Section A7.2.1 Aerobic degradation in soil, initial study

Annex Points IIIA 7.4 and IIIA 12.1.1

5.2	**Results and discussion**	Cypermethrin was relatively rapidly degraded. A number of intermediate degradation products were formed and either mineralised or transformed into bound residues. Most of the "bound" radiolabelled material was distributed between the humic acid, fulvic acid and humin fractions.
5.2.1	Degradation rate and half-life	Estimation of the DT_{50} was not a focus of the studies summarised here. Nevertheless, half-lives were found to lie in a range between 2 and 4 weeks. For a more thorough investigation of the degradation rate please refer to section A7.2.1.
5.3	**Conclusion**	As demonstrated in reference A7.2.2.1/01, the patterns of degradation products show no significant differences between Cypermethrin and Alphacypermethrin. Thus, it is concluded by extrapolation that the established metabolic pathway for Cypermethrin is also valid for Alphacypermethrin.
5.3.1	Reliability	2
5.3.2	Deficiencies	No The studies were conducted according to state-of-the-art methodology available at that time and no deficiencies were reported.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Reference	The Applicant's version is acceptable with the following amendment: AL-620-008
Materials and Methods	The Applicant's version is acceptable with the following amendment: Section 3.1.3 Radiochemical purity : 99,9% Section 3.4 Table A7.2.2.1- 3 : Silt [%] Sandy loam: 6.0 Organic matter [%] Clay: 1.83; Sandy loam: 1,37
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.2.2.1- 3: Characterisation of the test soils.

Origin	Brenes, Spain	Los Palacios, Spain	Leiston, UK
Soil texture	Sandy clay	Clay	Sandy loam
pH	8.0	7.7	6.8
Clay [%]	33.3	65.7	23.5
Sand [%]	53.5	1.9	76.5
Silt [%]	13.2	32.4	6
Organic matter [%]	1.4	1.8	1.4

Table A7.2.2.1- 4: Description of the different test setups and test conditions.

Test design	Description
(i) Degradation under aerobic conditions	Glass jars with loose screw caps, so that volatile products could escape
(ii) Degradation under anaerobic conditions	In conical flasks, treated soil samples were covered with distilled water to a depth of approx. 1 cm, swept out with a stream of nitrogen and the flasks closed with ground glass stoppers; anaerobic conditions were maintained by purging with nitrogen at weekly intervals
(iii) Balance study and CO_2 evolution	Treated Brenes sandy clay soil was placed in a three-necked round-bottomed flask; air was drawn continuously through the system and the traps were sampled at regular intervals for radio-assay; at the end of the study (26 weeks) the soil was also sampled and extracted with acetonitrile:water mixture (7:3 v/v) in order to complete the radioactivity balance
(iv) Comparison of the mineralisation rate of different isomers	Biometer flasks, 250 ml (Figure 2 in the study report) were used, constituting conical flasks with side-arms containing 10% w/v potassium hydroxide in water; Brenes sandy clay soil treated with differently labelled Cypermethrin (as specified in section 3.1 above) was weighed into the flasks; aliquots of the potassium hydroxide solution containing trapped $^{14}CO_2$ were taken for radio-assay at regular intervals; oxygen was gently bubbled in through the side arm at intervals to prevent the soil in the flasks from becoming anaerobic

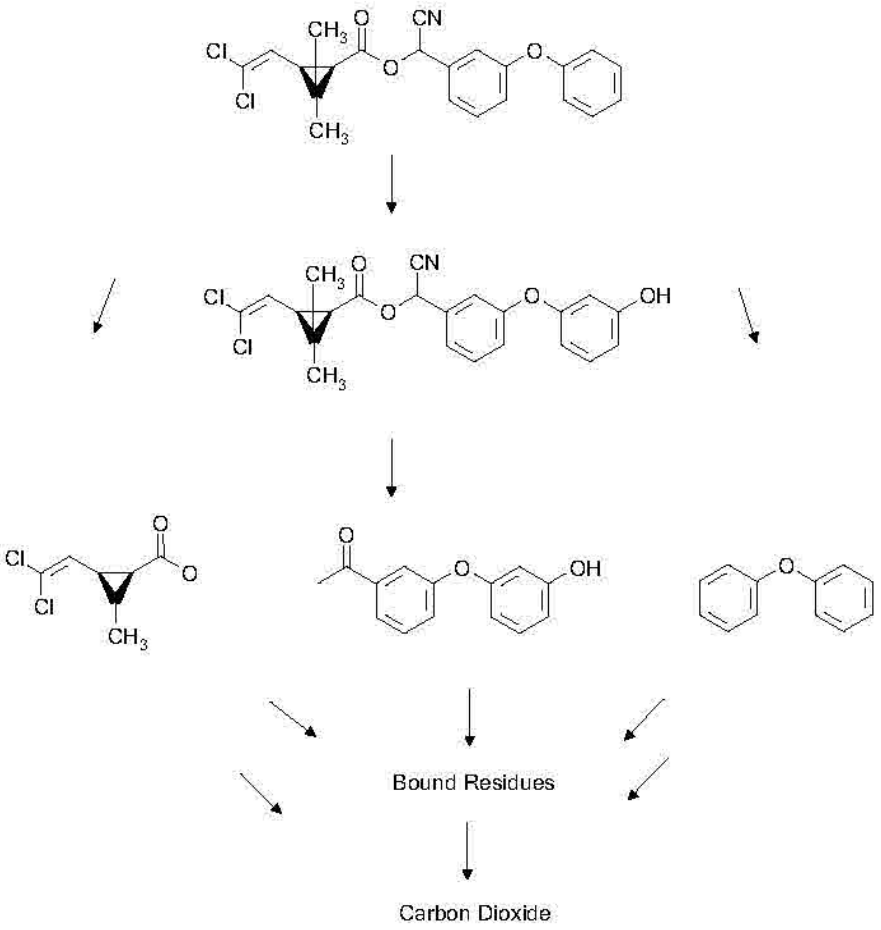

Figure A7.2.2.1- 1: Proposed degradation pathway of Cypermethrin in soil.

Section A7.2.2.1
Annex Points IIIA 7.4
IIIA 12.1.1
and IIIA 12.1.4

The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

– supportive data –

The following reference is considered to contain additional information concerning rate and route of degradation of alphacypermethrin in soil, addressing the half-life of a particular metabolite, and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.2.2.1/05**

Beigel C (2002) Calculation of DT_{50} and DT_{90} values of 3-phenoxybenzoic acid (metabolite of cypermethrin and alphacypermethrin) in two soils treated with cis-cypermethrin. BASF Corporation, Princeton, NJ, USA, Report no. EXA 02-006, February 20, 2002 (unpublished), BASF RDI No.: AL-620-014.

Guidelines: Not Applicable

GLP: Not applicable, study not subject to GLP.

Summary:

The major degradation route in soil of cypermethrin as well as alphacypermethrin involves hydrolysis at the ester linkage leading to the formation of the 3-phenoxybenzoic acid metabolite (also noted as SD 36750, or CL 206128). The first-order DT_{50} and DT_{90} values of cis-cypermethrin and 3-phenoxybenzoic acid metabolite (CL 206128) in two soils from the aerobic soil degradation study presented in A7.2.2.1/02 were calculated. The rates of degradation of the parent material, and of formation and degradation of CL 206128 in the two soils were estimated based on first-order kinetics, using a three-compartment model developed with the software ModelMaker 4.0 to fit the measured data (Figure A7.2.2.1- 2).

The degradation of cis-cypermethrin and formation and degradation of the 3-phenoxybenzoic acid metabolite in the two soils was accurately described by the three-compartment model using first-order kinetics, as suggested by r^2 values of 0.995 to 0.973 for the sandy clay and sandy loam soils, respectively. The type-1 error rate of the rate constant parameter for degradation of cypermethrin to CL 206128 showed a level of confidence above 99% in the two soils, indicating that the rate constant parameter contributed significantly to the fitting of the data, and could therefore be estimated. The type-1 error rate of the rate constant parameter for degradation of CL 206128 also showed a level of confidence above 99% in the Brenes sandy clay soil. The standard deviations are sufficiently low to assure that the estimations are reliable. However, the level of confidence for the rate constant parameter for CL 206128 in the Leiston sandy loam soil was very low, below 40%, indicating that the estimate for this parameter would not be reliable. This resulted from the low levels of 3-phenoxybenzoic acid observed in this soil, and the small number of data points available for the estimation.

The DT_{50} and DT_{90} values calculated from the estimated rate constants are presented in Table A7.2.2.1- 5.

The DT_{50} values were then standardized to the FOCUS reference temperature and moisture conditions of 20°C and pF2 (field capacity) using the correction methods recommended by FOCUS. The standardized first-order DT_{50} values are presented below.

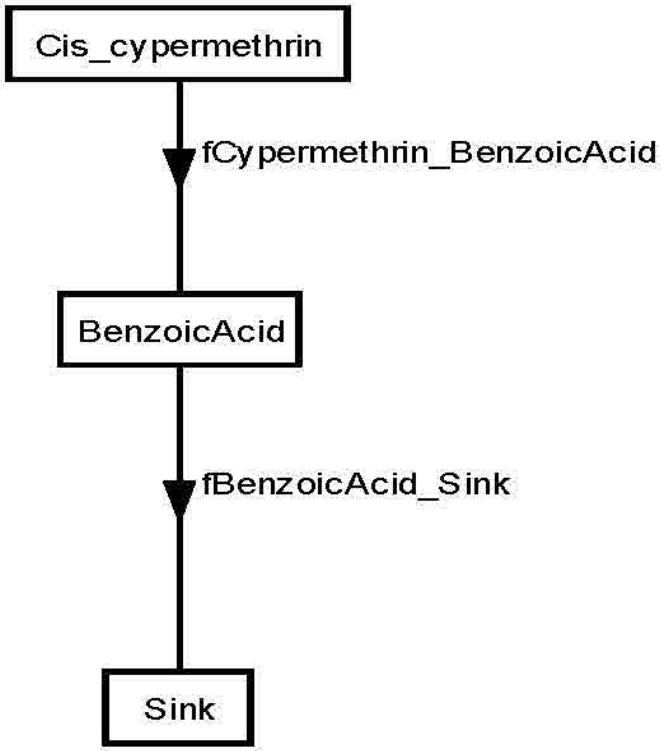

Figure A7.2.2.1- 2: Three-compartment model for description of the degradation of cis-cypermethrin and formation and degradation of the 3-phenoxybenzoic acid metabolite in soil.

Table A7.2.2.1- 5: First-order DT_{50} and DT_{90} values of cis-cypermethrin and 3-phenoxybenzoic acid metabolite in the Brenes and Leiston soils, estimated with ModelMaker 4.0

Soil	Cis-cypermethrin		3-phenoxybenzoic acid		r^2
	DT_{50} [d]	DT_{90} [d]	DT_{50} [d]	DT_{90} [d]	
Brenes sandy clay	30.9	103	2.92	9.70	0.995
Leiston sandy loam	29.0	96.2	0.729*	2.42*	0.973

*) The confidence level of the estimated rate constant of the 3-phenoxybenzoic acid in this soil was below 40%, indicating that the DT values may not be reliable

Table A7.2.2.1- 6: First-order DT_{50} values of cis-cypermethrin and 3-phenoxybenzoic acid metabolite in the Brenes and Leiston soils, estimated with ModelMaker 4.0 and corrected to the FOCUS reference conditions of 20°C and pF2 (field capacity).

Soil	**First-order DT_{50} corrected to 20°C [d]**		**First-order DT_{50} corrected to 20°C and pF2 [d]**	
	Cis-cypermethrin	**3-phenoxybenzoic acid**	**Cis-cypermethrin**	**3-phenoxybenzoic acid**
Brenes sandy clay	44.8	4.23	23.7	2.24
Leiston sandy loam	42.0	1.06*	42.0	1.06*

*The confidence level of the estimated rate constant of the 3-phenoxybenzoic acid in this soil was below 40%, indicating that the DT_{50} value may not be reliable

Section A7.2.2.2 **Field soil dissipation and accumulation**
Annex Point IIIA 12.1.1

Official use only

1 REFERENCE

1.1 Reference

A7.2.2.2/01:

Bosio P (1983) Residues of WL 85871 and metabolites in soil from U.K. treated with FASTAC – 1981/82 trials. Shell Chimie, Berre, France, Report no. BEGR.83.040, May 10, 1983 (unpublished), BASF RDI No.: AL-790-009.

A7.2.2.2/02:

Forbes S, Knight C (1983) Analysis of soil from UK for residues of WL85871 – soil persistence trial – first year. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. SBGR.83.162, March 1983 (unpublished), BASF RDI No.: AL-790-006.

A7.2.2.2/03:

Forbes S, MacKay C (1983) Analysis of soil from UK (Coates) for residues of WL85871 (FASTAC) – soil persistence trial – first year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.83.418, December 1983 (unpublished), BASF RDI No.: AL-790-012.

A7.2.2.2/04:

Forbes S, Burden A (1983) Analysis of soil from UK (Reculver) for residues of WL85871 (FASTAC) – soil persistence trial – second year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.84.005, December 1983 (unpublished), BASF RDI No.: AL-790-007.

A7.2.2.2/05:

Forbes S, Burden A (1983) Analysis of soil from UK (Hoath) for residues of WL85871 (FASTAC) – soil persistence trial – second year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.84.006, December 1983 (unpublished), BASF RDI No.: AL-790-010.

A7.2.2.2/06:

Forbes S, Wales GH (1985) Analysis of soil from UK (Reculver) for residues of FASTAC* (WL85871) – soil persistence trial – third year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.85.070, March 1985 (unpublished), BASF RDI No.: AL-790-008.

A7.2.2.2/07:

Forbes S, Wales GH (1985) Analysis of soil from UK (Coates) for residues of FASTAC* (WL85871) – soil persistence trial – second year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.85.071, February 1985 (unpublished), BASF RDI No.: AL-790-013.

A7.2.2.2/08:

Forbes S, Wales GH (1985) Analysis of soil from UK (Hoath) for residues of FASTAC* (WL85871) – soil persistence trial – third year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.85.072, February 1985 (unpublished), BASF RDI No.: AL-790-011.

Section A7.2.2.2 **Field soil dissipation and accumulation**
Annex Point IIIA 12.1.1

		A7.2.2.2/09: Coveney PC, Forbes S (1986) Analysis of soil from UK (Coates) for residues of "FASTAC" (WL85871) – soil persistence trial – third year. Shell Research Ltd, SRC, Sittingbourne, UK. Report no. SBGR.86.201, September 1986 (unpublished), BASF RDI No.: AL-790-014.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No Standardised guidelines are currently not available.	
2.2	**GLP**	No Studies were conducted prior to implementation of GLP.	
2.3	**Deviations**	Not applicable	
		3 MATERIALS AND METHODS	
3.1	**Test material**	EC formulation of alphacypermethrin	
3.1.1	Lot/Batch number	Not reported	
3.1.2	Specification	EC formulation	
3.1.3	Purity	Not reported	
3.1.4	Further relevant properties	For physical-chemical properties of the active substance, please refer to section A3.	
3.1.5	Method of Analysis	GC-ESD following SAMS 354-1, a former version of SAMS 354-2, which was validated as reported in reference A4.2/01.	X
3.2	**Degradation products**	No	
3.2.1	Method of analysis of degradation products		
3.3	**Reference substance**	No	
3.3.1	Method of analysis of reference substance		

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA 12.1.1

3.4	**Soil types**	Please refer to Table A7.2.2.2- 1.	X
3.5	**Testing procedure**		
3.5.1	Test system	A series of field soil dissipation studies with alphacypermethrin have been conducted in the UK and trials included repeated annual applications for up to three years.	
3.5.2	Test conditions	Field tests Application rate = 0.5 kg a.s./ha using a precision sprayer.	
3.6	**Test performance**	Soil cores of 0–15 cm depth were taken and subjected to analysis. 15–30 cm cores were also taken at time points varying between 2 and 52 weeks post application, depending on the individual trial.	
		4 RESULTS	
4.1	**Field dissipation**	A series of field soil dissipation studies with alphacypermethrin have been conducted in the UK and trials included repeated annual applications for up to three years. The results of these trials are summarised in Table A7.2.2.2- 1.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A series of field soil dissipation studies with alphacypermethrin have been conducted in the UK and trials included repeated annual applications for up to three years.	
5.2	**Results and discussion**	The results as summarised in Table A7.2.2.2- 1 show considerable variability in DT_{50} and DT_{90} values.	
5.3	**Conclusion**	In view of the result from reference A7.2.1/01, yielding a degradation half-life of 21 days for alphacypermethrin, the studies summarised in the current section would not have been necessary. Nevertheless, since they may provide supportive information, they are quoted here for the sake of completeness.	
5.3.1	Reliability	2	
5.3.2	Deficiencies	Yes Reporting of test design and performance is relatively poor. However, these studies are considered to be of supportive character only since the laboratory study presented in section A7.2.1 provided sufficient information	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

EVALUATION BY RAPPORTEUR MEMBER STATE (*)

Date

February 2009

Materials and Methods

The Applicant's version is acceptable with the following amendments:
Section 3.1.5
GC-ECD (instead of GC-ESD)
Section 3.4
Table A7.2.2.2- 1

Soil texture	Reference
Loam	A7.2.2.2/01
Sandy clay	A7.2.2.2/02
Silty loam	A7.2.2.2/03
Sandy clay	A7.2.2.2/04
Loam	A7.2.2.2/05
Sandy clay	A7.2.2.2/06
Silty loam	A7.2.2.2/07
Loam	A7.2.2.2/08
Silty loam	A7.2.2.2/09

Results and discussion

The Applicant's version is considered to be acceptable

Conclusion

The Applicant's version is considered to be acceptable

Reliability

2

Acceptability

Acceptable

Remarks

COMMENTS FROM ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Table A7.2.2.2- 1: Summary of field soil persistence data on alphacypermethrin.

