This showed that test animals were sufficiently sensitive and that potential adverse effects of exposure to test-item residues could be detected with the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed with permethric-acid in standard soil (LUFA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett et al. 1994). Validity criteria were fulfilled and no major deviations were noted. x Permethric-acid was mixed homogeneously through standard soil (LUFA 2.1, organic carbon content of 1.21 ± 0.27) at five nominal rates of 10, 32, 100, 316 and 1000 mg/kg dry soil. The control was treated with deionised water and dimethoate at a rate of 5.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeifer* per container. Five units were prepared for the water control, 4 units for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation. Following the exposure period, effects on reproduction were tested on an untreated layer of plaster of Paris. Reproduction was examined only for the females of the control and the females of the two highest concentrations of the test item which caused less than 50% corrected mortality (i.e. 100 and 316 mg test item/kg soil (dw)). After 7 days in an untreated mating units, 20 females of each of the test item treatments and the water treatment were transferred to reproduction units (1 mite/unit) to determine egg production. After 3 days all females were transferred to a second series of identical reproduction units and 4 days later the females were removed. This allowed two oviposition assessments in a 7-day period. Reproduction units were kept for egg hatch determination for an additional 7 days. Mortality and reproduction success in the treatment groups was statistically compared to the water control group.
5.2	**Results and discussion**	After 14 days of exposure, seven percent of adult mites died in the control. Mortality in the concentrations of 10, 32 and 100 mg test item/kg soil (dw) ranged from 6.3 – 13.8% mortality (corresponding to a corrected mortality according to Abbott (1925) from –0.8 to 7.3%). At the concentrations of 316 and 1000 mg test item/kg soil (dw) 30.0 and 93.8% mortality was observed, respectively (corrected mortality 24.7 and 93.3%). The ANOVA and the Dunnett's t-test (1-sided, $p \leq 0.05$) showed a significant difference in the mortality after 14 days between the control and these concentrations. The LC50 value calculated by Probit analysis using Linear Max. Likelihood Regression was determined as 400.9 mg test item/kg soil (dw) (95% confidence limits could not be calculated due to

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		mathematical reasons). Based upon the statistically significant different at 316 mg/kg soil (dw), the $NOEC_{Mortality}$ was determined to be 100 mg test item/kg soil (dw) and the $LOEC_{Mortality}$ was determined to be 316 mg test item/kg soil (dw). Reproduction in both the 100 and 316 mg/kg dry soil treatments were 23.7 and 26.4 juveniles per female over the 7-day reproduction period, with the control having produced 24.1 juveniles per female. The statistical analysis (Welch t-test; 1-sided, $p < 0.05$) showed no significant difference, thus the $NOEC_{Reproduction}$ was determined as 316 mg/kg soil.	
5.2.1	LC_{50}	400.9 mg/kg dry soil	
5.3	**Conclusion**	Permethric-acid had no adverse effects on mortality of *Hypoaspis aculeifer* in artifical soil at concentrations of <100 mg/kg dry soil (NOEC) and theLC_{50} was 400.9 mg/kg dry soil. There were no adverse effects on reproduction at concentrations of >316 mg/kg dry soil.	x
5.3.1	Other Conclusions	Validity criteria were fulfilled	
5.3.2	Reliability	1	
5.3.3	Deficiencies	None	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2006/09/29
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted with the following comment: To 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and therefore it is beta-cyfluthrin-permetric-acid.
Conclusion	LC_{50} : 400.9 mg /kg soil dw Other conclusions: $NOEC_{Mortality}$ = 100 mg /kg soil dw $NOEC_{Reproduction}$ > 316 mg/kg soil dw Applicant's version can be adopted.
Reliability	1
Acceptability	acceptable
Remarks	The test was conducted at continual darkness, but this is not relevant for this species.
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

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Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.5.2.1/03-1: Test organisms

Criteria	Details
Species/strain	*Hypoaspis aculeifer* CANESTRINI (Acari: Laelapidae)
Source of the initial stock	[redacted]
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult *H. aculeifer* were transferred to 2 synchronisation units (approx. 180 females and 20 males per unit). Food and water was added. Four days before the start of the test all test organisms except eggs were removed. Water was added. Three days later the first protonymphs hatched and the organisms used in the test differ in age by a maximum of 2 days.

