Table A7.1.1.1.1- 1: Type and composition of buffer solutions (specify kind of water if necessary).

pH	Type of buffer (final molarity)	Composition
4	0.01 M potassium hydrogenphosphate	Tenfold dilution of 0.1 M potassium hydrogenphosphate buffer with bidistilled water and re-adjustment of pH
7	0.01 M TRIS-HCl	Tenfold dilution of 0.1 M TRIS-HCl buffer with bidistilled water
9	0.01 M borate buffer	Tenfold dilution of 0.1 M borate buffer with bidistilled water

Table A7.1.1.1.1- 2: Description of test solution.

Criteria	Details
Purity of water	Bidistilled water
Preparation of test medium	pH4: 2.04 g potassium hydrogenphosphate (0.1M) + 3.5 mL 0.1 M NaOH to pH4 and 100 mL with bi-distilled water pH 7: 1.21 g Tris to 100 mL with bi-distilled water (0.1M) to pH 7.0 with 90 mL 0.1M HCl pH9: 0.618 g boric acid to 100 mL with bi-distilled water (0.1M) to pH 9.0 with 24 mL 0.1M NaOH
Test concentrations [mg/l]	0.2mg/L (0.5% acetone); preliminary test 0.02mg/L (0.4% acetone) ; pH 4 and 7 0.001mg/L (0.1% acetone) ; pH 9
Temperature [°C]	pH 4: 50°C pH 7: 50, 60 and 75°C pH 9: 25and 50°C
Controls	None
Identity and concentration of co-solvent	Acetone: 0.1–0.5 % as given above
Replicates	One per sampling

Table A7.1.1.1.1- 3: Description of test system.

Glassware	Tightly closed vessels
Other equipment	Water bath pH meter Packard liquid scintillation counter
Method of sterilization	Test solutions: sterile filtration Incubation vessels: autoclaving for at least 30 min at 120°C.

Table A7.1.1.1.1- 4: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 50°C.

Compound	Sampling times (days)			
	3	5	7	10
Parent compound	81.5	72.5	73.95	62.17
Transformation product 1: WL 42049	5.4	7.75	6.9	17.1
Volatiles (if measured)	n.d.	n.d.	n.d.	n.d.
Total % recovery	87.1	80.7	81.0	79.3

Table A7.1.1.1.1- 5: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 60°C.

Compound	Sampling times (days)					
	0	2	4	7	9	11
Parent compound	80.2	67.8	63.9	33.6	34.2	17.4
Transformation product 1: WL 42049	n.d.	16.43	33.8	41.6	53.9	59.2
Transformation product 2: unknown	n.d.	n.d.	n.d.	1.9	2.6	5.9
Volatiles (if measured)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Total % recovery	80.3	84.7	98.3	77.5	91.2	82.5

Table A7.1.1.1.1- 6: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 75°C.

Compound	Sampling times (days)			
	1	2	3	4
Parent compound	55.9	32.2	19.9	14.3
Transformation product 1 WL 42049	16.1	22.3	29.1	31.6
Transformation product 2 unknown	n.d.	2.6	4.4	4.5
Volatiles (if measured)	n.d.	n.d.	n.d.	n.d.
Total % recovery	74.7	58.6	55.6	51.4

Table A7.1.1.1.1- 7: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 9 and 25°C.

Compound	Sampling times (days)						
	0	1	2	3	4	7.2	11
Parent compound	103.5	83.2	66.1	51.5	39.7	26.7	10.3
Transformation product 1: WL 42049	n.d.	21.2	34.3	49.4	54.3	74.8	88.6
Transformation product 2: unknown	n.d.	n.d.	n.d.	n.d.	3.0	n.d.	n.d.
Volatiles (if measured)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Total % recovery	103.9	104.4	100.4	100.9	97.0	102.5	100.2

Table A7.1.1.1.1- 8: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 9 and 50°C.

Compound	Sampling times (hours)								
	0	1	2	3	4	6	8	10	24
Parent compound	103.2	88.6	67.5	58.2	35.7	28.4	15.3	35.1	4.7
Transformation product 1: WL 42049	1.0	16.5	33.6	45.3	64.7	69.8	85.1	59.9	86.6
Transformation product 2: unknown	n.d.	n.d.	n.d.	n.d.	n.d.	1.0	n.d.	n.d.	n.d.
Volatiles (if measured)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
Total % recovery	104.2	105.1	101.1	103.5	101.0	99.6	100.6	95.4	94.0

Table A7.1.1.1.1- 9: Dissipation times (DT_{50}) and hydrolysis rate constants of the test compound at pH 7 and pH 9.

	pH 7			pH 9	
	50°C	60°C	75°C	25°C	50°C
DT_{50}	27 d	5.3 d	2.0 d	3.5 d	3.0 h
k	0.0257 d^{-1}	0.132 d^{-1}	0.3388 d^{-1}	0.0083 h^{-1}	0.2337 h^{-1}
r	–0.9985	–0.9829	–0.9953	–0.9966	–0.9920

Table A7.1.1.1.1- 10: Specification and amount of transformation products.

CAS-Number	CAS and/or IUPAC chemical name(s)	Amount [%] of parent compound measured at		
		pH 4	pH 7	pH 9
39515-51-0	3-phenoxybenzaldehyde	n.d.	59	88.6
	unknown	n.d.	< 10%	< 10%

Tables in reference to part "Results and discussion" above:

Table A7.1.1.1.1- 11: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 50°C.

Phase	Sampling times (days)			
	3	**5**	7	**10**
1. EtAc	80.8	73.1	74.4	67.6
2. EtAc	6.1	7.1	6.4	11.7
Subtotal	86.9	80.2	80.8	79.3
Aqueous phase at pH 1	0.2	0.5	0.2	<0.05
Total % recovery	**87.1**	**80.7**	**81.0**	**79.3**

Table A7.1.1.1.1- 12: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 60°C.

Phase	Sampling times (days)					
	0	**2**	**4**	**7**	**9**	**11**
1. EtAc	69.9	67.6	71.8	56.2	58.7	58.2
2. EtAc	10.3	15.8	19.2	16.2	23.9	21.4
3. EtAc	n.d.	0.8	6.7	4.7	8.1	2.9
Subtotal	80.2	84.2	97.7	77.1	90.7	82.5
Aqueous phase	0.1	0.5	0.6	0.4	0.5	<0.05
Total % recovery	**80.3**	**84.7**	**98.3**	**77.5**	**91.2**	**82.5**

Table A7.1.1.1.1- 13: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 7 and 75°C.

Phase	Sampling times (days)			
	1	**2**	**3**	**4**
1.EtAc	62.7	50.8	49.5	46.4
2. EtAc	9.3	6.4	4.0	4.1
Subtotal	72.0	57.2	53.5	50.5
Aqueous phase	2.7	1.4	2.1	0.9
Total % recovery	**74.7**	**58.6**	**55.6**	**51.4**

Table A7.1.1.1.1- 14: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 9 and 25°C.

Phase	Sampling times (days)						
	0	**1**	**2**	**3**	**4**	**7.2**	**11**
1. Hexane	99.2	99.2	95.6	96.0	91.5	95.7	93.1
2. Hexane	4.3	5.2	4.8	4.9	5.5	5.8	5.8
Subtotal	103.5	104.4	100.4	100.9	97.0	101.5	98.9
Aqueous phase	0.4	<0.05	<0.05	<0.05	<0.05	1.0	1.3
Total % recovery	**103.9**	**104.4**	**100.4**	**100.9**	**97.0**	**102.5**	**100.2**

Table A7.1.1.1.1- 15: Hydrolysis of test compound and transformation products, expressed as percentage of initial concentrations, at pH 9 and 50°C.

Phase	Sampling times (hours)								
	0	**1**	**2**	**3**	**4**	**6**	**8**	**10**	**24**
1. Hexane	101.4	97.8	96.4	97.1	94.8	96.6	97.8	87.8	84.9
2. Hexane	7.3	7.3	4.7	6.4	5.7	2.6	2.6	7.2	6.4
Subtotal	104.2	105.1	101.1	103.5	100.5	99.2	100.4	95.0	91.3
Aqueous phase	<0.05	<0.05	<0.05	<0.05	0.5	0.4	0.2	0.4	2.7
Total % recovery	**104.2**	**105.1**	**101.1**	**103.5**	**101.0**	**99.6**	**100.6**	**95.4**	**94.0**

Table A7.1.1.1.1- A: Metabolite patterns in the organic phase after hydrolysis of ^{14}C-Alphacypermethrin (0,02 µg/ml) at pH 7 and 50°C (in percentage of the radioactivity recovered).

	Time interval (days)			
	3	5	7	10
Identity				
parent	93.6	89.8	91.3	78.4
WL 42049	6.2	9.6	8.5	21.6
Total % recovery	**99.8**	**99.4**	**99.8**	**100**

Table A7.1.1.1.1- B: Metabolite patterns in the organic phase after hydrolysis of ^{14}C-Alphacypermethrin (0,02 µg/ml) at pH 7 and 60°C (in percentage of the radioactivity recovered).

	Time interval (days)					
	0	2	4	7	9	11
Identity						
parent	99.9	80.0	65.0	43.4	37.5	21.1
WL 42049	n.d.	19.4	34.4	53.7	59.1	71.7
Unknown	n.d.	n.d.	n.d.	2.4	2.9	7.2
Total % recovery	**99.9**	**99.4**	**99.4**	**99.5**	**99.5**	**100**

Table A7.1.1.1.1- C: Metabolite patterns in the organic phase after hydrolysis of ^{14}C-Alphacypermethrin (0,02 µg/ml) at pH 7 and 75°C (in percentage of the radioactivity recovered).

	Time interval (days)			
	1	2	3	4
Identity				
parent	74.8	55.0	35.8	27.9
WL 42049	21.6	38.1	52.4	61.5
Unkown	n.d.	4.5	8.0	8.8
Total % recovery	**96.4**	**97.6**	**96.2**	**98.2**

Table A7.1.1.1.1- D: Metabolite patterns in the organic phase after hydrolysis of ^{14}C-Alphacypermethrin (0,001µg/ml) at pH 9 and 25°C (in percentage of the radioactivity recovered).

	Time interval (days)						
	0	1	2	3	4	7.2	11
Identity							
parent	99.6	79.7	65.8	51.0	40.9	26.0	10.3
WL 42049	n.d.	20.3	34.2	49.0	56.0	73.0	88.4
Unknown	n.d.	n.d.	n.d.	n.d.	3.1	n.d.	n.d.
Total % recovery	**99.6**	**100**	**100**	**100**	**100**	**99.0**	**98.7**

Table A7.1.1.1.1- E: Metabolite patterns in the organic phase after hydrolysis of ^{14}C-Alphacypermethrin (0,001µg/ml) at pH 9 and 50°C (in percentage of the radioactivity recovered).

	Time interval (days)								
	0	1	2	3	4	6	8	10	24
Identity									
parent	99.0	84.3	66.8	56.2	35.9	28.5	15.2	36.8	5.0
WL 42049	1.0	15.7	33.2	43.8	64.1	70.1	84.6	62.8	92.1
Unknown	n.d.	n.d.	n.d.	n.d.	n.d.	1.0	n.d.	n.d.	n.d.
Total % recovery	**100**	**100**	**100**	**100**	**99.5**	**99.6**	**99.8**	**99.6**	**97.1**

Section A7.1.1.1.1
Annex Point IIA 7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products
– Supportive data –

The following reference is considered to contain additional information concerning hydrolysis as a function of pH and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.1.1.1.1/02**

Salisbury K, Weaver RC, Langner EJ (1984) The hydrolysis of Fastac (WL85871). SRC, Sittingbourne, UK, Report no. SBRN.84.172 June 1984, BASF RDI No.: AL-322-001 (unpublished).

Guidelines: Guideline not stated but similar to OECD 111

GLP: No

Material and methods:

The hydrolytic stability of Alphacypermethrin was tested at pH 5, 7, and 9 at different temperatures in buffer solutions containing 1% acetone.

Analytics: GC

Findings:

Alphacypermethrin was readily hydrolysed at alkaline pH values by ester cleavage to give DCVA and PBA. The half-lives at 22°C were calculated to be 162 days, 46 days and 2.9 hours, respectively, in pH 5, 7 and 9 buffers.

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 study was investigated at pH 5 as lowest values whereas OECD 111 uses pH 4, thus deviation. However, BE CA considered this like a minor deviation and believes that this will not affect validity of results.
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 A7.1.1.1.2
Annex Point IIA 7.6.2.2

Phototransformation in water including identity of transformation products

Official use only

1 REFERENCE

1.1	**Reference**	**A7.1.1.1.2/01:** Concha M, Yan Z, Beigel C (2001) BAS 310 I (Alphacypermethrin): aqueous photolysis. PTRL West, Inc., Hercules, CA, USA, Report no. ENV 01-037, October 24, 2001, BASF RDI No.: AL-324-003 (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**	Yes Society of Toxicology and Chemistry SETAC-Europe procedures for assessing the environmental fate and ecotoxicity of pesticides, part 1, fate and behaviour in the environment, 10, aqueous photolysis
2.2	**GLP**	Yes
2.3	**Deviations**	Yes

3 MATERIALS AND METHODS

3.1	**Test material**	As given in section A2: BAS 310I (Alphacypermethrin)
3.1.1	Lot/Batch number	1. AC 12041-138 2. AC 12041-143
3.1.2	Specification	As given in section A2: Deviating from specification given in section A2 as follows:
3.1.3	Purity	1. 84.5 µCi/mg 97.1% 2. 80.5 µCi/mg 91.9%
3.1.4	Radio-labelling	1. Benzyl ring-U-^{14}C, [Bz-^{14}C]-alphacypermethrin 2. Cyclopropane-1-^{14}C, [Cp-^{14}C]-alphacypermethrin

Section A7.1.1.1.2 **Phototransformation in water including identity of transformation products**
Annex Point IIA 7.6.2.2

3.1.5	UV/VIS absorption spectra and absorbance value	An UV-VIS spectrum is presented in the report on page 72.	
3.1.6	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 Aqueous hydrolysis studies: 1) [^{14}C]-alphacypermethrin was not hydrolysed at pH 4, was hydrolysed at pH 7 (DT_{50} ca. 67 days) and was rapidly hydrolysed at pH 9 (DT_{50} ca.3.5 days) at 25°C. [Reference: van Dijk A (1993) Hydrolysis determination of ^{14}C-alphacypermethrin at different pH values. RCC, Itingen, Switzerland, Report no. 307383] 2) Alphacypermethrin was readily hydrolysed at alkaline pH values by ester cleavage. The half-lives at 22 °C were calculated to be 162 days, 46 days and 2.9 hours, respectively, in pH 5, 7 and 9 buffers. [Reference: Salisbury K, Weaver RC, Langner EJ (1984) The hydrolysis of Fastac (WL85871). SRC, Sittingbourne, UK, Report no. SBRN.84.172]	
3.2	**Reference substance**	No	
3.3	**Test solution**	See Table A7.1.1.1.2- 1 for details.	X
3.4	**Testing procedure**		
3.4.1	Test system	See Table A7.1.1.1.2- 2 for details	
3.4.2	Properties of light source	See Table A7.1.1.1.2- 2 for details	
3.4.3	Determination of irradiance	Artificial irradiance: A p-nitroacetophenone/pyridine chemical actinometer was used. The intensity of irradiance was measured by the decrease of concentration of p-nitroanisole, which is proportional to the number of quanta striking the sample. p-nitroacetophenone: 10^{-5} M, pyridine: 3.85×10^{-2} M	
3.4.4	Temperature	Irradiation samples: 21.8 ± 0.5 °C Dark control : 22.0 ± 0.1 °C	
3.4.5	pH	pH 5 ± 0.1	
3.4.6	Duration of the test	1. [Bz-^{14}C]-alphacypermethrin: 15 days 2. [Cp-^{14}C]-alphacypermethrin: 28 days 3. Dark control: 18 days and 28 days, respectively	
3.4.7	Number of replicates	2	

Section A7.1.1.1.2 **Phototransformation in water including identity of transformation products**
Annex Point IIA 7.6.2.2

3.4.8	Sampling	1. [Bz-14C]-alphacypermethrin: 0, 8 and 16h, 1, 2, 4, 7 and 15 days of exposure. dark control: 8 and 16h, 1, 2, 4, 7 and 18 days of exposure 2. [Cp-14C]-alphacypermethrin: 0, 1, 2, 4, 8, 15 and 28 days of exposure. dark control: 1, 2, 4, 8, 15 and 28 days of exposure	
3.4.9	Analytical methods	The samples were acidified with 3–4 drops 12N HCl. The samples and sample holders were extracted with ethyl acetate (3 times). Aliquots of the organic layer and the aqueous phase were radio-assayed by LSC. The organic layers were than concentrated under reduced pressure, evaporated to dryness and re-dissolved in 200µL acetonitrile:water 1:1 (v/v). Aliquots were analysed by HPLC and TLC and radio-assayed by LSC. The water phase were combined with an equal volume of acetonitrile : acetone 1:1 (v/v) and concentrated under reduced pressure. Aliquots were analysed by HPLC and radio-assayed by LSC. The actinometer solutions were analysed by HPLC-UV. For p-nitroacetophenone 5 standards with concentrations of 1.17×10^{-5} to 17.6×10^{-5} mg/L resulted in a correlation coefficient of 1.0.	
3.5	**Transformation products**	Yes	
3.5.1	Method of analysis for transformation products	By co-chromatography with analytical reference standards by HPLC and one-dimensional TLC and LC-MS.	
		4 RESULTS	
4.1	**Screening test**	Performed After 3 days of exposure, alphacypermethrin comprised 22.2% of the applied dose in the light exposed sample and 90.4% in the dark control. These results were used to set the sampling for the definitive exposure.	
4.2	**Actinometer data**	Data on the actinometry with p-nitroacetophenone/pyridine are presented in Table A7.1.1.1.2- 3.	
4.3	**Controls**	Initial concentration: 0.002 µg/L Final concentration: 0.0021 g/L and 0.0019 g/L, respectively.	X
4.4	**Photolysis data**		
4.4.1	Concentration values	Please refer to Table A7.1.1.1.2- 5 and Table A7.1.1.1.2- 6. A graphical presentation is given in Figure A7.1.1.1.2- 1 and Figure A7.1.1.1.2- 2.	

