### Section A7.5.1.1/01

		1 REFERENCE	Official use only
1.1	Reference	(2000)	ant
		Cyfluthrin tech.: Determination of effects on carbon transformation in soil  Report No.: LKC-C-54/06, BES Ref: M-265819-01-1  Report date: 08 February 2006  unpublished  Yes  Bayer CropScience AG  Data submitted to the MS after 13 May 2000 on existing a.s. for the	docume
1.2	Data protection	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2		agh of	
1.2.3	Criteria for data protection	purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY SURANCE OECD Guideline N°217 Yes None	
2.1	Guideline study	OECD Guideline N°217	
2.2	GLP	Yes	
2.3	Deviations	None REGIST	
		3 MATERIALS AND METHODS	
3.1	Test material	Cyfluthrin technica?	
3.1.1	Lot/Batch number	SC21163S81,000	
3.1.2	Specification	SC21163S81 Code 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	Product Further relevant properties Method of malysis  Reference substance	Analytical certificate of December 02, 2005 approved until December 02, 2006	
3.2	Method of analysis  Method of analysis	Sodium chloride	
3.41	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 $0-20\mathrm{cm}$ 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	

### Section A7.5.1.1/01

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 <sub>2</sub> measurement
3.3.7	Duration of the test	28 days
3.3.8	Sampling	CO <sub>2</sub> measurement  28 days  Samples were taken on day 0 and after 28 days of incubation  No  Control: sieved soil treated with 10 g ground quartz sand on dry weight. X
3.3.9	Monitoring of TS concentration	No tre Dasis
3.3.10	Controls	soil
		Solvent control: sieved soil treated with 10 g group quartz sand/kg dry weight soil with acetone (0.63 ml acetone was dixed with 9 g quartz sand)
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 RESULTS OF
4.1	Range finding test	Not performed both
4.1.1	Concentration	Not relevant
4.1.2	Effect data	Not relevant
4.2	Results test substance	rd and
4.2.1	Concentration Effect data Results test substance Initial concentrations of test substance Actual concentrations of test, abstance	3, 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry weight soil.
4.2.2	Actual conventrations of test substance	no measurements conducted during test
4.2.3	Growth curves	Not applicable
4.2.45 NA	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

### Section A7.5.1.1/01

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	nent
4.4.2	Results	16 g NaCl/kg dry weight soil distinct and long-term (> 28 days) influences on microbial mineralization of carbon  5 APPLICANT'S SUMMARY AND CONCLUSION The influence of Cyfluthrin technical on carbon transformation in soil	ocin.
5.1	Materials and methods	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 confuthrin 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	
5.2	Results and discussion	maximum respiration rate. Statistically significant differences (Williams test, $\alpha = 0.05$ , two-sided) concerning the CO <sub>2</sub> production/hour/ks 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.	X
5.2.1	NOEC	3 mg Cyfluthrin tech./kg dry weight soil	
5.2.2	EC <sub>10</sub>	11 mg Cyfluthrin tech. /kg dw weight soil. (95% confidence limit: 3 – 23 mg/kg)	
5.2.3	EC <sub>50</sub>	EC50: Not determine dance to mathematical reasons.  EC25: 157 mg Cyfuthrin tech. /kg dry weight soil. (95% confidence limit: 71 – 749 mg/kg)	
5.3	Conclusion	agitor	
5.3.1	Reliability	1 Evally	
5.3.2	Deficiencies	North	
WAR	MING. This document toms po	3 mg Cyfluthrin tech./kg dry weight soil  11 mg Cyfluthrin tech. /kg dry weight soil. (95% confidence limit: 3 – 23 mg/kg)  EC50: Not determined the to mathematical reasons.  EC25: 157 mg Cyfluthrin tech. /kg dry weight soil. (95% confidence limit: 71 – 749 mg/kg)  1 None  None  1 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 occurringed damage to the microflora, a solvent control (ground quartz sand and acetone) has been performed and was considered at evaluation of the results.  Applicant's version is acceptable with following amendments:  5.2  See Annex 2: Evaluation by Rapporteur Member State, GAP—Tables
Results and discussion	Applicant's version is acceptable with following amendments:
	5.2
	See Annex 2: Evaluation by Rapporteur Member State, GA-Tables
	CA table 1: modified A7.5.1.1/01-5: Effects on non-ranget soil micro-organisms after 28 days  5.2.3  EC 50: > 300 mg/kg
	522
	5.2.5 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.  1  Acceptable  None  COMMENTS FROM
Reliability	1 grade
Acceptability	Acceptable 300000
Remarks	None None
	COMMENTS FROM
Date	Gige date of comments submitted
Materials and Methods  Results and discussion  Conclusion  Reliability	X.
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion docu	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability Remarks	Discuss if deviating from view of rapporteur member state

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.  0-20 cm  Loamy sand soil
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%  0.1%  5.0 mon/100 c dry 20 obt soil
Nitrogen content [% dry weight]	0.1%
Cation exchange capacity	5.9 mep/100 g dry weight soil
Initial microbial biomass	461 mg microthal C/kg dry weight soil 3.8% of so Oorganic (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  Pretreatment  Evaluation data pack?	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: Texp system

Criteria (15)	Details
Culturing apparatus	Brown glass bottles closed with parafilm
Number of vessels / concentration	Three replicates per concentration
Aeration de vice	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	ground quartz sand  Not relevant  Not relevant
Other procedures	none

#### Table A7.5.1.1/01-4: Test conditions

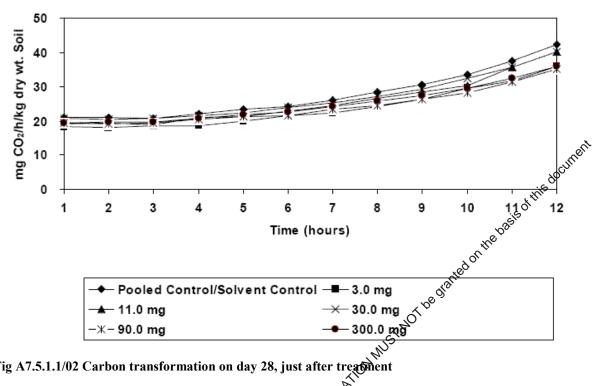
Criteria	Details (Veg
Organic substrate	- STAN
Incubation temperature	20±2°C 24M
Soil moisture	45% of the maximum water holding capacity
Method of soil incubation	indixaual subsamples
Aeration	

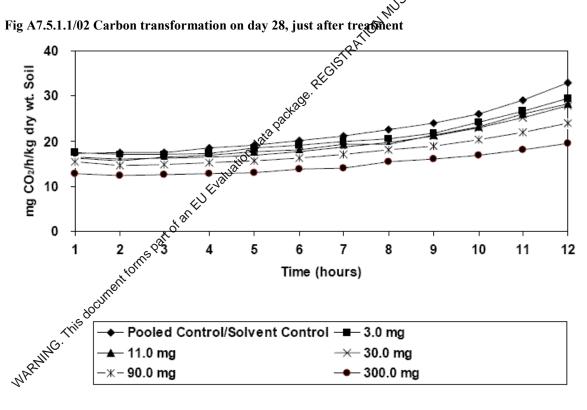
Table A7.5.1.1/01-5: Effects on non-targer soil micro-organisms

Test item	Cyfluthrin tech. Soil micro-organism, carbon-transformation (loamy sand soil)			
Test object	Soil micro-organism, carbon-transformation (loamy sand 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  3.0  11.0	265.7	100		
3.0 30°C	248.5	94		
	238.2	90*		
30.0 <sub>E</sub> NIT	235.4	89*		
96.0	212.2	80*		
300.0	177.1	67*		

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

Fig A7.5.1.1/01 Carbon transformation on day 0, 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	Cyfluthrin tech.		
Test object	Soil micro-organism, carbon-transformation (loamy sand soil)		
Mg test item/kg dry	Mg CO <sub>2</sub> /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 yourte
90.0	212.2	80*	20 this
300.0	177.1	67*	33
* Statistically significan	t difference to the pool	led control (Will	iams - test $\alpha = 0.05$ two-sides
WARMING. This document is	sms part of an EU Evaluation	bata padkade. Peters	in respiration rate  0 6 10 11 20 33 iams - test, $\alpha = 0.05$ , two-sides particles of the standard of the

<sup>\*</sup> Statistically significant difference to the pooled control (Williams - test,  $\alpha = 0.05$ , two-sides)

### Section A7.5.1.1/02

		1 REFERENCE	Official use only
1.1	Reference	Cyfluthrin tech.: Determination of effects on nitrogen transformation in soil,  Report No.: LKC-N-62/06, BES Ref: M-265333-01-1 Report date: 08.02.2006 unpublished  Yes  Bayer CropScience AG  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 SURANCE  OECD Guideline N°216  Yes  None	document
1.2	Data protection	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2		wedo.	
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 SURANCE OECD Guideline N°216 Yes None	
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 technica R	
3.1.1	Lot/Batch number	SC21163S81 Color 2  As given in section 2	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	98,8%	
3.1.4	Purity Composition of Product Further relevant properties Method of malysis Reference substance	Not relevant	
3.1.5	Further relevant properties	none	
3.1.6	Method of shalysis	Analytical certificate of December 02, 2005 approved until December 02, 2006	
3.2	Reference substance	Sodium chloride	
3.41	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	

### Section A7.5.1.1/02

		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	Inhibition of microbial nitrogen transformation  Ammonium, nitrite and nitrate measurement  28 days  Samples were taken on day0 and after 28 days of incubation  No  Control: sieved soil treated with 10 g ground quartz same/kg dry weight
3.3.10	Controls	soil
		weight soil with acetone (0.54 mL acetone was mixed with 9 g quartz sand)
3.3.11	Statistics	The software used to perform the statistical analysis was ToxRat Pro 2.09 (released October 30, 2005); (Rafte, 2002).
	્યું <sup>ત</sup>	For the determination of the NORC/LOEC the control and the solvent control were pooled, because there was no statistically significant difference (Student t-Test to homogeneous variances, a = 0.05, one-sided smaller). Data (anythin 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 every 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  Not performed  Not relevant
1.1	Range finding test	Not performed
1.1.1	Concentration	Not relevant
1.1.2	Effect de la	Not relevant
	Results test substance Initial concentrations	
1.3.18	Initial concentrations of test substance	3, 11, 30, 90 and 300 mg Cyfluthrin tech./kg dry weight soil.
1.2.2	Actual concentrations of test substance	no measurements conducted during test
1.2.3	Growth curves	Not applicable
1.2.4	Cell concentration data	Not applicable
1.2.5	Concentration/ response curve	See fig A7.5.1.1/02-1