Country	Soil texture	Formulation	Application rate [kg as/ha]	Application date	DT_{50} [d]	DT_{90} [d]	Reference
UK	Loam	EC	0.5	May 1983	<14	35	A7.2.2.2/01
UK	Sandy Loam	EC	0.5	August 1981	35	>280	A7.2.2.2/02
UK	Silty Loam	EC	0.5	June 1982	56	<385	A7.2.2.2/03
UK	Sandy Loam	EC	0.5	August 1982	14–28	163–345	A7.2.2.2/04
UK	Clay Loam	EC	0.5	August 1982	26	<345	A7.2.2.2/05
UK	Sandy Loam	EC	0.5	August 1983	<100	220–364	A7.2.2.2/06
UK	Silty Loam	EC	0.5	June 1983	28–56	224	A7.2.2.2/07
UK	Clay Loam	EC	0.5	August 1983	14	126–220	A7.2.2.2/08
UK	Silty Loam	EC	0.5	June 1984	<112	>350	A7.2.2.2/09

Section A7.2.2.3 **Extent and nature of bound residues**
Annex Point IIIA 12.1.4

Official use only

1 REFERENCE

1.1	**Reference**	**A7.2.2.3/01:** Standen ME (1978) The bioavailability and further degradation of bound residues arising from WL43467 in soils. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. BLGR.0079.78, June 1978 (unpublished), BASF RDI No.: CY-620-004.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2	Companies with letter of access	No
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	No GLP was not compulsory at the time the study was conducted.
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test material**	Cypermethrin, ^{14}C-labelled
3.1.1	Lot/Batch number	Not stated
3.1.2	Specification	Benzyl ring-labelled-^{14}C-Cypermethrin (WL43467) Specific activity = 7.8 µCi/mg For the experiment, the labelled substance was diluted with unlabelled Cypermethrin to give a final specific activity of 5.0 µCi/mg.
3.1.3	Purity	Radiochemical purity = 97.0%
3.1.4	Further relevant properties	If appropriate; give any substance specific properties affecting test performance/applicability of the method (substance stability, boiling point, vapor pressure curve, water solubility).

Section A7.2.2.3 Extent and nature of bound residues

Annex Point IIIA 12.1.4

3.1.5	Method of Analysis	Extraction: with acetonitrile:water (7:3 v/v), filtration; - soil residua further extracted with acetonitrile and diethyl ether concentration to an aqueous residue, then extraction with ethyl acetate or chloroform, dried over anhydrous sodium sulphate. Liquid scintillation counting (LSC): Standard routine using an Intertechnique SL33 counter with custom-made scintillation fluid. Combustion analysis: Unextracted radioactivity was determined by combustion analysis of solid samples in a furnace, followed by LSC as described above. Thin layer chromatography (TLC): Merck silica gel F_{254} plates and various solvent systems; location and quantification of radioactive sites by a thin-layer radio scanner. Radio-gas liquid chromatography: Used after initial separation by TLC and for some methylated degradation products. Gas liquid chromatography (GLC): Used for one methylated degradation product. Methylation: After separation by TLC some compounds, thought to be carboxylic acids, were eluted from the silica gel with methanol or acetone. Methylation of hydroxy compounds separated by TLC was carried out using diazomethane.
3.2	**Degradation products**	Degradation products tested: Yes
3.2.1	Method of analysis of degradation products	$^{14}CO_2$ was trapped from the exhaust air of the biometer flasks by Potassium hydroxide solution and quantified by LSC. Quantification of non-volatile degradation products by TLC, HPLC and LSC as described above. Identification by comparison with reference substances.
3.3	**Reference substance**	Yes Unlabelled reference substances as specified in Table 1 of the study report were used.
3.3.1	Method of analysis of reference substance	See 3.1.5 above.
3.4	**Soil types**	Sandy clay loam, Reculver, UK:

pH	Sand [%]	Clay [%]	Silt [%]	Organic matter [%]
6.7	66	22	12	2.4

Section A7.2.2.3 Extent and nature of bound residues

Annex Point IIIA 12.1.4

3.5	**Testing procedure**	Soil stored under outdoor conditions: Untreated Reculver soil (500g, moisture content 20.4%) was weighed into each of two plastic plant pots (5 inches diameter) containing a bed of small stones to cover the drainage holes, and the soil was lightly tamped. The ([^{14}C-benzyl]-Cypermethrin (5 mg dissolved in 0.8 ml atone) was added evenly to the surface of the soil using a microsyringe. Both pots were placed in an aluminium tray and stored in an outdoor enclosure from May–Oct 1976. No water was given in addition to rainwater. Soil stored in the laboratory: Reculver soil (l00 g) was weighed into a glass jar and [^{14}C-benzyl]-Cypermethrin (1 mg dissolved in 160 µl acetone) was added using a microsyringe. The soil was mixed during the addition of the radiolabel. After treatment the soil jar was closed with a screw cap which was left loose enough to allow any volatile products to escape. The jar was stored at 25°C ± 2°C in the dark until required. The moisture content of the soil was adjusted to its original value at frequent intervals, by the addition of distilled water. Bioavailability of bound residues: Three soil samples from study A7.2.2.1/02, containing bound residues after extraction, were each mixed with fresh untreated sandy clay soil (150g each) and transferred to small pots with drainage hole and a 2 cm layer of gravel. An untreated control was prepared equivalently. Wheat was sown (12 seeds per pot) to each of these samples. The pots were stored in a glasshouse. Further degradation of bound residues: Soil samples from study A7.2.2.1/02, containing bound residues after extraction, were transferred to biometer flasks, moisture adjusted frequently, and evolving CO_2 was trapped in potassium hydroxide solution

4 RESULTS

4.1	**Degradation of the active substance**	In the newly started outdoor and laboratory degradation experiments, unextracted radioactivity amounted to approx. 23–27% of AR. Weathering of the soils in the open did not give lower concentrations of bound residues or lower levels of recovered radioactivity than the soil stored indoors. Less than 0.01% of the applied radioactivity was present in the rainwater contained in the tray, indicating that there had been essentially no leaching of radioactivity from the outdoor soils.
4.2	**Bioavailability**	Radioactivity recovered from the immature wheat amounted to 0.14–0.58% of total. Thus, the bound residues may be considered to be bioavailable to only a limited extent.
4.3	**Mineralisation of bound residues**	Over an 18 week period 21–37% of $^{14}CO_2$ was formed, indicating that further degradation of these 'bound' residues even occur in soils.

Section A7.2.2.3 **Extent and nature of bound residues**
Annex Point IIIA 12.1.4

4.4	**Degradation products**	Only minor amounts of other degradation products were detected. The degradation products were identified as: 3-phenoxybenzoic acid (0.7–1.3%) WL 48394, a hydroxylated Cypermethrin ((1.0–1.5%) α-carboxy-3-phenoxybenzyl-2,2-dimethyl-3-(2',2'-dichlorovinyl)-cyclopropane carboxylate (0–1.5%)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The formation and degradation of bound residues in soil was investigated by (a) additional experiments using soil freshly treated with Cypermethrin, and (b) by submitting soils from previous experiments where bound residues had been formed to further degradation. In addition, the bioavailability of bound residues was investigated by growing wheat on equivalent soils samples as used for experiment (b). Standard radio-analytical techniques were employed.
5.2	**Results and discussion**	The further mineralisation of 'bound' residues was investigated by combining extracted soil containing 'bound' residues arising from [^{14}C] Cypermethrin treatments with fresh soil and monitoring $^{14}CO_2$ formation. Over an 18 week period 21–37% of $^{14}CO_2$ was formed, indicating that further degradation of these 'bound' residues even occur in soils.
5.3	**Conclusion**	
5.3.1	Reliability	2
5.3.2	Deficiencies	Yes The study is relatively poorly documented. However, this is not considered to affect the validity of the results.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
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Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.2.2.4 **Other soil degradation studies**
Annex Point IIIA 12.1.1

Official use only

1 REFERENCE

1.1	**Reference**	**A7.2.2.4/01:** van Dijk A, Burri R (1993) ^{14}C-Alphacypermethrin: study of its photodegradation in soil. RCC Umweltchemie AG, Itingen/BL, Switzerland, Report no. 299777, March 16, 1993, BASF RDI No.: AL-620-010 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes US EPA 540/9-82-021, N, 161-3
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	Benzyl ring-U-^{14}C Alphacypermethrin
3.1.1	Lot/Batch number	S 0819
3.1.2	Specification	Specific activity: 25.6 mCi/g
3.1.3	Purity	Radiochemical purity: 99.8 %
3.1.4	Further relevant properties	Water solubility at 20°C: pH 4 4.59 µg/L pH 7 5.80 µg/L pH 9 7.87 µg/L Distilled water 2.06 µg/L Vapour pressure: 3.4×10^{-7} Pa at 25 °C log P_{ow}: 5.5 ± 0.4

Section A7.2.2.4 Other soil degradation studies

Annex Point IIIA 12.1.1

3.1.5 Method of analysis

TLC, by co-chromatography of standards:
Pre-coated Silica gel 60F254 and RP-18F 254 plates (5 cm * 20 cm * 0.25mm);
Solvent systems used:

Chloroform	(100)
Chloroform/n-hexane	(50+50)
Chloroform/methanol	(90+10)
Chloroform/methanol/formic acid/Water	(75+20+4+2)
Chloroform/methanol/Water	(90+10+1)

UV detection: 254 nm (Standards)

HPLC, by co-chromatography of standards:
Column: Lichrosorb RP18 (25cm * 4.0 mm; 5µm):
Mobile phase A: acetonitrile
Mobile phase B: bidestilled water, pH adjusted to 2.6 with H2SO4
Flow rate: 1mL/min
UV detection: 210 nm (Standards)

Programme I
Isocratic: A+B (1+1, v/v)

Programme II
Gradient: 0-30 min from 0% A to 100% A
30-36 min 100% A
36-50 min 0% A

Programme III
Gradient: 0-20 min from 50% A to 100% A
20-31 min 100% A
31-45 min 0% A

Radioactivity measurement:
Liquid scintillation counting (fluids),
radio-activity monitoring flow cell system (HPLC)
Berthold Auotmatic TLC-Linear Analyser (LB 2842) (TLC)
or combustion (soil)

3.2 Degradation products

Reference	Purity
WL 85871	97.3%
WL 43481	-
WL 42641	-
WL 47133	-
WL 44607	99%
WL 42049	>95%
WL 46114	-%
WL 48489	-%
WL83140	-
Cis-permethrin	-
Trans-permethrin	-
WL 044607	99%

The structures are given in the report, table 1.

Section A7.2.2.4 Other soil degradation studies

Annex Point IIIA 12.1.1

3.2.1	Method of analysis for degradation products	Volatiles were driven out by a stream of air, and were trapped in ethylene glycol (org. volatiles) or in sodium hydroxide ($^{14}CO_2$) and were analysed by LSC for radioactivity. The soil samples were extracted by shaking (30 min) at room temperature with acetonitrile, methanol (1–3 times with 2–3 mL/g soil) and samples of day 8, 16 and 30 additionally with methanol /water (8+2, v/v, 1–2 times). All samples were afterwards extracted with methanol at 70°C (4–5 mL/g soil) under reflux. Residues were air dried and subjected to combustion analysis. Radioactivity in fractions was determined via LSC. The extracts were concentrated under vacuum. Analysis of the fractions was performed with TLC by co-chromatography of standards.	
3.3	**Reference substance**	None	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Soil types**	Sandy silty loam soil, soil characteristics are given in Table A7.2.2.4-1 below.	
3.5	**Properties of light source**	See Table A7.2.2.4-2 for details.	
3.6	**Testing procedure**		
3.6.1	Test substance concentration	4.0 mg [^{14}C]-Alphacypermetrin kg^{-1} dry soil This is equivalent to 30 times the maximum anticipated field application rate of 100 g a.i. ha^{-1}, supposing an uniform distribution in the top 5 cm layer and a specific soil weight of 1.5 g/cm^3.	X
3.6.2	Solvent	Acetone	
3.6.3	Method of application	Treatment solution: 490µL stock solution (401.5 µg [^{14}C]-Alphacypermethrin) in 13.5 mL acetone and 56 mL bi-distilled water. Treatment solution was mixed with 100 g soil, homogenised for 3 minutes and was applied to the surface of 16 clean glass-plates using a TLC-plate coater adjusted to a layer thickness of 1mm. Plates were then dried for 45 min.	
3.6.4	Sampling	Samples were taken and analysed after 0, 2, 4, 8, 16 and 30 days of illumination. Control samples: 2, 4, 8, 17* and 39* days *) Due to technical defect in the illumination system, samples had to be illuminated for additional 9 days to obtain a total of 30 illumination days. Consequently, time points of the dark control changed to 17 and 39 days.	
3.6.5	Number of replicates	1 plate	

Section A7.2.2.4 **Other soil degradation studies**
Annex Point IIIA 12.1.1

3.6.6	Testing conditions	Illuminated samples: 22°C ± 0.1°C (variation: transition period ± 5°C for about 15 min): Exception: day 1, 2 and 9 21.5–23.4°C and day 10 about 25°C; Light/dark cycle: 12hours; Metal chamber, aerobic conditions. Dark control: 22°C ± 3°C; Glass chamber, dark, air conditioned room, aerobic conditions. The chambers with the plates were air ventilated by means of a membrane pump and the outcoming air was trapped. The NaOH trap was exchanged at each time interval and additionally at day 21.	
		4 RESULTS	
4.1	**Degradation rate**	The distribution of recovered radioactivity as percent of the radioactivity recovered on the glass-plate at day 0 is presented in Table A7.2.2.4-3. At the end of the study, residual unchanged alphacypermetrin represented 46.7% (42.9% AR) in the illuminated samples and 80.8% (74.2% AR) in the dark samples of the radioactivity recovered on the glass-plate at day 0.	X
4.2	**Disappearance time**	The degradation of the parent compound can be described by first-order reaction kinetics with the following equations: Illumination: ln Ct = 4.612 – 0.023 t (r = –0.945) Dark: Ln Ct = 4.535 – 0.0036 t (r = –0.995) The DT_{50} for alphacypermethrin in soil samples under illumination conditions was calculated to be 31 days and under dark conditions to be 193 days. The degradation of the parent compound corrected by the soil degradation process can be described by first-order reaction kinetics: Ln Ct = 4.596 – 0.014 t (r = –0.913) The DT_{50} for alphacypermethrin was therefore calculated to be 51 days reflecting exclusively photolysis.	
4.3	**Degradation products**	The major product formed was 3-phenoxybenzoic acid (WL 44607) amounting to 17.9% (16.4%AR). Five other products were present in concentrations below 3% whereas one was identified as 3-phenoxybenzaldehyde (WL 42049). Up to 6.2% (5.7% AR) of $^{14}CO_2$ was formed after 30 days. A proposed degradation pathway is given in Figure A7.2.2.4-1.	

Section A7.2.2.4 **Other soil degradation studies**
Annex Point IIIA 12.1.1

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The photodegradation of [^{14}C-benzyl]-alphacypermethrin on soil surfaces was investigated according to EPA guideline 540/9-82-021, N, 161-3. The application rate was 4.0 mg/kg (corresponding to 30 times the recommended field rate of 100 g ai/ha) and treated soils were exposed to artificial sunlight with a 12 hour light/dark cycle for 30 days. The system used allowed the collection of volatiles.	
5.2	**Results and discussion**	The total recoveries ranged from 86.5 to 91.8 (mean 88.9 ± 2.0) and 82.5 to 91.8% (mean 87.4 ± 3.2) AR for illuminated and dark samples, respectively. Alphacypermethrin degraded on soil under illumination conditions simulating natural sunlight with a half life of 31 days. Taking into consideration the degradation of Alphacypermethrin in the dark, a half life of 51 days for photolysis could be calculated. TLC-analyses of the extracted radioactivity from illuminated soil plates showed mainly parent compound at all time intervals. With increasing illumination time, at least five radioactive fractions were detected. At illumination day 30, the major radioactive fraction (3-phenoxybenzoic acid) amounted to 17.9% (16.4% AR). The other radioactive fractions amounted to less than 3%, nevertheless one of these fractions could be characterised as 3-phenoxybenzaldehyde. In the dark control besides the parent compound three common radioactive fractions were detected in minor amounts (< 3%), one was characterised as 3-phenoxybenzoic acid. The non-extractable radioactivity increased to about 13.3% (12.2% AR) in the illuminated samples at the termination of the study compared to 0% in the dark control. Taking into account the specific occurrence of ^{14}C-CO_2 and the significant higher amounts of non-extractables in the illuminated samples compared to the dark controls, it can be concluded that Alphacypermethrin was degraded within 30 days to 3-phenoxybenzoic acid (WL 44607) and 3-phenoxybenzaldehyde (WL 42049) as well as mineralised by the process of photolysis.	X
5.3	**Conclusion**	It can be concluded that the rate of degradation of alphacypermethrin on soil surfaces is increased by artificial sunlight. The products formed by photochemical degradation were similar to those resulting from microbial and chemical degradation.	
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	April 2012
Materials and Methods	The Applicant's version is considered to be acceptable.
Results and discussion	The Applicant's version is considered to be acceptable with the following amendments: Section 4.1 Table A7.2.2.4-3 Non-extractable (combustion) at day 30 : 2.0 % (instead of 0.0)
Conclusion	The Applicant's version is considered to be acceptable with the following amendment: Section 5.2 Alphacypermethrin was degraded within 50 days (instead of 30 days)
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.2.2.4- 1: Soil used to investigate the rate of photodegradation.