Section A7.1.1.1.2 **Phototransformation in water including identity of transformation products**
Annex Point IIA 7.6.2.2

4.4.2	Mass balance	1. [Bz-^{14}C]-alphacypermethrin: Recovery of total initially applied radioactivity in the light exposed samples ranged from 90–107.6 % during study period of 0–18 days. Recovery of total initially applied radioactivity in the dark control ranged from 90.1–113.0 % during study period of 8h–18 days. Average: 100.1 ± 5.8% 2. [Cp-^{14}C]-alphacypermethrin: Recovery of total initially applied radioactivity in the light exposed samples ranged from 90.1–113.2 % during study period of 0–28 days. Recovery of total initially applied radioactivity in the dark control ranged from 95.9–100.7 % during study period of 1–28 days. Average: 98.1 ± 7.8%
4.4.3	k^c_p	0.3287 d^{-1}
4.4.4	Kinetic order	First order
4.4.5	k^c_p / k^a_p	0.699
4.4.6	Reaction quantum yield ($\phi^c E$)	8.12×10^{-3}
4.4.7	$k_p E$	Not stated in the report.
4.4.8	Half-life ($t_{1/2E}$)	The first-order degradation rate and DT_{50} values of alphacypermethrin and of the metabolites CL 206969 and CL 206128 (Bz-^{14}C-label), and CL 901649 (Cp-^{14}C-label) in the light exposed samples were estimated using the software tool ModelMaker V.4.0 (Cherwell Scientific Publishing Ltd., UK). The observed data from the benzyl and the cyclopropyl ^{14}C-label were modelled separately. A four-compartment mathematical model was developed to describe the experimental data from the Bz-^{14}C-label. The DT_{50} and DT_{90} values for alphacypermethrin and the degradation products are given in Table A7.1.1.1.2- 7.
4.5	**Specification of the transformation product**	The percentages of parent compound are given in Table A7.1.1.1.2- 5 and Table A7.1.1.1.2- 6. A graphical presentation thereof is given in Figure A7.1.1.1.2- 1 and Figure A7.1.1.1.2- 2. The transformation pathways are given in Figure A7.1.1.1.2- 3. The chemical names and percent of parent compound of the photolytical transformation products are given in tabular form (see Table A7.1.1.1.2- 4).

Section A7.1.1.1.2
Annex Point IIA 7.6.2.2

Phototransformation in water including identity of transformation products

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The photo-transformation of alphacypermethrin in water was tested according to SETAC Europe, Procedure for Assessing the Environmental Fate and Ecotoxicology of Pesticides, Part 1, Section 10. "Aqueous Photolysis".

The photodegradation of alphacypermethrin in water was investigated in sterile pH 5 buffer solution. Two radiolabelled test substances, [benzyl-U-^{14}C]-alphacypermethrin (Bz, uniformly labelled in the benzene ring) and [cyclopropane-1-^{14}C]-alphacypermethrin (Cp, labelled in the 1-position of the cyclopropane ring), were continuously exposed to artificial light in quartz tubes for 15 days and 28 days, respectively, at a concentration of 0.002 mg/L.

The irradiation was performed using a Suntest CPS+ apparatus equipped with a Xenon arc lamp which had wavelengths of < 290 nm filtered to simulate the spectrum of sunlight. The samples were placed in a temperature controlled deionised water bath maintained at an average of 21.8 ± 0.5°C throughout the course of the study. Dark control samples were run concurrently for each label in amber borosilicate glass bottles. The dark control samples were placed in an incubator and maintained at 22.0 ± 0.1°C for the study period.

Volatiles were trapped continuously in all samples using sets of one ethylene glycol trap for organic volatiles, and two aqueous KOH (10 % KOH solution) traps for CO_2. The quantitation and assignments of alphacypermethrin and metabolites was performed by HPLC analysis and the confirmation of metabolite identities was performed by co-spotting with authentic reference standards on one-dimensional thin layer chromatography (TLC) or by liquid chromatography/mass spectrometry (LC/MS).

For the determination of the quantum yield of BAS 310 I, a solution mixture of p-nitroacetophenone and pyridine in sterile water was used as a low optical density chemical actinometer. The actinometer samples were run concurrently alongside the Bz-labelled samples.

Section A7.1.1.1.2
Annex Point IIA 7.6.2.2

Phototransformation in water including identity of transformation products

5.2	**Results and discussion**	Radiocarbon recoveries ranged from 90 to 108.5 % of the nominal applied radioactivity (AR) in the light exposed samples and from 90.1 to 113.0 % in the dark controls samples for the study period. [^{14}C] alphacypermethrin degraded rapidly in the light exposed samples. Alphacypermethrin represented 52.5 % and 41.0 % AR in Bz- and Cp-labelled samples, respectively, after 2 days of exposure, and was below the detection limit for both labels by the end of the exposure period. The main metabolites observed in the Bz labelled light exposed samples were CL 206969 (3-phenoxybenzaldehyde), which reached a maximum of 15.9 % AR at day 2, and CL 206128 (3-phenoxybenzoic acid), which reached a maximum of 22.5 % AR at day 4. At the end of the exposure period, CL 206969 had declined to 4.1 % AR, and CL 206128 had declined to 8.5 % AR. The main metabolite observed in the Cp labelled light exposed samples was CL 901649 (cis + trans-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers), which reached a maximum of 43.7 % AR by day 8, subsequently declining to 34.8 % AR by day 28. Unextracted radiocarbon in the aqueous layers of the Bz-labelled samples increased to 26 % AR by the end of the exposure period. HPLC analysis of selected aqueous layers with a Bio-Rad Aminex HP-87H ion exchange column showed that the radiocarbon in the Bz-labelled samples was comprised of at least 4 polar components, each representing less than 8 % AR. Unextracted radiocarbon in the aqueous layers from the Cp-labelled samples represented 10.8 % AR at day 28. HPLC analysis (ion exchange) showed a transient metabolite eluting at 15 minutes, comprising up to 11 % AR in one replicate of the light exposed samples on day 8. The transient metabolite, identified by LC/MS as CL 1500788, was below the detection limit in the remaining light exposed samples after day 8. Volatiles trapped in the caustic traps (confirmed as CO_2 by $BaCl_2$ precipitation) represented an average of 21.4 % AR by the end of the study in the Bz-labelled samples, and 7.7 % AR in the Cp labelled samples. The radiocarbon recovered in the traps for organic volatiles was less than 3 % AR. Alphacypermethrin did not degrade significantly in the dark control samples and represented > 90% of the applied radioactivity at the end of the incubation period for both the Bz- and Cp-labelled exposures. Therefore, degradation in the irradiated samples can be attributed to photochemical reactions.
5.2.1	k^c_p	$0.3287\ d^{-1}$
5.2.2	k_pE	Not stated in the report.
5.2.3	ϕ^cE	8.12×10^{-3}
5.2.4	$t_{1/2E}$	The DT_{50} and DT_{90} values for alphacypermethrin and the degradation products are given in Table A7.1.1.1.2- 7. Accordingly, the environmental half-life of alphacypermethrin calculated for natural sunlight conditions ranges between 3.4 and 6.3 days.

Section A7.1.1.1.2 Phototransformation in water including identity of transformation products
Annex Point IIA 7.6.2.2

5.3	**Conclusion**	Alphacypermethrin (BAS 310 I) degraded rapidly in pH 5 buffer under photolysis conditions at 22°C, while remaining stable in the dark control. Photolytic degradation of alphacypermethrin in water will play an important role in its environmental fate profile.
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	February 2009
Materials and Methods	The Applicant's version is considered to be acceptable with the following amendment: Section 3.3 : Table A7.1.1.1.2-1 test concentration : 0,002 µg/ml or 0,002 mg/l
Results and discussion	The Applicant's version is considered to be acceptable with the following amendment: Section 4.3 Controls Initial concentration: 0,002 µg/ml (mg/l) Final concentration: 0,0021 µg/ml (mg/l) and 0,0019 µg/ml (mg/l)
Conclusion	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 A7.1.1.1.2- 1: Description of test solution and controls.

Criteria	Details
Purity of water	Sterile HPLC grade water
Preparation of test chemical solution	Buffer solution (0.05M sodium acetate buffer, pH5): 4.1g sodium acetate (6.3 g sodium acetate trihydrate) per 1000mL, pH adjustment by glacial acetic acid to pH 5. The buffer was filter sterilised through a 0.22 µm filter; The test solutions were prepared as follows: 500 µL of the dosing solution in acetonitrile were diluted in 75 mL sterile pH 5 buffer solutions
Test concentrations	0.002µg/L **(BE CA correction: 0.002 µg/ml)**
Temperature [°C]	21.8 ± 0.5°C 22.0 ± 0.1°C (dark control)
Preparation of a.s. solution	PNAP: 1×10^{-5} M PYR: 3.85×10^{-2} M k_a[a] = 0.4421 d^{-1}
Controls	Dark control
Identity and concentration of co-solvent	Acetonitrile below 0.01% (v/v)

Table A7.1.1.1.2- 2: Description of test system.

Criteria	Details
Laboratory equipment	*Reaction vessels:* Quartz sample tubes of 23 mm i.d. × 180 mm length, equipped with Teflon-lined silicon septum screw caps; dark control: 125 mL borosilicate amber bottles with Teflon-lined silicon septum screw caps *Trapping of volatiles:* Volatiles were trapped continuously during the study by drawing sterile ambient air through the samples connected to individual sets of traps containing (i) an ethylenglycol trap (10mL) and (ii) two KOH traps (10% by weight in water)
Test apparatus	A Heraeus Suntest CPS+ with a xenon irradiation source for irradiation of test samples was used
Properties of artificial light source:	
Nature of light source	Xenon lamp
Emission wavelength spectrum	300–800 nm
Light intensity	750 W/m² with an average intensity of 546 W/m² for the 300–800 nm range (this intensity is lower than the solar noon intensity at 40°N latitude in the 300–800 nm region (approx. 585 W/m²)
Filters	Quartz glass filter with IR reflective coating and a special UV glass filter blocking radiation below approx. 290 nm
Properties of natural sunlight:	Not applicable

Table A7.1.1.1.2- 3: Actinometer data.

PNAP/ pyridine concentrations	PNAP: 1×10^{-5} mol/l Pyridine: 3.85×10^{-2} mol/l
ϕ^a_E	6.51×10^{-4}
k^a_p	0.4421 d^{-1}

Table A7.1.1.1.2- 4: Specification and amount of transformation products.

CAS-Number	CAS and/or IUPAC chemical name(s)	Amount [%] of parent compound measured at pH 5	
		Max.	End of test
	3-phenoxybenzaldehyde (CL 206969)	15.9 % on day 2	4.1 %
	3-phenoxybenzoic acid (CL 206128)	22.5 % on day 4	8.5 %
	Cis + trans-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 901649)	43.7 % on day 8	34.8 %

Table A7.1.1.1.2- 5: Recovery of radioactivity and product balance following the aqueous photolysis of [Bz-^{14}C]-BAS 310 I at pH 5; values are averages of replicate samples.

Time	% of applied radioactivity							
	Organic layer residues				Aqueous layer residues**	CO_2	Volatiles	Total recovery
	BAS 310 I	CL 206969	CL 206128	Sum of other minor peaks*				
0 h	95.8	<1	<1	<1	<1	NA	NA	96.5
8 h	96.0	1.9	4.8	3.8	<1	<1	<1	107.6
16 h	83.9	1.3	5.6	5.0	<1	<1	<1	96.0
1 d	73.3	6.3	13.7	7.7	<1	<1	<1	102.1
2 d	52.5	15.9	17.1	12.7	3.7	<1	<1	102.5
4 d	27.7	12.9	22.5	24.5	6.8	2.8	0.4	97.5
7 d	9.8	8.9	14.9	40.3	15.6	5.3	1.5	95.7
15 d	<1	4.1	8.5	29.9	26.0	21.4	2.8	93.2

NA: Not applicable

*each peak <8% of applied dose at any sampling time

** each peak <6% of applied dose at any sampling time

Table A7.1.1.1.2- 6: Recovery of radioactivity and product balance following the aqueous photolysis of [Cp-^{14}C]-BAS 310 I at pH 5. Values are average of replicate samples.

Time	% of applied radioactivity							
	Organic layer residues				Aqueous layer residues**	CO_2	Volatiles	Total recovery
	BAS 310 I	CL 206969	CL 206128	Sum of other minor peaks*				
0 h	94.7	1.7	<1	6.4	<1	NA	NA	103.2
1 d	48.6	32.4	1.1	11.0	2.9	1.3	<1	97.3
2 d	33.6	38.1	5.4	17.1	6.9	2.0	<1	103.7
4 d	27.0	36.3	1.2	13.3	14.5	1.3	<1	93.8
8 d	6.5	43.7	3.0	31.2	14.7	4.1	<1	103.6
15 d	<1	34.8	24.1	21.8	9.8	6.9	1.1	98.5
28 d	<1	34.8	23.2	18.3	10.3	7.7	1.0	95.1

NA Not applicable

* Each peak <7.5% of applied dose at any sampling time

** The radiocarbon in the aqueous layers was comprised of several minor degradates and one transient degradate, CL 1500788 which reached 11% of dose at Day 8 (one replicate only) subsequently declining below detection limit in Day 15 and Day 28 samples

Table A7.1.1.1.2- 7: Estimated first-order DT_{50} and DT_{90} values of BAS 310 I and its degradation products estimated with ModelMaker 4.0.

	Artificial light exposure		Calculated solar exposure*	
	DT_{50} (days)	DT_{90} (days)	DT_{50} (days)	DT_{90} (days)
^{14}C-Bz label position				
BAS 310 I	2.2	7.3	6.3	20.9
CL 206969	3.8	12.5	10.9	35.7
CL 206128	2.2	7.2	6.3	20.6
^{14}C-Cp label position				
BAS 310 I	1.2	4.1	3.4	11.7
CL 901649	33.6	111.8	96.0	319.4

*based on 8.4 hours of artificial light irradiation = 1 solar day

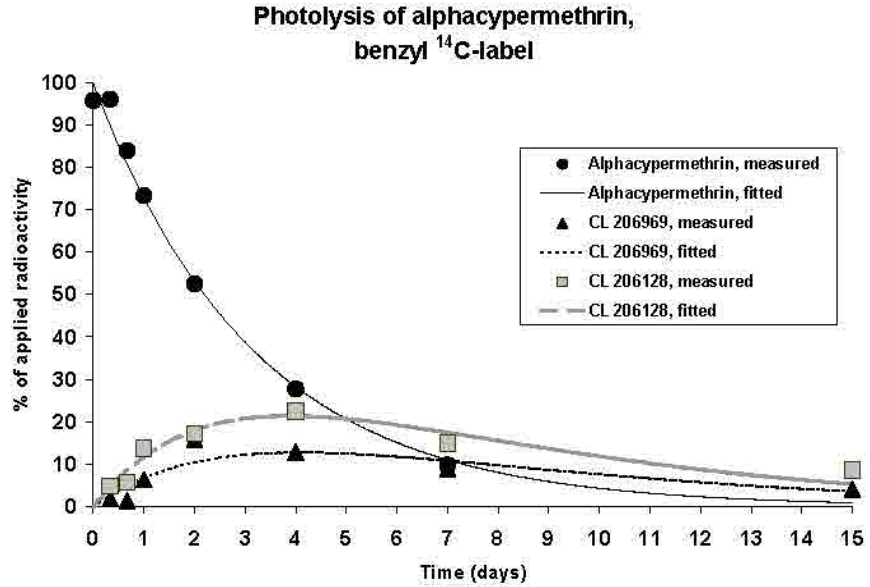

Figure A7.1.1.1.2- 1: Description of the photolysis of [^{14}C-Bz] BAS 310 I and photodegradates CL 206969 and CL 206128 using a four-compartment model with first-order kinetics in ModelMaker 4.0. Measured values are represented as average of replicates.

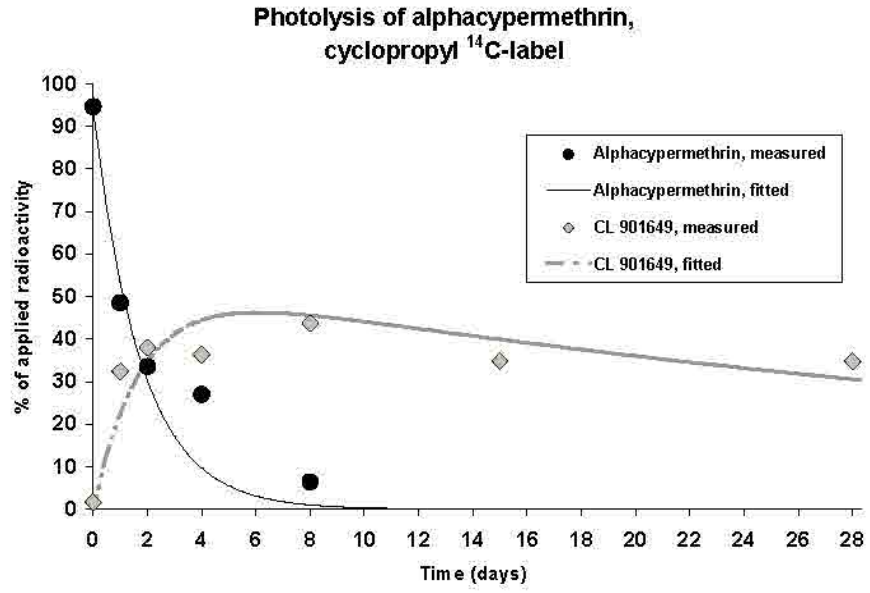

Figure A7.1.1.1.2- 2: Description of the photolysis of [^{14}C-Cp] BAS 310 I and photodegradate CL 901649 using a three-compartment model with first-order kinetics in ModelMaker 4.0. Measured values are represented as average of replicates.