### Section A7.5.1.1/02

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	art
4.2.7	Other observed effects	None	Jocumb
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	No effect Performed separately  16 g NaCl/kg dry weight soil distinct and long-term (> 28 days) influences on microbial mineralization of carbon  5 APPLICANT'S SUMMARY AND CONCLUSION The influence of Cyfluthrin technical ord hitrogen 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. Lucernegrass-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 <sub>10</sub>	> 300 yig Cyfluthrin tech. /kg dry weight soil.	X
5.2.3	EC <sub>50</sub>	300 mg Cyfluthrin tech. /kg dry weight soil.	
5.3	Conclusion		
5.3.1	Reliability torn's	1	
5.3.2	Deficienciere <sup>ent</sup>	N in the soil samples 28 days after treatment between the pooled control and all treatment froups.     300 mg Syfluthrin tech./kg dry weight soil.  300 mg Cyfluthrin tech. /kg dry weight soil.  300 mg Cyfluthrin tech. /kg dry weight soil.  None	
•	TING.		
NAR	\$		

	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 occurringed damage to the microflora, a solvent control (ground quartz sand and acetons) has been performed and was considered at evaluation of the results.  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, GAL—Tables
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, QA-Tables
	CA table 1: modified A7.5.1.1/02-5: Effects on non-target soil micro-organisms after 28 days  Significant effects on process of nitrogen transformation by the soil microflora
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.  1  Acceptable  None
Reliability	1 RA
Acceptability	Acceptable
Remarks	None &
	COMMENTS STRAITED
Date	Xata
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 (18	Discuss if deviating from view of rapporteur member state
Reliability on the	Discuss if deviating from view of rapporteur member state
Results and discussion  Conclusion  Reliability  Acceptability  Remarks (115)	Discuss if deviating from view of rapporteur member state
Remarks Ais	

NARHING

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.  0-20 cm  Loamy sand soil  5.6 (KCl)  1.2%  0.1%  5.9 mep/100 g dry weight soil
Depth of sampling [cm]	0-20 cm
Sand / Silt / Clay content [% dry weight]	Loamy sand soil
pН	5.6 (KCl)
Organic carbon content [% dry weight]	1.2% <b>rearies</b>
Nitrogen content [% dry weight]	0.1%
Cation exchange capacity	5.9 mep/100 g dry weight soil
Initial microbial biomass	461 mg microbad C/kg dry weight soil 3.8% of so Oorganic (c) content
Reference of methods	The cate on 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  Pretreatment	The soil was collected on October 28, 2005 and stored at $4 \pm 2$ °C until used
Pretreatment	Soil samples were passed through a 2 mm sieve

Table A7.5.1.1/02-2:

i retreatment	
Гable A7.5.1.1/02-2: Test system	
Criteria x 500	Details
Culturing apparatus	Brown glass bottles closed with parafilm
Number of vessels (concentration	Three replicates per concentration
Aeration devices	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	ground quartz sand  Not relevant  Not relevant  none
Other procedures	none

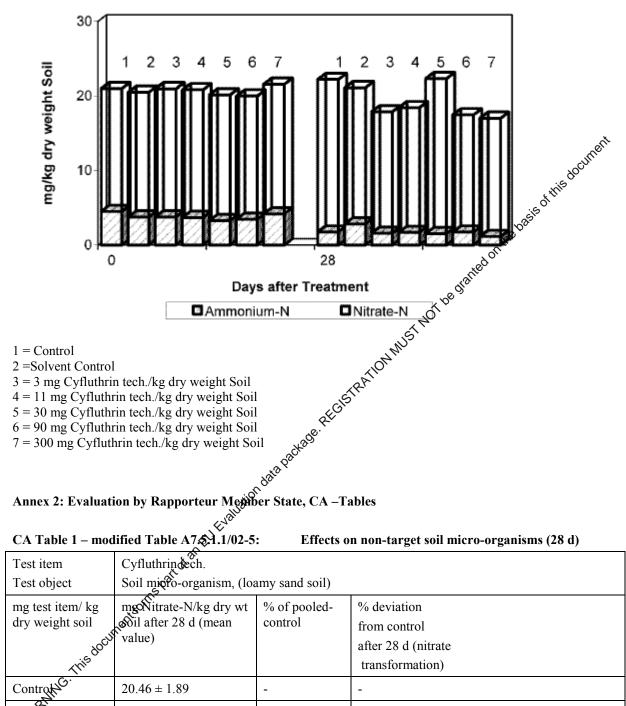
### Table A7.5.1.1/02-4: Test conditions

Criteria	Details (Ve
Organic substrate	Lucerne-grass-green meal Hoeveler Kraftforer, 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	Cyfluth Soil micro-organisr	rin tech.
Test object	Soil micro-organisr	n, (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 tom's	$20.46 \pm 1.89$	-
Control Solvent control Report	$18.29 \pm 1.57$	-
	$19.38 \pm 1.96$	100
3.0 (3.	$16.29 \pm 1.58$	84
Pooled control 80  3.0  11.0  360	$16.74 \pm 1.93$	86
36%	$20.81 \pm 0.99$	107
90.0	$15.72 \pm 3.67$	81
300.0	$15.87 \pm 2.92$	82

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



Effects on non-target soil micro-organisms (28 d)

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

Earthworm, acute toxicity test

		1 REFERENCE	Official use only
1.1	Reference	(1985). Acute toxicity of Cyfluthrin (Tech.) to Earthworms. Report No. HBF/Rg 54. BES Ref M-008890-01-1 Report date: Dates of study May to November 1985. Unpublished. Yes Bayer CropScience AG 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 Yes. OECD 207 No. (not required, as study started beforeabline 30 1988).	
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 thine 30 1988).	
2.3	Deviations	Number of replicates was reduced.	
		3 METHOD GRA	
3.1	Test material	Cyfluthrin tech	
3.1.1	Lot/Batch number	Yes. OECD 207 No, (not required, as study started before thine 30 1988). Number of replicates was reduced.  3 METHOD  Cyfluthrin tech Pt. 233 490 583.  as given in Section 2	
3.1.2	Specification	as given in Section 2	
3.1.3	Description	Sticky year owish substance	
3.1.4	Purity	92,4%	
3.1.5	Stability	92,0% Peleased 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.b	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
335	Test conditions	$22 \pm 2^{\circ}$ C, 70-90% RH, constant light (400-800 lux). See table	
5.5.5	1 on conditions	22 - 2 c, 10 70 70 1ct, constant light (400 000 tuty). See table	**

Earthworm, acute toxicity test

		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	After 14 days exposure the number of surviving animals and their weight alteration during the test was determined.  Not required according OECD 207  No details are presented in the report.  4 RESULTS  Not performed.  10, 100, 1000 mg/kg dry weight artificial soil.  See tables A7.5.1.2/01-5, A2.5.1.2/01-6  none  Weight alterations in the earthworms in comparison to the control were observed the artificial state of the control were observed to a reflect the control were observed to the contr
3.3.10	Statistics	No details are presented in the report.
		4 RESULTS
4.1	Filter paper test	Not performed .
4.2	Soil test	OH MILE
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, A\$2.5.1.2/01-6
4.2.3	Concentration / effect curve	none 88ta 9acte
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	Ent.
4.3.1	Mortality	observed for cyfluthrin at 10 mg a.i./kg dry weight substrate and above.  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 earthwords showing adverse effects	See table A7.5.1.2/01-5
4.3.3	Enture of adverse effects  Test with reference	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.

X

### Document IIIA / Section A7.5.1.2/01

### Earthworm, acute toxicity test

BPD Data Set IIIA / Annex Point IIIA XIII 3.2

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<sub>50</sub> was greater than 1000 mg/kg dry weight soil, the highest concentration tested.

5.2.1 LC<sub>0</sub>

5.2.2 LC<sub>50</sub> LC<sub>50</sub> >1000 mg/kg.

5.2.3 LC<sub>100</sub>

5.3 Conclusion

The LC<sub>50</sub> (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 x

weight substance.

5.3.1 Other Conclusions

5.3.2 Reliability 1

5.3.3 Deficiencies

# Evaluation by Competent Authorities

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

#### EVANUATION BY RAPPORTEUR MEMBER STATE

Date

3006/09/06

None

**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  $20 \pm 1$  °C.

Results and discussion

Applicant's version can be adopted.

Conclusion

Applicant's version can be adopted with the following comment:

LC<sub>0</sub>: not determinable

LC<sub>50</sub>: >1000 mg/kg dry weight substrate, (see above 5.2.2)

LC<sub>100</sub>: 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

Document IIIA / Section A7.5.1.2/01 BPD Data Set IIIA / Annex Point IIIA XIII 3.2

## Earthworm, acute toxicity test

	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	Give date of comments submitted  Discuss additional relevant discrepancies referring to the (sub)heading pathology 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 wate
Acceptability	Discuss if deviating from view of rapporteur menter state
Remarks	a kanala kan
	ckage.

Document IIIA, Section 7.5.1.2/01

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

the active ingredient was made up to 200 and evaporated to dryness before the
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exposed de appais d'inté de
vere placed over the test vessels to prevent
w n.

Table A7.5.1.2/01-2: Test organisms

Criteria	Details or the second
Species/strain	Earthworth (Eisenia foetida andrei).
Source of the initial stock	
Culturing techniques	Temperature 22 ± 2°C, 70 – 90 % relative humidity. 12:12 hour light dark cycle.
Culturing techniques  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 oak of an EU	On day prior to start of study, removed from breeding substrate and kept in test substrate under test conditions until study start.
Pre-treatment  Pre-treatment  Pre-treatment  Pre-treatment  Pre-treatment  Pre-treatment	

**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 <sub>3</sub> (pure) to adjust the pH to $6\pm0.5$ .
Test mixture	See above  1.5 L glass preserving jars  500 g dry weight.  10, 100, 1000 mg/kg artificial soil.
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. don'th
Number of earthworms/test concentration	30.
Number of earthworms/container	10.
Light source	30.  10.  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	<b>Details</b>
Test temperature	Temperature $20 \pm 1^{\circ}$ 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 NENO	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 $6\pm0.5$
Light intensity / photogeriod	Constant light 400 – 800 lux.
Relevant degradation products	None.