Table A7.5.2.1/03-2: Test system

Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic carbon 1.21%, pH value (0,01 M $CaCl_2$) 6.1.
Water holding capacity during the test	Water Holding Capacity (g/100 g) = 36.6
Size, volume and material of test container	Mortality phase: Glass container, 30 mL capacity, height 4 cm x 3.5 cm inner diameter. Reproduction phase: Plastic container, 12.5 mL capacity, height 2.9 cm x 2.7 cm inner diameter.
Amount of artificial soil (g)/ container	5.1 to 5.3 g
Nominal levels of test concentrations	Control (deionised water), 10, 32, 100, 316 and 1000 mg/kg dry soil
Number of replicates/concentration	4 (5 for water control)
Number of predator mites /test concentration	Mortality phase: 80 (100 control) Reproduction phase: 20
Number of predator mites /container	Mortality phase: 20 Reproduction phase: 1 per unit
Light source	None

Table A7.5.2.1/03-3: Test conditions

Criteria	Details
Test temperature	Maintained in an incubator at 25 ± 2°C.
Moisture content	WHC – Water holding capacity was approximately 40 to 60%
Climatic conditions during test	Not stated
Adjustment of pH	No
Light intensity / photoperiod	0 lux, continual darkness

Table A7.5.2.1/03-4: Mortality and Reproduction data

Treatment	Mortality after 14 days		Reproduction (fertile eggs/female/7 days)
Deionised water control	7%		24.1
Test Substance Concentration (nominal) [mg/kg artificial soil]	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)
10	5.9%	P>0.05	Not assessed
32	-0.8%	P>0.05	Not assessed
100	7.3	P>0.05	1.9%
316	24.7	P<0.05*	-9.3%
1000	93.3	P<0.05*	Not assessed

* Statistically significantly different from deionised water control.

Table A7.5.2.1/03-5: Effect data

	28 d [mg/kg soil dry weight]
LC_{50}	400.9

Table A7.5.2.1/03-6: Validity criteria for reproduction/mortality of *H. aculeifer* according to test guidelines

	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%	**Yes**	
Mean corrected mortality in toxic reference 50 - 100%	**Yes**	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)	**Yes**	