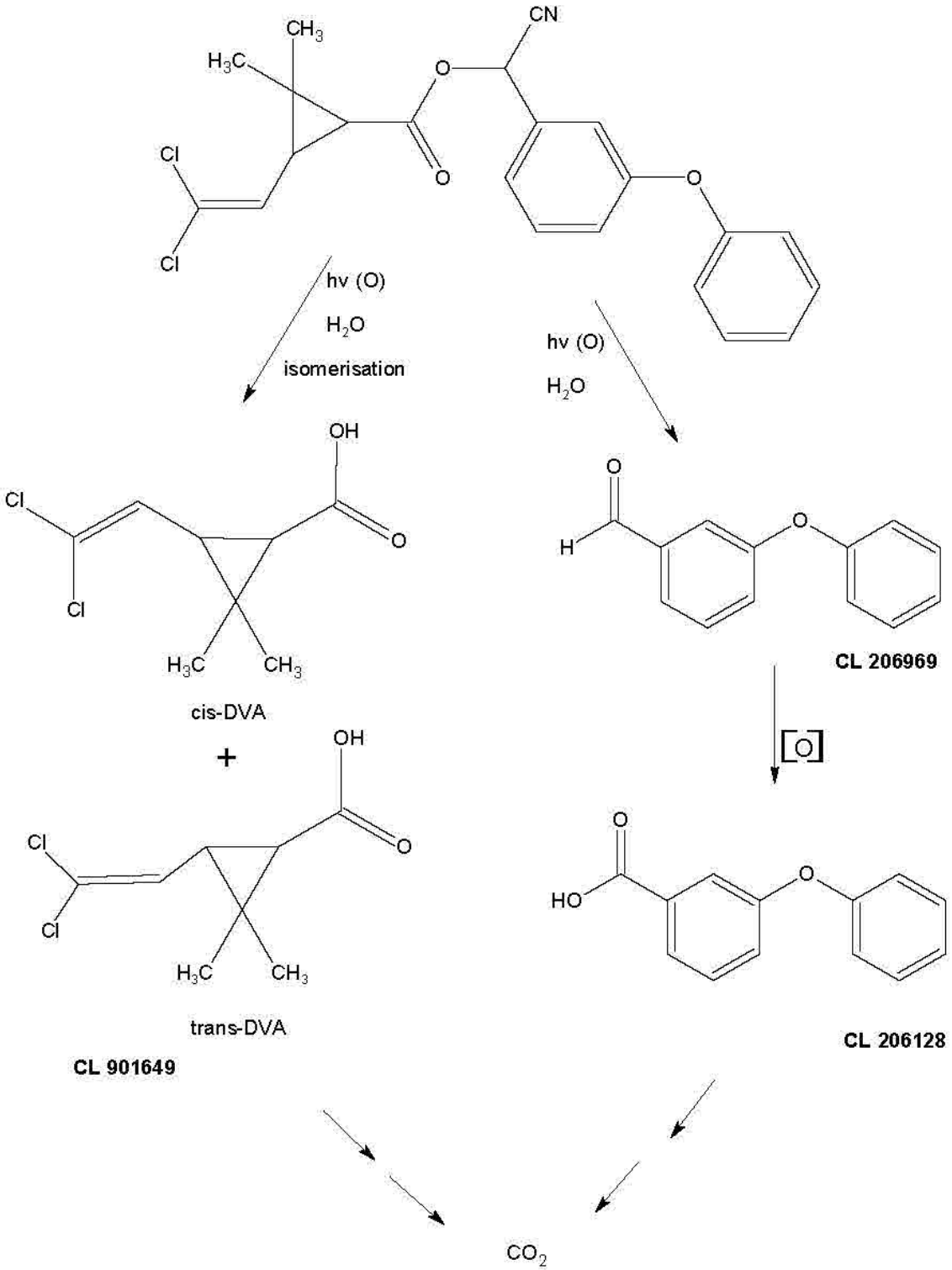

Figure A7.1.1.1.2- 3: Degradation pathway of Alphacypermethrin in pH 5 buffer when exposed to artificial light.

Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of transformation products
– Supportive data –

The following reference is considered to contain additional information concerning the phototransformation of alphacypermetrin in water and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.1.1.1.2/02**

Fisk PR (1994) Alphacypermethrin (FASTAC): Photodegradation in water (preliminary experiment), including a comparison with esfenvalerate. SRC, Sittingbourne, UK, Report no. SBTR.93.030, May 10, 1994, BASF RDI No.: AL-630-009 (unpublished).

Guidelines: Guideline not stated but similar to SETAC and OECD draft guideline

GLP: Yes

Material and methods:

A preliminary test on the photodegradation of alphacypermethrin and of a competitor material, esfenvalerate, in water (pH 7) was conducted. Aqueous solutions were exposed continuously to light using an artificial light source which simulated sunlight. Samples of the two individual test substances were taken after 2, 6 and 24 h of exposure. Mixed samples were analysed 48 h and 76 h of exposure. Analysis was performed by extraction with hexane followed by gas chromatography.

Findings:

The rates of photolysis of alphacypermethrin and esfenvalerate were compared. Under the conditions of the test, the half-life of alphacypermethrin and esfenvalerate was approx. 30 and less than 10 hours, respectively.

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: At pH 7 hydrolysis takes place, so study should be carried out at more acidic pH to avoid this effect.
Results and discussion	The Applicant's version is acceptable
Conclusion	The Applicant's version is acceptable
Reliability	2
Acceptability	Acceptable
Remarks	Supportive data not to be use in the risk assessment.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– closed bottle test –**

Official use only

1 REFERENCE

1.1	**Reference**	**A7.1.1.2.1/01:** Stone C, Watkinson R (1983) WL85871: An assessment of ready biodegradability. Shell Research Ltd, Sittingbourne Research Centre, Sittingbourne, UK, Report no. SBGR.83.206, October 10, 1983 (unpublished), BASF RDI No.: AL-690-001.
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**	Yes OECD 301D
2.2	**GLP**	No GLP was not compulsory at the time the study was conducted.
2.3	**Deviations**	Yes Insufficient number of sampling dates (see 3.3.8); Use of a detergent (see 3.3.4).

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	96.5% (w/w)
3.1.4	Further relevant properties	Water solubility approx. 5.80 µg/l at pH 7
3.1.5	Composition of Product	Not relevant; active substance was tested.
3.1.6	TS inhibitory to microorganisms	No
3.1.7	Specific chemical analysis	No

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– closed bottle test –**

3.2	**Reference substance**	Yes Benzoic acid, sodium salt
3.2.1	Initial concentration of reference substance	3.0 mg/l
3.3	**Testing procedure**	
3.3.1	Inoculum/ test species	As given in Table A7.1.1.2.1- 1.
3.3.2	Test system	The test system is described in Table A7.1.1.2.1- 2. Obviously, the test system is only poorly documented. The report states that the test was generally performed according to OECD 301D.
3.3.3	Test conditions	See Table A7.1.1.2.1- 3. Again, the test conditions are only poorly documented. The report states that the test was generally performed according to OECD 301D.
3.3.4	Method of preparation of test solution	In order to achieve sufficient solubility, the non-degradable detergent Dobane PT sulphonate at a final concentration of 0.58 mg/l (recalculated from the concentration in the stock solution of 0.24 g/l) was used for solubilisation of the test substance.
3.3.5	Initial TS concentration	2.9 mg/l alphacypermethrin
3.3.6	Duration of test	28 d
3.3.7	Analytical parameter	Oxygen concentration
3.3.8	Sampling	0, 5, 15, and 28 d
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/ nitrite measurement	No
3.3.11	Controls	Blank control (mineral medium only) Inoculum blank (detergent, mineral medium and inoculum) Procedural control (reference substance, detergent, inoculum) Toxicity control (test substance, reference substance, detergent, inoculum)
3.3.12	Statistics	ThOD according to OECD 301 D. Per cent degradation.

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– closed bottle test –**

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	Degradation is presented graphically in Figure A7.1.1.2.1- 1.
4.1.2	Degradation	No measurable degradation occurred.
4.1.3	Other observations	In the inoculum blank, oxygen consumption was more than 1.5 mg O_2/l (measurement mean = 1.8 mg/l). In the toxicity control, more than 25% degradation occurred. Thus, the test substance was not inhibitory to the inoculum. Oxygen concentration data (toxicity control):

Day	0	5	15	28
O_2 conc. [mg/l], repl. 1	8.9	5.7	4.9	3.6
O_2 conc. [mg/l], repl. 2		5.6	4.9	3.9

4.1.4	Degradation of TS in abiotic control	Not required.
4.1.5	Degradation of reference substance	See Figure A7.1.1.2.1- 1.
4.1.6	Intermediates/ degradation products	Not appropriate.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The ready biodegradability of alphacypermethrin, measured as per cent degradation, was tested using the closed bottle test (OECD guideline 301 D). The performance and reporting of the study deviated from the most recent version of the guideline as follows: the sampling dates were less frequent and spaced further apart than recommended, initial cell densities were not reported, the entire experimental procedure was insufficiently documented. The low water solubility of alphacypermethrin was appropriately accounted for by adding a non-degradable detergent. The nominal concentration of 2.9 mg/l fulfils the range specified by the guideline.
5.2	**Results and discussion**	In relation to the blank control, alphacypermethrin showed no degradation in the closed bottle test. The criterion for oxygen consumption in the blank inoculum (< 1.5 mg/l) was marginally failed.

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– closed bottle test –**

5.3	**Conclusion**	The formal validity criteria as given in Table A7.1.1.2.1- 4 were fulfilled. However, oxygen consumption in the blank control was slightly above the permitted value. Thus, the study should not be considered as fully valid. Irrespective of the restricted formal validity, the results indicate that alphacypermethrin does not fulfil the criteria of a readily biodegradable substance.
5.3.1	Reliability	3
5.3.2	Deficiencies	Yes Apart from the deviations and deficiencies discussed above, the study suffers from insufficient documentation of materials, methods and results. The sum of deficiencies renders the study to be of limited validity. Nevertheless, in view of the availability of higher-tier studies for water-sediment systems, the result "not biodegradable" may be taken forward to the risk assessment where this is not superseded by higher-tier 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	April 2012
Materials and Methods	BE CA agrees with the applicant's version
Results and discussion	BE CA agrees with the applicant's version
Conclusion	BE CA agrees with the applicant's version
Reliability	3
Acceptability	Not Acceptable
Remarks	Study is considered as additional information as higher tier studies are available (water-sediment degradation) to be used in the risk assessment.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.1.1.2.1- 1: Description of the inoculum.

Criteria	Details
Nature	Activated sludge
Species	Mixed microbial population
Strain	Not applicable
Source	Sewage treatment plant
Sampling site	Sittingbourne sewage works, UK
Laboratory culture	No
Method of cultivation	Not applicable
Preparation of inoculum for exposure	According to guideline
Pre-treatment	None
Initial cell concentration	Not reported

Table A7.1.1.2.1- 2: Description of the test system.

Criteria	Details
Culturing apparatus	Temperature controlled dark chamber
Number of culture flasks/concentration	2
Aeration device	Not stated
Measuring equipment	Not stated
Test performed in closed vessels due to significant volatility of test substance	No

Table A7.1.1.2.1- 3: Description of the test conditions.

Criteria	Details
Composition of the medium	Not reported
Additional substrate	None
Test temperature	20 ± 1 °C
pH	Not reported
Aeration of dilution water	Not reported
Suspended solids concentration	Not reported
Other relevant criteria	None

Table A7.1.1.2.1- 4: Pass levels and validity criteria for tests on ready biodegradability.

	Fulfilled	**Not fulfilled**
Pass levels		
60% removal of ThOD or ThCO2		X
Pass values reached within 10-d window/ 28-d test period		X
Criteria for validity		
Variation between replicates at the end of test < 20%	X	
Removal of reference substance reaches pass level by day 14	X	
Criteria for poorly soluble test substances		
Selection of suitable test method (closed bottle test)	X	

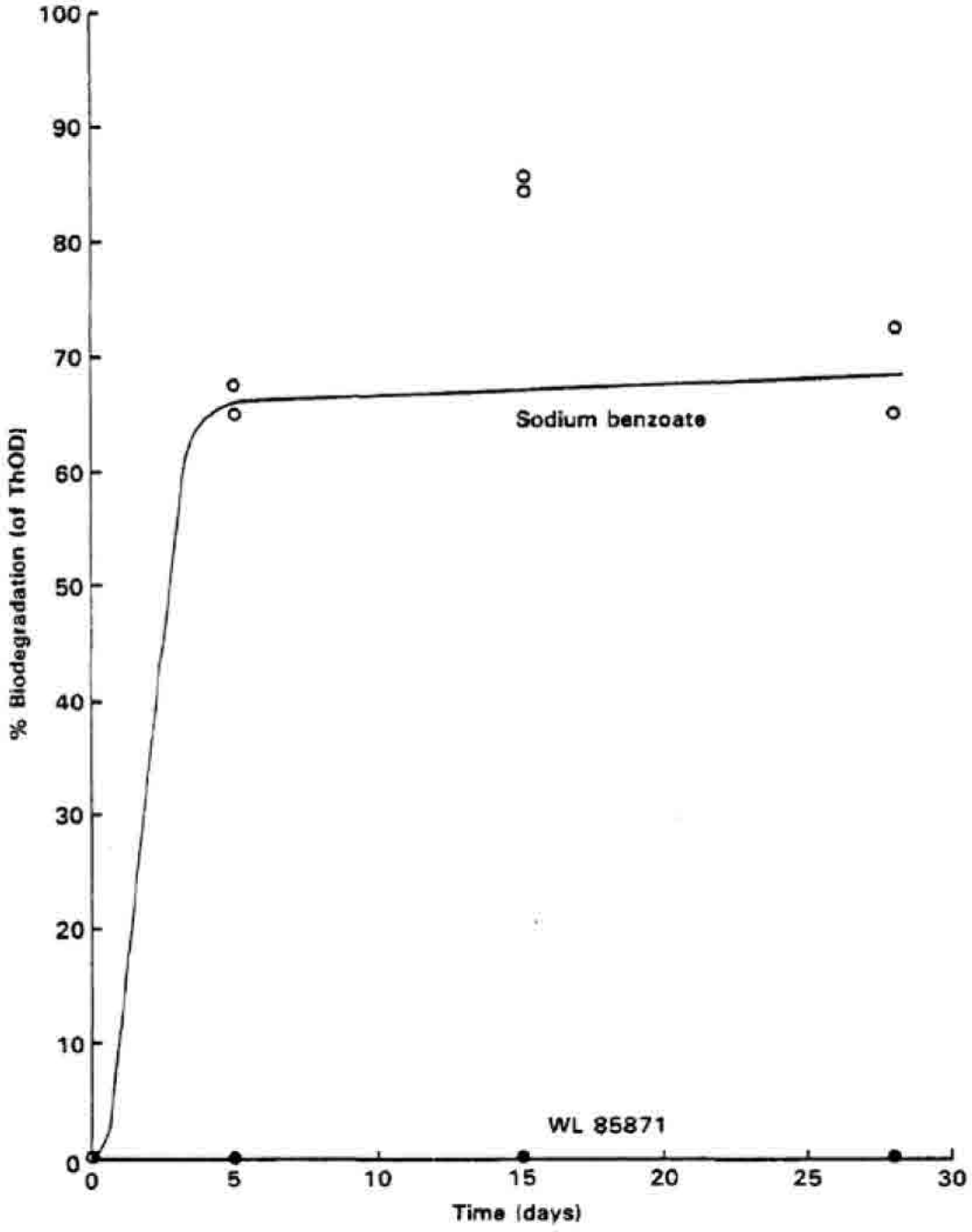

Figure A7.1.1.2.1- 1: Degradation of alphacypermethrin (filled circles) and the reference substance (open circles) in the closed-bottle test.

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– modified Sturm test –**

Official use only

1 REFERENCE

1.1	**Reference**	**A7.1.1.2.1/01:** Stone C, Watkinson R (1983) WL85871: An assessment of ready biodegradability. Shell Research Ltd, Sittingbourne Research Centre, Sittingbourne, UK, Report no. SBGR.83.206, October 10, 1983 (unpublished), BASF RDI No.: AL-690-001.
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**	Yes OECD 301B
2.2	**GLP**	No GLP was not compulsory at the time the study was conducted.
2.3	**Deviations**	Yes Insufficient number of sampling dates (see 3.3.8);

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	96.5% (w/w)
3.1.4	Further relevant properties	Water solubility approx. 5.80 µg/l at pH 7
3.1.5	Composition of Product	Not relevant; active substance was tested.
3.1.6	TS inhibitory to microorganisms	No
3.1.7	Specific chemical analysis	No

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– modified Sturm test –**

3.2	**Reference substance**	Yes Benzoic acid, sodium salt
3.2.1	Initial concentration of reference substance	20 mg/l
3.3	**Testing procedure**	
3.3.1	Inoculum/ test species	As given in Table A7.1.1.2.1- 5.
3.3.2	Test system	The test system is described in Table A7.1.1.2.1- 6. Obviously, the test system is only poorly documented. The report states that the test was generally performed according to OECD 301B.
3.3.3	Test conditions	See Table A7.1.1.2.1- 7. Again, the test conditions are only poorly documented. The report states that the test was generally performed according to OECD 301B.
3.3.4	Method of preparation of test solution	In order to achieve sufficient solubility, the non-degradable detergent Dobane PT sulphonate at a final concentration of 4.0 mg/l (recalculated from the concentration in the stock solution of 0.24 g/l) was used for solubilisation of the test substance.
3.3.5	Initial TS concentration	20 mg/l alphacypermethrin
3.3.6	Duration of test	28 d
3.3.7	Analytical parameter	Carbon dioxide evolution
3.3.8	Sampling	3, 7, 11, 18, 25, 27 and 28 d (the latter after acidification for complete CO_2 removal)
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/ nitrite measurement	No
3.3.11	Controls	Blank control (mineral medium only) Inoculum blank (detergent, mineral medium and inoculum) Procedural control (reference substance, detergent, inoculum)
3.3.12	Statistics	CO_2 evolution according to OECD 301B. Per cent degradation.