Table A7.5.1.2/01-5: Mortality data

Test Substance Concentration	Mortality			
(nominal/measured) <sup>1</sup>	Number		Percentage	
[mg/kg artificial soil]	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				ž.
Control	0	0	0	0 0 0 10 mis
10	0	0	0	0 2021
100	0	0	0	0 .;50
1000	1	3	6.7	18
Temperature [°C]	20 ± 1°C	20 ± 1°C		asis .
pH	$6.4 \pm 0.01$	$6.4 \pm 0.08$		Jor the loss is
•	$6.9 \pm 0.02$	$6.5 \pm 0.02$		" All's
Moisture content	$25.3 \pm 0.4$	$33.7 \pm 0.2$		, o

<sup>&</sup>lt;sup>1</sup> 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] <sup>1</sup>	95 % c l.
LC <sub>0</sub>	-	- <sup>LOIS</sup>
LC <sub>50</sub>	>1000 mg	-0 <sub>8</sub> .
LC <sub>100</sub>	-	oscho-

<sup>&</sup>lt;sup>1</sup> effect data are based on nominal concentration

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

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

Springtails, acute toxicity test

		1 REFERENCE	Official use only
1.1	Defenence	(1985).	
1.1	Reference	Acute toxicity of Cyfluthrin (Tech.) to Springtails (Folsomia Candida).	
			ment
		Bayer Report No. HBF Co 03. BES Ref. M-032023-01-1	lociii.
		Report date: 9 December 1985.	
	250, 200 750	Unpublished.	
1.2	Data protection	Yes.	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Criteria for data protection	Acute toxicity of Cyfluthrin (Tech.) to Springtails (Folsomia Candida).  Bayer Report No. HBF Co 03. BES Ref. M-032023-01-1 Report date: 9 December 1985. Unpublished. Yes. Bayer CropScience AG  Data submitted to the MS after 13 May 2000 on disting a.s. for the purpose of its entry into Annex I  2 GUIDELINES AND QUALITY ASSURANCE No, however based upon OECD 207. No, (not required, as study started before June 30 1988). Not applicable.  3 METHOD	
		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.	
		No, (not required, as study started before June 30 1988).  Not applicable.  3 METHOD  Cyfluthrin tech.  Pt. 233 490 583 888	
3.1	Test material	Cyfluthrin tech.	
3.1.1	Lot/Batch number	Pt. 233 490 5838000	
3.1.2	Specification	as given in Section 2	
3.1.3	Purity	92.1% & JO	
	Composition of Product	as given in Section 2	
3.1.5	Further relevant properties  Method of analysis  Reference substance  Method of analysis	Sticky yellowish substance.	
3.1.6	Method of analysis	None.	
3.2	Method of analysis 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	

# Springtails, acute toxicity test

		10% peat. See table A7.5.1.2/02-3
3.3.5	Test conditions	$20 \pm 1$ °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	Mortality was recorded.  After 14 days exposure the number of surviving animals was determined.  Not required according OECD 207  Probit analysis using the "Maximum-Likelihood" metabled.  4 RESULTS  Not performed.  1.0, 5.6, 10, 56, 100, 178, 316, 56 and 1000 mg/kg dry weight artificial soil.  See tables A7.5.1.2/02-5, AF.5.1.2/02-6  See figure 1
3.3.10	) Statistics	Probit analysis using the "Maximum-Likelihood" method.
		4 RESULTS
4.1	Filter paper test	Not performed.
4.2	Soil test	OKANI
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  none  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
4.2.4	Other effects	none giron
4.3	Results of controls	Evalue
	Mortality Me Que	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 diverse effects	See table A7.5.1.2/02-5
4.3.3	Nature of adverse effects Test with reference	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

# Springtails, acute toxicity test

		1000 mg cyfluthrin /kg of artificial soil consisting of 84% sand, 20% x 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.
5.2	Results and discussion	The LC <sub>50</sub> was 599 mg/kg dry weight soil. The acute no-observed-effect-concentration (NOEC) for <i>Folsomia candida</i> exposed to cyfluthrin was 10 mg/kg dry weight soil and the lowest-observed-effect-concentration was 56 mg/kg.  599 mg/kg (95% confidence interval 234-5639 mg as/kg dw/kg.  The LC <sub>50</sub> (test duration: 14 days, test species: <i>Folsogia candida</i> ) is 599
5.2.1	LC <sub>0</sub>	agais of the same
5.2.2	LC <sub>50</sub>	599 mg/kg (95% confidence interval 234-5639 mg as/kg dw)
5.2.3	$LC_{100}$	"sedo"
5.3	Conclusion	The LC <sub>50</sub> (test duration: 14 days, test species: Folsogia candida) is 599 mg a.i./kg dry weight substrate.
5.3.1	Other Conclusions	The LC <sub>50</sub> (test duration: 14 days, test species: Folsowia candida) is 599 mg a.i./kg dry weight substrate.  The acute No Observed Effect Concentration (NOEC) is 10 mg a.i./kg dry weight substance.
5.3.2	Reliability	11267 method for testing of effects on collembola, the appropriate soil test organism for an insegnicide, evaluates in addition the chronic effects
5.3.3	Deficiencies	None None

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date ment toms	EVALUATION BY RAPPORTEUR MEMBER STATE
Date Cent 10	2006/09/06
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version can be adopted.
Conclusion NART	Applicant's version can be adopted with the following comment: LC <sub>0</sub> : not determinable LC <sub>50</sub> : 599 mg/kg dry weight substrate LC <sub>100</sub> : 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  Discuss if deviating from view of rapporteur member state  Athis document
Remarks	d this

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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 On the Dans
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	Spangtails (Folsomia candida).
Source of the initial stock	
Culturing techniques	Temperature $20 \pm 1$ °C, $70 - 90$ % relative humidity, constant light.
Source of the initial stock  Culturing techniques  Age/weight  Pre-treatment  Age/weight	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 offis	Adult, 2 – 3 mm length.
Pre-treatment Pre-treatment Treatment 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 <sub>3</sub> (pure) to adjust the pH to $6\pm0.5$ .
Test mixture	See above unest
Size, volume and material of test container	100 ml glass beakers  50 g dry weight.
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 ned
Number of Springtails/test concentration	dry weight artificial soil.  3  30  The drop drop drop drop drop drop drop drop
Number of Springtails/container	10
Light source	Not stated.
Test performed in closed vessels due to significant volatility of test substrate	Yes. 100 moglass beakers with glass lid.

### Table A7.5.1.2/02-4: Test conditions

Criteria	Details
Test temperature	Temperature $20 \pm 1$ °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 (E)	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 $6 \pm 0.5$
Light intensity / photoperiod	Constant light 400 – 800 lux.
Relevant degración products	None.

Table A7.5.1.2/02-5: Mortality data

Test Substance Concentration		Mor	tality	
(nominal) mg/kg artificial soil  Pre-test		Number 14 d	Percentage 14 d	
Control		-	10	
Cyfluthrin	0.1	-	17	
	1	-	40	
	10	-	27	The dranted on the basis of this doct
	100	-	40	
	1000	-	73	80 <sup>C)</sup>
Main study				, this
Control		1	3	ais of
Cyfluthrin	1	2	7	. a bas
	5.6	1	3	Orth
	10	0	0	nted "
	56	4	13	" ota,
	100	6	20	1/2°
	178	5	17	
	316	13	4311	
	562	15	1020	
	1000	22	RP 73	
Temperature [°C]		$20 \pm 1^{\circ}$ C	`	
pH				
		6.2 \$30.06		
Moisture content (main test)		6.2 \$9.06 art start at end	ca. 24%*	
		at end	24.7%	

<sup>\*</sup> corresponding to 47.4 % of maximum water holding capacity

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

	14 d smg/kg soil] <sup>1</sup>	95 % c.l.
LC <sub>0</sub>		-
LC <sub>50</sub>	599	234 - >1000 mg a.i./kg
LC <sub>100</sub> cume	-	-

<sup>&</sup>lt;sup>1</sup> 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	

# Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

		1 REFERENCE	Official use only
1.1	Reference	1 REFERENCE  (2005)  Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the predaceous mite <i>Hypoaspis aculeifer</i> Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1).  Bayer AG, Report No. P14HR BES Ref M-258697-01-1 12 October 2005 Unpublished Yes  Bayer CropScience AG  Data submitted to the MS after 13 May 2000 of existing a.s for the	
1.2	Data protection	Yes	
1.2.1	Data owner	Bayer CropScience AG	
1.2.2	Companies with letter of access	natited of.	
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 SSURANCE	
2.1	Guideline study	Yes "OL <sup>M</sup>	
		Yes Guidance document on regulators resting procedures for pesticides with non-target arthropods (Barrett, & 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	standardization of test systems for assessing sub-lethal effects of chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).  Yes  None.  3 METHOD  Fluoro-3-phenoxybenzoic acid  M23458, AE F105561 001C94 0001  Not relevant, metabolite testing  94% w/w  Not relevant, metabolite testing	
3.1	Test material	6-Fluoro-3-phenoxybenzoic acid	
3.1.1	Lot/Batch number	M23458, AE F105561 001C94 0001	
3.1.2	Specification a for	Not relevant, metabolite testing	
3.1.3	Purity cume	94% w/w	
3.1.4	Composition of Product  Further relevant properties	Not relevant, metabolite testing	
3.48	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		

# Effects on beneficial arthropods other than bees



### BPD Data set IIIA/ Annex Point XIII.3

Anne	A I Ollit AIII.5	
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.  Mortality and reproduction  14 days after test initiation mortality was assessed. Reproduction was
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	tested on test concentrations showing less than 50% mortalite and the
3.3.7	Monitoring of test substance concentration	control by two reproduction sets, examined on day 28-30 and 32-34. No Mortality: The ANOVA and the Dunnett's t-toot (1-sided, $p \le 0.05$ )
3.3.8	Statistics	Mortality: The ANOVA and the Dunnett's t-toot (1-sided, $p \le 0.05$ ) Reproduction: Welch t-test; 1-sided, $p \le 0.05$ 4 RESULTS  9.4, 30.1, 94, 297 and 940 ang /kg dry soil
4.1	Soil test	gestr
4.1.1	Initial concentrations of test substance	9.4, 30.1, 94, 297 and 940 mg /kg dry soil
	Effects data Mortality/ Reproduction  Results of controls 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 13.65%. 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)
	- is dou	See table A7.5.1.2/03-4 and table A7.5.1.2/03-5
4.2	Results of controls	and the second contract of the second contrac
4.2.1 NAP	Results of controls  Floritality	In the control groups 3% (mean value) mortality of <i>H. aculeifer</i> 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

### Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

#### 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 Hyperaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed on 4-Fluoro-3-phenoxybenzoic acid in standard soil (LUERA 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett & al. 1994).