Soil type	**Speyer F3**	
Classification	Sandy silty loam (according to BBA)	
Source	LUFA Speyer /germany	
Soil history	Upper 20 cm layer The soil has not been subjected to any pesticide, organic or inorganic fertilizer treatment for the last 2 years.	
Particle size distribution [%]:	ISSS	USDA
Sand	70.1	39.8
Silt	14.7	45.0
Clay	15.2	15.2
Organic C [%]	1.2	
CEC [meq/100g]	13.0	
pH	7.3	
MWC [%]	45.7	
40% MCW [g H_2O/100g dry soil]	18.3	

CEC cation exchange capacity
MWC maximum water holding capacity
FC field capacity

Table A7.2.2.4- 2: Description of test system.

Criteria	**Details**
Laboratory equipment	Glass plates: 5 cm × 10 cm Metal chamber on the inside dull-black coated (size 20 cm × 30 cm) covered with a quartz plate Water bath for cooling the metal chamber Membrane pump CO_2-trap containing (sodium hydroxide) Ethylene glycol trap for org. volatiles
Test apparatus	Original HANAU Suntest CPS
Properties of artificial light source:	
Nature of light source	Xenon lamp 1.1 kWh
Emission wavelength spectrum	300–800 nm
Light intensity	400 W/m² to max. 765 W/m² Measured by means of a Lux-meter: 97KLux
Filters	Special UV-filter simulating sunlight outdoors (UV-edge 290 nm)

Table A7.2.2.4- 3: Distribution of radioactivity after application of [^{14}C]-Alphacypermethrin to soil and exposure to artificial sunlight or incubation in the dark.

Light exposure	**Sampling interval (days)**											
	0		**2**		**4**		**8**		**16****		**30*****	
EXTRACTED	I	II	I	II	I	II	I	II	I	II	I	II
Room temperature												
Acetonitrile	75.2	81.9	59.9	65.3	55	59.9	51	55.6	47	51.2	22.9	24.9
Methanol	14.4	15.7	24.7	26.9	26.2	28.5	24.9	27.1	23.9	26.1	21.8	23.8
Methanol/water (8+2, v/v)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	5.6	6.1	6.7	7.3	21.5	23.4
Reflux at 70°C												
Methanol	1.1	1.2	2.3	2.5	3.2	3.5	3.2	3.5	2.4	2.6	3.2	3.5
Subtotal	90.7	98.8	86.9	94.7	84.4	91.9	84.7	92.3	80	87.2	69.4	75.6
Non-extractable (combustion)	1.1	1.2	3.2	3.5	4.1	4.5	2.4	2.6	4.2	4.6	12.2	13.3
^{14}C-CO_2 (NaOH trapped)	n.d.	n.d.	0.3	0.3	0.6	0.7	1.3	1.4	2.2	2.4	5.7	6.2
Ethylene glycol trapped	n.d.	n.d.	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
Total	91.8	100.0	90.4	98.5	89.1	97.1	88.4	96.3	86.5	94.2	87.3	95.1
Mean (total)			I: 88.9 ± 2.0						II: 96.2 ± 1.7			
Incubation in the dark												
Room temperature												
Acetonitrile	75.2	81.9	53.6	58.4	57.9	63.1	48.1	52.4	49.4	53.8	48.9	53.3
Methanol	14.4	15.7	26.4	28.8	26.1	28.4	31.2	34.0	28.9	31.5	26.3	28.6
Methanol/water (8+2, v/v)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	3.8	4.1	4.0	4.4	4.1	4.5
Reflux at 70°C												
Methanol	1.1	1.2	3.3	3.6	2.9	3.2	2.9	3.2	2.4	2.6	1.3	1.4
Subtotal	90.7	98.8	83.4	90.8	86.9	94.7	86	93.7	84.7	92.3	80.6	87.8
Non-extractable (combustion)	1.1	1.2	3.6	3.9	2.8	3.0	1.2	1.3	1.2	1.3	0.0	0.0
^{14}C-CO_2 (NaOH trapped)	n.d.	n.d.	0.09	0.1	0.09	0.1	0.09	0.1	0.09	0.1	0.09	0.1
Ethylene glycol trapped	n.d.	n.d.	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05
Total	91.8	100.0	87	94.8	89.8	97.8	87.3	95.1	86	93.7	82.5	89.9
Mean (total)			I: 87.4 ± 3.2						II: 94.3 ± 2.9			

* : not further analysed

** : Including one day dark between illumination days 8 and 16.

*** : Including one day dark between illumination days 8 and 16, and 8 days dark between illumination days 16 and 30.

n.d. = not determined

I : percentage of applied radioactivity, calculated for the preparation of this dossier, not given in the report

II : percentage of the radioactivity recovered on the glass-plate at day 0.

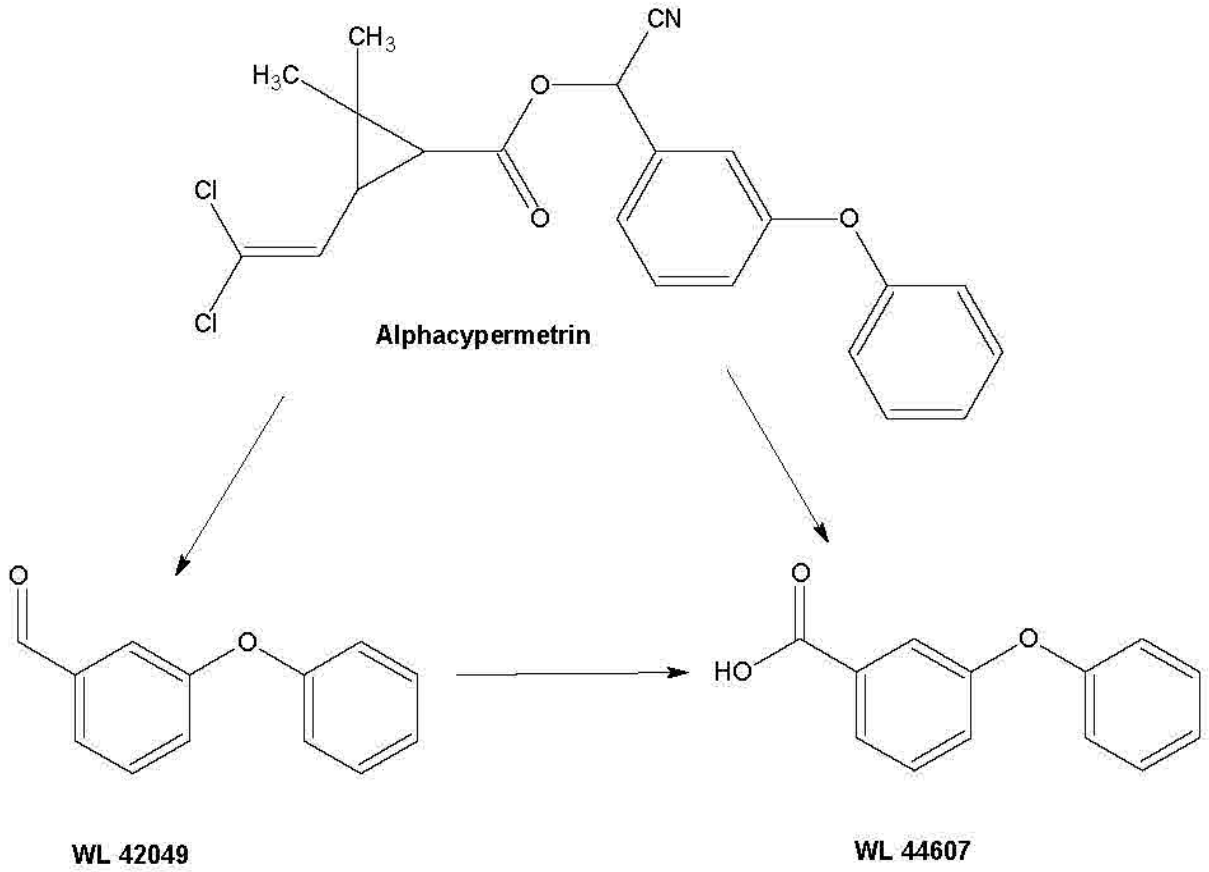

Figure A7.2.2.4- 1: Proposed photodegradation pathway for Alphacypermethrin in soil.

Section A7.2.3.1 Adsorption and desorption

Annex Point IIIA 12.1.2

Official use only

1 REFERENCE

1.1	**Reference**	**A7.2.3.1/01:** Hill A (1993) [Benzyl-^{14}C] WL85871 (FASTAC): Adsorption/ desorption in three soils. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. SBTR.93.042, October 12, 1993 (unpublished), BASF RDI No.: AL-620-011.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD 106 (1981)
2.2	**GLP**	Yes
2.3	**Deviations**	Yes A control sample with only 0.01 M $CaCl_2$ solution and without test item was not examined.

3 MATERIALS AND METHODS

3.1	**Test material**	Radio-labelled Alphacypermethrin (FASTAC), benzyl-^{14}C
3.1.1	Lot/Batch number	1288/1
3.1.2	Specification	Benzyl-^{14}C labelled
3.1.3	Purity	Radiochemical purity: 98.8%
3.1.4	Further relevant properties	Specific radioactivity: 191.7 µCi/mg Water solubility at approx. 23°C was approx. 2.0 µg/L

Section A7.2.3.1 Adsorption and desorption

Annex Point IIIA 12.1.2

3.1.5	Method of Analysis	Solutions were radio-assayed by LSC using Packard 2200 CA liquid scintillation counters and Packard polyethylene anti-static vials. In the preliminary tests, solutions were counted by LKB 'Optiphase' scintillation fluid. Throughout the adsorption/desorption tests Packard Ultima Gold XR was used. Furthermore, solutions were analysed by TLC using Merck 5715, F254 0.25 mm thin layer plates and the elution systems (i) toluene/ether/acetic acid (75:25:1, v/v) and (ii) acetone/hexane (1:4, v/v). Localisation and quantitation was carried out using a RITA-90 linear analyser. In order to determine the radiochemical purity and the stability of [^{14}C]-alphacypermethrin HPLC analysis was performed using Beckman System Gold with a reverse phase column and a flow-through UV detector and radio-detectors. Gradient elution using water and acetonitrile.	
3.2	**Degradation products**	Degradation products tested: Yes	
3.2.1	Method of analysis of degradation products	By TLC (for details see above).	
3.3	**Reference substance**	No	
3.3.1	Method of analysis of reference substance	Not applicable	
3.4	**Soil types**	See Table A7.2.3.1- 1.	
3.5	**Testing procedure**		
3.5.1	Test system	For details please refer to 3.6.1 and 3.6.2 below.	
3.5.2	Test solution and test conditions	0.25, 0.75, 1.0 and 4.0 µg of [^{14}C]-alphacypermethrin dissolved in acetone were mixed in 1 litre 0.01 M calcium chloride solution. The soil/solution ratio was set to 1:100.	X

Section A7.2.3.1 Adsorption and desorption

Annex Point IIIA 12.1.2

3.6 Test performance

3.6.1 Preliminary test

According to "OECD 106": Yes

Solubility:

Test 1: Solutions of 0.5 and 5.0 µg alphacypermethrin/litre were injected in four volumetric flasks, from which two had previously been silanised with a solution of dimethyldichlorosilane in chloroform (5%, v/v), drained and dried overnight at 210°C. For a time period of 12 days solutions were maintained at approx. 23 °C and periodically shaken and subsequently analysed by LSC.

Test 2: Aliquots of the 5.0 µg/l solution from Test 1 were taken from unsilanised flasks and added to two 30 ml glass centrifuge tubes and two 25 ml Beckman polycarbonate centrifuge tubes. Following incubation at approx. 23 °C for 6 days including periodic shaking and analysis by LSC, samples were centrifuged at 2600 rpm at the end and radio-assayed.

Test 3: Aliquots of the 5.0 µg/l solution from Test 1 were taken from unsilanised flasks and added to two 30 ml 'COREX' glass centrifuge tubes. After centrifugation at 8000 rpm samples were radio-assayed. Test 3 was repeated using 150 ml 'COREX' glass vessels and centrifuged at 5000 rpm.

Adsorption to test vessels:

Information on adsorption to vessel walls was derived from Test 2 and the step to determine the equilibration time.

Volatilisation from soil during drying process:

Dry Godstone sand and Woodstock clay soils were weighed into four 30 ml glass centrifuge tubes and an aliquot of the 5.0 µg/l solution from Test 1 was added to each soil. Samples were placed in a vacuum oven maintained at ambient temperature for 3 days. An acetonitrile/water solution (5ml, 70:30, v/v) was added to each tube, which was tumbled for 30 minutes, before being centrifuged. The supernatants were then radio-assayed.

Determination of the equilibrium time:

Moist Godstone sand soil (0.311 g) was filled into each of 10 x 30 ml stoppered glass tubes and 25 ml aliquots of the 5.0 µg/l solution from Test 1 were added so that the soil/solution ratio was set to 1:100. Two blanks without soil were incubated. After mixing at approx. 23 °C at time intervals of 2, 4, 8, 24 and 48 hours a pair was centrifuged and radio-assayed. The equilibrium time was reached after 2 hours but for convenience for working was taken as 22 hours.

Stability of [^{14}C]-alphacypermethrin:

Soil plugs from the determination of the equilibrium time were dried for 3 days at room temperature in a vacuum oven. After extraction with acetone and tumbling for 40 minutes, samples were centrifuged and supernatants were radio-assayed. The extracts from the 24 and 48 hour tubes were combined and analysed by two radio-TLC solvent systems and also by radio-HPLC.

Section A7.2.3.1 **Adsorption and desorption**
Annex Point IIIA 12.1.2

3.6.2	Screening test: Adsorption	According to (a)"OECD 106": Yes Soil adsorption: Following shaking and centrifugation of the four test solutions of [^{14}C]-alphacypermethrin, aliquots of 20 ml were pipetted into glass stoppered tubes filled with equivalents of 20 g dry soil. After approx. 22 hours of mixing samples were centrifuged and the supernatant (5 mL) was radio-assayed by LSC. The remainder of the supernatant was transferred into measuring cylinders, leaving about 0.5–1.0 ml in contact with soil. The supernatants were analysed by TLC. Glass adsorption: The same procedure as described above, except for omitting the desorption steps. Instead, soil plugs were dried in a vacuum oven at ambient temperatures. After transfer to graduated centrifuge tubes, samples were extracted with water/acetonitrile (5 ml, 30:70, v/v). The aqueous extracts were radio-assayed. The blank tubes (without soil samples) were shaken with acetone and aliquots were radio-assayed.	X
3.6.3	Screening test: Desorption	According to (a)"OECD 106": Performed Soil desorption: Calcium chloride solution (20 ml, 0.01 M) was added to the soil plugs, followed by mixing for 22 hours. Afterwards samples were treated as described for adsorption under 3.6.2 above. A 2nd desorption step was performed and the wet soils were then dried before being extracted with acetonitrile/water (70:30 v/v) and radio-assayed.	
3.6.4	HPLC-method	No	
3.6.5	Other tests	No	

4 RESULTS

4.1	**Preliminary test**	See Table A7.2.3.1- 2 to Table A7.2.3.1- 5.	
4.2	**Screening test: Adsorption**	See Table A7.2.3.1- 6.	
4.3	**Screening test: Desorption**	See Table A7.2.3.1- 8.	
4.4	**Calculations**		
4.4.1	Ka, Kd	Mean adsorption coefficients were 821 ml/g in Woodstock silty clay, 1042 ml/g in Elm Farm sandy loam and 868 ml/g in Godstone sand soil as presented in Table A7.2.3.1- 7. Desorption coefficients were not determined.	
4.4.2	Ka_{OC}, Kd_{OC}	Mean adsorption coefficients were 26 492 ml/g in Woodstock silty clay, 57 889 ml/g in Elm Farm sandy loam and 144 652 ml/g as presented in Table A7.2.3.1- 7. Desorption coefficients were not determined.	
4.5	**Degradation products**	Degradation products occurred but were not further described.	

Section A7.2.3.1 **Adsorption and desorption**
Annex Point IIIA 12.1.2

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Soil adsorption coefficients of alphacypermethrin were determined according to OECD 106 (1981).

No control sample with only 0.01 M $CaCl_2$ solution and without test item was examined.

5.2 Results and discussion

The tests of solubility of [^{14}C]-alphacypermethrin revealed that at least part of the test material was present as suspension and that silanisation increased the amount adsorbed to vessel surfaces (see Table A7.2.3.1- 2). Adsorption of [^{14}C]-alphacypermethrin to polycarbonate centrifuge tubes was far greater compared to unsilanised glass tubes (see Table A7.2.3.1- 3). The 2 day samples before and after shaking confirmed that much of the test item was suspended. The centrifugation of the glass tube samples led to approx. 20% decrease of [^{14}C]-alphacypermethrin in water after 6 days. Centrifugation at higher speed was intended to result in removal of any suspended material, leaving a predominance of dissolved [^{14}C]-alphacypermethrin (see Table A7.2.3.1- 4).

Volatilisation did not occur as outlined by recoveries of [^{14}C]-alphacypermethrin of 104 and 105% in Woodstock silty clay and 102 and 99% in Godstone sand soil.

The equilibrium was attained after approx. 2 hours. After 48 hours very little additional [^{14}C]-alphacypermethrin was adsorbed from solution (see Table A7.2.3.1- 5). Alphacypermethrin showed no tendency to degrade (99% purity) during 48 hours contact with soil and calcium chloride. Adsorption to glass vessels showed great reduction (approx. 10%) when soil was present.