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	Degradation is presented graphically in Figure A7.1.1.2.1- 2.

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA 7.6.1.1 **– modified Sturm test –**

4.1.2	Degradation	No measurable degradation (CO_2 evolution) occurred.
4.1.3	Other observations	None
4.1.4	Degradation of TS in abiotic control	Not required.
4.1.5	Degradation of reference substance	See Figure A7.1.1.2.1- 2.
4.1.6	Intermediates/ degradation products	Not appropriate.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The ready biodegradability of alphacypermethrin, measured as per cent degradation, was tested using the modified Sturm test (OECD guideline 301B). The performance of the study deviated from the most recent version of the guideline as follows: the sampling dates were less frequent and spaced further apart (see 3.3.6 above) than recommended (every 2–3 days in the first ten days). The low water solubility of alphacypermethrin was appropriately accounted for, by adding a non-degradable detergent. The nominal concentration of 20 mg/l fulfils the range specified by the guideline.
5.2	**Results and discussion**	As assessed by the amount of carbon dioxide evolved, alphacypermethrin showed no degradation in the modified Sturm test.
5.3	**Conclusion**	The formal validity criteria as given in Table A7.1.1.2.1- 4 were fulfilled. However, the conduct of the study, e.g. materials, methods, and results are only insufficiently documented. Raw data on CO_2 evolution are not provided. Thus, the study should not be considered as fully valid. Irrespective of these formal deficiencies, the results nevertheless indicate that alphacypermethrin does not fulfil the criteria of a readily biodegradable substance.
5.3.1	Reliability	3
5.3.2	Deficiencies	Yes As already discussed above, the study suffers from insufficient documentation of materials, methods and results, including raw data. These deficiencies render the study to be of limited validity. Nevertheless, in view of the availability of higher-tier studies for water-sediment systems, the result "not biodegradable" may be taken forward to the risk assessment where this is not superseded by higher-tier 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	3
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.1.1.2.1- 5: Description of the inoculum.

Criteria	Details
Nature	Activated sludge
Species	Mixed microbial population
Strain	Not applicable
Source	Sewage treatment plant
Sampling site	Canterbury sewage works, UK
Laboratory culture	No
Method of cultivation	Not applicable
Preparation of inoculum for exposure	According to guideline
Pre-treatment	None
Initial cell concentration	Not reported

Table A7.1.1.2.1- 6: Description of the test system.

Criteria	Details
Culturing apparatus	Not reported
Number of culture flasks/concentration	2
Aeration device	Not stated
Measuring equipment	Standard laboratory equipment for titration
Test performed in closed vessels due to significant volatility of test substance	No

Table A7.1.1.2.1- 7: Description of the test conditions.

Criteria	Details
Composition of the medium	Not reported
Additional substrate	None
Test temperature	Not reported
pH	Not reported
Aeration of dilution water	Yes; with CO_2-free air at 60 mL/min
Suspended solids concentration	Not reported
Other relevant criteria	None

Table A7.1.1.2.1- 8: Pass levels and validity criteria for tests on ready biodegradability.

	Fulfilled	Not fulfilled
Pass levels		
60% removal of ThOD or ThCO2		X
Pass values reached within 10-d window/ 28-d test period		X
Criteria for validity		
Variation between replicates at the end of test < 20%	X	
Removal of reference substance reaches pass level by day 14	X	
Criteria for poorly soluble test substances		
Selection of suitable test method (CO_2 evolution test)	X	

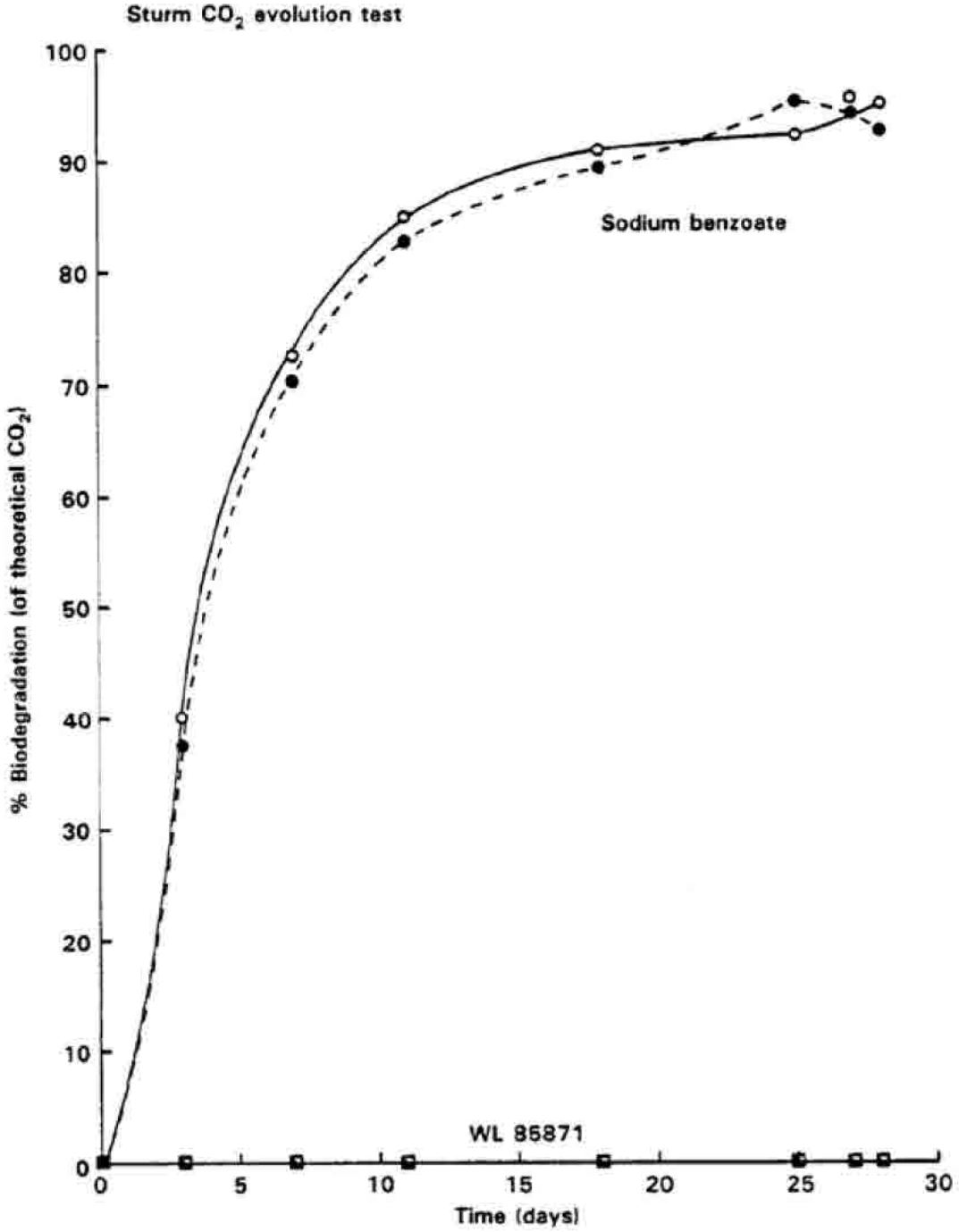

Figure A7.1.1.2.1- 2: Degradation of alphacypermethrin (squares) and the reference substance (circles) in the modified Sturm test.

Section A7.1.1.2.2 Inherent biodegradability

Annex Point IIA 7.6.1.2

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	According to the TNsG on data requirements (e.g. chapter 3, section 7.0.2.2.2), tests on inherent biodegradability are required for the core data set of active substances 'where appropriate'. However, it is also stated that this endpoint may generally not be appropriate since these tests provide only information of limited value for the risk assessment. For alphacypermethrin, water-sediment degradation studies are available. These higher-tier studies are suitable for a sufficiently accurate prediction of the fate of the active substance in the aquatic compartment. Thus, with respect to aquatic biodegradation a test on inherent biodegradability is not considered to be required. According to the available ready biodegradability tests, albeit they are of limited validity, alphacypermethrin is not readily biodegradable. Hence, a degradation rate in the STP of zero would be assigned by default. This is considered to be sufficient for the environmental risk assessment in view of the limited exposure. Regarding the envisaged field of use (insecticide for domestic hygiene only applied indoors), high and/or regular releases of alphacypermethrin to the sewerage are not anticipated. Instead, such releases are expected to occur only infrequently. Thus continuous release is not foreseen; releases are rather described as intermittent. The active substance was shown to be non-toxic to microorganisms in sewage sludge (see section A7.4.1.4), thus indicating absence of significant risk for the biological performance of sewage treatment plants. Furthermore, exposure of sewage treatment plants to alphacypermethrin via other routes is not expected. In conclusion, due to limited exposure and availability of other data on degradation in aqueous media, the conduct of a study on inherent biodegradability is not considered to be required.	
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	BE CA agree with the Applicant's justifications	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.1.1.2.3 Biodegradation in seawater

Annex Point IIIA 12.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	In view of the nature of the biocidal product – a suspension concentrate – and of the intended use pattern – insect control for hygiene in domestic premises – direct release to seawater must be considered absolutely unlikely. Regarding the envisaged use pattern, testing for biodegradation in seawater is not required according to the BPD, and thus no data are submitted.	
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 is acceptable because of the reasons given.	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.1.2.1.1 Biological sewage treatment: aerobic biodegradation

Annex Point IIIA 12.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	Following the intended uses (insecticide for domestic hygiene only applied indoors), release of significant amounts of the substance to sewage treatment plants is not anticipated: Any release to the sewerage is considered to be indirect, e.g. as a consequence of cleaning operations in treated premises. Such releases are anticipated to occur only infrequently. Since continuous release is not foreseen, releases are instead characterised as intermittent. The active substance was shown to be non-toxic to microorganisms in sewage sludge (see section A7.4.1.4), thus indicating absence of significant risk for the biological performance of sewage treatment plants. Furthermore, exposure of sewage treatment plants to Alphacypermethrin via other routes is not expected. In conclusion, conduct of a study on aerobic biodegradation in STPs is not considered to be required.	
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	BE CA agree with the Applicant's justifications
Conclusion	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.1.2.1.2 Biological sewage treatment: anaerobic biodegradation

Annex Point IIIA 12.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**Other justification** [ ]	
Detailed justification:	According to subchapter 7.1.2.1.2 of the TNsG on data requirements, anaerobic biodegradation testing is required only if exposure to anaerobic conditions is likely. Further, it is explicitly mentioned that "this may be the case with veterinary hygiene biocidal products and biocidal pest control products to be used in animal housing where release into manure storage facilities is possible". Regarding the envisaged field of use (insecticide for domestic hygiene only applied indoors), exposure to such anaerobic conditions can safely be considered not to occur. Nevertheless, due to its physical-chemical properties Alphacypermethrin may partition to the sediment, where anaerobic conditions may prevail. However, a water-sediment degradation study is available (section A7.1.2.2.2). Since this experiment represents a higher-tier study, inherently also investigating degradation under anaerobic conditions in the sediment, performance of a screening study on anaerobic biodegradability is not considered to be required.	
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 justifications are acceptable	
Conclusion	Acceptable	
Remarks		
	COMMENTS FROM ...	
Date		
Evaluation of applicant's justification		
Conclusion		
Remarks		

Section A7.1.2.2.1 Aerobic aquatic degradation study

Annex Point IIIA 12.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	In view of the inherent property of Alphacypermethrin to partition predominantly to the sediment (under equilibrium conditions) water-sediment degradation studies were carried out. Accordingly, higher-tier studies appropriately covering the endpoint "aerobic degradation in water" are available. The reader is referred to section A7.1.2.2.2.	
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 justifications are acceptable
Conclusion	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

Official use only

1 REFERENCE

1.1	**Reference**	**A7.1.2.2.2/01:** Mamouni A (1993) FASTAC (Benzyl-^{14}C): Degradation and metabolism in aquatic systems. RCC Umweltchemie AG, Itingen, Switzerland, Report no. 305864, October 18, 1993 (unpublished), BASF RDI No.: AL-630-011. **A7.1.2.2.2/02:** Völkl S (1993) FASTAC (Cyclopropyl-^{14}C): Degradation and metabolism in aquatic systems. RCC Umweltchemie AG, Itingen, Switzerland, Report no. 316326, November 30, 1993 (unpublished), BASF RDI No.: AL-630-012. **A7.1.2.2.2/03:** Beigel C (2001a) Calculation of first-order DT_{50} and DT_{90} values of alphacypermethrin in the water and sediment phases of river-sediment and pond-sediment aquatic Systems. BASF Agro Research, Princeton, NJ, USA, Report no. EXA-01-023, June 20, 2001 (unpublished), BASF RDI No.: AL-630-015. **A7.1.2.2.2/04:** Beigel C (2001b) Calculation of first-order DT_{50} and DT_{90} values of alphacypermethrin metabolites CL 206128 and CL 912554 in the water and sediment phases of river-sediment and pond-sediment aquatic Systems. BASF Agro Research, Princeton, NJ, USA, Report no. EXA-01-006, January 31, 2001 (unpublished), BASF RDI No.: AL-630-014. **Remark:** The above references are, for convenience, merged into one single study summary for the following reasons: Studies A7.1.2.2.2/01 and /02 employ two different radiolabels for investigating the same process, and studies A7.1.2.2.2/03 and /04 report the state-of-the-art modelling of degradation rates and pathways based on the experimental data from the other two studies.	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**	Yes BBA guideline part IV: 5-1, December 1990	
2.2	**GLP**	Yes	

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

2.3	**Deviations**	No		
		3 MATERIALS AND METHODS		
3.1	**Test material**	a) Radio-labelled Alphacypermethrin (FASTAC), benzyl-^{14}C b) Radio-labelled Alphacypermethrin (FASTAC), cyclopropyl-1-^{14}C c) Non labelled standard substance (Alphacypermethrin)		
3.1.1	Lot/Batch number	a) 92008 b) S 1230 c) 1071/004/90		
3.1.2	Specification	a) Benzyl-^{14}C labelled b) cyclopropyl-1-^{14}C labelled		
3.1.3	Purity	a) Radiochemical purity: > 99% b) Radiochemical purity: > 99% c) 99.8%		
3.1.4	Further relevant properties	a) Specific radioactivity: 80.32 mCi/mmole (191 µCi/mg) b) Specific radioactivity: 56 mCi/mmole (134 mCi/g)		X
3.1.5	TS inhibitory to microorganisms	No		
3.1.6	Specific chemical analysis	Radio-TLC		
3.2	**Reference substance**	Alphacypermethrin WL 46114 WL 44607 WL 43480 WL 42049 WL 48489 WL 83140 WL 47133	> 99% – – – > 95% – – –	
		The structure of the reference compounds is given in table 1 on page 60 of the original report (A7.1.2.2.2/01).		
3.3	**Testing procedure**			
3.3.1	Inoculum/ test species	Two different aquatic micro-ecosystems containing a sediment layer. The water/sediment samples were taken from the river Rhine and a pond called "Judenweiher", respectively, both from the area close to Rheinfelden, Switzerland. The characterisation of the sediments is presented in Table A7.1.2.2.2-1		
3.3.2	Test system	See Table A7.1.2.2.2-2		
3.3.3	Test conditions	See Table A7.1.2.2.2-2		

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

3.3.4	Method of preparation of test solution	a) Benzyl-^{14}C-alphacypermetrin *(i) Low dose treatment:* Application solution: 0.485 mg a.i./ 25 mL acetone Aliquots of 400 µl of the application solution containing 7.73 µg a.i. were applied dropwise to each test vessel. *(ii) High dose treatment:* Application solution: 353.19 µg a.i./ 5 mL acetone Aliquots of 540 µl of the application solution containing 38.14 µg a.i. were applied dropwise to two test vessels per system. *(iii) Reserve (4 flasks):* Application solution: 90.58 µg a.i./ 5 mL acetone Aliquots of 425 µl of the application solution containing 7.7 µg a.i. were applied dropwise to two test vessels per system. b) Cyclopropyl-1-^{14}C-alphacypermetrin *(i) Low dose treatment:* Application solution: 397.7 µg a.i./ 20 mL acetone Aliquots of 390 µl of the application solution containing 7.8 µg a.i. were applied dropwise to each test vessel. *(ii) High dose treatment:* Application solution: 291.7 µg a.i./ 3 mL acetone Aliquots of 400 µl of the application solution containing 38.9 µg a.i. were applied dropwise to two test vessels per system.
3.3.5	Initial TS concentration	i) 14 µg a.i./l This concentration was derived from application of the max. recommended field rate of 42 g a.i./ ha assuming that the a.i. is homogeneously distributed in a natural water column of 30 cm depth. ii) 70 µg a.i./l (5 times the recommended field rate), for isolation or identification purpose of major metabolites (were not analysed).
3.3.6	Duration of test	105 days
3.3.7	Analytical parameter	Radioactivity measurement of volatile compounds: i) CO_2: samples from sodium hydroxide solution were diluted with water and measured by LSC. ii) Organic volatiles: samples from ethylene glycol were measured by LSC. Radioactivity measurement of solid samples (e.g. sediment): after extraction soil samples were homogenised in a mortar, submitted to combustion and the liberated $^{14}CO_2$ analysed by LSC. Radioactivity in the aqueous samples, in the ethyl acetate extracts of the water phase and in the extracts from the sediment was measured by LSC. TLC was performed on silica gel 60 F 254 TLC plates with different solvent systems.