The test compound was mixed homogeneously though standard soil (LUFA 2.1, organic carbon content  $1.27 \pm 0.27$ ) 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 3.0 mg/kg dry soil was used as the toxic reference. The bioassax was initiated by confining 20 protonymphs of *Hypoaspis aculeio* per container. Five units were prepared for the water control, 4 maits for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation.

Following the exposure partial, effects on reproduction were tested on an untreated layer of placter 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 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.

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

5.2 Results and enterms discussion

WARMING

Document IIIA, Section 7.5.1.2/03

### Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

		statistical difference to the untreated control Thus the NOEC <sub>Reproduction</sub> was determined as 297 mg/kg soil.
5.2.1	LR <sub>50</sub>	>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 mg/kg soil (dw). The NOEC reproduction was determined with 397.0 mg test item/kg soil.
531	Other Conclusions	Validity criteria were fulfilled

	mg test item/kg soil.
5.3.1 Other Conclusions	Validity criteria were fulfilled
5.3.2 Reliability	1 ged or
5.3.3 Deficiencies	Validity criteria were fulfilled  1  No  Exclustion by Computant Authorities
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPEORTEUR MEMBER STATE
Date	2006/09/29 Applicant's version acceptable.
Materials and Methods	Applicant's version acceptable.
Results and discussion	Applicant's version can be adopted with the following comments:
Conclusion	therefore is beta-cyfluthrin-4-Fluoro-3-phenoxybenzoic acid.  To 5.2 Y. The endpoint of mortality is LC <sub>50</sub> instead of LR <sub>50</sub> .  Lo <sub>50</sub> : > 940 mg/kg soil dw  Other conclusions: NOEC <sub>Mortality</sub> > 940 mg/kg soil dw  NOEC <sub>Reproduction</sub> = 297 mg/kg soil dw  Applicant's version can be adopted.  1  acceptable  The test was conducted at continual darkness, but this is not relevant for this species
Reliability next le	1
Acceptability 80cul	acceptable
Remarks This	The test was conducted at continual darkness, but this is not relevant for this species.
WARTH!	This study summary is the same as A 7.5,2.1/02.
4.	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
	The state of the s

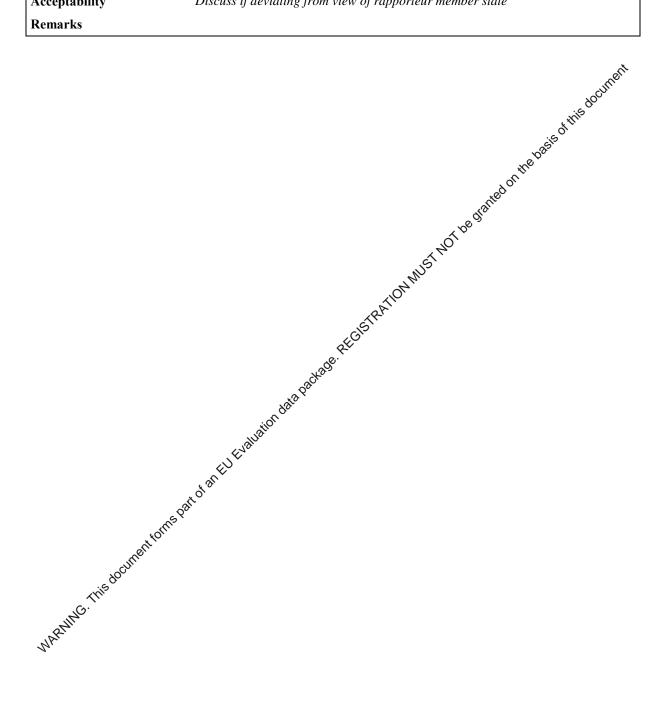
Conclusion

Reliability

Discuss if deviating from view of rapporteur member state

Discuss if deviating from view of rapporteur member state

Bayer Environmental Sci	ience Cyfluthrin	April 2006	
Document IIIA/ Section 7.5.1.2/03 BPD Data set IIIA/ Annex Point XIII.3	Effects on beneficial arthropods other than bees	x	
Acceptability Remarks	Discuss if deviating from view of rapporteur member state		



### Table A7.5.1.2/03-1: Test organisms

Criteria	Details
Species/strain	Hypoaspis aculeifer Canestrini (Acari: Laelapidae)
Source of the initial stock	
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult <i>H. aculeifer</i> 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 gold		
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 <sub>2</sub> ) 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		
Amount of artificial soil (g)/ container  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 ment	None		

# Table A7.5 7.2/03-3: Test conditions

Tubic 11112/100 C. Test conditions				
Criteria	Details			
West temperature	Maintained in an incubator at $25 \pm 2$ °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)	Corrected mortality after 14 days		Reproduction after 7 days (% reduction relative to control)	
[mg/kg artificial soil]				
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%*	

<sup>\*</sup> Statistically significantly different from deionised water control.

**Table A7.5.1.2/03-5: Effect data** 

	28 d [mg/kg soil dry weight] <sup>1</sup>
LC <sub>50</sub>	>940

<sup>&</sup>lt;sup>1</sup> 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

0.		
Jage	fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25% 2000	Yes	
Mean corrected mortality in toxic reference 50 300%	Yes	
Mean reproduction deionised water control ≥18°	Yes	
(fertile eggs/female/7 days)		

## Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

			1 REFERENCE	Official use only
1.1	ı	Reference	(2005);	
			Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction of the predaceous mite <i>Hypoaspis aculeifer</i> Canestrini (Acari: Laelapidae) in standard soil (LUFA 2.1).,  Report No. P15HR BES N° M-259607-01-1 27 October 2005 unpublished Yes  Bayer CropScience AG  Data submitted to the MS after 13 May 2000 of existing a.s for the	Pociti
1.2	2	Data protection	Yes	
1.2	2.1	Data owner	Bayer CropScience AG	
1.2	2.2		draftic	
1.2	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	1	Guideline study	Yes Guidance document on regulatery testing procedures for pesticides with	
			non-target arthropods (Barrefoet al. 1994).  SECOFASE, Final Report. Development, improvement and	
2.2	2	GLP	Yes & Zaza	
2.3	3	Deviations	chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996).  Yes  None.	
3.1	1	Test material	METHOD  Signard trans -2. (2.2 dishloravinyl) 2.2 dimethyloylogropage carbovylic	
		Lot/Batch number  Specification	acid (Beta-Cyfluthrin Permethric-acid ) ( 1:1 mixture of the cis- and trans- isomer)	
3.1	1.1	Lot/Batch number	a. (cis-isomer) 920622ELB03 b. (trans-isomer) 920622ELB04	
3.1			Not relevant, metabolite testing	
3.1	1.3	Purityis	99.8% w/w	
2 1		Composition of Product	1:1 mixture of the cis- and trans- isomer	
3.1	1.5	Further relevant properties	Stability under correct storage conditions: June 02, 2010	
3.1	1.6	Method of analysis	The test item was identified by MS and NMR,	
3.2	2	Toxic standard	Yes, Dimethoate	
3.2	2.1	Method of analysis for reference substance	N/A	
3.3	3	Test methods		

## Effects on beneficial arthropods other than bees



#### BPD Data set IIIA/ Anney Point XIII 3

Anne	Annex Point XIII.3		
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.  Mortality and reproduction  14 days after test initiation mortality was assessed: Reproduction was	
3.3.5	Test parameter	Mortality and reproduction	
3.3.6	Examination	examined on test concentrations showing less than 50% more lity and	
3.3.7	Monitoring of test substance concentration	the control by two reproduction sets, examined on day 28-30 and 32-34.  No	
3.3.8	Statistics	Mortality: A One-Way Analysis of Variance (MOVA), followed by a Dunnett's t-test (1-sided, p ≤ 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 ≤ 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	80 to A	
	Initial concentrations	10. 22. 100%16 and 1000 mg/bg dry soil	
/1	Initial concentrations	III 47 IIII (4 Ib and IIIII) mg/kg dry cod	

4.1.1 Initial concentrations of test substance

10, 32, 100316 and 1000 mg/kg dry soil

4.1.2 Effects data 4. MARING. This document toms part to

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,  $p \le 0.05$ ) 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

4.2.1 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

## Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

- 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
- 4.3.2 Results

The toxic reference, dimethoate, caused 96.4% corrected mortality. This southern showed that test animals were sufficiently sensitive and discountern adverse effects of experience. adverse effects of exposure to test-item residues could be detected with the test system.

## APPLICANT'S SUMMARY AND CONCLUSION

#### 5.1 Materials and methods

Effects on survival and reproduction of the predaceous mite Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae) performed with permethric-acid in standard soil (LUFA 24) 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 hoppingeneously through standard soil

(LUFA 2.1, organic carbon content of  $1.21 \pm 0.27$ ) 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 Hyperaspis 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.

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,  $p \le 0.05$ ) 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

RAMAC. This document toms Results and discussion

## Effects on beneficial arthropods other than bees



BPD Data set IIIA/ Annex Point XIII.3

mathematical reasons).

Based upon the statistically significant different at 316 mg/kg soil (dw), the NOEC<sub>Mortality</sub> was determined to be 100 mg test item/kg soil (dw) and the LOEC<sub>Mortality</sub> 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 with significant difference, thus the NOEC<sub>Reproduction</sub> was determined as 316 mg/kg soil.

5.2.1 LC<sub>50</sub> 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 the LC<sub>50</sub> was 400.9 mg/kg dry soil. There were no adverse effects on reproduction at concentrations of >350 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<sub>Mortality</sub> = 100 mg /kg soil dw

NOEC<sub>Reproduction</sub> > 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 number. 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	d this
ing. This document to me	Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  And the deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur me

## Table A7.5.1.2/04-1: Test organisms

Criteria	Details
Species/strain	Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae)
Source of the initial stock	
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult <i>H. aculeifer</i> 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**

Table 117.5.1.2/04-2. Test system	
Criteria	Details grant
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic arbon 1.21%, pH value (0,01 M CaCl <sub>2</sub> ) 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, heigh 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
Amount of artificial soil (g)/ container  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 A7.5.2.04-3: Test conditions

Table 11/10/12/01 D. Test conditions		
Critera	Details	
Test temperature	Maintained in an incubator at $25 \pm 2$ °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		_	oduction /female/7 days)		
Deionised water control	7%			24.1	
Test Substance Concentration (nominal)		l mortality after 4 days	Reproduction	on after 7 days elative to control)	
[mg/kg artificial soil]					
10	5.9%	P>0.05	Not a	issessed	
32	-0.8%	P>0.05	Not a	issessed	
100	7.3	P>0.05	1	.9%	cum
316	24.7	P<0.05*	-9	0.3%	800
1000	93.3	P<0.05*	Not a	assessed	of this
LC <sub>50</sub>	28 d [n	ng/kg soil dry we	ight]	dianted on	
Table A7.5.1.2/04-6:	Validity crit guidelines	eria for reprodu	ction/mortality g	M. aculeifer acc	cording to test
M	. 1 4	1 < 250/		fulfilled	Not fulfilled
Mean mortality in deionised water control ≤ 25%  Mean corrected mortality in toxic reference 50 - 100%			CLEA.	Ves	
Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)			REGIST	Yes	
		Jaluation data padkade		ssessed  9% 0.3% ssessed  fulfilled Yes Yes Yes	

Statistically significantly different from deionised water control.