The mean recoveries of the soil adsorption/desorption and the glass adsorption steps were 104 and 96.4% of AR across all concentration levels and soils. X

The percentage amounts of [^{14}C]-alphacypermethrin adsorbed to soil are far greater for the lower test concentrations compared to the highest concentration (see Table A7.2.3.1- 6). Similar results were obtained for the glass adsorption step. This effect is unlikely to be explained by saturation of the organic carbon binding sites, in view of approximate ratios of organic C to [^{14}C]-alphacypermethrin of 15 000:1 to 1.24×10^6:1.

The detection of degradation products in the adsorption supernatants was attributed to the fact that samples were left unrefrigerated for several days prior to analysis.

Adsorption coefficients as outlined below (see Table A7.2.3.1- 7) indicate strong adsorption of [^{14}C]-alphacypermethrin to soil. Freundlich exponents were 1.75 (Woodstock silty clay), 2.03 (Elm Farm sandy loam) and 2.09 (Godstone sand) suggesting a non-linear adsorption behaviour.

Desorption steps resulted in less than 5% of [^{14}C]- alphacypermethrin being released from soil or vessel surface (see Table A7.2.3.1- 8).

5.2.1 Adsorbed a.s. [%] –

Section A7.2.3.1 Adsorption and desorption

Annex Point IIIA 12.1.2

5.2.2	K_a	Woodstock silty clay: Elm Farm sandy loam Godstone sand soil: (Mean values)	821 ml/g 1042 ml/g 868 ml/g
5.2.3	K_d	Not determined	
5.2.4	$K_{a,OC}$	Woodstock silty clay: Elm Farm sandy loam: Godstone sand soil: (Mean values)	26492 ml/g 57889 ml/g 144652 ml/g
5.2.5	K_a/K_d	Not applicable	
5.2.6	Degradation products (% of a.s.)	No degradation of the test item occurred.	
5.3	**Conclusion**	The study was performed in full compliance with OECD guideline 106 (1981) and is therefore considered to be valid without restrictions. The strong adsorption of [^{14}C]-alphacypermethrin to soil with mean K_{OC} values ranging from 26 492 to 144 652 ml/g, indicated an immobile behaviour according to the SSLRC mobility classification (K_{OC} > 4000 ml/g).	
5.3.1	Reliability	1	
5.3.2	Deficiencies	Apart from the minor deviations mentioned above: 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	April 2012
Materials and Methods	The Applicant's version is acceptable with the following amendments: Section 3.5.2 Four concentrations are tested instead of 5 recommended in OECD 106 Section 3.6.2 0,20 g of dry soil (instead of 20 g)
Results and discussion	
Conclusion	The Applicant's version is acceptable with the following amendments: Section 5.2 Table A7.2.3.1-6 See numbers underlined in the table A7.2.3.1-6 BE CA corrections: ng/g 0.02 0.400 7.50
Reliability	1
Acceptability	Acceptable
Remarks	BE CA considers the deviations as of minor importance and not affecting the scientific relevance of the test.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.2.3.1- 1: Classification and physico-chemical properties of soils used as adsorbents.

	Godstone	Elm Farm	Woodstock
Soil order	n.s.	n.s.	n.s.
Soil series	n.s.	n.s.	n.s.
Classification	Sand	Sandy loam	Silty clay
Location	n.s.	n.s.	n.s.
Horizon	n.s.	n.s.	n.s.
Sand [%]	91	58	18
Silt [%]	5	27	46
Clay [%]	4	15	36
Organic carbon [%]	0.6	1.8	3.1
Carbonate as $CaCO_3$	n.s.	n.s.	n.s.
insoluble carbonates [%]	n.s.	n.s.	n.s.
pH (1:1 H_2O)	6.7	7.1	6.8
Cation exchange capacity (MEQ/100 g)	1.0	10.9	25.7
Extractable cations (MEQ/100 g)	n.s.	n.s.	n.s.
Ca	n.s.	n.s.	n.s.
Mg	n.s.	n.s.	n.s.
Na	n.s.	n.s.	n.s.
K	n.s.	n.s.	n.s.
H	n.s.	n.s.	n.s.
Special chemical/mineralogical features	n.s.	n.s.	n.s.
Clay fraction mineralogy	n.s.	n.s.	n.s.

Table A7.2.3.1- 2: Results of preliminary test to determine solubility (Test 1).

Sample	Concentration [µg/l]	Days after treatment					
		0	0.2	4	5	8	12
Non silanised	0.5	0.57	0.50	0.43	0.44	0.43	0.41
Silanised	0.5	0.36	0.29	0.23	0.22	0.20	0.22
Non silanised	5.0	5.86	5.42	4.04	4.03	3.91	3.85
Silanised	5.0	5.12	3.84	1.09	1.04	1.07	1.10

Table A7.2.3.1- 3: Results of preliminary test to determine solubility (Test 2).

Sample	Concentration [µg/l]	Concentration after 2 days [µg/l]	
		Before shake	After shake
Glass tube 1	5.0	1.82	3.22
Glass tube 2	5.0	1.71	2.97
Polycarbonate tube 1	5.0	0.27	0.19
Polycarbonate tube 2	5.0	0.24	0.20

Table A7.2.3.1- 4: Results of preliminary test to determine solubility (Test 3).

Sample	Concentration [µg/l]	Concentration [µg/l]	
		Before centrifugation	After centrifugation
Replicate 1	5.0	3.85	2.04
Replicate 2	5.0	3.85	2.08

Table A7.2.3.1- 5: Results of preliminary test for determination of the equilibration time.

Sample no.	Time [h]	Radioactivity recovered [%]				Recovery [% of AR]
		Supernatant	Soil	Vessel walls	Total	
1	2	4.4	85.8	9.8	100	97
2	2	4.8	88.9	6.3	100	
3	4	5.0	83.8	11.2	100	101
4	4	5.2	89.7	5.1	100	
5	8	4.4	90.1	5.5	100	103
6	8	4.9	83.7	11.4	100	
7	24	4.4	89.6	6.0	100	102
8	24	4.5	87.7	7.8	100	
9	48	7.8	86.2	6.0	100	100
10	48	5.0	92.0	3.0	100	

Table A7.2.3.1- 6: Results of screening test – adsorption.

	Godstone				Elm Farm				Woodstock			
Concentration of test material [ng/40ml]	3.38	8.46	14.66	59.50	3.38	8.46	14.66	59.50	3.38	8.46	14.66	59.50
After contact of 22 hours with soil	–	–	–	–	–	–	–	–	–	–	–	–
Correction for blank with soil	–	–	–	–	–	–	–	–	–	–	–	–
Correction for blank without soil	0.17	0.28	1.07	1.43	0.08	0.24	0.36	0.75	0.04	0.12	0.32	0.51
Final corrected concentration [ng/40ml]	3.21	8.18	13.59	58.07	3.3	8.22	14.3	58.75	3.34	8.34	14.34	58.99
Initial concentration of test solution [mg/l]	–	–	–	–	–	–	–	–	–	–	–	–
Decrease in concentration [mg/l]	–	–	–	–	–	–	–	–	–	–	–	–
Quantity adsorbed [µg]	2.99	7.62	11.92	31.45	3.11	7.74	12.92	33.49	3.00	7.82	12.83	35.51
Quantity of soil [g of oven-dried equivalent]	0.393	0.409	0.400	0.403	0.411	0.403	0.395	0.398	.0400	0.401	0.405	0.403
Quantity adsorbed [µg] per gram of soil	7.61	18.63	29.80	78.04	7.57	19.21	32.71	84.15	75.00	19.50	31.68	88.11
Test material adsorbed [%]	93.1	93.2	87.7	54.2	94.2	94.2	90.3	57.0	89.8	93.8	89.5	60.2
Temperature [°C]	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Volume of solution recovered after centrifugation [ml]	19.5	19.75	19.5	19.25	19.5	19.5	19.5	19.5	19.25	19.5	19.75	19.25
Volume of solution not recovered [ml]	0.5	0.25	0.5	0.75	0.5	0.5	0.5	0.5	0.75	0.5	0.25	0.75
Corresponding quantity of test substance [ng]	0.0845	0.1058	0.3665	2.2313	0.0845	0.2115	0.3665	1.4875	0.1268	0.2115	0.1833	2.2313

Table A7.2.3.1- 7: Adsorption coefficients.

Soil	Soil type	Nominal concentration [µg a.i./L]	K_a [ml/g]		K_{OC} [ml/g]		Freundlich exponent [1/n]
Woodstock	Silty clay	0.25	849		27396		
		0.75	1463	Mean = 821	47180	Mean = 26492	1.7473
		1.0	829		26732		
		4.0	144		4661		
Elm Farm	Sandy loam	0.25	1553		86289		
		0.75	1560	Mean = 1042	86694	Mean = 57889	2.0295
		1.0	924		51354		
		4.0	130		7218		
Godstone	Sand	0.25	1349		224786		
		0.75	1314	Mean = 868	219023	Mean = 144652	2.0877
		1.0	696		115988		
		4.0	113		18811		

Table A7.2.3.1- 8: Results of screening test – desorption.

Soil	Godstone				Elm Farm				Woodstock			
Sample	**0.2**	**0.5**	**1.0**	**2.0**	**0.2**	**0.5**	**1.0**	**2.0**	**0.2**	**0.5**	**1.0**	**2.0**
Temperature [°C][a]	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Concentration in combined washings [mg/l]	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.
Quantity of test material adsorbed to glass and soil [ng]	2.69	7.87	8.73	26.96	3.16	7.72	9.15	28.84	1.65[b]	8.53	9.67[c]	29.47
Quantity desorbed after step 1 [ng]	<LD	0.27	0.55	1.87	<LD	0.24	0.45	2.00	<LD	0.19	0.45[c]	2.29
Quantity desorbed after step 2 [ng]	<LD	0.16	0.36	1.02	<LD	0.16	0.26	0.91	<LD	0.14	0.28[c]	0.90
% adsorbed test material, which is desorbed after step 1	–	3.33	3.64	2.97	–	2.55	2.93	3.23	–	2.16	3.08	3.76
% adsorbed test material, which is desorbed after step 2	–	1.97	2.39	1.62	–	1.70	1.69	1.47	–	1.59	1.94	1.48
% adsorbed test material, which is not desorbed	–	94.7	93.97	95.41	–	95.75	95.38	95.3	–	96.25	94.98	94.76

a) ambient temperature

b) sample discarded due to suspected cross contamination, therefore represents 2x amount in solution at start

c) values were halved owing to an accidental double dose

Section A7.2.3.1 Adsorption and desorption

Annex Point IIIA 12.1.2 **– supportive data –**

The following reference is considered to contain additional information concerning the mobility of alphacypermethrin in soil, addressing the adsorption and desorption of a particular metabolite. The metabolite in question, 3-phenoxybenzoic acid, however, accounted for a maximum of 5.44% of the parent compound in the soil degradation study (A7.2.1/01) and is therefore formally not necessary. In view of the expected low exposure of soil to alphacypermethrin from its use in PT 18, an adsorption/desorption study is likewise not required for risk assessment. However, for the sake of completeness, the results of this study are presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.2.3.1/02**

Holman JC (2002) ^{14}C-CL 206128 (Metabolite of BAS 310 I, alphacypermethrin): adsorption/desorption on soils. BASF Agro Research, Princeton, NJ, USA, Report no. 67694, March 28, 2002 (unpublished), BASF RDI No.: AL-620-015.

Guidelines: OECD Guideline for Testing of Chemicals No. 106, Adsorption/Desorption

GLP: Yes (This laboratory was inspected by United States Environmental Protection Agency (US EPA) Office of Enforcement and Compliance Assurance)

Test system:

The test substance used in this study was [3-Phenoxy ring-U-^{14}C-] CL 206128 (chemical purity: 101.6%, radiopurity: 99.6%, specific activity: 101.2 µCi/mg). The adsorption was determined on four German soils. The properties of the soils are shown in A7.2.3.1-9.

Table A7.2.3.1-9: Characteristics of the German soils used in sorption study with 3-phenoxy-[ring-U-^{14}C] CL 206128.

Source	Engelstadt/ Benz, Germany	Ingelheim/ Moers, Germany	Schwabenheim, Germany	Speyer, Germany
Soil Type	Silty loam	Sandy loam	Silty loam	Loamy sand
% Sand	13	43	13	82
% Silt	61	35	68	13
% Clay	26	22	19	5
% O.C.	2.27	1.33	1.09	2.29
pH	7.4	7.6	5.9	5.9
C.E.C. [meq/100 g]	17	15	9.0	9.7
MWHC	47.5	37.1	36.0	44.3
Water holding capacity at 0 bar	47.5	37.1	36.0	44.3

The soils were passed through a 2 mm sieve before use. Preliminary screening tests were performed to determine the soil/water ratio to be used and the time to reach equilibrium. For the definitive portion of the study solutions were prepared at measured concentrations of 5.0, 1.0, 0.5, 0.1, and 0.05 µg/ml, in 0.01 M calcium chloride. A 5 g soil sample was shaken at 20 ± 1°C with 5 mL of each of the five concentrations of test substance for 48 hours to reach equilibrium. After separation of the water from the soil via centrifugation, the aqueous solution was assayed by liquid scintillation counting.

A desorption step was performed in which a 5 mL of fresh 0.01 M $CaCl_2$ was added back to each test sample tube and the mixture was shaken for 66 hours. The samples were treated the same as during the adsorption. The

samples were extracted twice with 5 ml of acetonitrile and the soil marc was combusted to determine mass balance.

Findings:

The average soil distribution coefficients for adsorption, Kd_{ads}, the Freundlich adsorption coefficients, Kf and 1/n, the adsorption coefficient normalized for organic carbon, Kf_{OC} and the desorption coefficient, Kd_{des}, were determined for each of the four soils, and are listed in Table A7.2.3.1-10.

Table A7.2.3.1-10: Sorption of 3-phenoxy [ring-U-^{14}C] CL 206128 in four German soils.

Soil	Kd_{ads}	Kf_{ads}	Kf_{OC}	1/n	r^2	Kd_{des}
German silty loam soil	1.73	1.01	44	0.756	0.9964	5.07
German sandy loam soil	1.31	0.90	67	0.817	0.9960	4.66
German silty loam soil	1.93	0.95	81	0.704	0.9976	4.50
German loamy sand soil	2.93	2.08	91	0.861	0.9995	3.39

Conclusion:

The adsorption Kf_{OC} values of CL 206128 were in the range of 44 to 91 L kg^{-1}. The corresponding 1/n values ranged from 0.704 to 0.861, showing high non-linearity of the sorption process, with higher sorption at low concentrations. These results indicate moderate adsorption of ^{14}C-CL 206128 on the four German soils tested.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

EVALUATION BY RAPPORTEUR MEMBER STATE (*)

Date

February 2009

Materials and Methods

The Applicant's version is considered to be acceptable

Results and discussion

The Applicant's version is acceptable with the following amendments:

Table A7.2.3.1-10: Sorption of 3-phenoxy [ring-U-^{14}C] CL 206128 in four German soils.

Soil	Kd_{ads}	Kf_{ads}	Kf_{oc}	1/n	r^2	Kd_{des}
Engelstadt/Benz (Silty loam)	1.82	1.04	46	0.747	0.9976	5.37
Ingelheim/ Moers (Sandy loam)	1.31	0.90	67	0.817	0.9960	4.66
Schwabenheim (Silty loam)	1.93	0.95	87	0.704	0.9976	4.50
Speyer (Loamy sand)	2.93	2.08	91	0.861	0.9995	3.39

Conclusion

The Applicant's version is considered to be acceptable

Reliability

2

Acceptability

Acceptable

Remarks

COMMENTS FROM ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section A7.2.3.2 Mobility

Annex Point IIIA 12.1.3 – supportive data –

By way of read-across from Cypermethrin, the following references are considered to contain additional information concerning the mobility of alphacypermethrin in soil: Although the fulfilment of this data requirement is not required since (i) the lower-tier studies presented in previous sections provide sufficient information and (ii) according to model calculations (EUSES, see Doc. II) contamination of groundwater is not expected, the available references from the PPP dossier are also submitted for the sake of completeness and are presented as a joint summary in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.2.3.2/01**

Jackson C (1977) The leaching of WL 43467 through laboratory soil columns. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. BLGR.0150.77, December 1977 (unpublished), BASF RDI No.: CY-620-002.

Guidelines: Non-guideline study

GLP: No (study performed prior to implementation of GLP)

Reference: **A7.2.3.2/02**

Stevens JEB, Hill IR (1980) Cypermethrin: mobility of cypermethrin and its degradation products in soil columns. ICI Plant Protection Division, Report no. RJ 0166B, December 03, 1980 (unpublished), BASF RDI No.: CY-620-005.

Guidelines: Non-guideline study

GLP: No (study performed prior to implementation of GLP)

Summary:

The leaching behaviour of freshly applied or aged [^{14}C] Cypermethrin was investigated on a sandy loam soil (A7.2.3.2/01). Leachate from columns (32 cm x 4.5 cm id) which were freshly treated with Cypermethrin, then eluted with water at a rate of 2 ml/hour for 45 days, contained a total of only 0.8–1.2% of the applied radioactivity. Analysis of soil sections showed that very little movement of radiolabelled material below 2 cm had occurred.