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

3.3.8	Sampling	a) Benzyl-^{14}C-alphacypermethrin 0h, 6h, 24h and 2, 7, 14, 30, 61and 105 days after the treatment in duplicate. Additional samples were taken from the reserves on day 28 and 29, respectively. Sodium hydroxide solutions: Sampled and analysed at each sampling interval and on day 44, 72 and 89. Ethylene glycol solutions: Sampled and measured at each sampling interval and replaced only after 7, 44, 57, 72 and 89. b) Cyclopropyl-1-^{14}C-alphacypermethrin 0h, 6h, 24h and 2, 7, 14, 30, 62 and 105 days after the treatment in duplicate. Sodium hydroxide solutions/ Ethylene glycol solutions: Sampled and analysed at each sampling interval or about every two weeks.	
3.3.9	Intermediates/ degradation products	Identified by TLC (co-chromatography with reference substances)	
3.3.10	Nitrate/ nitrite measurement	Not applicable	
3.3.11	Controls	Untreated control (without test substance) with acetone in an equal amount as used for the experiments with the a.i.	
3.3.12	Statistics	DT_{50} values of alphacypermethrin in the total system were mentioned in both reports (A7.1.2.2.2/01 and A7.1.2.2.2/02). However, those values were calculated using 1.5th order, or first and 1.5th order kinetics based on the square-root of time, and are therefore not suitable. New calculations (first order dissipation rates) were performed using the parameter estimation program ModelMaker, considering the degradation of the parent compound in the separate water and sediment phases of the two systems (A7.1.2.2.2/ 03), and the formation and degradation of the corresponding metabolites in the total systems (A7.1.2.2.2/ 04).	
		4 RESULTS	
4.1	**Degradation of test substance**		
4.1.1	Graph	For the degradation of the parent compound see Figure A 7.1.2.2.2-1 to A7.1.2.2.2-4 For the degradation of the metabolites see Figure A7.1.2.2.2-5 to A7.1.2.2.2-9	X

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

4.1.2	Degradation	A comprehensive overview of the results of the TLC analysis of the water and sediment extracts is shown in Table A7.1.2.2.2-4 and Table A7.1.2.2.2-5 for the benzyl-label and in Table A7.1.2.2.2-6 and Table A7.1.2.2.2-7 for the cyclopropyl-label. Estimated breakpoints and dissipation rates of alphacypermethrin and the two major metabolites are given in Table A7.1.2.2.2-9 and Table A7.1.2.2.2-10. Reliable first-order DT_{50} and DT_{90} values of alphacypermethrin were calculated in the water and sediment phases of the pond and river water-sediment systems, and are listed in Table A7.1.2.2.2-8. Reliable first-order DT_{50} and DT_{90} values of the metabolites were calculated in the water and sediment phases of the pond and river water-sediment systems, and are listed in Table A7.1.2.2.2-11.
4.1.3	Other observations	The total recoveries averaged 90.1 ± 9.6% of the total applied radioactivity for the Rhine system and 91.9 ± 5.4% for the pond system, in the experiments with benzyl-^{14}C-alphacypermethrin. The total recoveries averaged 94.3 ± 9.2% of the total applied radioactivity for the Rhine system and 100.8 ± 8.2% for the pond system, in the experiments with cyclopropyl-1-^{14}C-alphacypermethrin. The distribution of the radioactivity in the different compartments is given in table A7.1.2.2.2-3.
4.1.4	Degradation of TS in abiotic control	Not performed
4.1.5	Degradation of reference substance	Not applicable

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

4.1.6	Intermediates/ degradation products	The major metabolite observed with the benzyl-label was identified (by co-chromatography with reference substances) as 3-phenoxybenzoic acid (WL 44607, CL 206128) which was formed by hydrolysis of the ester bond of the parent compound. It reached a maximum of 17–18% AR in the water phase, but was further degraded to CO_2 towards the end of the study. All other metabolites appearing in water or sediment never exceeded 6 % AR. The major metabolite observed with the cyclopropyl-label was identified as cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (WL 43480, CL 912554). It reached maximum amounts of 29 and 47 % AR in the water phases and 9.5 and 19.5 % AR in the sediment extracts for the river and the pond system, respectively. CL 912554 was further degraded towards the end of the study and was not detected in the water extracts after 105 days, while sediment levels decreased to 1.8 and 1.4 % AR in the pond and river systems, respectively. In the pond system, none of the other metabolites exceeded 10% AR in the water phase or in the sediment. In the river system, one unknown metabolite, denoted as RW9, reached 11% AR in the water phase at the end of the study. RW9 appeared at the later sampling times, following the decline of CL 912554, which suggests being a likely degradation product of CL 912554. Furthermore, RW9 appears very early in the TLC chromatograms, indicating that it is very polar. Identification of this metabolite could not be achieved. Since the parent and all other metabolites had already degraded at this time, it can be concluded that RW9 would not increase in concentration. Mineralisation was increasing considerably in this system at the end of the study, and it can be assumed that the polar metabolite RW9 will further degrade to CO_2. RW9 was not detected in the pond system.	X

Section A7.1.2.2.2 **Water/sediment degradation study**
Annex Point IIIA 12.2.1

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The distribution and degradation of BAS 310 I was studied in two natural water-sediment systems taken from the river Rhine and a pond called "Judenweiher", respectively, both from the area close to Rheinfelden, Switzerland. One study was performed with the benzyl-U-^{14}C-labelled test substance (Bz-^{14}C) with a specific radioactivity of 191.7 µCi/mg (7.1 MBq/mg) and a radiochemical purity of >99%. The second study was performed with the cyclopropyl-1-^{14}C-labelled test compound (Cp-^{14}C) with a specific radioactivity of 134 µCi/mg (4.96 MBq/mg) and a radiochemical purity of 99%.

BAS 310 I (alphacypermethrin) was applied to the water at a rate of 7.8 µg a.s./test vessel, corresponding to an application rate of 42 g a.s./ha when related to a 30 cm deep water body. The test vessels were incubated in the dark at a temperature of 20 ± 2 °C for up to 105 days. Aeration was achieved by gentle agitation of the water phase with a suspended magnetic stirrer and a continuous stream of air over the water surface. Test vessels were collected in duplicate at selected time points. Liquid-liquid extraction of the water phase of the samples was performed with ethyl acetate, while the sediment phase was extracted with acetonitrile. In addition, the sediment phase of samples at later time points was Soxhlet-extracted either with methanol or acetonitrile. The extracts were analyzed by TLC.

The experiments were performed in compliance with BBA guideline part IV: 5-1 (December 1990).

Calculations (first order dissipation rates) were performed using the parameter estimation program ModelMaker, considering the degradation of the parent compound in the separate water and sediment phases of the two systems (ref. A7.1.2.2.2/03), and the formation and degradation of the corresponding metabolites in the total systems (ref. A7.1.2.2.2/04).

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

5.2	**Results and discussion**	Mineralisation was high in all systems, reaching 33–53 % of applied radioactivity (AR) after 105 days of incubation, depending on label and water-sediment system. The material balance was above 90 % for most of the sampling times with some (11) exemptions. However, it could be shown that this was caused by losses of $^{14}CO_2$ during the measurements of parameters after sampling and during extraction of the water and sediment phases. Therefore, the low material balance does not influence the results obtained for the active substance or its metabolites. The 30- and 105-day sediment samples of the river and the pond system were further analyzed by NaOH extraction and fractionation into humin, humic acids and fulvic acids. LSC measurements showed that most of the radioactivity was associated with the insoluble humin or high molecular humic acids. After 105 days, less than 6% AR (benzyl-label) and 7.5% AR (cyclopropyl-label) was associated with fulvic acids. The major metabolite observed with the benzyl-label was identified as 3-phenoxybenzoic acid which reached a maximum of 17–18 % AR in the water phase, but was further degraded to CO_2 towards the end of the study. The major metabolite observed with the cyclopropyl-label was identified cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers, which reached a maximum amounts of 29 and 47% AR in the water phases and 9.5 and 19.5% AR in the sediment extracts for the river and the pond system, respectively. It was further degraded towards the end of the study and was not detected in the water extracts after 105 days, while it decreased in the sediment levels. In the river system, one unknown metabolite, noted RW9, reached 11% AR in the water phase at the end of the study. Identification of this metabolite could not be achieved. Since the parent and all other metabolites had already degraded at this time, it can be concluded that RW9 would not increase in concentration. Mineralisation was increasing considerably in this system at the end of the study, and it can be assumed that the polar metabolite RW9 will further degrade to CO_2. RW9 was not detected in the pond system. The DT_{50} of alphacypermethrin in water ranged from 0.5 to 2 days, and in sediment from 6 to 35 days. The DT_{50} of the metabolites cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers in the total system ranged from 14 to 37 days, and the DT_{50} of 3-phenoxybenzoic acid ranged from 2 to 3 days.	X

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA 12.2.1

5.3	**Conclusion**	In natural water-sediment systems, alphacypermethrin disappeared rapidly from the water phase due to strong adsorption to the sediment and fast metabolisation. Alphacypermethrin was also readily eliminated in the sediment phase, by metabolisation and formation of bound residues. The DT_{50} in water ranged from 0.5 to 2 days, and in sediment from 6 to 35 days. The main products formed were 3-phenoxybenzoic acid and cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers, both of which underwent further degradation to $^{14}CO_2$. The DT_{50} of cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers in the total system ranged from 14 to 37 days, and the DT_{50} of 3-phenoxybenzoic acid ranged from 2 to 3 days. The study is well documented and reported. A material balance was performed at all samplings by radioactive analysis.	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	Yes The material balance was not above 90 % at all sampling times (11 exemptions). However, it could be shown that this was caused by losses of $^{14}CO_2$ during the measurements of parameters after sampling and during extraction of the water and sediment phases. Therefore, the low material balance does not influence the results obtained for the active substance or its metabolites. Furthermore, the total recoveries averaged above 90% in all systems.	

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
References	The Applicant's version is acceptable with the following comment: A7.1.2.2.2/02: ^{14}C-Alphacypermethrin (instead of FASTAC).
Guidelines and quality assurance	The Applicant's version is acceptable with the following comment: Section 2.2 A7.1.2.2.2/03 and A7.1.2.2.2/04 GLP guidelines did not apply.
Materials and Methods	The Applicant's version is acceptable with the following comments: Section 3.1.4 Properties such as water/organic solvents solubility, vapour pressure, hydrolysis rate etc. would be useful.
Results and discussion	The Applicant's version is acceptable with the following amendments: Section 4.1.1 Figure A7.1.2.2.2-4: Description of alphacypermethrin degradation in a pond (instead of river) water-sediment system. Section 4.1.6 WL 43480, CL 912554 reached maximum amounts of 29.4% and 47.3% AR in the water phases and 9.0% and 19.5% AR in the sediment extracts for river and pond system, respectively.
Conclusion	The Applicant's version is acceptable with the following amendments: Section 5.2 The same changes as section 4.1.6 Section 5.2 up to 11% (instead of 11%) Section 5.3 The DT_{50} in water ranged from 0.4 (instead of 0.5) to 2 days
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.1.2.2.2- 1: Characterisation of the water/sediment systems.

Designation	**River Rhine**	**Pond "Judenweiher"**
Origin	**Rheinfelden, Switzerland**	**Rheinfelden, Switzerland**
Sediment		
Sand [%]	90.1 [a] / 80.9 [b]	53.6 [a] /42.8 [b]
Silt [%]	6.0 [a] / 15.2 [b]	21.0 [a] /31.8 [b]
Clay [%]	3.9 [a] / 3.9 [b]	25.4 [a] /25.4 [b]
Textural class (German scheme)	Loamy sand	Sandy clay
pH (KCl)	7.8	7.1
Organic C [%]	0.9	5.4
Total N [g/kg]	0.68	1.65
Total P [g/kg]	0.41	0.69
Biomass [mg C/100 g]	51.1	480
Water		
pH	8.2	7.2
Hardness [°dH]	14	22
TOC [mg C/l]	9.3 [a] /3.0 [b]	9.3
Total N [mg/l]	1.58	0.97
Ortho phosphorous [mg/l]	0.12	0.05

a): properties existent in the experiments with Benzyl-^{14}C-alphacypermetrin

b): properties existent in the experiments with Cyclopropyl-1-^{14}C-alphacypermethrin

Table A7.1.2.2.2- 2: Test system and test conditions.

Criteria	Details	
Culturing apparatus	All-glass metabolism apparatus with an open gas-flow system: Gas washing bottle with 500 mL water to moisten the incoming air Glass vessels (1L Steilbrust, inner diameter 10.6 cm, surface 88.2 cm^2) containing 550 ml water and 190–275 g sediment for benzyl-^{14}C-alphacypermetrin and 300–350 g for cyclopropyl-1-^{14}C-alphacypermethrin) Rubber tube with bar magnet enclosed in glass tubing CO_2 trap, gas washing bottles with 50 mL 2N NaOH Trap for org. volatile substances, gas washing bottles with 50 mL ethylene glycol	
Number of culture flasks/concentration	2 flasks per sampling time and system 2 untreated controls per system 2 flasks for each of the two water sediment system were treated with a higher concentration (5 times the max. recommended field rate).	
Aeration device	The system was ventilated with a moistened AND CO_2-free air stream at a flow rate of about 60–80mL/minute. The water phase was slowly stirred by a magnetic stirrer to maintain oxygen uptake.	
Measuring equipment	pH-meter (with pH-electrode or redox electrode), oximeter, photometer Total organic carbon analyser Model TOC-500 Flow meter (Brooks Instr. N.V. Veenendal, Netherlands) Liquid scintillation counter (Packard)	
Composition of medium	See table A7.1.2.2.2-1	
Additional substrate	No	
Pre-incubation of the test systems	Yes, 20 days	
Test temperature	20 ± 2 °C	
pH	Benzyl-^{14}C-alphacypermetrin River system: 8.59 ± 0.09 Pond system: 7.64 ± 0.19	Cyclopropyl-1-^{14}C-alphacypermethrin River system: 8:26–8:61 Pond system: 8:42–8:56
Oxygen content [mg /l]	Benzyl-^{14}C-alphacypermetrin River system: 4.93 ± 0.35 Pond system: 5.07 ± 0.52	Cyclopropyl-1-^{14}C-alphacypermethrin River system: 3:6–6:5 Pond system: 5.9–9.6
Redox potential in water [mV]	Benzyl-^{14}C-alphacypermetrin River system: 200 ± 5 Pond system: 181 ± 11	Cyclopropyl-1-^{14}C-alphacypermethrin River system: 182–318 Pond system: 140–210
Aeration of dilution water	No	
Suspended solids concentration	Not determined	
Other relevant criteria	a) the test was conducted in the dark,	

Table A7.1.2.2.2- 3: Material balance and distribution of radioactivity after application of [benzyl-^{14}C]-BAS 310 I or [cyclopropyl-1-^{14}C]-BAS 310 I to water-sediment systems (% AR).

DAT	Water	Sediment			CO_2	Balance
		Extractable*	Bound residues	Total		
[Benzyl-^{14}C]-BAS 310 I						
River Rhine						
0	49.9	49.3	0.7	50.0	n.d.	99.9
0.25	40.2	55.2	1.6	56.7	n.d.	96.9
1	37.0	57.8	2.0	59.7	0.1	96.8
2	32.4	60.8	3.3	64.1	0.2	96.7
7	24.8	55.1	8.3	63.2	1.7	89.7
14	18.1	42.3	19.4	61.8	6.5	86.3
30	5.5	39.4	20.5	59.9	21.5	86.9
61	1.8	27.1	23.2	50.3	38.0	90.0
105	1.9	22.6	18.9	41.4	24.9	68.1
Pond						
0	61.2	36.0	0.9	36.9	n.d.	98.0
0.25	50.4	46.9	0.9	47.8	n.d.	98.2
1	45.4	44.0	2.1	46.1	0.1	91.6
2	41.7	49.1	4.9	53.9	0.2	95.8
7	31.2	45.1	14.8	59.9	3.2	94.3
14	19.5	37.3	25.5	62.7	11.2	93.4
30	10.7	12.9	37.3	50.2	26.1	86.9
61	0.8	9.8	25.6	35.4	49.0	85.1
105	0.9	8.7	21.2	29.9	53.1	83.9
[Cyclopropyl-1-^{14}C]-BAS 310 I						
River Rhine						
0	53.7	41.0	1.9	42.8	n.d.	96.5
0.25	25.1	50.1	0.3	50.4	<0.1	75.4
1	33.2	56.3	1.6	57.9	<0.1	91.1
2	27.8	73.7	2.9	76.6	<0.1	104.4
7	28.4	57.0	3.9	60.9	0.2	89.6
14	38.2	59.0	6.1	65.1	0.6	104.0
30	42.1	41.0	13.8	54.7	3.9	100.7
60	22.2	33.1	16.9	50.0	16.1	88.3
105	226	26.1	16.2	42.4	33.2	98.4
Pond						
0	55.4	42.6	2.3	44.9	n.d.	100.3
0.25	35.3	50.1	0.2	50.3	<0.1	85.5
1	54.3	50.3	2.6	52.9	<0.1	107.1
2	47.0	57.4	3.0	60.4	<0.1	107.3
7	48.3	52.6	7.4	60.0	0.1	108.2
14	52.4	45.4	10.3	55.7	0.2	108.2
30	53.1	32.4	15.4	43.9	2.2	103.2
60	31.6	31.1	21.6	49.5	8.1	92.4
105	8.9	8.5	37.1	45.4	40.0	94.7

n.d. = not determined

* including soxhlet extraction

Table A7.1.2.2.2- 4: TLC analysis of water and sediment extracts after application of [benzyl-^{14}C]-BAS 310 I to the River Rhine system (% AR).