Table A7.5.1.2/04-5:

	28 d [mg/kg soil dry weight]
LC <sub>50</sub>	400.9

**Table A7.5.1.2/04-6:** 

	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	Yes	
(fertile eggs/female/7 days)		
Mean mortality in deionised water control ≤ 25%  Mean corrected mortality in toxic reference 50 - 100%  Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)  REC  (fertile eggs/female/7 days)		

Document IIIA/ Sections 7.5.1.3	Acute toxicity to plant.		
BPD Data Set IIA/ Annex Point XIII.3.2			
	JUSTIFICATION FOR NON-SUBMISSION OF DATA  Officia use onl		
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [✓]		
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 physiotoxic		
Undertaking of intended data submission [ ]	necessary.		
	Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
	EVALUATION BY RAPKORTEUR 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 distify 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 furnigation, release to soil is possible.		
Remarks	I ST.		
ó	COMMENTS FROM OTHER MEMBER STATE (specify)		
Date toms D	Give date of comments submitted		
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state		
Conclusion is Conclusion in Conclusion in Conclusion is Conclusion in Conclusion in Conclusion is Conclusion in Co	Discuss if deviating from view of rapporteur member state		

BPD Data Set IIIA / Annex Point IIIA,XIII.3.2 Reproduction study with other soil non-target macroorganism

Official use only REFERENCE (2006)1.1 Reference Cyfluthrin tech.: Influence on the reproduction of the Collembola Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

GUIDELINES AND QUALITY ASSURANCE (1999) Soil quality - Inhibianth following Candidates

1. Guidelines and Candida species, Folsomia Candida tested in artificial soil., 1.2 Data protection 1.2.1 Data owner 1.2.2 1.2.3 Criteria for data protection 2.1 Guideline study 2.2 GLP 2.3 Deviations None MATERIAL AND METHODS Cyfluthrin technical 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification As given in section 2 3.1.3 Purity Not relevant 3.1.4 Composition of Product 3.1.5 Further relevant none 3.1.6 Method of analysis Analytical certificate of December 02, 2005 approved until December Reference substance Betosip, active ingredient: Phenmedipham. Method of analysis for reference substance 3.3 **Testing procedure** 3.3.1 Preparation of the test Cyfluthrin was dissolved in acetone and then mixed with quartz to substance prepare stock solution. See table A7.5.2.1/01-1 3.3.2 Application of the At the test start water and stock solution were mixed into the artificial soil. See table A7.5.2.1/01-1 test substance 3.3.3 Test organisms Springtails Folsomia candida (collembola, Isotomidae) see table

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

# Reproduction study with other soil non-target macroorganism

		A7.5.2.1/01-2
	est system	Test soil : Artificial soil consisting of 10 % peat, 20 % Kaolin clay and 70 % quartz sand adjusted to pH $6\pm0.5$ with 0.45 % Calcium carbonate. See table A7.5.2.1/01-3
3.3.5 T	Test conditions	See table A7.5.2.1/01-4
3.3.6 I	Ouration of the test	28 days
3.3.7 T	Test parameter(s)	Mortality and reproduction
3.3.8 E	Examination / Sampling	After 28 days
3.3.9 N	Monitoring of TS concentration	No Red on Mr.
3.3.10 (	Controls	Control: artificial soil mixed with ground quartz sand
		See table A7.5.2.1/01-4  28 days  Mortality and reproduction  After 28 days  No  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)  Toxrat Pro 2.09 (released October 3002005)
3.3.11 S	Statistics	Toxrat Pro 2.09 (released October 30,2005)
		carbonate. See table A7.5.2.1/01-3  See table A7.5.2.1/01-4  28 days  Mortality and reproduction  After 28 days  No  Control: artificial soil mixed with ground quartz sand with acctone (3 ml acetone for 5g quartz sand; acetone is evaporated for 45 min under a fume hood)  Toxrat Pro 2.09 (released October 30.0005)  4 RESULTS  Not performed  Not relevant  Not relevant  Not relevant  Official 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)  Toxrat Pro 2.09 (released October 30.0005)  4 RESULTS  Not performed  Not relevant  Official soil dry weight  No measured  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
4.1 F	Range finding test	Not performed Not performed
4.1.1	Concentrations	Not relevant
4.1.2 N	Number/ percentage of animals showing dverse effects	Not relevant for Bo
4.1.3 N	Nature of adverse effects	Not relevant
4.2 F	Results test ubstance some	
4.2.1 I	nitial concernations of test substance	3,11, 30, 90 and 300 mg test item/kg artificial soil dry weight
4.2.2 A	Actual concentrations Etest substance	No measured
4.2.354 VA	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
345.0	Concentration / esponse curve	See fig A7.5.2.1/01-1
4.2.5	Other effects	none
4.3 F	Results of controls	

# Reproduction study with other soil non-target macroorganism

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	Performed once a year  89, 133, 200, 300 and 450 mg Betosip/kg artificial soil dry weight.  The mortality rate of adult collembolan was 8%, 15%, 20%, 8% 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
		With 200, 300 and 450 mg Betosip/kg artificial soil do 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 <i>Folsomia Candida</i> 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 race of 24% was found in the item concentration of 90 and 300 mg cyclothrin/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 Aluthrin/kg artificial soil dry weight
5.2.2	LOEC	300 mg cyfluthrin/kg artificial soil dry weight
5.3	Conclusion	300 mg cyfluthrin/kg artificial soil dry weight  The NOEC and LOEC reproduction was 90 and 300 mg cyfluthrin/kg artificial soil dry weight, respectively  The validity criteria have been fulfilled (See table A7.5.2.1/01-6)
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

"ING.	<b>Evaluation by Competent Authorities</b>
Washing.	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

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

# Reproduction study with other soil non-target macroorganism

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	COMMENTS FROM  Give date of comments submitted  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  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  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 members ate
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteus member state
Remarks	4h
ne <sup>s</sup>	Give date of comments submitted  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  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state

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

Dispersion	Yes			
Vehicle	Yes, quartz sand			
Concentration of vehicle			nl acetone and mixed with 9 g quartz for 45 minutes under a fume hood	
	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).			
	with quartz sand to r data were documente	ealise the dema ed in the follow	appropriate amounts were mixed unded test concentrations. The exact ring table. At test start water and the nixed into the artificial soil.	
	Actual amount of stock solution in g	Mixed with quartz sand (g)	Corresponding nominal concentration (mg cyfluthrin/kg applicial soil dry weight)	
	0.1517 (stock II)	4.85	36	
	0.0543 (stock I)	4.85 4.95 4.882 4.855 3.50	11	
	0.1526 (stock I)	4.888	30	
	0.4520 (stock I)	€£.55	90	
	1.5033 (stock I) Yes	3.50	300	
	-O			
Vehicle control performed	Yes vo			

Table A7.5.1.1-2: Test or sanisms

Criteria do	Details	
Criteria Species/strain	Springtails Folsomia candida (collembola, Isotomidae)	
Source of the initial stock		
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

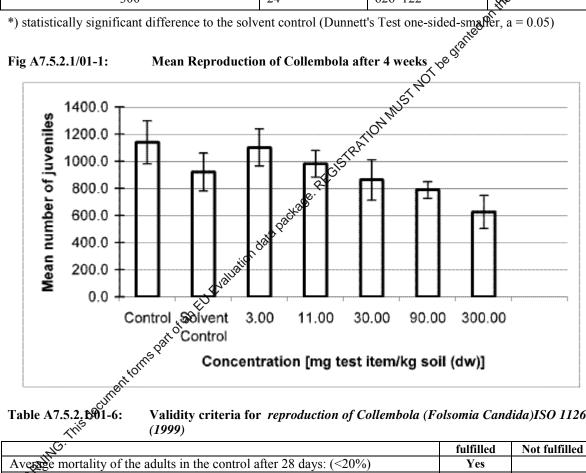
Criteria	Details		
Artificial soil test substrate	Sphagnum peat(Air dried and finely ground): 10%		
	• Kaolin clay: 20%		
	(Content of Kaolin (AI2Si205(OH)4) = 56 %		
	• Industrial quartz sand (Sort: F 36): 70%		
	(Particle size: 0.20 mm - 0.05 mm = 68.2 %)		
	Calcium carbonate (CaC03): 0.45%		
	(For adjustment of pH to $6.0 \pm 0.5$ )		
	Maximum water holding capacity (WHCmax): 7503 g water per 100 g artificial soil.		
Test mixture	water per 100 g artificial soil.  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	anied.		
Nominal levels of test concentrations	3,11, 30, 90 and 300 mg sest item/kg artificial soil dry weight		
Number of replicates/concentration	5 (+1 without Codembola 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 STRA		
Number of collembola/container	Source: artificial light, intensity: start: 555 Lx 14 days: 585 Lx		
Light source	Source: artificial light, intensity:		
. gade	start: 555 Lx		
kata .	14 days: 585 Lx		
ajion	end: 575 LX		
Levaluation do	(Integrated luxmeter of the climatic chamber)		
Test performed in closed vessels to significant volatility of test substrate	No		

Table A7.5.2.1/01-4: Loth Test conditions

Criteria <sub>curt</sub> e	Details
Test temperature	20 + 2 °C (continuously recorded by a thermo hydrograph integrated in the climatic chamber)
Moissure content	Start : 25.59% to 27.50% End : 23.89% to 25.59%
рН	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	Cyfluthrin technical			
Test object	Folsomia candida			
Exposure	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 ant	
11	12	981 98	107 NOCUME	
30	12	863 150	94 <sub>th</sub> is	
90	24	789 61	120 107 94 86 sis of this document	
300	24	626 122	(Contraction of the Contraction	