In a parallel study, the mobility of aged residues was investigated by treating soil columns, as above, but waiting 28 days before leaching in the same manner. Leachate from the 'aged' study also contained only 0.6–0.7% of the applied radioactivity. There was little movement of radiolabelled material below 2 cm in the soil. The 0–2 cm soil sections from both studies were extracted and analysed for Cypermethrin and its degradation products. The major components in the 0–2 cm layer were Cypermethrin, the amide derivative, PBA and unextracted radioactivity.

A separate aged leaching study with four soils was reported (A7.2.3.2/02). Clay loam, loamy sand, coarse sand and peat were used with organic matter contents of 13.9, 1.9, 1.0 and 55.0% respectively.

[^{14}C-Benzyl] Cypermethrin was incubated in each soil at a concentration of 0.1 kg/ha for 21 days, after which samples of treated soil were placed on soil columns (30 cm) for leaching with calcium chloride solution over a 10 week period. A sample of treated soil was analysed and shown to contain mainly Cypermethrin and 'bound' residues together with small amounts (<5% each) of PBA, 3-phenoxybenzaldehyde and 4'-hydroxycypermethrin. Less than 1.5% of the applied radioactivity was present in the leachate, and less than 5% of the applied radioactivity leached below the 5 cm soil depth in the columns.

This study confirms the very low mobility of Cypermethrin and its degradation products in soils. By way of read-across, this is considered to be also the case with Alphacypermethrin.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable with the following amendment: Columns (40 cm x 4.5 cm id)
Results and discussion	The Applicant's version is considered to be acceptable with the following amendment: A separate aged leaching study with four soils was reported (A7.2.3.2/02). Clay loam, loamy sand, coarse sand and peat were used with organic matter contents of 13.9, 1.9, 1.0 and 72.7% respectively.
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.3.1
Annex Point IIIA 7.5

Phototransformation in air (estimation method), including identification of breakdown products

Official use only

1 REFERENCE

1.1	**Reference**	**A7.3.1/01:** Mangels G (1995) Alphacypermethrin: Estimation of the photochemical oxidation rate in the atmosphere. American Cyanamid Company, Princeton, NJ, USA, Report no. ENV 95017, March 09, 1995 (unpublished), BASF RDI No.: AL-324-002.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF AG
1.2.2	Companies with letter of access	No
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not applicable (model calculation)
2.2	**GLP**	No Not applicable (model calculation)
2.3	**Deviations**	Not applicable (model calculation)

3 MATERIALS AND METHODS

3.1	**Test material**	As given in Section A2.
3.1.1	Lot/Batch number	Not applicable
3.1.2	Specification	As given in Section A2.
3.1.3	Purity	For estimation, 100 % purity was assumed.
3.1.4	Further relevant properties	Not applicable
3.1.5	Method of analysis	Not applicable
3.2	**Degradation products**	The formation of degradation products was not considered in this study.
3.3	**Estimation method**	
3.3.1	Test system	Model calculation (SRC) on the basis of a well-defined and generally accepted structure-activity relationship (Atkinson, 1987), according to which the OH-reaction constants and, subsequently, atmospheric half-lives may be estimated.

Section A7.3.1
Annex Point IIIA 7.5

Phototransformation in air (estimation method), including identification of breakdown products

4 RESULTS

4.1	**Rate constants**	$k_{OH} = 37.0116 \times 10^{-12}$ cm³/molecule × s k_{Ozone}: not available
4.2	**Half life**	12-hour day, 1.5×10^6 OH/cm³, US-EPA preferences: $t_{½}$ (•OH) = 3.47 h $t_{½}$ (Ozone): not available
4.3	**Specification of breakdown products**	The formation of breakdown products was not examined.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The atmospheric photo-oxidative degradation of Alphacypermethrin by hydroxyl radicals was estimated using structure-activity relationships (SAR), with the help of the software model AOPWIN. No guidelines for this purpose are available, but the method applied rests on generally accepted scientific principles, as also recommended by the TNG on data requirements.
5.2	**Results and discussion**	The results suggest that Alphacypermethrin is rapidly degraded in the atmosphere by photo-oxidative processes. The numerical half-lives are summarised below. The TNG on data requirements recommend an assessment of potential breakdown products, as well as an assessment of further interactions of substances with atmospheric processes. Due to the extremely low vapour pressure of Alphacypermethrin (see Section A3.2), the potential for global warming, stratospheric ozone depletion, tropospheric ozone formation, and acidification, is considered to be negligible. Furthermore, according to the considered reactions, the formation of volatile compounds that might interact with atmospheric processes is not expected. Thus, the results from the current study are considered to be sufficient for the assessment of the fate of the substance in air.
5.2.1	Half life	12-hour day, 1.5×10^6 OH/cm³, US-EPA preferences: $t_{½}$ (•OH) = 3.47 h $t_{½}$ (Ozone): not available
5.3	**Conclusion**	Phototransformation of Alphacypermethrin has been estimated according to generally accepted principles. Thus, this calculation was considered to be valid.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	April 2012
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable with the following comment: In addition and according to the TGD Part II chapter 3, 2.3.6.3., photolysis in air was calculated using the following: $kdeg_{air} = k_{OH} \times OHCONC_{air} \times 24 \times 3600$ where: $OHCONC_{air} = 5 \times 10^5$ OH molecule/ cm^3 $k_{OH} = 37.0116 \times 10^{-12}$ cm^3/mol.sec Resulting in a pseudo-first order rate of degradation in air of 1.60 day.
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.3.2 Fate and behaviour in air, further studies

Annex Point IIIA 12.3

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Exposure of the atmosphere to Alphacypermethrin is considered to be extremely unlikely: The substance is non-volatile and will not be applied as a fumigant or by spraying. Thus, exposure to air is limited and the substance is considered to cause no risks to the atmospheric environment. In view of the limited exposure, the data requirements on fate and behaviour in air are considered to be completely covered by Section A7.3.1.	
Undertaking of intended data submission [ ]		

	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)	
Date	March 2009	
Evaluation of applicant's justification	Applicant's justification are considered to be acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1

Official use only

1 REFERENCE

1.1	**Reference**	**A7.4.1.1/01:** [redacted] (1983) WL85871 and cypermethrin: a comparative study of their toxicity to the fathead minnow *Pimephales promelas* (Rafinesque). [redacted], Report no. SBGR.82.298, March 02, 1983, BASF RDI No.: AL-512-002 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No The study was conducted prior to adoption of OECD guidelines. However, performance of the study was consistent to OECD 203 in all important aspects.	
2.2	**GLP**	No GLP was not mandatory when the study was conducted.	
2.3	**Deviations**	Yes Number of test concentrations (see 4.2.1 below).	

3 MATERIALS AND METHODS

3.1	**Test material**	As given in Section A2.	
3.1.1	Lot/Batch number	OCD/7	
3.1.2	Specification	As given in Section A2.	
3.1.3	Purity	≥ 94.4% w/w	
3.1.4	Composition of product	Not applicable	X
3.1.5	Further relevant properties	Water solubility approx. 5.80 µg/l	X
3.1.6	Method of analysis	GC-ECD following extraction from water samples with hexane.	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Yes In view of the low water solubility, stock solutions were equilibrated using test substance coated carrier material in order to ensure constant concentrations (see Table A7.4.1.1- 1 for details).	
3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance	Not applicable	
3.4	**Testing procedure**		
3.4.1	Dilution water	Details are given in Table A7.4.1.1- 2.	
3.4.2	Test organisms	Fathead minnow, as described in Table A7.4.1.1- 3.	
3.4.3	Test system	See Table A7.4.1.1- 4.	
3.4.4	Test conditions	As given in Table A7.4.1.1- 5.	
3.4.5	Duration of the test	96 h	
3.4.6	Test parameter	Mortality	
3.4.7	Sampling	From the inflow tube.	
3.4.8	Monitoring of TS concentration	Yes, one day prior to introduction of the fish (–1) and on day 2.	
3.4.9	Statistics	LC_{50} by probit analysis of log-transformed concentrations (means of measured values).	
		4 RESULTS	
4.1	**Limit Test**	Not performed	
4.1.1	Concentration		
4.1.2	Number / percentage of animals showing adverse effects		
4.1.3	Nature of adverse effects		
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	Nominal: 0.2, 0.5, 1.0, 2.0 µg/l Day "–1", measured: 0.15, 0.695, 1.1, 1.95 µg/l (means)	
4.2.2	Actual concentrations of test substance	For actual initial concentrations, please see 4.2.1 above. Day 2, measured: 0.15, 0.49, 0.77, 1.95 µg/l (means) Means of all measurements: 0.15, 0.59, 0.93, 1.95 µg/l	X

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1

4.2.3	Effect data (Mortality)	The mortality data are given in Table A7.4.1.1- 6. LC_{50} = 0.93 µg/l (95%CI = 0.78–1.2). The LC_{50} was estimated based on mean measured concentrations.	X
4.2.4	Concentration / response curve	A graphical presentation is given in Figure A7.4.1.1- 1.	
4.2.5	Other effects	None	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	No adverse effects were observed in control fish (also see Table A7.4.1.1- 6).	
4.3.2	Nature of adverse effects	Not applicable.	
4.4	**Test with reference substance**	No (not required according to OECD 203).	
4.4.1	Concentrations		
4.4.2	Results		

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	An acute toxicity test of Alphacypermethrin to freshwater fish was performed using *Pimephales promelas*. The test was conducted prior to publication of OECD or EU guidelines. However, performance of the study was consistent to OECD 203 in all important aspects. The use of only four instead of five test concentrations is considered as a deviation of minor importance since the dose-response relationship was unequivocal and allowed a proper estimation of the LC_{50} (96 h). The study was performed using a continuous flow-through system, at nominal concentrations of 0.2, 0.5, 1.0 and 2.0 µg/l. Although analytical measurements confirmed that nominal concentrations were mostly maintained within ± 20% of nominal (apart from the 77% figure at 1.0 µg/l on day 2), the evaluation of the test results was based on measured concentrations.
5.2	**Results and discussion**	Alphacypermethrin is poorly soluble in water. However, the target concentrations of the test substance in the flow-through system could be achieved by a generator device, using pumice coated with Alphacypermethrin. According to the analytical results, test substance concentrations were satisfactorily stable over the test period.
5.2.1	LC_0	0.15 µg/l, measured
5.2.2	LC_{50}	0.93 µg/l (95%CI = 0.78–1.2), measured
5.2.3	LC_{100}	1.95 µg/l, measured

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1

5.3	**Conclusion**	As summarised in Table A7.4.1.1- 8, the validity criteria were fulfilled. Deviating from recent guideline criteria, only four instead of five test concentrations were employed. However, since an unequivocal dose-response relationship could be established, this is regarded as a deviation of minor importance and the test is considered to be valid.
5.3.1	Other conclusions	The test was conducted prior to establishment of GLP procedures. Therefore, a reliability of "2" is assigned, basically for formal reasons.
5.3.2	Reliability	2
5.3.3	Deficiencies	No The deviations from recent guidelines as repeatedly discussed above are considered to be of minor importance but not as deficiencies. The non-reporting of fish body size may be considered as a minor reporting deficiency (fish weights were reported instead).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is acceptable with the following comments: Section 3.1.4 No details on the racemisation product WL 86711 "In these studies, between 30 and 50 % of the WL85871 originally produced was present as WL86711 but nothing is known of the toxicity of WL 86711 to fish". Section 3.1.5 Water solubility 5.80 µg/l at pH 7
Results and discussion	The Applicant's version is acceptable with the following amendments: Section 4.2.2 C3 = 0.94 µg/l Section 4.2.3 Table A7.4.1.1- 6 : Test substance concentration (nominal) [µg/l] (instead of mg/l)
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	More details should be given on product of racemisation WL 86711
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.4.1.1- 1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	Stock solutions were prepared by passing filtered (8 µm) dechlorinated tap water up through a glass column containing 250 g of sieved pumice (particle size >2 mm) onto which 0.25 g of test substance had been adsorbed. The test substance was adsorbed onto the pumice by dissolving it in 250 ml of Analar acetone, pouring the acetone onto the pumice, and then evaporating the acetone by passage of air. After preparation of the columns, diluent water was pumped through these at approximately 50 mL min^{-1} for at least 2 weeks prior to their use in tests to allow them to stabilise.

Table A7.4.1.1- 2: Dilution water.

Criteria	Details
Source	Tap water, filtered (8 µm), dechlorinated
Alkalinity	253–275 mg/l
Hardness	259–300 mg/l
pH	7.3–7.8
Oxygen content	8.3–9.1 mg/l
Conductance	500–580 µS/cm
Holding water different from dilution water	No

Table A7.4.1.1- 3: Test organisms.

Criteria	Details
Species/strain	*Pimephales promelas*
Source	Not reported
Wild caught	Not reported
Age/size	Mean weight = 0.74 g (SD = 0.14)
Kind of food	Not reported
Amount of food	Not reported
Feeding frequency	Not reported
Pre-treatment	Not reported
Feeding of animals during test	No

Table A7.4.1.1- 4: Test system.

Criteria	Details
Test type	Flow-through
Renewal of test solution	Flow-rate = 20 mL/min
Volume of test vessels	1 l (test solution volume)
Volume/animal	0.25 l
Number of animals/vessel	4
Number of vessels/concentration	4
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1- 5: Test conditions.

Criteria	Details
Test temperature	Mean = 24.2°C Range = 22.1–25.0°C
Dissolved oxygen	Mean = 8.6 mg/l Range = 7.5–9.6 mg/l
pH	Mean = 7.9 (control), 8.0 (top concentration) Range = 7.8–8.1
Adjustment of pH	No
Aeration of dilution water	Yes: slight aeration via a tube in the test vessel
Intensity of irradiation	Not reported
Photoperiod	18:6 h (L:D)

Table A7.4.1.1- 6: Mortality data.

Test substance concentration (nominal) [mg/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Control	0	0	0	0	0	0	0	0
0.2	0	0	0	0	0	0	0	0
0.5	0	0	1	2	0	0	6	13
1.0	2	3	5	7	13	19	31	44
2.0	16	16	16	16	100	100	100	100
Temperature [°C]	See Table A7.4.1.1- 5							
pH	See Table A7.4.1.1- 5							
Oxygen [mg/l]	See Table A7.4.1.1- 5							

Table A7.4.1.1- 7: Effect data.

	48 h [µg/l][1]	95 % CI	96 h [µg/l][1]	95 % CI
LC_0	0.49 (m)	–	0.15 (m)	–
LC_{50}	1.1 (m)	– [2]	0.93 (m)	0.78–1.2
LC_{100}	1.95 (m)	–	1.95 (m)	–

1) m = effect data are based on measured concentrations
2) CI not determinable due to steep dose-response curve

Table A7.4.1.1- 8: Validity criteria for acute fish test according to OECD Guideline 203.

	Fulfilled	Not fulfilled
Mortality of control animals <10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥80% of initial concentration during test		X [1]
Criteria for poorly soluble test substances	X	

1) Effects were evaluated based on measured concentrations

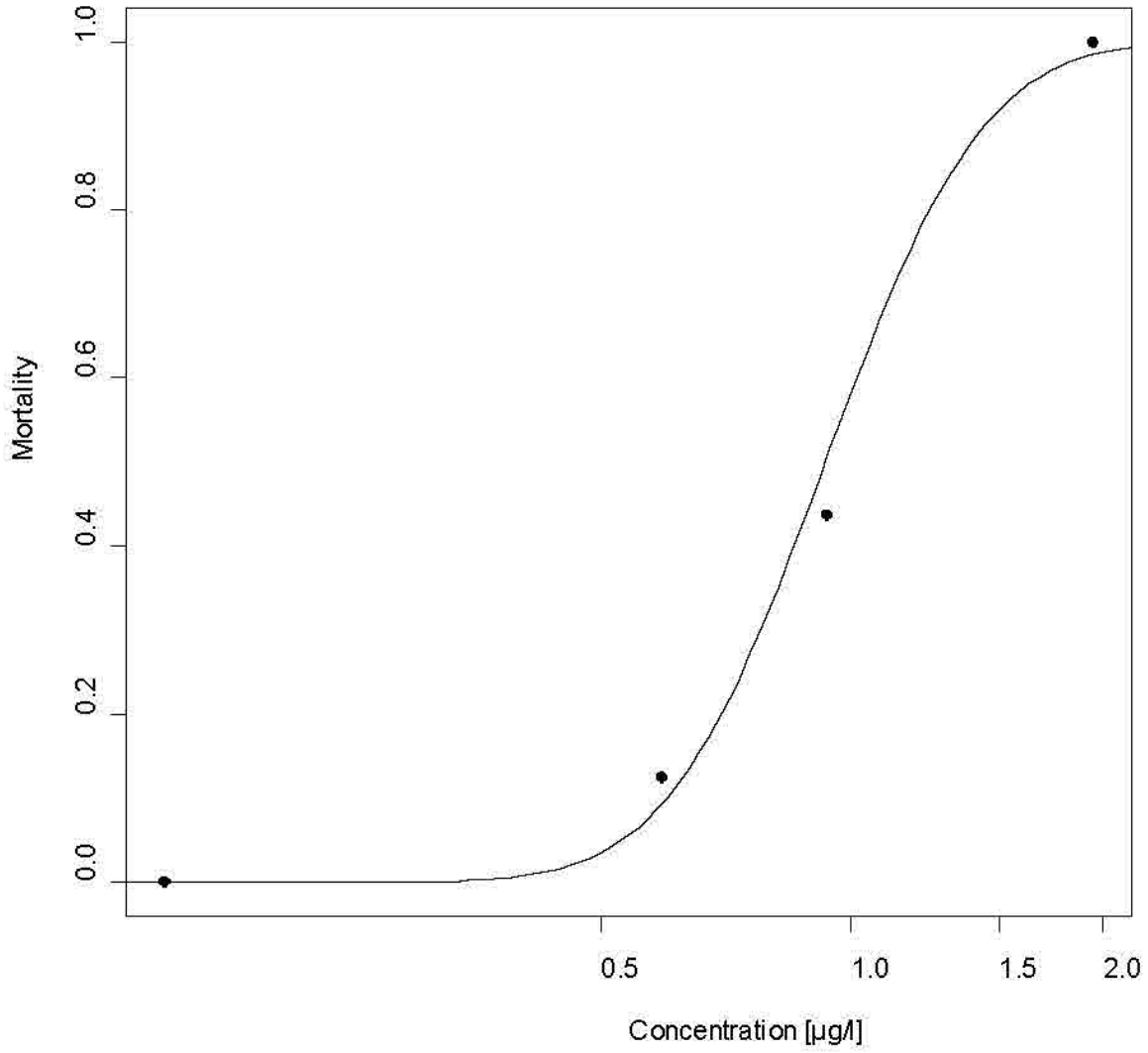

Figure A7.4.1.1- 1: Concentration-response curve: relative mortality in relation to concentration (*x*-axis log-scaled) of Alphacypermethrin, and the fitted probit function.