DAT	BAS 310 I	M3 WL44607 (CL 206128)	M5 unknown	M6 unknown	others*
Water					
0	49.9	n.d.	n.d.	n.d.	n.d.
0.25	39.0	n.d.	n.d.	n.d.	1.2
1	34.0	n.d.	n.d.	n.d.	3.0
2	15.9	11.6	1.7	0.4	2.8
7	1.6	17.3	n.d.	n.d.	5.9
14	1.4	11.9	0.8	0.2	3.7
30	n.d.	1.8	n.d.	n.d.	3.7
61	n.a.	n.a.	n.a.	n.a.	n.a.
105	n.a.	n.a.	n.a.	n.a.	n.a.
Sediment					
0	49.3	n.d.	n.d.	n.d.	n.d.
0.25	53.7	n.d.	n.d.	1.5	n.d.
1	52.5	n.d.	n.d.	5.3	n.d.
2	54.9	n.d.	2.0	3.8	n.d.
7	36.5	4.4	5.8	1.7	6.7
14	27.0	3.9	3.0	2.6	5.9
30	21.7	1.4	4.9	4.0	7.5
61	14.6	n.d.	3.2	3.1	6.1
105	12.9	0.2	1.9	3.1	4.3

* sum of 4 additional peaks (each <5 % AR)

n.a. = not analyzed

n.d. = not detected

Table A7.1.2.2.2- 5: TLC analysis of water and sediment extracts after application of [benzyl-^{14}C]-BAS 310 I to the pond system (% AR).

DAT	BAS 310 I	M3 WL44607 (CL 206128)	M5 unknown	M6 unknown	others*
Water					
0	61.2	n.d.	n.d.	n.d.	n.d.
0.25	50.4	n.d.	n.d.	n.d.	n.d.
1	42.6	n.d.	n.d.	n.d.	2.8
2	28.8	9.6	0.7	1.2	1.4
7	8.0	18.0	n.d.	3.0	3.1
14	n.d.	16.2	n.d.	0.3	3.0
30	n.d.	2.3	n.d.	0.5	7.1
61	n.a.	n.a.	n.a.	n.a.	n.a.
105	n.a.	n.a.	n.a.	n.a.	n.a.
Sediment					
0	34.9	n.d.	n.d.	n.d.	1.0
0.25	45.0	n.d.	n.d.	n.d.	1.9
1	30.5	n.d.	n.d.	n.d.	n.d.
2	46.8	n.d.	n.d.	1.2	1.0
7	27.9	5.1	n.d.	4.9	4.1
14	19.8	4.4	5.0	5.3	2.8
30	4.1	2.0	n.d.	1.6	5.2
61	4.0	0.5	1.4	0.4	3.4
105	2.0	0.9	1.3	0.9	3.6

* sum of 7 additional peaks (each <4.5 % AR)

n.a. = not analyzed

n.d. = not detected

Table A7.1.2.2.2- 6: TLC analysis of water and sediment extracts after application of [cyclopropyl-1-^{14}C]-BAS 310 I to the River Rhine system (% AR).

DAT	BAS 310 I	RW1/RS1 WL43480 (CL 912554)	RW7 unknown	RW9/RS5 unknown	RS2 unknown	Others*	Radioactivity remaining in water phase after extraction
Water							
0	48.2	n.d.	n.d.	n.d.		n.d.	5.5
0.25	18.1	2.4	n.d.	n.d.		1.8	2.8
1	18.2	7.1	n.d.	n.d.		7.7	2.2
2	3.5	16.6	n.d.	n.d.		4.8	2.9
7	0.7	22.5	0.5	0.3		3.6	0.8
14	0.8	29.4	n.d.	n.d.		5.9	2.1
30	n.d.	26.9	n.d.	4.1		9.5	1.6
61	n.d.	n.d.	7.5	10.4		n.d.	4.3
105	n.d.	n.d.	8.2	11.2		3.3	n.d.
Sediment							
0	37.0	1.5		n.d.	2.5	n.d.	
0.25	43.5	3.4		n.d.	n.d.	n.d.	
1	48.0	0.9		n.d.	7.4	n.d.	
2	61.8	1.6		n.d.	10.3	n.d.	
7	41.6	6.3		n.d.	9.2	n.d.	
14	41.2	9.5		n.d.	2.8	5.6	
30	20.4	9.0		0.9	n.d.	8.6	
61	19.2	3.3		2.2	1.4	4.9	
105	17.0	1.8		2.3	2.2	2.4	

* sum of several peaks (each <6 % AR)

n.a. = not analyzed

n.d. = not detected

Table A7.1.2.2.2- 7: TLC analysis of water and sediment extracts after application of [cyclopropyl-1-^{14}C]-BAS 310 I to the pond system (% AR).

Time	BAS 310 I	PW1/PS1 WL43480 (CL 912554)	PW3 unknown	PS4 unknown	Others	Radioactivity remaining in water phase after extraction
Water						
0	49.5	n.d.	n.d.		n.d.	6.0
0.25	26.6	3.2	n.d.		1.6	4.0
1	33.1	9.5	2.6		2.7	6.3
2	15.8	19.3	3.6		3.4	4.9
7	2.7	40.3	1.6		2.6	1.1
14	n.d.	47.3	1.6		2.6	0.8
30	n.d.	41.9	7.6		2.9	0.8
61	n.d.	17.9	8.9		3.0	1.8
105	n.d.	n.d.	4.7		4.3	n.d.
Sediment						
0	40.8	1.8		n.d.	n.d.	
0.25	47.1	n.d.		n.d.	n.d.	
1	43.3	3.1		n.d.	3.9	
2	51.9	0.8		n.d.	4.7	
7	32.9	9.4		6.2	4.1	
14	16.9	19.5		6.6	2.4	
30	4.7	16.8		2.4	4.5	
61	5.6	15.7		1.0	5.6	
105	1.6	1.4		0.5	4.9	

n.d. = not detected

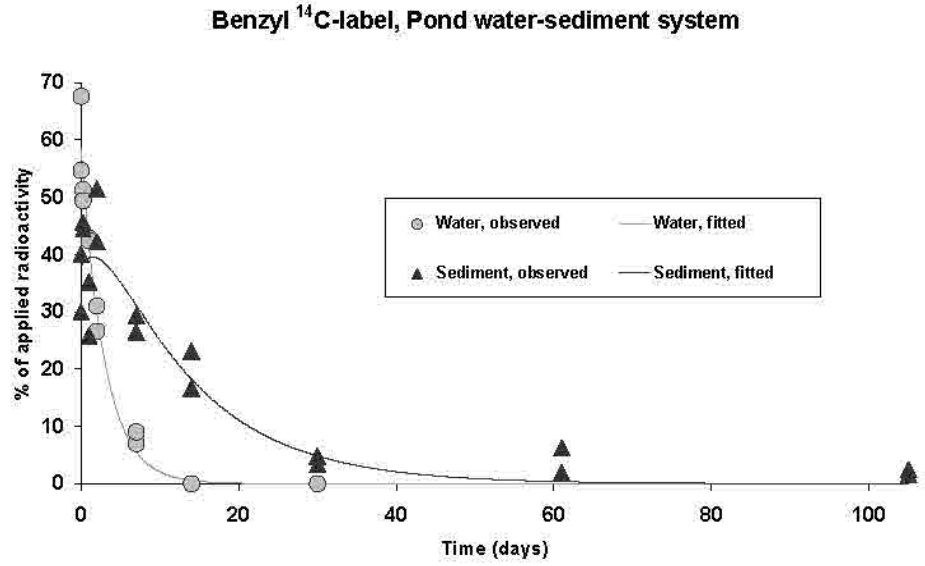

Figure A7.1.2.2.2- 1: Description of alphacypermethrin degradation in a pond water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

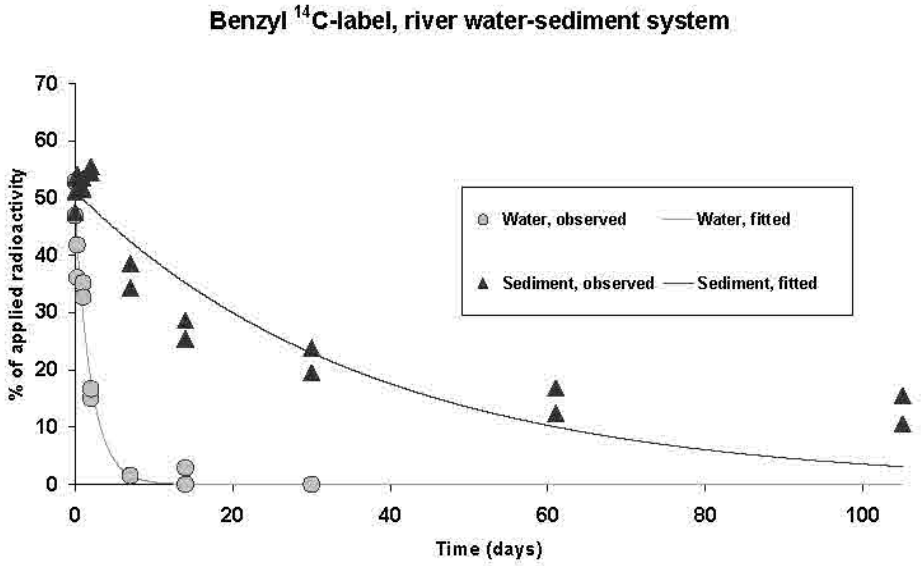

Figure A7.1.2.2.2- 2: Description of alphacypermethrin degradation in a river water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

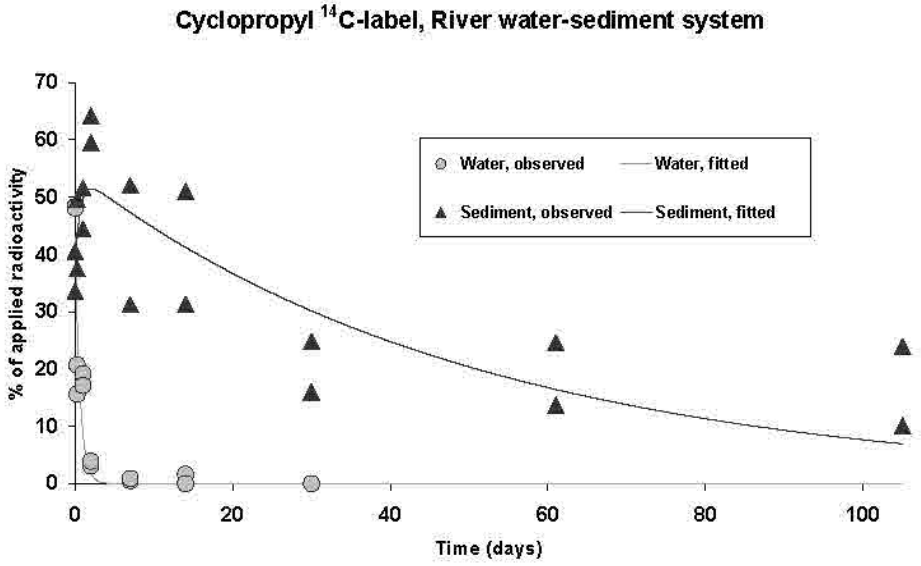

Figure A7.1.2.2.2- 3: Description of alphacypermethrin degradation in a river water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

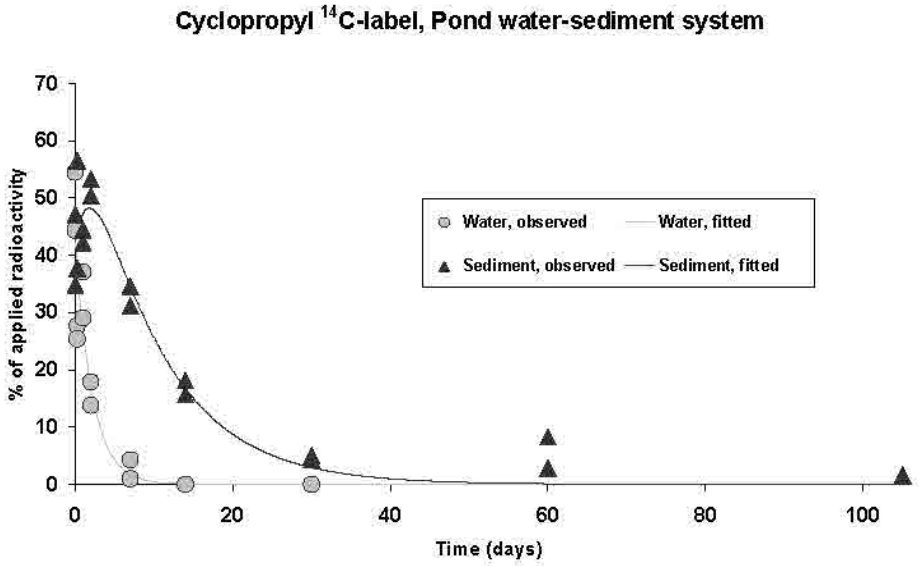

Figure A7.1.2.2.2- 4: Description of alphacypermethrin degradation in a river **(BE CA correction: pond)** water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

Table A7.1.2.2.2- 8: Estimated DT_{50} and DT_{90} values for alphacypermethrin in the water and sediment phases of the pond and river water-sediment aquatic systems estimated with ModelMaker 4.0.

Aquatic system	^{14}C-label position	Water		Sediment	
		DT_{50} (days)	DT_{90} (days)	DT_{50} (days)	DT_{90} (days)
Pond					
	Benzyl	2.1	6.9	8.3	27.4
	Cyclopropyl	1.5	5.1	6.4	21.1
River					
	Benzyl	1.4	4.7	25.9	86.2
	Cyclopropyl	0.4	1.5	35.4	117.5

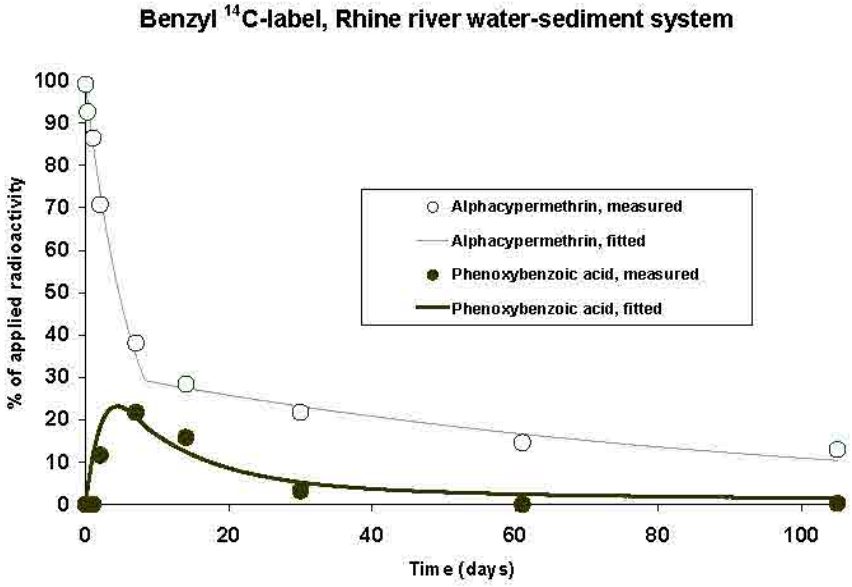

Figure A7.1.2.2.2- 5: Description of the dissipation of alphacypermethrin and formation and decline of the metabolite 3-phenoxybenzoic acid (CL 206128) in a river water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

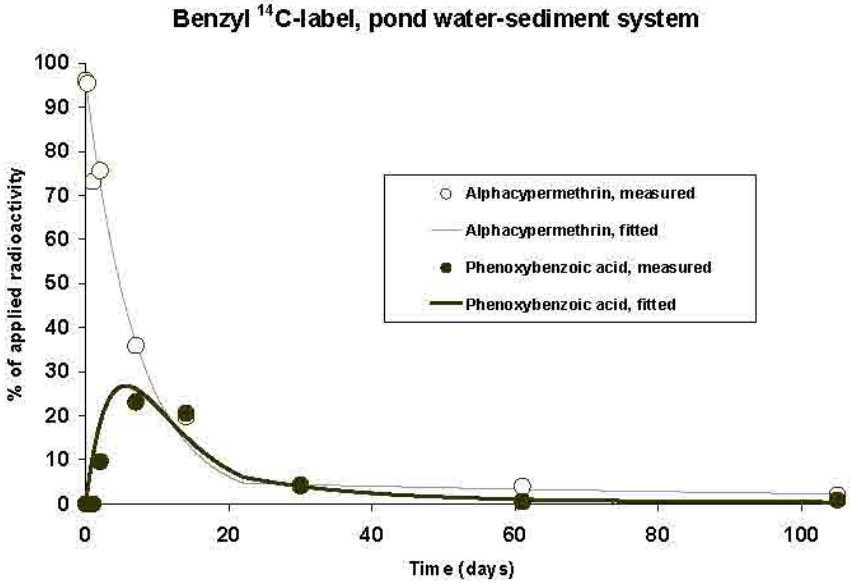

Figure A7.1.2.2.2- 6: Description of the dissipation of alphacypermethrin and formation and decline of the metabolite 3-phenoxybenzoic acid (CL 206128) in a pond water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

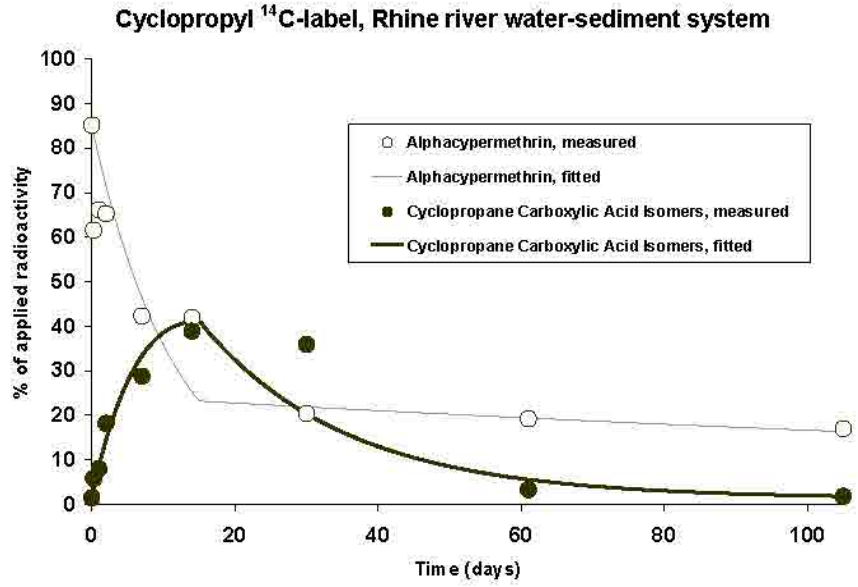

Figure A7.1.2.2.2- 7: Description of the dissipation of alphacypermethrin and formation and decline of the metabolite cyclopropane carboxylic acid isomers (CL 912554) in a river water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

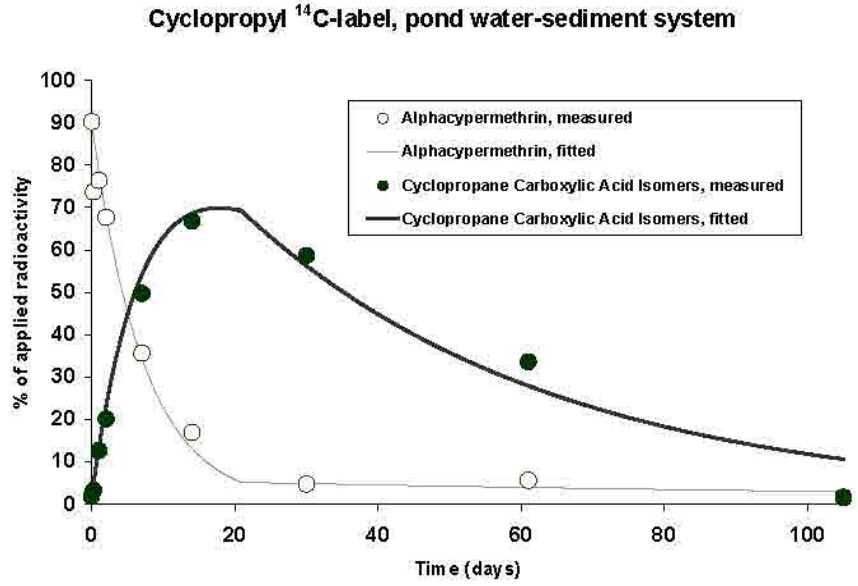

Figure A7.1.2.2.2- 8: Description of the dissipation of alphacypermethrin and formation and decline of the metabolite cyclopropane carboxylic acid isomers (CL 912554) in a pond water-sediment system. The measured data (symbols) were fitted with ModelMaker 4.0 (lines).