Validity criteria for reproduction of Collembola (Folsomia Candida)ISO 11267

fulfilled	Not fulfilled
Yes	
Yes	
Yes	
	Yes Yes

## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

Official use only 1 REFERENCE 1.1 Reference 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

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uidance document on regulators testing proun-target arthropods (Barrett et al. 1000)

COFASE, Final Row

udardization of 'micals on' Beta-Cyfluthrin FPB-acid: Effects on survival and reproduction of the 1.2 Data protection 1.2.1 Data owner 1.2.2 Companies with letter of access 1.2.3 Criteria for data protection 2.1 Guideline study chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996). GLP 2.2 Yes METHOD 2.3 Deviations None. پرمین کالنوری 3.1 Test material X 3.1.1 Lot/Batch number so M23458, AE F105561 001C94 0001 Specification Not relevant, metabolite testing 3.1.3 Purity 94% w/w Composition of Not relevant, metabolite testing Further relevant Stability under correct storage conditions: April 19,2007 properties 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 N/A for reference substance 3.3 Test methods

## Effects on beneficial arthropods other than bees

#### BPD Data set IIIA/ Annex Point XIII.3

Annex Point XIII.3		
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.  Mortality and reproduction  14 days after test initiation mortality was assessed. Reproduction was
3.3.5	Test parameter	Mortality and reproduction
3.3.6	Examination	tested on test concentrations showing less than 50% mortalite and the
3.3.7	Monitoring of test substance concentration	No  Mortelity: The ANOVA and the Dynastics 1 10th (1 sided as < 0.05)
3.3.8	Statistics	
		Reproduction: Welch t-test; 1-sided, p \le 0.05  4 RESULTS  9.4, 30.1, 94, 297 and 940 mg/kg dry soil
4.1	Soil test	ast.
4.1.1	Initial concentrations of test substance	9.4, 30.1, 94, 297 and 940 mg /kg dry soil  Mortality: There was no concentration dependent mortality after 14
	Effects data Mortality/ Reproduction  Results of controls  Controls  Reproduction	days. Mortality radged from 5.00 - 16.25% in the treated samples corresponding to a corrected mortality according to Abbott (1925) from 2.06 to 13.68%. 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)
4.2	Results of controls	
4.2.1	Results of controls Controls	In the control groups 3% (mean value) mortality of <i>H. aculeifer</i> 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.
1.0		

Performed

Test with toxic

4.3

## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

#### 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 Hyperaspis aculeifer CANESTRINI (Acari: Laelapidae) was performed on 4- x Fluoro-3-phenoxybenzoic acid in standard soil (LUES 2.1) in accordance with standard characteristics of extended laboratory trials as formulated in the SETAC-guidance document (Barrett 2 al. 1994).

The test compound was mixed homogeneously though standard soil (LUFA 2.1, organic carbon content  $1.27 \pm 0.27$ ) 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 3.0 mg/kg dry soil was used as the toxic reference. The bioassay was initiated by confining 20 protonymphs of *Hypoaspis aculeir* per container. Five units were prepared for the water control, 4 pairs for treatment rate and 3 units for the toxic reference. Mortality was assessed 14 days after initiation.

Following the exposure partial, effects on reproduction were tested on an untreated layer of placter 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 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.

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<sub>Mortality</sub> was determined as > 940 mg test item/kg soil (dw). The LOEC<sub>Mortality</sub> 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

5.2 Results and entering discussion

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## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

		statistical difference to the untreated control Thus the NOEC <sub>Reproduction</sub> was determined as 297 mg/kg soil.	
5.2.1	LR <sub>50</sub>	>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 948 mg/kg soil (dw). The NOEC reproduction was determined with 397.0 mg test item/kg soil.  Validity criteria were fulfilled  1  No	ocumer
5.3.1	Other Conclusions	Validity criteria were fulfilled	
5.3.2	Reliability	1 Tredo.	
5.3.3	Deficiencies	No Carte day.	

	Evaluation by Competent Authoraties
	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 of acceptable.
Results and discussion	To 3.1, 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and
Conclusion (Office)	therefore is beta-cyfluthrin-4-Fluoro-3-phenoxybenzoic acid.  To 5.3 Y. The endpoint of mortality is LC <sub>50</sub> instead of LR <sub>50</sub> .  L <sub>650</sub> : > 940 mg/kg soil dw  Other conclusions: NOEC <sub>Mortality</sub> > 940 mg/kg soil dw  NOEC <sub>Reproduction</sub> = 297 mg/kg soil dw  Applicant's version can be adopted.  1  acceptable  The test was conducted at continual darkness, but this is not relevant for this species
Reliability nent	1
Acceptability 80CU	acceptable
Remarks This	The test was conducted at continual darkness, but this is not relevant for this species.
WARE	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

Bayer Environmental Sci	ience Cyfluthrin	April 2006
Document IIIA/ Section 7.5.2.1/02 BPD Data set IIIA/ Annex Point XIII.3	Effects on beneficial arthropods other than bees	
Acceptability Remarks	Discuss if deviating from view of rapporteur member state	

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## Table A7.5.2.1/02-1: Test organisms

Criteria	Details
Species/strain	Hypoaspis aculeifer Canestrini (Acari: Laelapidae)
Source of the initial stock	
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult <i>H. aculeifer</i> 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 gold	
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 <sub>2</sub> ) 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	
Amount of artificial soil (g)/ container  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 ment	None	

## Table A7.5.2.1/02-3: Test conditions

Critteria Test temperature	Details
Test temperature	Maintained in an incubator at $25 \pm 2$ °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	Mortalit	y after 14 days	-	oroduction	
D : 1 1 1	,	20/	(tertile eg	gs/female/7 days	)
Deionised water contr Test Substance Concentration (nominal)	Corrected	3% d mortality after 14 days		21.95 etion after 7 days a relative to contr	rol)
[mg/kg artificial soil]	0.50/	D> 0.05	NI.	4 1	
9.4	8.5%	P>0.05	NO No	t assessed	
30.1	3.4%	P>0.05	NO.	t assessed	
94	2.1%	P>0.05	No	ot assessed	- 'ochu.
297	13.7%	P>0.05		8.4%	- His O
940 * Statisti	9.8%	P>0.05 ly different from		29.4%*	
Table A7.5.2.1/02-5:	28 d [mg	/kg soil dry weigl	ht] <sup>1</sup>	The diani	
LC <sub>50</sub>		>940		1 HO1	
effect data are based on nominal (n) concentrations					
	( )		10H1		
Table A7.5.2.1/02-6:	Validity criter	ia for reproduct	ion/mortality	of H. aculeifer ac	ecording to test
		, 20°.		fulfilled	Not fulfilled
Mean mortality in deionis	sed water contro	$01 \leq 25\%$		Yes	
Mean corrected mortality	in toxic referen	ice 50 3000%		Yes	
Mean reproduction deionised water control 310  Yes  (fertile eggs/female/7 days)			Yes		
Mean reproduction deion (fertile eggs/female/7 day	is part of an Euler's	·			ecording to test  Not fulfilled

Statistically significantly different from deionised water control.

Table A7.5.2.1/02-5:

	28 d [mg/kg soil dry weight] <sup>1</sup>
LC <sub>50</sub>	>940

<sup>&</sup>lt;sup>1</sup> effect data are based on nominal (n) concentrations

Table A7.5.2.1/02-6:

1,00	fulfilled	Not fulfilled
Mean mortality in deionised water control $\leq 25\%$	Yes	
Mean corrected mortality in toxic reference 50,3900%	Yes	
Mean reproduction deionised water control ≥18	Yes	
(fertile eggs/female/7 days)		

## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

Official use only 1 REFERENCE (2005);1.1 Reference Data submitted to the MS after 13 May 2000 of existing a.s for the purpose of the entry of the existing active substance into Annex I

! GUIDELINES AND QUALITY ASSURANCE

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uidance document on regulatory testing interest arthropods (Barretto)

COFASE, Final indardization mical. Beta-Cyfluthrin Permethric-acid: Effects on survival and reproduction 1.2 Data protection 1.2.1 Data owner 122 1.2.3 Criteria for data protection 2.1 Guideline study chemicals on fauna in the soil ecosystem (Løkke & van Gestel 1996). GLP 2.2 Yes 2.3 Deviations None. **ETHOD** Ois and trans -3-(2,2-dichlorovinyl)2,2-dimethylcylopropane carboxylic 3.1 Test material acid (Beta-Cyfluthrin Permethric-acid ) (1:1 mixture of the cis- and trans- isomer) a. (cis-isomer) 920622ELB03 3.1.1 Lot/Batch number b. (trans-isomer) 920622ELB04 Not relevant, metabolite testing Purktis 99.8% w/w Composition of 1:1 mixture of the cis- and trans- isomer Product 3.1.5 Further relevant Stability under correct storage conditions: June 02, 2010 properties 3.1.6 Method of analysis The test item was identified by MS and NMR, Toxic standard Yes, Dimethoate 3.2.1 Method of analysis N/A for reference substance 3.3 Test methods

## Effects on beneficial arthropods other than bees

#### BPD Data set IIIA/ Annex Point XIII.3

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

Mortality/escape rate was determined after 14 days of exposure, 3.3.4 Test duration reproduction was determined after 34 days.

Mortality and reproduction 3.3.5 Test parameter

14 days after test initiation mortality was assessed; Reproduction was 3.3.6 Examination 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 (NOVA), followed by a Dunnett's t-test (1-sided,  $p \le 0.05$ ) was used to determine whether or not there were significant differences. The Loso value was calculated by Probit analysis using Linear Max. Likelihood Regression.

Reproduction: The Welch t-test for inhomogeneous variances (1-sided,  $p \le 0.05$ ) was used to determine significant differences

The statistical software package ToxRat Professional 2.09 was used for these calculations.

# 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/ ARMING. This document forms f

Moreality: 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,  $p \le 0.05$ ) 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

#### Results of controls

4.2.1 Mortality In the control groups 7% (mean value) mortality of H. aculeifer occurred.

The mean reproductive performance of the controls was 24.1 (no of 4.2.2 Reproduction 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

## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

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

4.3.2 Results

The toxic reference, dimethoate, caused 96.4% corrected mortality. This southern showed that test animals were sufficiently sensitive and discountern adverse effects of experience. adverse effects of exposure to test-item residues could be detected with the test system.

## 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 24) in accordance with x 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 hoppingeneously through standard soil (LUFA 2.1, organic carbon content of  $1.21 \pm 0.27$ ) 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 Hyperaspis 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.