Document IIIA/ Sections 7.5.2.2 **BPD Data Set IIA/ Annex Point XIII.3.2**	**Long term test with terrestrial plants.**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Cyfluthrin is a general insecticide used worldwide as broadcast and seed treatment application on a wide variety of crops without phytotoxic effects. Therefore a long term test with terrestrial plants was not considered as necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is not comprehensible, because there are no data from PPP available, which justify this statement.	
Conclusion	The justification for non-submission of data is acceptable because it is only data requirement on PT18 if products used outside buildings as well as products to be used by gassing, fogging or fumigation, release to soil is possible.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.3.1.1 **BPD Data Set IIA/ Annex Point XIII.1.1**	**Acute oral toxicity.**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Solfac® EW050 and Raid® cyfluthrin Foam is to be used indoor in rural hygiene and household application, respectively. When manure/sludge is sprayed on grassland, cyfluthrin residues which are adsorbed on organic matter of manure/sludge are unlikely to contaminate plants leaves. The crop rotational study demonstrated that no residues were detected on forage, straw and grain of plant grown of treated soil (10 applications at the rate of 28 g cyfluthrin./ha/application). Therefore, birds are unlikely to be exposed to cyfluthrin when it is used as recommended on the label. The existing acute toxicity studies with birds are considered as non relevant.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	The justification for non-submission of data is acceptable because acute test with avian is only data requirement on PT18 if products used outside buildings in the form of baits, granulates and powder.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.3.1.2 **BPD Data Set IIA/ Annex Point XIII.1.2**	**Short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Solfac® EW050 and Raid® cyfluthrin Foam is to be used indoor in rural hygiene and household application, respectively. When manure/sludge is sprayed on grassland, cyfluthrin residues which are adsorbed on organic matter of manure/sludge are unlikely to contaminate plants leaves. The crop rotational study demonstrated that no residues were detected on forage, straw and grain of plant grown of treated soil (10 applications at the rate of 28 g cyfluthrin./ha/application). Therefore, birds are unlikely to be exposed to cyfluthrin when it is used as recommended on the label. The existing short term toxicity studies with birds are considered as non relevant.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	The justification for non-submission of data is acceptable because short-term toxicity with avian is only data requirement on PT18 if products used outside buildings in the form of baits, granulates and powder.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.3.1.3 **BPD Data Set IIA/ Annex Point XIII.1.2**	**Effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Solfac® EW050 and Raid® cyfluthrin Foam is to be used indoor in rural hygiene and household application, respectively. When manure/sludge is sprayed on grassland, cyfluthrin residues which are adsorbed on organic matter of manure/sludge are unlikely to contaminate plants leaves. The crop rotational study demonstrated that no residues were detected on forage, straw and grain of plant grown of treated soil (10 applications at the rate of 28 g cyfluthrin./ha/application). Therefore, birds are unlikely to be exposed to cyfluthrin when it is used as recommended on the label. The existing studies on effect of cyfluthrin on bird reproduction are considered as non relevant.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	The justification for non-submission of data is acceptable because effects on avian reproduction are only data requirement on PT18 if products used outside buildings in the form of baits, granulates and powder.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.4.1 **BPD Data Set IIA/ Annex Point XIII.3.1**	**Acute toxicity to honeybees and other beneficial arthropods, for example predators**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Solfac® EW050 and Raid® Cyfluthrin Foam is to be used indoor in rural hygiene and household application, respectively. When manure/sludge is sprayed on grassland, cyfluthrin residues which are adsorbed on organic matter of manure/sludge are unlikely to contaminate plants leaves. The crop rotational study demonstrated that no residues were detected on forage, straw and grain of plant grown of treated soil (10 applications at the rate of 28 g cyfluthrin./ha/application). Therefore, honeybees and other beneficial arthropods are unlikely to be exposed to cyfluthrin when it is used as recommended on the label. The existing acute studies on honeybees and other beneficial arthropods are considered as non relevant.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/23	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	The non-submission of data is acceptable.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.5.1 BPD Data Set IIA/ Annex Point VII.7.5	Bioconcentration, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	**Official use only**
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [✓]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	As explained in the Environmental Risk Assessment (Doc IIC, point 2.4), cyfluthrin does not present a risk of secondary poisoning in the environment. Furthermore, a rough estimation of the risk of secondary poisoning based on the Technical Guidance Document on Risk Assessment Part II (page 131) is presented below. When birds and mammals consume worms, this includes the gut of the earthworms which can contain substantial amounts of soil. The exposure of predators (birds and small mammals) may be affected by the amount of active substance in this consumed soil. The $PEC_{oral\ predator}$ is calculated as: $PEC_{oral\ predator} = C_{earthworm}$ where $C_{earthworm}$ is the total concentration of the active substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the active substance to the soil present in the earthworms gut. The total concentration in an entire worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and guts contents (through soil concentration). Based on the following equation, the concentration of deltamethrin in an entire worm is: $C_{earthworm} = [(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})] / [1 + (F_{gut} \times CONV_{soil})]$ $C_{earthworm}$ = 0.151 mg/kg wet earthworm = $PEC_{oral\ predator}$ With: ▪ $BCF_{earthworm}$ = 12,000 $L.kg_{wet\ earthworm}^{-1}$ (see Point A7.5.5) ▪ $C_{porewater}$ = 1.38 x 10^{-5} mg/L (see Doc IIB-3 page 24) ▪ C_{soil} = 3.06 x 10^{-2} mg/kg wet weight soil (see Doc IIB-3 page 24) ▪ F_{gut} = 0.1 (TGD on Risk Assessment page 132) $CONV_{soil} = RHO_{soil} / (F_{solid} \times RHO_{solid})$ = 1700 / (0.6 / 2500) = 1.13 In the Review Report for the active substance cyfluthrin, Document 6843/VI/97-final, December 2002, the lowest NOEC given for reproductive toxicity to birds is 250 ppm (mallard duck). Taking into account a safety factor of 30 (Table 23 of the TGD on Risk Assessment Part II, page 130), a **$PNEC_{bird}$ of 8.3 mg/kg food** is obtained. Considering the chronic and reproductive NOAEL from a two generation rat study ([redacted] 1997, BES Ref. M-032020 -01-1) and a chronic 2-year rat study ([redacted], 1997 and 2000, BES Ref. M-044524-02-1) of 50 ppm, and taking into account a safety factor of 30 (Table 23 of the TGD on Risk Assessment Part II, page 130), a **$PNEC_{small\ mammal}$ of 1.67 mg/kg food** is obtained. Therefore, by comparing the $PEC_{oral\ predator}$ with the respective PNEC, **PEC/PNEC ratios of 0.0183 and 0.091** are obtained for birds and mammals, respectively, indicating that there is **no unacceptable risk** for earthworm-eating birds or mammals. Therefore, further study is not required.	