Table A7.1.2.2.2- 9: Estimated breakpoints and dissipation rates of alphacypermethrin and CL 206128 in river-sediment and pond-sediment systems (^{14}C-benzyl label). Biphasic first-order kinetics modelled and optimised with ModelMaker 4.0.

Aquatic system	Break point a [d]	Rate first phase (k_1)	Rate second phase (k_2)
		Alphacypermethrin	
River water	8.30	0.1473	0.0107
		Phenoxybenzoic acid	
		0.3300	0.0896
		Alphacypermethrin	
Pond water	21.94	0.1370	0.0089
		Phenoxybenzoic acid	
		0.2286	0.0615

Table A7.1.2.2.2- 10: Estimated breakpoints and dissipation rates of alphacypermethrin and CL 912554 in river-sediment and pond-sediment systems (^{14}C-cyclopropyl label). Biphasic first-order kinetics modelled and optimised with ModelMaker 4.0.

Aquatic system	Break point a (days)	Rate first phase (k_1)	Rate second phase (k_2)
		Alphacypermethrin	
River water	15.05	0.0863	0.0039
		Cyclopropane carboxylic acid isomers	
		0.0486	0.0338
		Alphacypermethrin	
Pond water	20.88	0.1375	0.0067
		Cyclopropane carboxylic acid isomers	
		0.0154	0.0233

Table A7.1.2.2.2- 11: Estimated half-life values for the first and second phase (HF_1 and HF_2, respectively), and calculated DT_{50} and DT_{90} values for CL 206128 (phenoxybenzoic acid) and CL 912554 (cyclopropane carboxylic acid isomers) in river-sediment and pond-sediment systems estimated with ModelMaker 4.0.

^{14}C-label position	Aquatic system	HF_1 (days)	HF_2 (days)	DT_{50} (days)	DT_{90} (days)
			Phenoxybenzoic acid		
Benzyl	River	2.1	7.7	2.1	7.0
	Pond	3.0	11.3	3.0	10.1
			Cyclopropane carboxylic acid isomers		
Cyclopropyl	River	14.3	20.5	14.3*	61.5
	Pond	45.0	29.8	36.8	105.9

*An incorrect value of 13.9 is listed in the study report. The correct value is 14.3

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA, XII.2.1 – Supportive data –

The following reference is considered to contain additional information concerning the degradation of alphacypermethrin in water/sediment systems and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.1.2.2.2/05**

Dutton AJ, Pearson N (1988) An outdoor tank experiment to study the fate of "FASTAC" in the aquatic environment. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. SBGR.87.125, March 21, 1988 (unpublished), BASF RDI No.: AL-630-007.

Guidelines: No guideline stated

GLP: No

Material and methods:

An outdoor study on the fate and effects of alphacypermethrin in a natural water/sediment system was conducted in tanks of size 70 cm x 70 cm x 80 cm deep containing pond water and sediment. They were treated separately in the [^{14}C-benzyl] or [^{14}C-cyclopropyl] alphacypermethrin at 15 g a.i./ha, and concentrations of alphacypermethrin and metabolites were determined in water and sediment for up to 202 days after treatment.

Findings:

The maximum concentrations of alphacypermethrin in the water were found 1 day after treatment and the DT_{50} (water) was 2–4 days. Metabolites detected in the water during the study were 3-phenoxybenzoic acid (PBA), 2,2-dimethyl-3-(2^1, 2^1-dichlorovinyl) cyclopropane carboxylic acid (DCVA) and more polar unidentified products. Both PBA and DCVA comprised $\geq$ 50% of the total residue present 16 days after treatment. Alphacypermethrin was rapidly taken up by the sediment (mainly in the top 1 cm layer).

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: July 1987 (instead of March 21, 1988)
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 A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA, XII.2.1 – Supportive data –

The following reference is considered to contain additional information concerning the degradation of alphacypermethrin in water/sediment systems and is thus presented in an abbreviated format (adopted from the PPP-dossier) as supportive data:

Reference: **A7.1.2.2.2/06**

Pearson N (1990) The fate of FASTAC in experimental ponds. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. SBGR.88.177, July 24, 1990, BASF RDI No.: AL-630-008 (unpublished).

Guidelines: No guideline stated

GLP: No

Material and methods:

The fate of alphacypermethrin in natural pond water, and their associated sediments, was investigated in the field using an EC formulation of alphacypermethrin.

Findings:

There was a loss of alphacypermethrin from the water, with less than 2% of the applied dose remaining in the water after one week. The concentration of alphacypermethrin in the sediment decreased with a half-life of approximately one month.

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: GLP : Yes
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 A7.1.3 Adsorption/desorption screening test

Annex Point IIA 7.7

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	In view of the availability of a full-scale adsorption/desorption test (A7.2.3.1) providing detailed information on the sorption behaviour of Alphacypermethrin, the performance of a screening study is not considered to be required.	
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 A7.1.4.1 Field study on accumulation in the sediment

Annex Point IIIA 12.2.2

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	According to the TNG on data requirements, chapter 3, a field study on accumulation in the sediment is only required if non-extractable residues are formed exceeding 70% of the initial dose in the water/sediment study or if the mineralization rate in the water/sediment system is less than 5% in 100 days. Since in the water/sediment study (see section A7.1.2.2.2) the amount of bound residues clearly falls below the 70% threshold and mineralisation is relatively rapid, the conduct of a field study is not considered to be necessary.	
Undertaking of intended data submission [ ]		

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	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 A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4, 12.1.1

Official use only

1 REFERENCE

1.1	**Reference**	**A7.2.1/01:** Gedik L, Keirs D (2001) [^{14}C]-Alphacypermethrin (BAS 310 I): Degradation in soil under aerobic conditions. Inveresk Research, Tranent, UK, Report no. 399307, September 10, 2001, BASF RDI No.: AL-620-013 (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 SETAC Europe, OECD Draft Guideline No. 307 (1999)
2.2	**GLP**	Yes
2.3	**Deviations**	Yes Degradation tested in one soil only (sandy loam, pH = 6.5) A concentration of 10 times the maximum anticipated field application rate was used.

3 MATERIALS AND METHODS

3.1	**Test material**	1.	Benzyl ring-U-^{14}C Alpacypermetrin
		2.	Benzyl ring-U-^{14}C/ benzyl-7-^{13}C Alphacypermetrin
3.1.1	Lot/Batch number	1.	AC 12041-138
		2.	AC 12041-146
3.1.2	Specification	1.	Specific activity: 84.5 µCi/mg
		2.	Specific activity: 27.04 µCi/mg
3.1.3	Purity	1.	Radiochemical purity: 99.5 % Chemical purity: 97.1 %
		2.	Radiochemical purity: 98.08 % Chemical purity: > 95.1 %

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4, 12.1.1

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
3.1.5	Method of analysis	HPLC, by co-chromatography of standards: Column: Lichrosorb RP18 (25cm * 4.6 mm; 5µm): Mobile phase A: 0.1% formic acid in deionised water Mobile phase B: 0.1% formic acid in acetonitrile Gradient over 90 min. Flow rate: 1mL/min UV detection: 254 nm (Standards) Recovery from HPLC: 92-108% of AR Recovery from HPLC (fulvic acid fraction): 88% of AR TLC, by co-chromatography of standards: Silica gel 60F254 TLC-plate Chloroform:methanol (9:1,v/v) UV detection: 254 nm (Standards) <u>Radioactivity measurement:</u> liquid scintillation counting (fluids), radiodetector (HPLC) phosphor imager (TLC) or combustion (soil) <u>Detection limit:</u> LSC: 30 dpm above background Chromatographic analysis: twice background

3.2 Degradation products

Reference	Batch	CAS-No	Purity
CL 900049	AC 10194-61	67375-30-8	96.1%
CL 949371	AC 10242-107	None	90%
CL 949372	AC 11303-63	None	98%
CL 213336	AC 11303-72	35065-12-4	94%
CL 206969	AC 11304-76	39515-51-0	99%
CL 206138	AC 10194-100	13826-35-2	99%
CL 206128	AC 12251-34	3739-38-6	99%
CL 117585	AC 12042-88	None	97%

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4, 12.1.1

3.2.1	Method of analysis for degradation products	Volatiles were driven from the headspace of the flask by a stream of air, and were trapped in ethanediol (org. volatiles) or in sodium hydroxide ($^{14}CO_2$). The soil samples were extracted by shaking (1 h) with acetonitrile: water (7:3, v/v, 4 times with 100 mL). Radioactivity in fractions was determined via LSC. Residues were air dried and subjected to combustion analysis. Following extraction, the organic matter from day 120 samples was fractionated into humin, fulvic acid and humic acid. Analysis of the fractions was performed with HPLC (radio-detector) by co-chromatography of standards (UV-detection) and TLC for confirmation purpose.
3.3	**Reference substance**	None
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Soil types**	Sandy loam soil, soil characteristics are given in Table A7.2.1- 1 below.
3.5	**Testing procedure**	
3.5.1	Test substance concentration	0.307 mg [^{14}C]-Alphacypermethrin kg^{-1} dry soil This is equivalent to approximately 300 g a.i. ha^{-1}, or 10 times the maximum anticipated field application rate for agricultural use. 1.5 mg [^{13}C/ ^{14}C]-Alphacypermethrin kg^{-1} dry soil, to be used for metabolite identification.
3.5.2	Solvent	Acetonitrile
3.5.3	Method of application	100 µL containing 30.65 µg of [^{14}C]-Alphacypermethrin in acetonitrile solution was applied to the surface of each sample of soil (100g), resulting in a final soil concentration of 0.307 mg/kg. The radioactive application to each soil sample was equivalent to 2.59 µCi. 100 µL containing 144.60 µg of [^{13}C/ ^{14}C]-Alphacypermethrin in acetonitrile solution was applied to the surface of each sample of soil (100 g), resulting in a final soil concentration of 1.45 mg/kg. The radioactive application to each soil sample was equivalent to 3.91 µCi. The solvent control was treated with 100 µL acetonitrile. Following application the contents of each flask were gently tumbled to incorporate the test substance into the soil before re-connecting to the air flow system.
3.5.4	Sampling	Samples were taken and analysed at 0, 3, 7, 14, 28, 42, 70 and 120 days following application. 120 days for [^{13}C/ ^{14}C]-Alphacypermethrin samples, which were not used for further analysis.
3.5.5	Number of replicates	2 individual flasks

Section A7.2.1 **Aerobic degradation in soil, initial study**
Annex Points IIIA 7.4, 12.1.1

3.5.6	Testing conditions	10°C ± 2°C and 20°C ± 2°C for the [^{14}C]-Alphacypermethrin samples 10°C ± 2°C and 20°C ± 2°C for the control 20°C ± 2°C for the [^{13}C/ ^{14}C]-Alphacypermethrin samples Aerobic conditions, in the dark, 50% maximum water holding capacity. A stream of moist, CO_2-free air, at a flow rate of 5–10mL/min, was drawn over the surface of each sample of soil and left each flask passing trough 3 traps. Trap 1: safety trap Trap 2: ethandiol (ca. 50g) to trap non-specific ^{14}C-organic volatiles Trap 3: sodium hydroxide (0.5 M) to trap liberated $^{14}CO_2$.	
		4 RESULTS	
4.1	**Degradation rate**	The distribution of recovered radioactivity as per cent of applied is presented in Table A7.2.1- 2. At the end of the study, residual unchanged alphacypermethrin represented 26.67% and 7.49% (10 and 20°C, respectively) of the initially applied radioactivity.	
4.2	**Disappearance time**	Following simple first-order kinetics, the DT_{50} of alphacypermethrin was 21 and 55 days at 20°C and 10°C, respectively. Following biphasic first order kinetics, the DT_{50} of alphacypermethrin was 19 and 50 days at 20°C and 10°C, respectively. The DT_{50} and DT_{90} values were estimated using ModelMaker 4.0 (see Table A7.2.1- 3).	
4.3	**Degradation products**	[^{14}C]-Alphacypermethrin was degraded to several components in sandy loam soil at 20°C and 10°C. The major degradation product was $^{14}CO_2$ (51% and 32%, respectively). Four minor degradates, including CL 206128 and three unknowns as well as polar material were extracted from the soil. Other unknown minor components (<1% AR) associated with the fulvic acid fractions were also detected in some samples. Bound (non-extractable) residues increased from 0% to 34% until the end of the study. A proposed degradation pathway is given in Figure A7.2.1- 1.	X

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4, 12.1.1

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The rate and route of degradation of [^{14}C]-Alphacypermethrin was investigated in a sandy loam soil at 20°C and 10°C according to OECD Draft Guideline No. 307. A concentration of 0.307 mg [^{14}C]-Alphacypermethrin kg^{-1} dry soil was used in this study in order to facilitate the detection of alphacypermethrin and its degradation products. This is equivalent to approximately 300 g a.i. ha^{-1}, or 10 times the maximum anticipated field application rate. The incubation conditions were: aerobic, in the dark, 10 and 20°C, 50% maximum water holding capacity. A system with continuous aeration and trapping of volatiles was used.	
5.2	**Results and discussion**	The total recoveries ranged from 95 to 103 and 93 to 101% AR for 10 and 20°C samples, respectively. Alphacypermethrin was rapidly degraded in soil at 10°C and 20°C. Alphacypermethrin quantitatively accounted for the applied radioactivity at zero time and these levels subsequently decreased to a mean of 26.67% AR at 10°C and 7.49% AR at 20°C on day 120. In addition to the parent compound, low levels of CL 206128 (3-phenoxybenzoic acid) were detected on day 7 at both temperatures accounting for less that 9% of the applied radioactivity. A minor unknown component, designated A, was detected in all samples after day 3. At 10°C, unknown A accounted for a maximum of 8.14% AR in a single replicate on day 14 and subsequently decreased to a mean of 5.29% AR on day 120. At 20°C, levels of this compound accounted for a maximum of 5.12% AR in a single day 7 replicate and subsequently decreased to a mean of 1.71% AR at study termination. Two other minor components, designated B and C, and polar material were detected at intervals throughout the incubation period at both temperature groups each accounting for less than 5% of the applied radioactivity. The non-extractable radioactivity increased to about 34 and 37% AR for 10°C and 20°C samples, respectively, at the termination of the study. HPLC analysis of the fulvic acid fractions of the organic matter indicated the presence of minor components (<1% AR). Alphacypermethrin was not detected in any of the fulvic acid fractions.	
5.3	**Conclusion**	Alphacypermethrin degraded rapidly in sandy loam soil at 10°C and 20°C under the conditions of the study. DT_{50} (20 °C) = 20 d $^{14}CO_2$ was the principal degradation product detected. Based on the results of this study and the estimated DT_{50} data, it is unlikely that Alphacypermethrin will persist in soil.	X
5.3.1	Reliability	1	

Section A7.2.1 **Aerobic degradation in soil, initial study**
Annex Points IIIA 7.4, 12.1.1

5.3.2	Deficiencies	No The following deviations occurred but these are not considered as deficiencies: The test guideline specified in the report (OECD Draft Guideline No. 307) usually requires testing in more than one soil, whereas the "additional data requirements" as specified in chapter 3 of the TNsG clearly advocate the use of one soil only for the elucidation of the soil degradation pathway. A concentration of 10 times the maximum anticipated field application rate was used in this study in order to facilitate the detection of alphacypermethrin and its degradation products. Nevertheless, the high concentration did not appear to have affected the degradation of the test item. Therefore, this study is considered to be valid without restriction for the fulfilment of the current data requirement.

	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 comments/amendments: Section 4.3 Bound (non-extractable) residues increased from 0% to 34% or 37% until the end of the study, respectively at 10°C and 20°C
Conclusion	The Applicant's version is acceptable with the following amendment: Section 5.3 DT_{50} (20°C) = 20,6 d (or 21 d) (instead of 20 d)
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.2.1- 1: Soil used to investigate the rate of degradation of Alphacypermethrin.