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to fish and is thus presented in tabular format as supportive data: (study is non-GLP study)

Reference	Title	System	Results
A7.4.1.1/02: [redacted] (1981) [redacted] Report no. SBGR.81.277, December 29, 1981 (unpublished), BASF RDI No.: AL-511-001.	WL85871 and cypermethrin: a comparative study of their acute toxicity to *Salmo gairdneri*, *Daphnia magna* and *Selenastrum capricornutum*.	Aquatic toxicity test on *Salmo gairdneri*; Semi-static test design (renewal of test solutions every 12 h), 96 h exposure, test concentrations 0.4, 0.65, 1.0, 1.5, 2.5, 4.0, and 6.5 µg/l; Analytical verification of TS concentrations: yes; Estimation of LC_{50} by probit analysis on log-transformed concentrations (nominal).	Alphacypermethrin concentrations decreased substantially during 12 h. However, in view of the frequent renewal of the test solution continuous exposure to nominal concentrations may be assumed. LC_{50} = 2.8 µg/l (95% CI = 2.2–3.4 µg/l)

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is acceptable with the following amendment: LC_{50} = 2,8 µg/l (95% CI = 2,1 – 3,5 µg/l)
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to fish, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.1/03**

[redacted] (2002) CL 912554 (metabolite of BAS 310I, Alpha-Cypermethrin) – acute toxicity study on the bluegill sunfish (*Lepomis macrochirus*) in a static system over 96 hours. [redacted], Report no. 14F0420/015033, March 05, 2002 (unpublished), BASF DocID: 2002/1004682.

Guidelines: EPA 72-1, EC C.1 (92/69/EEC), OECD 203

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Material and methods:

Test substance: CL 912554; batch No. AC 12717-65; purity : 99.0%.

Test species: Bluegill sunfish (*Lepomis macrochirus*), mean body length 5.4 (4.5–6.2) cm; mean body weight 2.0 (1.0–2.8) g.

Test design: Static system (96 hours); 10 fish per aquarium (loading about 0.8 g fish/L) and per concentration.

Test concentrations: Control, 0, 0, 100, 100, 100 mg/L (nominal).

Test conditions: Temperature approx. 22°C; pH 7.5–8.5; oxygen content > 80% saturation; total hardness about 2.5 mmol/L; acid capacity about 5.5 mmol/L.

Analytics: The test concentrations were analysed by HPLC.

Statistics: None, since no lethality was observed at the highest tested concentration. The median lethal concentration (LC_{50}) was above this value.

Findings:

The analytically determined concentrations of the test substance in the test water were in the range of ±10% of the nominal concentration in all tested concentrations throughout the exposure period.

Biological results: The fish were observed for survival and toxic signs (changes in appearance, swimming behavior, and behavior in comparison to controls) within 1 hour of exposure and then 4, 24, 48, 72 and 96 hours after start of exposure. CL 912554 caused no mortality to bluegill sunfish at concentrations of 100 mg/L (Note: The death of 1/10 fish after 48 h in one 100 mg/L concentration group was considered not to be caused by the test substance). No symptoms such as apathy, convulsions, narcotic-like state and swimming near the bottom were observed.

Table A7.4.1.1- 9: Toxicity (96 h) of CL 912554 to Bluegill sunfish (*Lepomis macrochirus*).

Concentration [mg CL 912554/L]	Control	Control	102.8	102.8	102.8
Mortality [%]	0	0	0	0	10
Symptoms	none	none	none	none	none

Conclusions:

Based on analytically determined concentrations, the median lethal concentration LC_{50} of CL 912554 on Bluegill sunfish was > 102.8 mg/L. The NOEC was 102.8 mg CL 912554/L.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA 7.1 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to fish, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.1/04**

[redacted] (2002) CL 206128 (metabolite of BAS 310I, Alpha-Cypermethrin) – acute toxicity study on the bluegill sunfish (*Lepomis macrochirus*) in a static system over 96 hours. [redacted] Report no. 14F0418/015034, March 05, 2002 (unpublished), BASF DocID: 2002/1004683.

Guidelines: EPA 72-1, EEC 92/69, OECD 203

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Material and methods:

Test substance: CL 206128; batch No.AC 12251-34; purity : 99.0%.

Test species: Bluegill sunfish (*Lepomis macrochirus*), mean body length 5.4 (4.5–6.2) cm; mean body weight 2.0 (1.0–2.8) g.

Test design: Static system (96 hours); 10 fish per aquarium (loading about 0.8 g fish/L) and per concentration.

Test concentrations: Control, 0, 0, 100, 100, 100 mg/L (nominal).

Test conditions: Temperature approx. 22°C; pH 7.5–8.5; oxygen content > 80% saturation; total hardness about 2.5 mmol/L; acid capacity about 5.5 mmol/L.

Analytics: The test concentrations were analysed by HPLC.

Statistics: None, since no lethality was observed at the highest tested concentration. The median lethal concentration (LC_{50}) was above this value.

Findings:

The analytically determined concentrations of the test substance in the test water were in the range of ±10% of the nominal concentration in all tested concentrations throughout the exposure period.

Biological results: The fish were observed for survival and toxic signs (changes in appearance, swimming behavior, and behavior in comparison to controls) within 1 hour of exposure and then 4, 24, 48, 72 and 96 hours after start of exposure. CL 206128 caused no mortality to bluegill sunfish at concentrations of 100 mg/L. No symptoms such as apathy, convulsions, narcotic-like state and swimming near the bottom were observed.

Table A7.4.1.1- 10: Toxicity (96 h) of CL 206128 to Bluegill sunfish (*Lepomis macrochirus*).

Concentration [mg CL 206128/L]	Control	Control	103.2.	103.2	103.2
Mortality [%]	0	0	0	0	10
Symptoms	none	none	none	none	none

Conclusions:

Based on analytically determined concentrations, the median lethal concentration LC_{50} of CL 206128 on bluegill sunfish was > 103.2 mg/L. The NOEC was 103.2 mg CL 206128/L.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2

Official use only

1 REFERENCE

1.1	**Reference**	**Cross-reference to A7.4.1.1/02:** [redacted] (1981) WL85871 and cypermethrin: a comparative study of their acute toxicity to *Salmo gairdneri, Daphnia magna* and *Selenastrum capricornutum*. [redacted], Report no. SBGR.81.277, December 29, 1981 (unpublished), BASF RDI No.: AL-511-001.	X
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC.	

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No The study was conducted prior to adoption of OECD guidelines. However, performance of the study was consistent to OECD 202 in all important aspects.	
2.2	**GLP**	No GLP was not mandatory when the study was conducted.	
2.3	**Deviations**	Not applicable	

3 MATERIALS AND METHODS

3.1	**Test material**	As given in Section A2.	
3.1.1	Lot/Batch number	Not allocated. Two batches of Alphacypermethrin (WL85871) were obtained from a pilot plant. Production dates were November 17, 1980 and February 19, 1981.	
3.1.2	Specification	As given in Section A2.	
3.1.3	Purity	November 17, 1980: 93.4% February 19, 1981: 95.7% It is not reported which batch was used for the *Daphnia* test.	
3.1.4	Composition of product	Not applicable (technical grade active substance).	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2

3.1.5	Further relevant properties	Alphacypermethrin is only poorly soluble in water (4.59 µg/l at pH 7 and 7.87 µg/l at pH 9 according to OECD 105 test, ref. A3.5/01). In the current study, stable saturation concentrations in a range of 5.2 to 9.6 µg/l were achieved.	X
3.1.6	Method of analysis	Gas chromatography, electron capture detection (GC-ECD).	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Yes Stock solutions were prepared using acetone as solvent. Final acetone concentrations in the test solutions did not exceed 0.5 mL/L (0.005% v/v). Also see Table A7.4.1.2- 1.	
3.3	**Reference substance**	No A conventional reference substance according to OECD test guideline 202 was not investigated. However, Alphacypermethrin was tested concurrently with Cypermethrin. Therefore, a comparison of the toxicity of these two substances is possible.	
3.3.1	Method of analysis for reference substance	Gas chromatography, electron capture detection (GC-ECD).	
3.4	**Testing procedure**		
3.4.1	Dilution water	Details are given in Table A7.4.1.2- 2.	
3.4.2	Test organisms	*Daphnia magna*, as described in Table A7.4.1.2- 3.	
3.4.3	Test system	Please refer to Table A7.4.1.2-4.	
3.4.4	Test conditions	Test conditions are specified in Table A7.4.1.2-5.	
3.4.5	Duration of the test	48 h	
3.4.6	Test parameter	Immobility of the daphnids.	X
3.4.7	Sampling	At the start and the end of each renewal period.	
3.4.8	Monitoring of TS concentration	Yes 0 h, 24 h (old and new solution), 48 h.	
3.4.9	Statistics	EC_{50} by probit analysis on log-transformed concentrations (nominal).	
		4 RESULTS	
4.1	**Limit Test**	Not performed.	
4.1.1	Concentration		
4.1.2	Number/ percentage of animals showing adverse effects		
4.1.3	Nature of adverse effects		

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2

4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	Nominal: 0.5, 1.0, 1.5, 4.0, 10 µg/l Measured, 0 h: 0.5, 0.9, 1.3, 4.8, 8.5 µg/l	
4.2.2	Actual concentrations of test substance	Nominal: 0.5, 1.0, 1.5, 4.0, 10 µg/l Measured, 24 h: 0.7, 0.7, 0.7, 2.4, 2.0 µg/l Remark: Under the test conditions, alphacypermethrin undergoes isomerisation, resulting in a racemate coded as "WL86711". The measured concentrations therefore refer to the sums of both alphacypermethrin and WL86711.	X
4.2.3	Effect data (Immobilisation)	The immobilisation data are given in Table A7.4.1.2-6. EC_{50} = 0.3 µg/l (95%CI = 0.2–0.4 µg/l). The EC_{50} was estimated based on nominal concentrations.	
4.2.4	Concentration / response curve	Although not provided in the original study report, a graph has been plotted upon dossier preparation, as presented in Figure A7.4.1.2- 1.	
4.2.5	Other effects	None	
4.3	**Results of controls**	No immobilisation, no trapping at the water surface (also see Table A7.4.1.2-6).	
4.4	**Test with reference substance**	Not performed.	
4.4.1	Concentrations		
4.4.2	Results		
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	An acute toxicity test of Alphacypermethrin to freshwater invertebrates was performed using *Daphnia magna*. The test was conducted prior to publication of OECD or EU guidelines. However, performance of the study was similar to the OECD 202 test method. The study employed a semi-static test design, with renewal test solutions after 24 h. Acetone was used as a co-solvent in view of the low water solubility. A solvent control was not performed. The study used 30 *Daphnia* per treatment level, which is in excess of recent standards. The water volume per individual was also in excess of recent guideline requirements. The analytical measurements demonstrate that Alphacypermethrin was not stable under the employed test conditions. However, in view of the semi-static test design exposure to nominal concentrations may be assumed to have been maintained to a sufficient degree.	X
5.2	**Results and discussion**		
5.2.1	EC_0	< 0.1 µg/l	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2

5.2.2	EC_{50}	0.3 µg/l (95%CI = 0.2–0.4 µg/l)
5.2.3	EC_{100}	1.5 µg/l
5.3	**Conclusion**	The test substance proved to be unstable under the employed conditions. However, the semi-static test design partially circumvented this problem, so that this validity criterion is considered to be fulfilled. Apart from this deviation, all other validity criteria are likewise fulfilled.
5.3.1	Reliability	2
5.3.2	Deficiencies	With respect to the recent guideline version, the study has some minor reporting deficiencies (mineral ratios of water, description of the origin and breeding of the Daphnia, aeration, lighting). Furthermore, a solvent control was not performed. However, in view of the study date and the unequivocally high toxicity of the active substance this is considered to be of minor importance. Overall, the described deficiencies do not invalidate study and the data can be used in the context of classification and labelling. For risk assessment purposes, higher tier studies are available that supersede the current data.

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Reference	The applicant's version is considered to be acceptable with the following amendment: Section 1.1 WL85871 and cypermethrin : A comparison of their acute toxicity to Salmo gairdneri, Daphnia magna and Selenastrum capricornutum (instead of : a comparative study of)
Materials and Methods	The applicant's version is considered to be acceptable with the following amendment: Section 3.1.5 Further relevant properties : 5,80 µg/l at pH 7 instead of 4,59 µg/l (4,59 µg/l at pH 4) Section 3.4.6 Test parameter : immobility of the daphnids was recorded after 10 seconds instead of 15 seconds
Results and discussion	The applicant's version is considered to be acceptable with the following comment: Section 4.2.2 High differences between nominal and measured concentrations
Conclusion	The applicant's version is considered to be acceptable with the following comment: Section 5.1 A solvent control should have been performed
Reliability	2
Acceptability	Acceptable
Remarks	
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Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.4.1.2- 1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	Yes Organic solvent: acetone
Concentration of vehicle	Max. 0.005% (v/v)
Vehicle control performed	Not reported
Other procedures	None

Table A7.4.1.2- 2: Dilution water.

Criteria	Details
Source	Tap water
Alkalinity	Not reported
Hardness	260 ± 20 mg/L $CaCO_3$
pH	8.2 ± 0.3
Ca / Mg ratio	Not reported
Na / K ratio	Not reported
Oxygen content	9.1 ± 0.4 mg/L
Conductance	Not reported
Holding water different from dilution water	Not reported

Table A7.4.1.2- 3: Test organisms.

Criteria	Details
Species/strain	*Daphnia magna,* strain ATCC 22662
Source	Shell Toxicology Laboratory (Tunstall), derived from a strain obtained from I.R.Ch.A., France
Age	< 24 h
Breeding method	Not reported
Kind of food	Not reported
Amount of food	Not reported
Feeding frequency	Not reported
Pre-treatment	Not reported
Feeding of animals during test	Not reported, but the methods description suggests that the test animals were not fed

Table A7.4.1.2-4: Test system.

Criteria	Details
Renewal of test solution	Semi-static (renewal after 24 h)
Volume of test vessels	150 mL (100 mL water volume)
Volume/animal	10 mL
Number of animals/vessel	10
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.2-5: Test conditions.

Criteria	Details
Test temperature	20 ± 2°C
Dissolved oxygen	9.1 ± 0.4 mg/L
pH	8.2 ± 0.3
Adjustment of pH	No
Aeration of dilution water	Not reported
Quality/Intensity of irradiation	Not reported
Photoperiod	Not reported

Table A7.4.1.2-6: Immobilisation data.

Test substance concentration (nominal) [mg/l]	Immobile *Daphnia*				Oxygen [mg/l] 48 h	pH 48 h	Temperature [°C] 48 h
	Number		Percentage				
	24 h	48 h	24 h	48 h			
0.0 (control)	0	0	0	0	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
0.1	0	4	0	13.3	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
0.2	1	13	3.3	43.3	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
0.5	3	23	10	76.7	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
1.0	9	26	30	86.7	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
1.5	23	30	76.7	100	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
2.5	29	30	96.7	100	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
4.0	30	30	100	100	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
6.5	30	30	100	100	9.1 ± 0.4	8.2 ± 0.3	20 ± 2
10	30	30	100	100	9.1 ± 0.4	8.2 ± 0.3	20 ± 2

Table A7.4.1.2-7: Effect data.

	EC_{50}[1]	95 % CI	EC_0[1]	EC_{100}[1]
24 h [µg/l]	1.1	0.8–1.4	0.1	4.0
48 h [µg/l]	0.3	0.2–0.4	<0.1	1.5

[1] based on measured concentrations

Table A7.4.1.2-8: Validity criteria for acute *Daphnia* immobilisation test according to OECD Guideline 202.