Document IIIA/ Sections 7.5.5.1	**Bioconcentration, further studies**
BPD Data Set IIA/ Annex Point VII.7.5	
Undertaking of intended data submission [ ]	
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/10/30
Evaluation of applicant's justification	We can not follow the argumentation of the applicant in all points.The calculated $BCF_{earthworm}$ indicates a bioaccumulation potential for all four diastereoisomeres of cyfluthrin and bioaccumulation via the terrestrial food chain has to be assumed.
Conclusion	Despite the high estimated BCF values no study on terrestrial bioaccumulation was demanded, as currently no OECD guideline is available. Furthermore, at the moment there is no experience to assess the outcoming BCF values of such a study. Therefore, the justification is acceptable.
Remarks	None
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.5.5 Bioconcentration, terrestrial

Annex Point IIA7.5

			Official use only
		1 REFERENCE	
1.1	**Reference**	Not applicable	
1.2	**Data protection**	No	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection	No data protection claimed	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, not applicable	
2.2	**GLP**	No	
2.3	**Deviations**	No, not applicable	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Not applicable	
3.1.1	Lot/Batch number	Not applicable	
3.1.2	Specification	Not applicable	
3.1.3	Purity	Not applicable	
3.1.4	Further relevant properties	Not applicable	
3.1.5	Radiolabelling	Not applicable	
3.1.6	Method of analysis	Not applicable	
3.2	**Reference substance**	Not applicable	
3.2.1	Method of analysis for reference substance	Not applicable	
3.3	**Testing/estimation procedure**	*Non-entry field*	
3.3.1	Test system/ performance	Not applicable	
3.3.2	Estimation of	According to the Technical Guidance Document (TGD) on Risk Assessment of Chemical Substances[1], an estimation of the bioconcentration	

[1] TGD, 2003. Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and

Section A7.5.5 Bioconcentration, terrestrial

Annex Point IIA7.5

bioconcentration factor in terrestrial organisms can be made using Kow value and the following equation (82d):

$$BCF_{earthworm} = [0.84 + 0.012 \times Kow] / RHO_{earthworm}$$

where for $RHO_{earthworm}$ a value of 1 (kg $_{wwt}$/L) can be assumed by default. Partition coefficient (n-octanol/water) for cyfluthrin diastereosiomers were determined using the shaking method according to OECD Guidelines, No. 107 (Krohn, J (1987) , BES Ref: M-043120-01-1)

Diastereoisomer	Kow	LogKow	Standard deviation
1	1,000,000	6.00	560,000
2	870,000	5.94	530,000
3	1,100,000	6.04	570,000
4	820,000	5.91	600,000

4 RESULTS

4.1	**Experimental data**	*Non-entry field*
4.1.1	Mortality/behaviour	Not applicable
4.1.2	Lipid content	Not applicable
4.1.3	Concentrations of test material during test	Not applicable
4.1.4	Bioconcentration factor (BCF)	Not applicable
4.1.5	Uptake and depuration rate constants	Not applicable
4.1.6	Depuration time	Not applicable
4.1.7	Metabolites	Not applicable
4.1.8	Other Observations	Not applicable
4.2	**Estimation of bioconcentration**	Based on a Kow value of $1x10^6$, $BCF_{earthworm}$ is 12,000 L $kg_{wet\ earthworm}^{-1}$ (rounded value)

Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

Section A7.5.5 Bioconcentration, terrestrial

Annex Point IIA7.5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Not applicable

5.2 Results and discussion

According to the Technical Guidance Document (TGD) on Risk Assessment of Chemical Substances[2], an estimation of the bioconcentration factor in terrestrial organisms can be made using Kow value and the following equation (82d):

$$BCF_{earthworm} = [0.84 + 0.012 \times Kow] / RHO_{earthworm}$$

where for $RHO_{earthworm}$ a value of 1 (kg_{wwt}/L) can be assumed by default.

Based on a Kow value of $1x10^6$, $BCF_{earthworm}$ is 12,000 $L.kg_{wet\ earthworm}^{-1}$ (rounded value)

The bioconcentration study in fish showed that the BCF_{fish} ([redacted] 1984 – cf. Point 7.4.3.3.1) is much lower than the therotical BCF_{fish} calculated under Point 7.4.2. The estimated BCF is more than 50-fold higher than the experimental BCF.