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,  $p \le 0.05$ ) 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

RAMAC. This document toms Results and discussion

## Effects on beneficial arthropods other than bees

BPD Data set IIIA/ Annex Point XIII.3

mathematical reasons).

Based upon the statistically significant different at 316 mg/kg soil (dw), the NOEC<sub>Mortality</sub> 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

with the control having produced 24.1 juveniles per female. The statistical analysis (Welch t-test; 1-sided, p < 0.05) shows significant difference, thus the NOTE

mg/kg soil.

5.2.1 LC<sub>50</sub> 400.9 mg/kg dry soil

Permethric-acid had no adverse effects on mortality of Hypoaspis x 5.3 Conclusion

aculeifer in artifical soil at concentrations of <100 mg/kg dry soil (NOEC) and theLC<sub>50</sub> was 400.9 mg/kg dry soil. There were no adverse

effects on reproduction at concentrations of >350 mg/kg dry soil.

5.3.1 Other Conclusions Validity criteria were fulfilled

1 5.3.2 Reliability

5.3.3 Deficiencies None

**Evaluation by Competent Authorities** 

Use separate "evaluation boxes" to provide transparency as to the

comments and views submitted

JAON BY RAPPORTEUR MEMBER STATE

20006/89/29 Date

Materials and Methods Applicant's version is acceptable.

'Applicant's version can be adopted with the following comment: Results and discussion

To 5.1 and 5.3: The test substance is a metabolite of beta-Cyfluthrin, and

therefore it is beta-cyfluthrin-permetric-acid.

LC<sub>50</sub>: 400.9 mg/kg soil dw Conclusion

Other conclusions: NOEC<sub>Mortality</sub> = 100 mg /kg soil dw

NOEC<sub>Reproduction</sub> > 316 mg/kg soil dw

Applicant's version can be adopted.

Reliability

Acceptability acceptable

The test was conducted at continual darkness, but this is not relevant for this Remarks

species.

COMMENTS FROM ... (specify)

Give date of comments submitted Date

Discuss additional relevant discrepancies referring to the (sub)heading numbers Materials and Methods

and to applicant's summary and conclusion.

Discuss if deviating from view of rapporteur member state

<b>Bayer Environmental Scien</b>	ce Cyfluthrin	April 2006
Document IIIA/ Section 7.5.2.1/03 BPD Data set IIIA/	Effects on beneficial arthropods other than bees	
Annex Point XIII.3		
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	nent
Remarks		document

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## Table A7.5.2.1/03-1: Test organisms

Criteria	Details
Species/strain	Hypoaspis aculeifer CANESTRINI (Acari: Laelapidae)
Source of the initial stock	
Culturing techniques	Not stated.
Age	protonymphs (maximum 2 days old)
Pre-treatment	Six days before the test, adult <i>H. aculeifer</i> 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**

1 abic 117.5.2.1705-2. 1 est system	
Criteria	Details
Artificial soil test substrate	LUFA 2.1 sand (obtained from Landwirtschaftliche Untersuchungs- und Forschungsanstalt Speyer, Germany); organic arbon 1.21%, pH value (0,01 M CaCl <sub>2</sub> ) 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 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
Amount of artificial soil (g)/ container  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 A7.52.1/03-3: Test conditions

Critera	Details
Test temperature	Maintained in an incubator at $25 \pm 2$ °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	Mortalit	y after 14 days	-	oduction	
Deionised water control		7%		/female/7 days) 24.1	
Test Substance Concentration (nominal)		d mortality after d days	Reproducti	on after 7 days relative to control)	
[mg/kg artificial soil]					
10	5.9%	P>0.05	Not	assessed	
32	-0.8%	P>0.05	Nota	assessed	
100	7.3	P>0.05	1	.9%	cur
316	24.7	P<0.05*	_9_	9.3%	.5800
1000	93.3	P<0.05*	Not a	assessed	Of HAIS
Table A7.5.2.1/03-5:	28 d [r	ng/kg soil dry we	ight]	antedon	o.
Table A7.5.2.1/03-6:	Validity crit	eeria for reprodu	ction/mortality	of H. aculeifer ac	cording to test
			OZ	fulfilled	Not fulfilled
Mean mortality in deionis	ed water con	$trol \le 25\%$	- CAN	Yes	
Mean corrected mortality Mean reproduction deioni (fertile eggs/female/7 days	sed water cons)	atrol $\geq 10$	RECENT	Yes	
	Ü	walkation data package		assessed assessed .9% 0.3% assessed  fulfilled Yes Yes Yes	

Statistically significantly different from deionised water control.

Table A7.5.2.1/03-5:

	28 d [mg/kg soil dry weight]	
LC <sub>50</sub>	400.9	

Table A7.5.2.1/03-6:

, o <sup>44</sup> 0.	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	Yes	
(fertile eggs/female/7 days)		
Mean mortality in deionised water control ≤ 25%  Mean corrected mortality in toxic reference 50 - 100%  Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)  Mean reproduction deionised water control ≥10 (fertile eggs/female/7 days)		

Document IIIA/ Sections 7.5.2.2	Long term test with terrestrial plants.
BPD Data Set IIA/ Annex Point XIII.3.2	
	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 physiotoxic effects. Therefore a long term test with terrestrial plants was not
Undertaking of intended data submission [ ]	considered as necessary.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPEORTEUR MEMBER STATE
Date	2007/03/20
Evaluation of applicant's justification	Applicant's justification is not comprehensible, because there are no data from PPF available, which distify 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	I WE
6	COMMENTS FROM OTHER MEMBER STATE (specify)
Date "Olfns"	Give date of comments submitted
Evaluation of applicant's justification	comments from other member state  Significant on F 176 in products used outside outside outside say well as products to be used by gassing, fogging or fumigation, release to soil is possible.  COMMENTS FROM OTHER MEMBER STATE (specify)  Give date of comments submitted  Discuss if deviating from view of rapporteur member state
justification goods  Conclusion	Discuss if deviating from view of rapporteur member state
NART NART	

Document IIIA/ Sections 7.5.3.1.1	Acute oral toxicity.	
BPD Data Set IIA/ Annex Point XIII.1.1		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]	Jocument
Limited exposure [ ]	Other justification [x]	36
Detailed justification:	Solfac® EW050 and Raid® cyfluthrin Foam is to be used indoo in rural hygiene and household application, respectively.  When manure/sludge is sprayed on grassland, cyfluthriw residues which	
	When manure/sludge is sprayed on grassland, cyfluthrid residues which are adsorbed on organic matter of manure/sludge are unlikely to contaminate plants leaves. The crop rotational stady demonstrated that no residues were detected on forage, straw and grain of plant grown of treated soil (10 applications at the rate of 28% cyfluthrin./ha/application).	
	Therefore, birds are unlikely to be expected to cyfluthrin when it is used as recommended on the label.	
	The existing acute toxicity stuckes with birds are considered as non relevant.	
Undertaking of intended data submission [ ]	relevant.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date uns P	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Date  Evaluation of applicant's justification  Conclusion is don't repair to the conclusion is a conclusion. The conclusion is a conclusion in the conclusion in the conclusion is a conclusion in the conclusion in the conclusion in the conclusion is a conclusion in the conclusion in	The justification for non-submission of data is acceptable because acute to avian is only data requirement on PT18 if products used outside buildings 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 Remarks	Discuss if deviating from view of rapporteur member state	

Cyfluthrin

Document IIIA/ Sections 7.5.3.1.2	Short-term toxicity	
BPD Data Set IIA/ Annex Point XIII.1.2		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]  Other justification [x]	Current
Limited exposure [ ]	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, cyfluthrid 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% cyfluthrin./ha/application).	
	Therefore, birds are unlikely to be expected 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 [ ]	The existing short term toxicity andies with birds are considered as non relevant.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the countents and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date ms 2	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Date Evaluation of applicant's justification Conclusion	The justification for non-submission of data is acceptable because short-tertoxicity with avian is only data requirement on PT18 if products used outsibuildings in the form of baits, granulates and powder.	
Remarks		
1.	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 Remarks	Discuss if deviating from view of rapporteur member state	

Document IIIA/ Sections 7.5.3.1.3	Effects on reproduction	
BPD Data Set IIA/ Annex Point XIII.1.2		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]	ocument
Limited exposure [ ]	Other justification [x]	
Detailed justification:	Solfac® EW050 and Raid® cyfluthrin Foam is to be used indow 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 c cyfluthrin./ha/application).	
	Therefore, birds are unlikely to be expected 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 [ ]	The existing studies on effect of cyfluthrin on bird reproduction are considered as non relevant.	
	Evaluation by Competent Authorities	
	Use sevarate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date msp	2007/03/20	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Date Evaluation of applicant's justification Conclusion	The justification for non-submission of data is acceptable because effects reproduction are only data requirement on PT18 if products used outside by 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	Acute toxicity to honeybees and other beneficial arthropods, for example predators
BPD Data Set IIA/ Annex Point XIII.3.1	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA  Officia use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [x]
Limited exposure [ ]	Other justification [x]
Detailed justification:	Solfac® EW050 and Raid® Cyfluthrin Foam is to be used indow 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 stady 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 a recommended on the label.
	The existing acute studies on have been and other beneficial arthropods are considered as non relevant.
Undertaking of intended data submission [ ]	are considered as non relevants
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
o d	EVALUATION BY RAPPORTEUR MEMBER STATE
Date  Evaluation of applicant's	2007/03/23
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion 5000	The non-submission of data is acceptable.
justification Conclusion	
, aRM	COMMENTS FROM OTHER MEMBER STATE (specify)
Remarks.  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 [ ]	ment	
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.	c <del>s.</del>	
	When birds and mammals consume worms, this includes the out 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 Cearthworm		
	where C <sub>earthworm</sub> 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 of 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 deltamethen in an entire worm is:		
	$C_{\text{earthworm}} = \left[ \left( \text{BCF}_{\text{earthworm}} \times C_{\text{porewater}} \right) + \left( C_{\text{soil}} \times F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 + \left( F_{\text{gut}} \times \text{CONV}_{\text{soil}} \right) \right] / \left[ 1 +$		
	C <sub>earthworm</sub> = 0.15 to mg/kg wet earthworm = PEC <sub>oral predator</sub> With:  C <sub>porewater</sub> = 12,000 L.kg <sub>wet earthworm</sub> - (see Point A7.5.5)  C <sub>porewater</sub> = 1.38 x 10 <sup>-5</sup> mg/L (see Doc IIB-3 page 24)		
	C = 1.28 × 10 <sup>-5</sup> mg/L (see Doc IIP 2 page 24)		
	C <sub>soil</sub> = $3.06 \times 10^{-2}$ mg/kg wet weight soil (see Doc IIB-3 page 24)		
nt tome	F <sub>gut</sub> = 0.1 (TGD on Risk Assessment page 132) CONV <sub>soil</sub> = RHO <sub>soil</sub> / (F <sub>solid</sub> x RHO <sub>solid</sub> ) = 1700 / (0.6 / 2500) = 1.13		
WARTING. This document forms	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.		
Ner	Considering the chronic and reproductive NOAEL from a two generation rat study ( 1997, BES Ref. M-032020 -01-1) and a chronic 2-year rat study ( 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 <sub>small mammal</sub> of 1.67 mg/kg food is obtained.		
	Therefore, by comparing the PEC <sub>oral predator</sub> with the respective PNEC, <b>PEC/PNEC ratios of 0.0183 and 0.091</b> are obtained for birds and mammals, respectively, indicating that there is <b>no unacceptable risk</b> for earthworm-eating birds or mammals.		
	Therefore, further study is not required.		