	Fulfilled	**Not fulfilled**
Immobilisation of control animals <10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance ≥80% of initial concentration during test		X [1]
Criteria for poorly soluble test substances:		

1) However, this was circumvented by the semi-static test design; therefore the test is considered valid

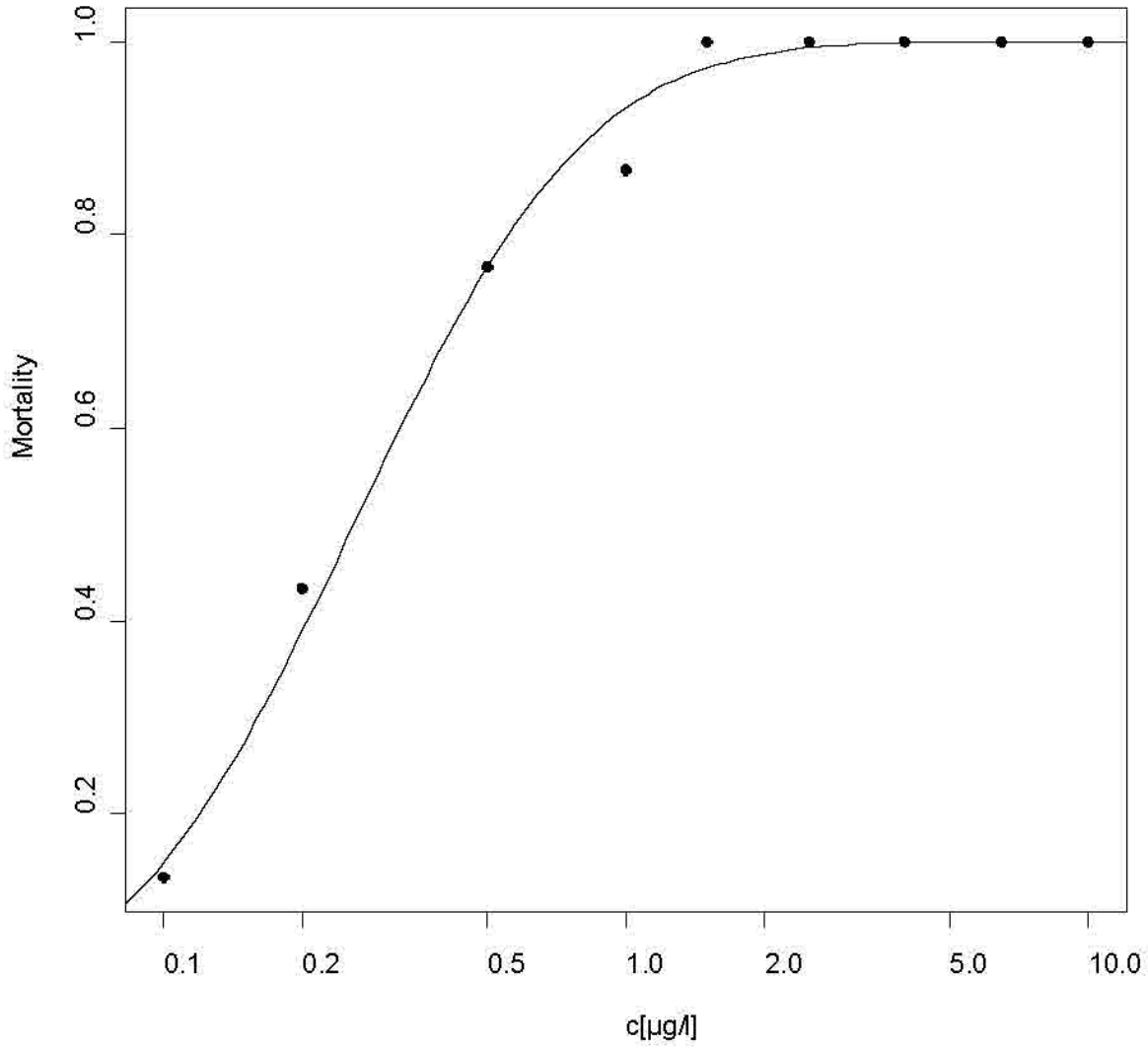

Figure A7.4.1.2- 1: Concentration-response curve: relative mortality in relation to concentration (*x*-axis log-scaled) of Alphacypermethrin, and the fitted probit function.

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to invertebrates, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.2/01**

Jatzek J (2001) Reg. No. 4080830: determination of the acute effect on the swimming ability of the water flea *Daphnia magna* STRAUS. BASF, Ludwigshafen, Germany, Report no. 01/0420/50/1, November 29, 2001 (unpublished), BASF DocID: 2001/1017462.

Guidelines: OECD 202, EC C.2 (92/32/EEC)

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Materials and methods:

Test substance: Reg No. 4080830 (synonymous with CL 912554); batch AC 12717-65; purity: 99%.

Test species: Waterflea (*Daphnia magna* STRAUS), neonates with age at test initiation 2–24 hours; culture conditions in accordance with test conditions.

Test design: Static test (48 hours), 5 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility (and other effects) after 24 and 48 hours.

Test concentrations: Control, 6.25, 12.5, 25, 50, 100 mg/L (nominal).

Test conditions: Dilution water "M4", pH 6.9–8.0, oxygen content 8.4 to 8.9 mg/L, glass vessels, test volume 50 mL, no feeding, no aeration, temperature 19.8–22.7°C*; light:dark 16:8 hours, light intensity 1–8 µE/(m^2.s) at a wavelength of 400–750 nm. (*due to a technical problem, a max temp of 22.7°C occurred for 2 hours only, with no impact on the outcome of the study).

Analytics: Analytical verification of test substance concentrations was conducted using HPLC.

Statistics: Due to the results of the test no statistical evaluation of the data was performed at 24 h. For the statistical evaluation of the 48-h EC50 the moving average method was used.

Findings:

Analytical measurements: The measured values ranged form 97.8 to 100% of nominal at the beginning of the test and from 99.3 to 101% at the end of the test, confirming the nominal data. Therefore the following biological results are based on nominal concentrations.

Biological results:

EC_{50} (48 h) = 61.9 mg/L (95% CI = 52.1–73.5 mg/L)

NOEC (48 h) = 25 mg/L

Table A7.4.1.2- 9: Effect of CL 912554 (Reg. No. 4080830) on *Daphnia magna* mobility.

Concentration [mg/L] nominal	Control	6.25	12.5	25	50	100
Immobile (24 hours) [%]	5	0	0	0	5	35
Immobile (in 48 hours) [%]	5	0	5	0	30	95

Conclusions:

In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} of CL 912554 was determined to be 61.9 mg/L. The NOEC was 25 mg CL 912554/L (nominal).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The applicant's version is considered to be acceptable with the following comment: More details should be given on Reg No. 4080830 (CL 912554)
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to invertebrates, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.2/02**

Jatzek J (2001) CL 206128 (Metabolite of BAS 310I, α-Cypermethrin) – determination of the acute effect on the swimming ability of the water flea *Daphnia magna* STRAUS. BASF, Ludwigshafen, Germany, Report no. 01/0418/50/1, September 12, 2001 (unpublished), BASF DocID: 2001/1014673.

Guidelines: OECD 202, EEC 92/32

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Materials and methods:

Test substance: CL 206128 (Reg. No. 130213); batch AC 12251-34; purity: 99%.

Test species: Waterflea (*Daphnia magna* STRAUS), neonates with age at test initiation 2–24 hours; culture conditions in accordance with test conditions.

Test design: Static test (48 hours), 6 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility (and other effects) after 24 and 48 hours.

Test concentrations: Control, 3.13, 6.25, 12.5, 25, 50, 100 mg/L (nominal).

Test conditions: Dilution water "M4", pH 7.0–8.1, oxygen content 8.4 to 9.1 mg/L, glass vessels, test volume 50 mL, no feeding, no aeration, temperature 19.8-22.7 °C*; light:dark 16:8 hours, light intensity 1–8 µE/(m²*s) at a wave length of 400-750 nm. (*due to a technical problem, a max temp of 22.7 °C occurred for 2 hours only, with no impact on the outcome of the study)

Analytics: Analytical verification of test substance concentrations was conducted using HPLC.

Statistics: For the statistical evaluation of the EC50 the moving average method was used.

Findings:

Analytical measurements: The measured values ranged form 96.1 to 101% of nominal at the beginning of the test and from 97.2 to 101% at the end of the test, confirming the nominal data. Therefore the following biological results are based on nominal concentrations.

Biological results:

EC_{50} (48 h) = 39.0 mg/L (95% CI = 30.0–50.8 mg/L)

NOEC (48 h) = 12.5 mg/L

Table A7.4.1.2- 10: Effect of CL 206128 (Reg. No. 130213) on *Daphnia magna* mobility.

Concentration [mg/L] nominal	Control	3.13	6.25	12.5	25	50	100
Immobile (24 hours) [%]	0	5	0	0	0	25	65
Immobile (in 48 hours) [%]	0	10	10	10	30	60	100

Conclusions:

In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} of CL 206128 was determined to be 39.0 mg/L. The NOEC was 12.5 mg CL 206128/L (nominal).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable even if minor deviations occurred: pH 7 (7.5-8.5) and 22,7°C (18-22 ± 1°C)
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA 7.2 **– Supportive data –**

The following reference is considered to contain additional information concerning acute toxicity to invertebrates, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.2/03**

Jatzek J (2002) CL 206969 – determination of the acute effect on the swimming ability of the water flea *Daphnia magna* STRAUS. BASF, Ludwigshafen, Germany, Report no. 01/0419/50/2, September 12, 2001 (unpublished), BASF DocID: 2002/1004857.

Guidelines: OECD 202, EEC 92/32

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Materials and methods:

Test substance: CL 206969 (Reg. No. 4080665); batch AC 11304-76; purity: 99.4%.

Test species: Waterflea (*Daphnia magna* STRAUS), neonates with age at test initiation 2–24 hours; culture conditions in accordance with test conditions.

Test design: Static test (48 hours), 6 test concentrations plus control, 4 replicates with 5 daphnids in each; assessment of immobility (and other effects) after 24 and 48 hours.

Test concentrations: Control, 0.16, 0.31, 0.63, 1.25, 2.5, 5, 10 mg/L (nominal).

Test conditions: Dilution water "M4", pH 7.0–8.1, oxygen content 8.4 to 9.1 mg/L, glass vessels, test volume 50 mL, no feeding, no aeration, temperature 18–22°C; light:dark 16:8 hours, light intensity 1-8 µE/(m^2.s) at a wavelength of 400–750 nm.

Analytics: Analytical verification of test substance concentrations was conducted using HPLC.

Statistics: For the statistical calculation of the EC_{50} the graphical method by means of log-probit paper was used.

Findings:

Analytical measurements: The measured values at test initiation ranged from 2.4% to 74.1% of nominal values. At test termination, only 3.1% of the nominal content of the 10 mg/L sample was measured. For samples in the 0.16 to 5 mg/L range, the test substance was not detected. The low recoveries were explained by rapid oxidation of the phenoxybenzaldehyde. Therefore, the biological results are based on measured values that are considered over-conservative.

Biological results:

EC_{50} (48 h) = 0.8 mg/L (2.7 mg/L nominal)

NOEC (48 h) = 0.286 mg/L (1.25 mg/L, nominal)

Table A7.4.1.2- 11: Effect of CL 206969 (Reg. No. 4080665) on *Daphnia magna* mobility.

Concentration [mg/L] measured	Control	0.0019	0.020	0.103	0.286	0.726	1.77	3.86
Immobile (24 hours) [%]	0	0	5	0	0	5	35	100
Immobile (in 48 hours) [%]	0	0	10	0	10	30	100	100

Conclusions:

In a 48 hours static acute toxicity study with *Daphnia magna* the EC_{50} of CL 206969 was determined to be 0.8 mg/L (2.7 mg/L, nominal). The NOEC was 0.286 mg CL 206969/L (1.25 mg/L, nominal).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is acceptable with the following amendments: Test design: 7 test concentrations (instead of 6) Test conditions: dilution water "M4" pH 7.7 (instead of 7.0) – 8.1 Oxygen content 6.4 to 8.6 (instead of 8.4 - 9.1) mg/l Test volume 20 ml (instead of 50 ml) No details on water-solubility
Results and discussion	The Applicant's version is acceptable with the following comment: The measured values at test initiation ranged from 2,4 % to 74,1 % of nominal values
Conclusion	The Applicant's version is considered to be acceptable
Reliability	2
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.3 **Growth inhibition test on algae**
Annex Point IIA 7.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	**A7.4.1.3/01:** Jatzek J (2002) BAS 310 I – determination of inhibitory effect on the cell multiplication of unicellular green algae. BASF, Ludwigshafen, Germany, Report no. 01/0265/60/1, March 18, 2002 (unpublished), BASF DocID: 2002/1004851.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	BASF	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EU method C.3 (92/69/EEC), OECD guideline 201 (1984)	
2.2	**GLP**	Yes	
2.3	**Deviations**	Yes/No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in Section A2.	
3.1.1	Lot/Batch number	AC 12395-18	
3.1.2	Specification	As given in Section A2.	
3.1.3	Purity	96.1%	
3.1.4	Composition of product	Not applicable.	
3.1.5	Further relevant properties	Alphacypermethrin is only poorly soluble in water (4.59 µg/l at pH 7 and 7.87 µg/l at pH 9 according to OECD 105 test, ref. A3.5/01). In the current study, acetone was used as a solubilising agent, by which concentrations up to 1.0 mg/l could be achieved.	X
3.1.6	Method of analysis	GC-ECD	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Yes; See Table A7.4.1.3- 1.	

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA 7.3

3.3	**Reference substance**	Yes Potassium dichromate Tests with reference substance are performed routinely in regular intervals. The test referred to in this study was conducted on January 11, 2002.
3.3.1	Method of analysis for reference substance	Not reported.
3.4	**Testing procedure**	
3.4.1	Culture medium	OECD 201 nutrient solution, pH approx. 8.
3.4.2	Test organisms	*Pseudokirchneriella subcapitata,* as described in Table A7.4.1.3- 2.
3.4.3	Test system	Details are given in Table A7.4.1.3-3.
3.4.4	Test conditions	Test conditions are presented in Table A7.4.1.3-4.
3.4.5	Duration of the test	72 h
3.4.6	Test parameter	*In vivo* chlorophyll-a-fluorescence (pulsed excitation with light flashes of 435 nm wavelength).
3.4.7	Sampling	0, 24, 48, 72 h
3.4.8	Monitoring of TS concentration	Yes At 0 and 72 h
3.4.9	Statistics	Comparison of areas under the growth curve and comparison of growth rates, according to the procedures specified in EC method C.3. EC_{50} could not be estimated due to the low inhibitory effect within the tested concentration range.

4 RESULTS

4.1	**Limit Test**	Not performed
4.1.1	Concentration	
4.1.2	Number/ percentage of animals showing adverse effects	
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.05, 0.1, 0,22, 0.5 and 1.0 mg/l

Section A7.4.1.3 **Growth inhibition test on algae**
Annex Point IIA 7.3

4.2.2	Actual concentrations of test substance	Nominal: 0.05 0.1 0.22 0.5 1.0 Measured, 0 h: 0.042 0.096 0.18 0.44 0.90 Measured, 72 h: 0.019 – 0.086 0.33 0.89 The 0.1 mg/l sample taken at 72 h could not be analysed due to damaging of the sample container.
4.2.3	Growth curves	The graph is presented in Figure A7.4.1.3- 1.
4.2.4	Concentration-response curve	A graphical representation is given in Figure A7.4.1.3- 2.
4.2.5	Cell concentration data	See Table A7.4.1.3-5.
4.2.6	Effect data (cell multiplication inhibition)	E_bC_{50} (72 h) > 1.0 mg/l E_rC_{50} (72 h) > 1.0 mg/l
4.2.7	Other observed effects	Morphological effects on the cells were not observed.
4.3	**Results of controls**	Please refer to Table A7.4.1.3-5.
4.4	**Test with reference substance**	Separate test performed routinely in regular intervals. The test referred to in this study was conducted on January 11, 2002.
4.4.1	Concentrations	Not reported
4.4.2	Results	E_bC_{50} (72 h) = 0.73 mg/l

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The inhibitory effect of Alphacypermethrin on the growth of green algae was tested using *Pseudokirchneriella subcapitata*, according to OECD guideline 201 and EC method C.3. Cell densities were estimated indirectly by measuring Chlorophyll-a fluorescence. Concentrations of the test substance were monitored by GC-ECD. Acetone was used as a co-solvent at concentrations of 0.01% (v/v).
5.2	**Results and discussion**	In the lower test concentrations (0.05–0.5 mg/l), the test substance was degraded to < 80% of nominal. At the highest test concentration (1.0 mg/l), in contrast, the actual value was found to be within 80 % of nominal. Since there was no difference in the inhibitory effect between the top-level and the lower concentrations, the results are nevertheless considered valid. Reference to nominal concentrations is justified.
5.2.1	NOE_rC	Not reported.
5.2.2	E_rC_{50}	> 1.0 mg/l
5.2.3	E_bC_{50}	> 1.0 mg/l
5.3	**Conclusion**	
5.3.1	Reliability	1
5.3.2	Deficiencies	None

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is acceptable with the following amendment: Section 3.1.5 Water solubility 5,80 at pH 7 (instead of 4,59, corresponding to pH 4)
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.4.1.3- 1: Preparation of TS solution for poorly soluble or volatile test substances.

Criteria	Details
Dispersion	No
Vehicle	Yes Acetone
Concentration of vehicle	0.01% (v/v) i.e. 10 µl of diluted stock solution per 100 ml test preparation
Vehicle control performed	Yes Solvent control in quintuplicate
Other procedures	None

Table A7.4.1.3- 2: Test organisms.

Criteria	Details
Species	*Pseudokirchneriella subcapitata*
Strain	SAG 61.81
Source	Collection of algal cultures; University of Göttingen (Germany)
Laboratory culture	Yes
Method of cultivation	A seed culture was incubated for 4 days at 23 °C ± 2 °C; final cell density: 276×10^4 cells/ml
Pre-treatment	Pre-culture: seed-culture was taken to inoculate a pre-culture (initial cell density: 10^4 cells/mL); the pre-culture was incubated for 3 days at 23 ± 2 °C; final cell density: 44×10^4 cells/mL
Initial cell concentration	10^4 cells/ml

Table A7.4.1.3-3: Test system.