Furthermore, studies on rats showed a high degree of absorption of the orally dosed radioactivity followed by fast elimination from the body mainly via the urine. Thus, >97 % of the orally administered dose had been eliminated after two days.

Such difference between estimated BCF and experimental BCF can be expected also for terrestrial organisms.

5.3 Conclusion

Based on a Kow value of $1x10^6$, $BCF_{earthworm}$ is estimated around 12,000 $L.kg_{wet\ earthworm}^{-1}$. This value is a worst-case estimation

5.3.1 Reliability

Not applicable

5.3.2 Deficiencies

Not applicable

[2] TGD, 2003. Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

Section A7.5.5 Bioconcentration, terrestrial

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Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/10/24
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version adopted with following amendment: 4.2 Estimation of bioconcentration: The applicant has calculated the $BCF_{earthworm}$ for diastereoisomere 1 with a log P_{OW} of 6, resulting in a $BCF_{earthworm}$ of 12000 $kg_{wwt}.L^{-1}$. The calculated $BCF_{earthworm}$ for the other diastereoisomeres of cyfluthrin is: Diastereoisomere 2 (log P_{OW} 5.94): 10452 $kg_{wwt}.L^{-1}$ Diastereoisomere 3 (log P_{OW} 6.04): 13159 $kg_{wwt}.L^{-1}$ Diastereoisomere 4 (log P_{OW} 5.91): 9755 $kg_{wwt}.L^{-1}$ 5.2 Results and discussion: The calculated $BCF_{earthworm}$ for the four diastereoisomeres of cyfluthrin according to TGD is: Diastereoisomere 1 (log P_{OW} 6.00): 12000 $kg_{wwt}.L^{-1}$ Diastereoisomere 2 (log P_{OW} 5.94): 10452 $kg_{wwt}.L^{-1}$ Diastereoisomere 3 (log P_{OW} 6.04): 13159 $kg_{wwt}.L^{-1}$ Diastereoisomere 4 (log P_{OW} 5.91): 9755 $kg_{wwt}.L^{-1}$
Conclusion	We can not follow the argumentation of the applicant in all points. The calculated $BCF_{earthworm}$ for the four isomeres of cyfluthrin is ranging between 13159 $kg_{wwt}.L^{-1}$ for diastereoisomere 3 with a log P_{OW} of 6.04 and 9755 $kg_{wwt}.L^{-1}$ for diastereoisomere 4 with a log P_{OW} of 5.91. Thus, the calculation of the BCF indicates a bioaccumulation potential for all four diastereoisomeres of cyfluthrin. Despite the high estimated BCF values no study on terrestrial bioaccumulation was demanded, as currently no OECD guideline is available. Furthermore, at the moment there is no experience to assess the outcoming BCF values of such a study. The overall assessment of the bioaccumulation potential can be found in Doc. IIA.
Reliability	1
Acceptability	Acceptable
Remarks	None

Section A7.5.5 Bioconcentration, terrestrial

Annex Point IIA7.5

	COMMENTS FROM...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Findings	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document IIIA/ Sections 7.5.6 BPD Data Set IIA/ Annex Point XIII.3	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Environmental risk assessment based on long term terrestrial test such as soil micro-organisms and the springtail *Folsomia Candida* , indicated a very low potential for risk with The PEC/PNEC is <<1.Therefore, further studies on terrestrial non-target organisms are not justified.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	The justification for non-submission of data is acceptable.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.7.1.1 **BPD Data Set IIA/ Annex Point XIII.3.4**	**Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment** **Acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Acute oral tests were performed on rats and are presented under point A6.1.1. In addition, there are no uses which would raise a concern of a severe risk for the terrestrial environment. Therefore additional mammalian species testing are not justified. .	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2006/11/15	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.7.1.2 **BPD Data Set IIA/ Annex Point XIII.3.4**	**Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment** **Short term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Short term toxicity studies were performed on rats and dogs and are presented under point A6.3. In addition, there are no uses which would raise a concern of a severe risk for the terrestrial environment. Therefore additional mammalian species testing are not justified.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2006/11/15	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Document IIIA/ Sections 7.5.7.1.3 **BPD Data Set IIA/ Annex Point XIII.3.4**	**Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment** **Effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [✓]** **Other justification [ ]**	
Detailed justification:	Effects on reproduction were studied on rats and rabbit and are presented under point A6.8. In addition, there are no uses which would raise a concern of a severe risk for the terrestrial environment. Therefore additional mammalian species testing are not justified.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2006/11/15	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	
Remarks	-	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		