Bioconcentration, further studies
Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted  EVALUATION BY RAPPORTEUR MEMBER STATE  2008/10/30  We can not follow the argumentation of the applicant in all points. The calculated
EVALUATION BY RAPPORTEUR MEMBER STATE
2008/10/30 <sub>208</sub> 2i5
We can not follow the argumentation of the applicant in all points. The calculated BCF <sub>earthworm</sub> indicates a bioaccumulation potential for all four diastereoisomeres of cyfluthrin and bioaccumulation via the terrestrial food chain has to be assumed.
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.  None
None TO <sup>X</sup>
COMMENTS FROM OTHER STEMBER STATE (specify)
Give date of comments submitted
Discuss if deviating from Sew of rapporteur member state
Discuss if deviating from view of rapporteur member state
adion
Discuss if deviating from view of rapporteur member state

## Section A7.5.5 Bioconcentration, terrestrial

Annex Point IIA7.5

		1 REFERENCE	Official use only
1.1	Reference	Not applicable	asc uniy
1.2	Data protection	No	×
1.2.1	Data owner	Bayer CropScience AG	inuel.
1.2.2	Companies with letter of access	is of this do	
1.2.3	Criteria for data protection	Not applicable No Bayer CropScience AG  No data protection claimed  2 GUIDELINES AND QUALITY ASSURANCE OF THE PARTY OF THE	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	No, not applicable	
2.2	GLP	No SET	
2.3	Deviations	No, not applicable	
		3 MATERIALS AND METHODS	
3.1	Test material	Not applicable	
3.1.1	Lot/Batch number	Not applicable at 200	
3.1.2	Specification	Not applicable & and applicable	
3.1.3	Purity	Not applicable ion	
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 Culter	Not applicable	
3.2.1	Method of analysis for eference	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 <sup>1</sup> , an estimation of the bioconcentration	

<sup>1</sup> 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

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600,000

### 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<sub>earthworm</sub> 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 dexiation
1	1,000,000	6.00	nied 560,000
2	870,000	5.94	530,000
3	1,100,000	6,00	570,000
		_	

820,000

	DECLIE TO
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	Non-entry field  Not applicable  Not applicable  Not applicable  Not applicable  Not applicable
4.1.4	Bioconcentration factor (BCF)	Not applicable
4.1.5	Uptake and depuration rate constants  Depuration time  Metabolites	Not applicable
4.1.6	Depuration time	Not applicable
4.1.7	Metabolites	Not applicable
4.1.8	Metabolites Other Observations Estimation of	Not applicable
4.2 3 <sup>1</sup> P	Estimation of bioconcentration	Based on a Kow value of $1x10^6$ , BCF earthworm is $12,000 \text{ L kg}_{\text{wet earthworm}}^{-1}$ (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 <sup>2</sup> , an estimation of the bioconcentration of 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 <sub>earthworm</sub> a value of 1 (kg wwt/L) can be assumed by default.  Based on a Kow value of $1 \times 10^6$ , BCF <sub>earthworm</sub> is $12,000 \times 10^{10}$ kg wet earthworm (rounded value)  The bioconcentration study in fish showed that the BCF <sub>fish</sub> (1984 of Point 7.4.3.3.1) is much by were then the theoretical
		$BCF_{earthworm} = [0.84 + 0.012 \times Kow] / RHO_{earthworm}$
		where for RHO earthworm a value of 1 (kg wwt/L) can be assumed by default.
		Based on a Kow value of 1x10 <sup>6</sup> , BCF <sub>earthworm</sub> is 12,000 kg g <sub>wet earthworm</sub> -1 (rounded value)
		The bioconcentration study in fish showed that the BCF <sub>fish</sub> (1984 – cf. Point 7.4.3.3.1) is much lower than the therotical BCF <sub>fish</sub> calculated under Point 7.4.2. The estimated BCF is more than 50-fold higher than the experimental BCF.
		Furthermore, studies on rats showed whigh degree of absorption of the orally dosed radioactivity followed by fast elimination from the body mainly via the urine. Thus, >970% 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 Kowy value of 1x10 <sup>6</sup> , BCF <sub>earthworm</sub> is estimated around 12,000 L.kg <sub>wet earthword</sub> . This value is a worst-case estimation
5.3.1	Reliability	Not applicable
5.3.2	Deficiencies	L.kg <sub>wet earthworth</sub> . This value is a worst-case estimation  Not applicable  Not applicable
		ints part
	ment to	S <sup>*</sup>
	is docum	
	MC. Thi	
<i>'</i> 12.	ARTI.	
7		

<sup>&</sup>lt;sup>2</sup> 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

## Annex Point IIA7.5

	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 400cum
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version adopted with following amendment:
	4.2 Estimation of bioconcentration:
	EVALUATION BY RAPPORTEUR MEMBER STATE  2008/10/24  Applicant's version is acceptable.  Applicant's version adopted with following amendment:  4.2 Estimation of bioconcentration:  The applicant has calculated the BCF <sub>earthworm</sub> for diastereoisomere 1 with a log Pow of 6, resulting in a BCF <sub>earthworm</sub> of 12000 kg <sub>wwt</sub> .L <sup>-1</sup> . The calculated BCF <sub>earthworm</sub> for the other diastereoisomeres of cyfluthrin is:
	Diastereoisomere 2 (log Pow 5.94): 10452 kgww 0 1
	other diastereoisomeres of cyfluthrin is:  Diastereoisomere 2 (log Pow 5.94): 10452 kgwwt. L <sup>-1</sup> Diastereoisomere 3 (log Pow 6.04): 13159 kgwwt. L <sup>-1</sup>
	Diastereoisomere 4 (log Pow 5.91): 975 kgwwt.L -1
	5.2 Results and discussion:
	Diastereoisomere 4 (log Pow 5.91): 9750 kg <sub>wwt</sub> .L <sup>-1</sup> 5.2 Results and discussion:  The calculated BCF <sub>earthworm</sub> for the four diastereoisomeres of cyfluthrin according to TGD is:
	Diastereoisomere 1 (log Fow 6.00): 12000 kg <sub>wwt</sub> .L <sup>-1</sup>
	Diastereoisomere 2 dog Pow 5.94): 10452 kg <sub>wwt</sub> .L <sup>-1</sup>
	0
	Diastereoisomers 3 (log Pow 6.04): 13159 kg <sub>wwt</sub> .L <sup>-1</sup> Diastereoisomere 4 (log Pow 5.91): 9755 kg <sub>wwt</sub> .L <sup>-1</sup>
Conclusion  Conclusion  This document of the conclusion of the con	We can not follow the argumentation of the applicant in all points. The calculated
KING.	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  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state  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	n the

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

MARMING

Document IIIA/ Sections 7.5.7.1.1	Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment		
BPD Data Set IIA/ Annex Point XIII.3.4	Acute oral toxicity		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only	
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [✓]	gournent	
Limited exposure [ ]	Other justification [ ]	ocui	
Detailed justification:	Actue of a lests 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		
Undertaking of intended data submission [ ]	severe risk for the terrestrial environment. Therefore additional mammalian species testing are not justified.		
	Evaluation by Competent Authorities		
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted		
	EVALUATION BY RAPPORTEUR MEMBER STATE		
Date  Evaluation of applicant's justification	2006/11/15 Applicant's justification is acceptable.		
Conclusion	Applicant's distification is acceptable.		
Remarks	- NEW		
	COMMENTS FROM OTHER MEMBER STATE (specify)		
Date	Give date of comments submitted		
Evaluation of applicants justification	Discuss if deviating from view of rapporteur member state		
Conclusion Remarks Tries	COMMENTS FROM OTHER MEMBER STATE (specify)  Give date of comments submitted  Discuss if deviating from view of rapporteur member state  Discuss if deviating from view of rapporteur member state	<u> </u>	

NARHING

Document IIIA/ Sections 7.5.7.1.2	Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment	
BPD Data Set IIA/ Annex Point XIII.3.4	Short term toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Officia use onl
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [✓]	CIMET.
Limited exposure [ ]	Other justification [ ]	
Detailed justification:	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]  Short term toxicity studies were performed on rats and does 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 [ ]	nus'	
	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	EVALUATION BY RAPPORTEUR MEMBER STATE  2006/11/15 Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	
Remarks	I st.	
Ó	COMMENTS FROM OTHER MEMBER STATE (specific)	
Date korns	Give date of comments submitted	
Date  Evaluation of applicant's justification  Conclusion is  Remarks:	Discuss if deviating from view of rapporteur member state	
Conclusion is Conclusion in Conclusion in Conclusion is Conclusion in Co	Discuss if deviating from view of rapporteur member state	

Document IIIA/ Sections 7.5.7.1.3	Tests with mammals in rare cases on basis of concern of severe risk for the terrestrial environment	
BPD Data Set IIA/ Annex Point XIII.3.4	Effects on reproduction	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [✓]	ocime
Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [√]  Other justification [ ]  Effects on reproduction were studied on rats and rabbit and are presented	
Detailed justification:	under point A6.8. In addition, there are no uses which would raise a concern of a severe risk for the terrestrial environment. Therefore	
Undertaking of intended data submission [ ]	Evaluation by Competent Authorities	
	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 X <sup>Q</sup> Q <sup>Q</sup>	
Evaluation of applicant's justification	EVALUATION BY RAPPORTEUR MEMBER STATE  2006/11/15 Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable.	
Remarks	* all	
6	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date (Olfn <sup>5</sup> )	Give date of comments submitted	
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state	
Date Evaluation of applicant's justification Conclusions Remarks	Discuss if deviating from view of rapporteur member state	