Criteria	Details
Volume of culture flask	250 mL
Culturing apparatus	Climate chamber
Light quality	Continuous light (white fluorescent lamps), approx. 60–120 µE/(m² × s), λ = 400–700 nm
Procedure for suspending algae	Shaking
Number of vessels/ concentration	3 per test concentration; 5 blank controls and solvent controls, respectively
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.3-4: Test conditions.

Criteria	Details
Test temperature	23 ± 2°C
pH	Start: 7.7–7.8 End: 8.0–8.3
Aeration of dilution water	Yes Test vessels were plugged with gas permeable silicone sponge caps and shaken continuously
Light intensity	60–120 µE/(m² × s)
Photoperiod	Continuously

Table A7.4.1.3-5: Cell concentration data.

Test substance concentration, nominal/measured [mg/l]	Cell concentration: fluorescence (relative units)							
	Measured				Percent of control			
	0 h	24 h	48 h	72 h	0 h	24 h	48 h	72 h
0.0 (control)	26	128	585	2614	–	–	–	–
0.0 (solvent control)	26	131	619	2407	100	100	100	100
0.05	26	121	544	2138	100	92	88	89
0.1	26	115	442	1859	100	88	71	77
0.22	26	118	537	2066	100	90	87	86
0.5	26	123	489	1842	100	94	79	77
1.0	26	124	518	1885	100	94	84	78

Temperature [°C]: 23 ± 2

pH: 7.8–8.3

Table A7.4.1.3- 6: Validity criteria for algal growth inhibition test according to OECD Guideline 201.

	Fulfilled	Not fulfilled
Cell concentration in control cultures increased at least by a factor of 16 within 3 days	X	
Concentration of test substance ≥80% of initial concentration during test	X [1]	
Criteria for poorly soluble test substances	X	

1) Whereas the test substance was degraded to < 80% of nominal in the lower test concentrations (0.05–0.5 mg/l), this criterion was fulfilled at the highest test concentration (1.0 mg/l). Since there was no difference in the inhibitory effect between the top-level and the lower concentrations, the results are nevertheless considered valid.

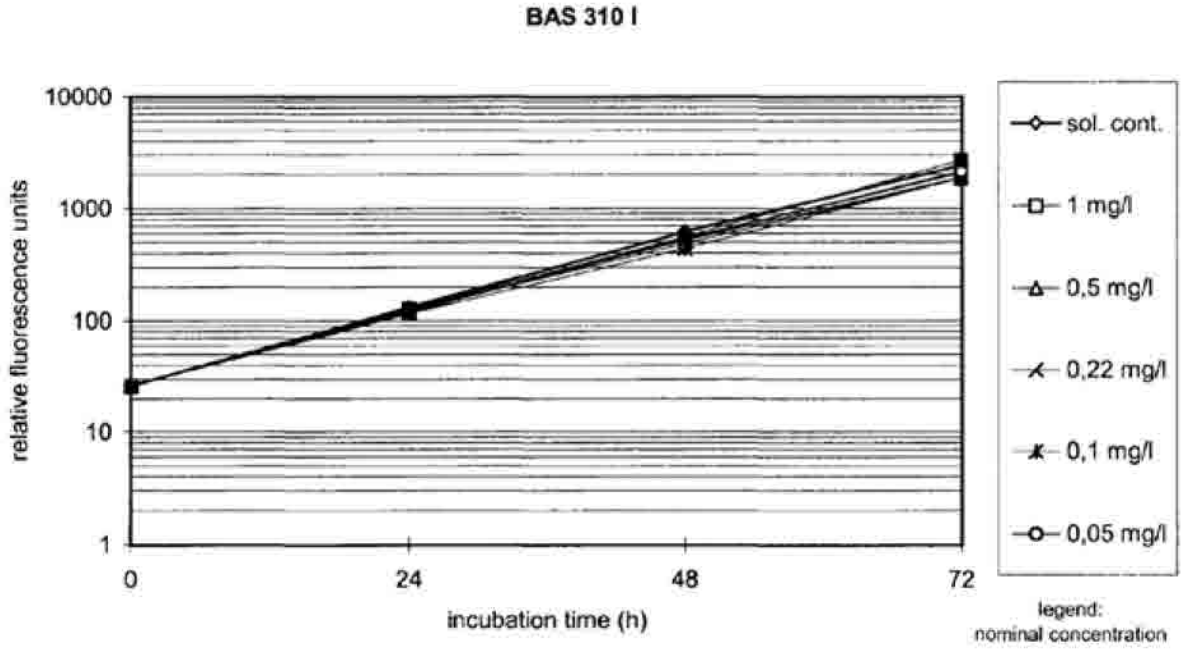

Figure A7.4.1.3- 1: Growth curves of *Pseudokirchneriella subcapitata* (relative fluorescence units) at different test substance concentrations.

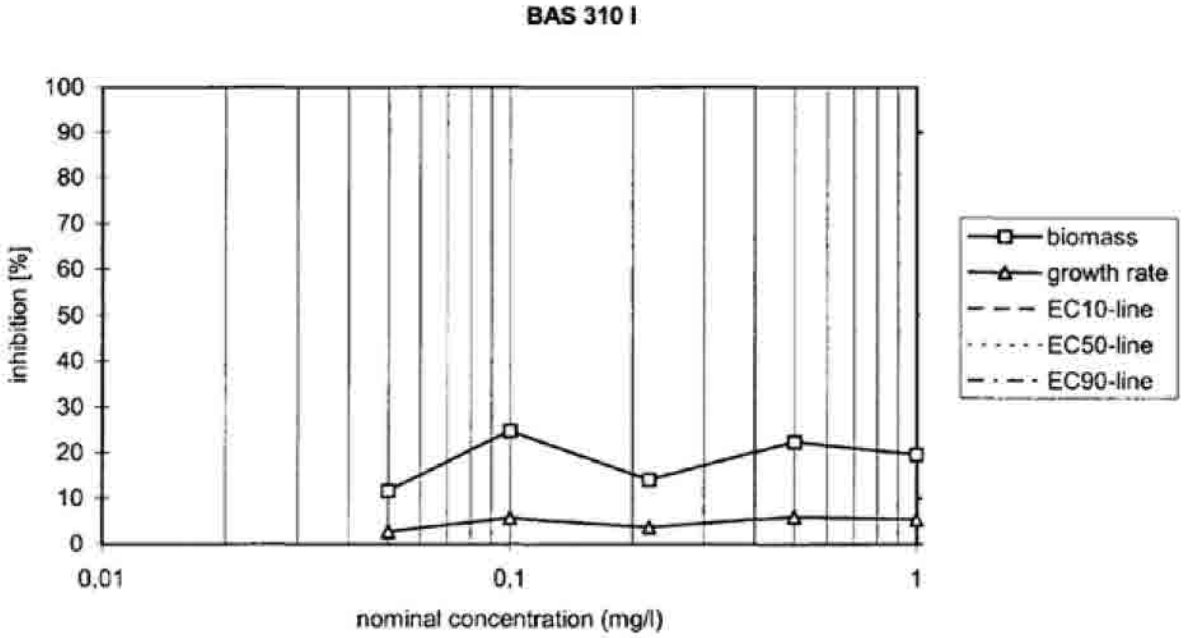

Figure A7.4.1.3- 2: Concentration-response relationship of the inhibitory effect of alphycypermethrin on algal growth (percent inhibition of the algal biomass and growth rates after 72 h).

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA 7.3 **– Supportive data –**

The following reference is considered to contain additional information concerning growth inhibition to algae, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.3/02**

Werner DI (2002) CL 912554 (metabolite of BAS 310I, α-Cypermethrin) – determination of the inhibitory effect on the cell multiplication of unicellular green algae. BASF, Ludwigshafen, Germany, Report No. 01/0420/60/2, February 15, 2002 (unpublished), BASF DocID: 2002/1004139.

Guidelines: EC C.3 (92/69/EEC), OECD 201

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Material and methods:

Test substance: CL 912554; batch no. AC 12717-65; purity: 99%.

Test species: The test strain (SAG 61.81) of *Pseudokirchneriella subcapitata* (KORSHIKOV) is obtained at regular intervals from SAG (Collection of algal cultures in Göttingen) and is kept in liquid culture in the Laboratory of Experimental Toxicology and Ecology at BASF AG Ludwigshafen.

Test design: Static system; test duration 72 hours; 5 test concentrations, each with 3 replicates plus a control with 5 replicates; daily assessments of growth.

Test concentrations: Control, 6.25, 12.5, 25, 50 and 100 mg/L.

Test conditions: OECD 201 nutrient solution, pH 7.7–8.1; glass Erlenmeyer flasks plugged with gas permeable silicone sponge caps; continuous shaking; initial cell densities 10^4 cells/mL; temperature 23 ± 2°C; continuous light (white fluorescent lamps), about 60–120 µE/(m².s) at a wavelength of 400–700 nm.

Analytics: Analytical verification of the test concentrations were conducted using HPLC.

Statistics: Standard procedures.

Findings:

Analytical measurements: The measured values ranged from 100.1% to 102.1% of nominal at the beginning of the test and from 100.9% to 101.8% at the end of the test, confirming the nominal data. Therefore the following biological results are based on nominal concentrations.

Biological results: No morphological effects on the algae were observed.

Effect on the development of biomass:

E_bC_{50} (0–72 h) = 31.6 mg/L

E_bC_{10} (0–72 h) = 14.2 mg/L

Effect on growth rate:

E_rC_{50} (0–72 h) = 70.0 mg/L

E_rC_{10} (0–72 h) = 25.4 mg/L

Table A7.4.1.3- 7: Effect of CL 912554 on the growth of *Pseudokirchneriella subcapitata.*

Concentration [mg/L]	Control	6.25	12.5	25	50	100
Inhibition (biomass) [%]	0.0	-6.4	4.3	34.5	80.2	92.8
Inhibition (growth rate) [%]	0.0	-2.1	0.8	9.3	38.4	62.3

Conclusion:
In a 72-hour algae test *with Pseudokirchneriella subcapitata* the E_bC_{50} of CL 912554 was determined to be 31.6 mg/L, the E_rC_{50} was 70.0 mg/L (nominal).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA 7.3 **– Supportive data –**

The following reference is considered to contain additional information concerning growth inhibition to algae, addressing the effects of an identified metabolite and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.4.1.3/03**

Werner DI (2002) CL 206128 (metabolite of BAS 310I, α-Cypermethrin) – determination of the inhibitory effect on the cell multiplication of unicellular green algae. BASF, Ludwigshafen, Germany, Report No. 01/0418/60/2, February 13, 2002 (unpublished), BASF DocID: 2002/1004140.

Guidelines: EC C.3 (92/69/EEC), OECD 201

GLP: Yes (laboratory certified by Landesanstalt fuer Pflanzenbau und Pflanzenschutz Rheinland-Pfalz, Mainz)

Material and methods:

Test substance: CL 206128; batch no. AC 12251-34; purity: 99%.

Test species: The test strain (SAG 61.81) of *Pseudokirchneriella subcapitata* (KORSHIKOV) is obtained at regular intervals from SAG (Collection of algal cultures in Göttingen) and is kept in liquid culture in the Laboratory of Experimental Toxicology and Ecology at BASF AG Ludwigshafen.

Test design: Static system; test duration 72 hours; 5 test concentrations, each with 3 replicates plus a control with 5 replicates; daily assessments of growth.

Test concentrations: Control, 6.25, 12.5, 25, 50 and 100 mg/L.

Test conditions: OECD 201 nutrient solution, pH 7.7–8.2; glass Erlenmeyer flasks plugged with gas permeable silicone sponge caps; continuous shaking; initial cell densities 10^4 cells/mL; temperature 23 ± 2°C; continuous light (white fluorescent lamps), about 60–120 µE/(m².s) at a wavelength of 400–700 nm.

Analytics: Analytical verification of the test concentrations were conducted using HPLC.

Statistics: Standard procedures.

Findings:

Analytical measurements: The measured values ranged from 99.3% to 100.0% of nominal at the beginning of the test and from 99.4% to 101.8% at the end of the test, confirming the nominal data. Therefore the following biological results are based on nominal concentrations.

Biological results: No morphological effects on the algae were observed.

Effect on the development of biomass:

E_bC_{50} (0–72 h) = 38.1 mg/L

E_bC_{10} (0–72 h) = 6.88 mg/L

Effect on growth rate:

E_rC_{50} (0–72 h) = 85.0 mg/L

E_rC_{10} (0–72 h) = 28.5 mg/L

Table A7.4.1.3- 8: Effect of CL 206128 on the growth of *Pseudokirchneriella subcapitata.*

Concentration [mg/L]	Control	6.25	12.5	25	50	100
Inhibition (biomass) [%]	0.0	8.1	22.0	29.8	63.2	91.2
Inhibition (growth rate) [%]	0.0	0.9	4.9	7.1	22.4	58.5

Conclusion:
In a 72-hour algae test with *Pseudokirchneriella subcapitata* the E_bC_{50} of CL 206128 was determined to be 38.1 mg/L, the E_rC_{50} was 85.0 mg/L (nominal).

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable
Results and discussion	The Applicant's version is considered to be acceptable
Conclusion	The Applicant's version is considered to be acceptable
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.4 **Inhibition to microbial activity (aquatic)**

Annex Point IIA 7.4 and IIIA 7.3

Official use only

1 REFERENCE

1.1	**Reference**	**A7.4.1.4/01:** Lebertz H, Zhjixing Y (2001) Alphacypermethrin (BAS 310 I): activated sludge, respiration inhibition test. Institut Fresenius, Taunusstein, Germany, Report no. IF-100/29753-00, March 30, 2001 (unpublished), BASF RDI No.: AL-690-005.
1.2	**Data protection**	Yes
1.2.1	Data owner	BASF
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I of Directive 98/8/EC.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD 209 (1984)
2.2	**GLP**	Yes
2.3	**Deviations**	Yes/No

3 MATERIALS AND METHODS

3.1	**Test material**	As given in Section A2.
3.1.1	Lot/Batch number	AC12395-18
3.1.2	Specification	As given in Section A2.
3.1.3	Purity	96.1%
3.1.4	Composition of product	Not applicable (technical grade active substance).
3.1.5	Further relevant properties	Alphacypermethrin is only poorly soluble in water (4.59 µg/l at pH 7 and 7.87 µg/l at pH 9 according to OECD 105 test, ref. A3.5/01). In the current study, it can be safely assumed that saturation was maintained at the higher test concentrations (see 4.1.1 below).
3.1.6	Method of analysis	Not required.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Please refer to Table A7.4.1.4- 1.

Section A7.4.1.4 **Inhibition to microbial activity (aquatic)**
Annex Point IIA 7.4 and IIIA 7.3

3.3	**Reference substance**	3,5-dichlorophenol
3.3.1	Method of analysis for reference substance	Not appropriate
3.4	**Testing procedure**	
3.4.1	Culture medium	Synthetic sewage feed, prepared in compliance with OECD 209.
3.4.2	Inoculum/test organism	Details are given in Table A7.4.1.4- 2.
3.4.3	Test system	See Table A7.4.1.4-3.
3.4.4	Test conditions	Test conditions are presented in Table A7.4.1.4-4.
3.4.5	Duration of the test	3 h
3.4.6	Test parameter	Inhibition of respiration
3.4.7	Analytical parameter	Oxygen concentration
3.4.8	Sampling	Continuous recording of oxygen concentration over a period of up to 10 min.
3.4.9	Monitoring of TS concentration	No
3.4.10	Controls	Two blank controls, abiotic control.
3.4.11	Statistics	Per cent respiration inhibition, as described in OECD guideline 209.

4 RESULTS

4.1	**Preliminary Test**	Performed: Range-finding test
4.1.1	Concentration	0.001, 0.005, 0.10, 10, 100 and 1000 mg/l
4.1.2	Effect data	No dose-dependent inhibition of respiration was observed. EC_{50} > 1000 mg/l EC_{20} > 1000 mg/l
4.2	**Results test substance**	A definitive test was not performed since the range-finding test yielded an unequivocally negative result with respect to respiration inhibition.
4.2.1	Initial concentrations of test substance	
4.2.2	Actual concentrations of test substance	
4.2.3	Growth curves	

Section A7.4.1.4 **Inhibition to microbial activity (aquatic)**
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4.2.4	Cell concentration data	
4.2.5	Concentration-response curve	
4.2.6	Effect data	
4.2.7	Other observed effects	
4.3	**Results of controls**	*Control without test substance:* Respiration rate = 0.85 mg O_2/(l × min) *Abiotic control:* Respiration rate = 0.0 mg O_2/(l × min)
4.4	**Test with reference substance**	Performed
4.4.1	Concentrations	5, 15, and 30 mg/l
4.4.2	Results	EC_{50} = 12 mg/l

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Inhibitory effects of Alphacypermethrin on microbial activity were tested by the activated sludge respiration inhibition test, following OECD guideline 209. No deviations from the guideline were reported. The testing procedure was restricted to the range-finding test in view of the absence of any inhibitory effects.
5.2	**Results and discussion**	Microbial respiration was not inhibited by Alphacypermethrin up to the maximum tested nominal concentration of 1000 mg/l. Alphacypermethrin is poorly soluble in water (see Section A3.5). Thus, it seems likely that at the higher nominal concentrations the test substance was not completely dissolved. However, it may safely be assumed that saturation was achieved at nominal concentrations higher than maximum water solubility. Thus, the results are considered valid without any restrictions, since the study convincingly demonstrated the lack of inhibitory effects within the range of the water solubility of the test substance.
5.2.1	EC_{20}	> 1000 mg/l
5.2.2	EC_{50}	> 1000 mg/l
5.2.3	EC_{80}	> 1000 mg/l