Soil designation	**Scotland, UK**	
Textural class (UK scheme)	Sandy loam	
Textural class (USDA scheme)	Sandy loam	
Origin	Scotland, UK	
Particle size distribution [%]:	UK	USDA
Sand	65.8	66.6
Silt	26.9	26.7
Clay	7.3	6.7
Organic C [%]	0.9	
Microbial biomass [mg C/100 g dry soil]	25.8 (Initial) 20.3 (Final at 20°C) 27.4 (Final at 10°C)	
CEC [meq/100 g]	9.7	
pH [100 mM KCl]	6.5	
Moisture Content [g H_2O/100 g dry soil]	8.2	
MWC [g H_2O/100 g dry soil]	42.2	
FC [g H_2O/100 g dry soil]	43.4 (at pF 0) 11.8 (at pF 2.5)	

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

Table A7.2.1- 2: Distribution of radioactivity after application of [^{14}C]-Alphacypermethrin to soil and incubation under aerobic conditions at 10 and 20°C (concentrations of the active substance and metabolites according to HPLC-results, values in% AR).

DAT	$^{14}CO_2$	Volatiles	Alpha-cypermethrin	CL 206128	Unknown A	Others*	Bound residues	Total
10 °C								
0	ns	ns	99.78	nd	nd	nd	0.41	100.19
3	1.13	nd	95.39	nd	3.65	nd	2.87	103.04
7	2.36	0.01	82.94	5.44	6.56	nd	3.86	101.17
14	6.45	0.02	76.36	nd	8.14	nd	10.37	101.34
28	12.33	0.05	62.76	nd	7.25	1.17	11.56	95.12
42	16.06	0.05	52.82	nd	6.35	2.79	18.49	96.56
70	22.39	0.07	40.76	nd	6.66	1.64	28.15	99.67
120	31.77	0.12	26.67	nd	5.29	4.12	33.62	101.59
20 °C								
0	ns	ns	97.60	nd	nd	nd	0.71	98.31
3	2.44	nd	89.05	nd	2.92	nd	5.26	99.67
7	4.84	0.02	74.79	1.89	4.85	nd	10.49	96.88
14	13.87	0.02	59.84	nd	3.62	1.35	18.53	97.23
28	25.64	0.05	35.98	nd	4.33	2.46	26.35	94.81
42	34.73	0.07	20.75	nd	3.70	3.75	30.27	93.27
70	41.15	0.09	15.49	nd	2.46	3.28	36.68	99.15
120	51.40	0.15	7.49	nd	1.71	3.06	36.77	100.58

ns = No sample

nd = not detected

* sum of unknown B, C, and polar; each individual peak <5% AR

Table A7.2.1- 3: Estimated first-order DT_{50} and DT_{90} values of Alphacypermethrin (ModelMaker 4.0).

Temperature	Kinetics	First-order DT_{50} [d]	First-order DT_{90} [d]	r^2
20°C				
	Simple first-order	20.6	68.3	0.987
	Biphasic first-order	19.3	104.0	0.997
10°C				
	Simple first-order	54.9	182.5	0.962
	Biphasic first-order	49.9	233.0	0.982

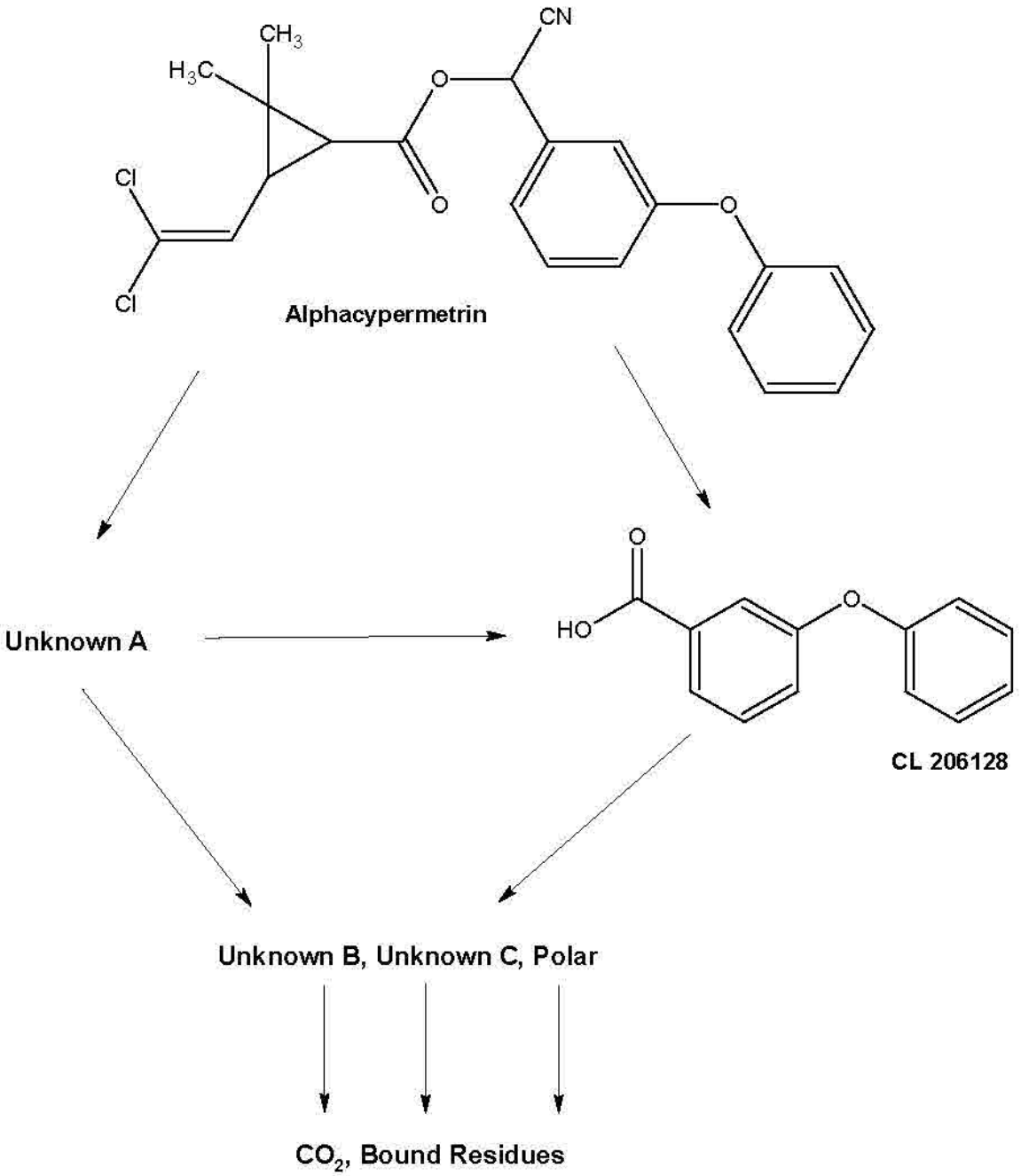

Figure A7.2.1- 1: Postulated route of degradation for Alphacypermethrin in soil.

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

Official use only

1 REFERENCE

1.1	**Reference**	**A7.2.2.1/01:** McMinn AL (1983) The degradation of the pyrethroid insecticides WL 85871 (FASTAC) and WL 43481 in soil. Shell Research Ltd, Sittingbourne, UK, Report no. SBGR.83.395, December 1983 (unpublished), BASF RDI No.: AL-620-005.
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**	Yes See 3.4

3 MATERIALS AND METHODS

3.1	**Test material**	1)	Benzyl ring-labelled-^{14}C-Alphacypermethrin (WL85871)
		2)	Benzyl ring-labelled-^{14}C-Cypermethrin (WL43467)
3.1.1	Lot/Batch number	1)	Batch 1, sample 594
		2)	Batch 1, sample 616
3.1.2	Specification	1)	Specific activity: 9.0 µCi/mg
		2)	Specific activity: 9.4 µCi/mg
3.1.3	Purity	1)	Radiochemical purity: 99%
		2)	Radiochemical purity: 99%

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

3.1.4	Further relevant properties	Alphacypermethrin: 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 (also see section A3) The metabolic pathway of Cypermethrin was established in study ***. Thus, Cypermethrin was included in this study in order to evaluate the potential equivalence of metabolic pathways between Cypermethrin and Alphacypermethrin.	X
3.1.5	Analytical methods	Extraction: with acetonitrile:water (7:3 v/v), filtration, concentration to an aqueous residue, then extraction with ethyl acetate or chloroform, dried over anhydrous sodium sulphate. Liquid scintillation counting (LSC): Standard routine using a Packard 460 D or Intertechnique SL33 counter with Packard ES 299 scintillation fluid. Combustion analysis: Unextracted radioactivity was determined by combustion analysis of solid samples (50–300 mg) in a Packard-Tricarb 3306 oxidiser, 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 moving head scanner, a linear analyser and autoradiography. HPLC: PAC Parisil 10 m, 250 × 4.6 mm I.D. column; mobile phase: dichloromethane:hexane (15:85 v/v).	
3.2	**Degradation products**		
3.2.1	Method of analysis for degradation products	$^{14}CO_2$ was trapped from the exhaust air by 2 M Potassium hydroxide solution and quantified by LSC. Basic volatiles trapped in 0.5 M sulphuric acid Organic volatiles trapped in 2-methoxyethanol Quantification of volatile and 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.	

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

3.3.1	Method of analysis for reference substance	See 3.1.5 above.	
3.4	**Soil types**	The soils and their physical properties are presented in Table A7.2.1- 1. Microbial biomass was not determined. No information on the storage time prior to the test is provided.	X
3.5	**Testing procedure**		
3.5.1	Test substance concentration	Nominal dose rate = 10 mg a.i./kg soil	
3.5.2	Solvent	Acetone	
3.5.3	Method of application	Treatment solution was added dropwise from a microsyringe. The soils were gently agitated during the addition of the insecticide to ensure even distribution of the compound in the soil.	
3.5.4	Testing apparatus	Not described in detail.	
3.5.5	Incubation period	52 weeks	
3.5.6	Incubation temperature	25 °C	
3.5.7	Moisture	Moisture was initially adjusted to 45 % of maximum MHC every 2 to 3 days by addition of distilled water.	
3.5.8	Sampling	After 2.5, 6. 10, 20 and 42 weeks.	

4 RESULTS

4.1	**Degradation rate**	Not reported	
4.2	**Disappearance time**	DT_{50} = 27 weeks, or 189 days (sandy clay loam, Reculver) DT_{50} = 13 weeks , 91 days (clay loam, Woodstock)	
4.3	**Degradation products**	An overview of recovered radioactivity, following a simplified classification scheme is presented in Table A7.2.2.1- 2. Although the degradation products were not rigorously identified, the patterns of products tentatively identified by TLC were not significantly different between Cypermethrin and Alphacypermethrin. Furthermore, they were very similar to those observed in the Cypermethrin studies (A7.2.2.1/02, 03, 04).	

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

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The aerobic degradation of Alphacypermethrin was studied comparatively to that of Cypermethrin in two standard soils (Reculver and Woodstock, UK) as a non-guideline study, prior to the issuing of agreed guidelines on this endpoint. The test was apparently conducted under radiochemical balance conditions. Description of the methods was relatively poor. In particular, microbial biomass of the soils was not determined and the period of storage prior to the test was not reported. No detailed information on the testing apparatus was given.
5.2	**Results and discussion**	The physico-chemical properties of Alphacypermethrin, such as solubility, hydrolytic stability, or volatility (see Section A3) are not considered to have negatively impacted the results. The DT_{50} of alphacypermethrin was found to be 27 weeks in sandy clay loam and 13 weeks in clay loam. There were no significant differences in the pattern of metabolites formed following treatment of either soil with Alphacypermethrin or Cypermethrin.
5.2.1	Degradation rate and half-life	DT_{50} = 27 weeks, or 189 days (sandy clay loam, Reculver) DT_{50} = 13 weeks , or 91 days (clay loam, Woodstock)
5.3	**Conclusion**	As demonstrated by comparison with references A7.2.2.1/02, 03, and 04, 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 (see study summary below) is also valid for Alphacypermethrin.
5.3.1	Reliability	2
5.3.2	Deficiencies	Yes The study is considered to be valid with restrictions due to the uncertainty about the microbial biomass and the poor documentation of methods as discussed under 5.1 above.

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 addition: Section 3.1.4 "The metabolic pathway of Cypermethrin was established in studies A7.2.2.1-02-03-04". The Applicant's version is acceptable with the following amendments: Section 3.4 Table A7.2.2.1-1
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	In the document IVA of this study, legends of Figures 1 and 2 p.15 and 16 are false.
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7.2.2.1- 1: Physical properties of the soils.

Origin	**Reculver, UK**	**Woodstock, UK**
Soil texture	Sandy clay loam	Clay loam
pH	5.7	7.5
Sand [%]	65.4	44.5
Silt [%]	9.0	22.1
Clay [%]	25.6	33.4
Organic matter [%]	2.9	3.6

Table A7.2.2.1- 2: Distribution of recovered radioactivity [% of AR] from soils treated with [^{14}C]-Alphacypermethrin (α) and Cypermethrin (Cyp.).

	Week											
	0		**2.5**		**6**		**10**		**20**		**42**	
	α	**Cyp.**	**α**	**Cyp.**	**α**	**Cyp.**	**α**	**Cyp.**	**α**	**Cyp.**	**α**	**Cyp.**
	Reculver											
Parent compound	99.8	100.1	91.0	97.3	90.6	82.2	67.9	61.3	61.9	47.9	28.9	17.7
Metabolites	—	—	3.4	1.5	4.3	6.3	2.9	6.2	3.3	5.5	2.6	1.8
Polar metabolites	—	—	1.2	0.5	0.5	0.9	0.7	0.7	0.7	1.1	0.7	0.4
Total organosoluble radioactivity	99.8	100.1	95.6	99.3	95.4	89.4	71.5	68.2	65.9	54.5	32.2	19.9
Total aqueous radioactivity	0.3	<0.05	0.6	0.7	0.5	0.5	2.2	2.1	1.2	1.2	0.3	0.1
Total extractable radioactivity	100.1	100.1	96.2	100.0	95.9	89.9	73.7	70.3	67.1	55.7	32.5	20.0
Total non-extractable radioactivity	0.1	0.1	2.0	0.1	6.0	4.0	6.0	8.0	9.0	12.0	18.0	37.7
	Woodstock											
Parent compound	99.4	99.8	79.8	82.2	69.9	73.1	58.2	59.1	32.3	37.8	21.6	30.2
Metabolites	—	—	3.3	3.0	4.2	4.1	2.9	6.2	3.1	2.0	2.2	2.7
Polar metabolites	—	—	0.1	0.5	0.2	0.2	0.6	0.7	0.4	0.4	0.5	0.7
Total organosoluble radioactivity	99.4	99.8	83.2	85.7	74.3	77.4	61.7	66.0	35.8	40.2	24.3	33.6
Total aqueous radioactivity	<0.05	<0.05	0.5	0.5	0.5	0.5	2.4	1.8	0.9	0.9	1.0	0.7
Total extractable radioactivity	99.5	99.8	83.7	86.2	74.8	77.9	64.1	67.8	36.7	41.1	25.3	34.3
Total non-extractable radioactivity	0.2	0.4	4.9	3.9	10.4	10.2	14.2	14.0	20.1	21.0	32.0	28.3

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4 and IIIA 12.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	**A7.2.2.1/02:** Standen ME (1976) The degradation of the insecticide WL 43467 in soil under laboratory conditions. Shell Research Ltd, Sittingbourne, UK, Report no. WKGR.0094.76, September 1976 (unpublished), BASF RDI No.: AL-620-010.	X
		A7.2.2.1/03: Roberts TR (1980) Appendices to Shell report no. WKGR.0094.76: The degradation of the insecticide WL 43467 in soil under laboratory conditions. Shell Research Ltd, SRC, Sittingbourne, UK, Report no. WKGR.0094.76, January 1980 (unpublished), BASF RDI No.: CY-620-010.	
		A7.2.2.1/04: Standen ME (1978) Further studies of the degradation of the insecticide WL43467 (Cypermethrin) in soil under laboratory conditions. Shell Research Ltd, Sittingbourne, UK, Report no. BLGR.0034.78, March 1978 (unpublished), BASF RDI No.: CY-620-003.	
		Remark: In order to facilitate establishment of the metabolic pathway of Alphacypermethrin in soil (by analogy to Cypermethrin), the above references are review in a joint summary for convenience.	
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 studies were conducted.	
2.3	**Deviations**	Yes See 3.4	

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4 and IIIA 12.1.1

3 MATERIALS AND METHODS

3.1	**Test material**	1)	Benzyl ring-labelled-^{14}C-Cypermethrin (WL43467)	
		2)	Benzyl ring-labelled-^{14}C-Cypermethrin, cis-isomers (WL43481)	
		3)	Cyclopropyl ring-labelled-^{14}C-Cypermethrin trans-isomer (WL42641)	
3.1.1	Lot/Batch number	Not reported		
3.1.2	Specification	1)	cis/trans-ratio = 3:7, specific activity: 10.3 µCi/mg	
		2)	Only cis, specific activity: 9.6 µCi/mg	
		3)	Only trans, specific activity: 9.6 µCi/mg	
3.1.3	Purity	1)	Radiochemical purity: 99%	
		2)	Radiochemical purity: 99%	X
		3)	Radiochemical purity: 99%	
3.1.4	Further relevant properties	The current studies were conducted to establish the metabolic pathway of Cypermethrin in soil. As demonstrated in reference A7.2.2.1/01, the patterns of degradation products show no significant differences between Cypermethrin and Alphacypermethrin. Thus, extrapolation of the metabolic pathway from Cypermethrin to Alphacypermethrin is considered feasible and valid.		

Section A7.2.1 Aerobic degradation in soil, initial study

Annex Points IIIA 7.4 and IIIA 12.1.1

3.1.5	Analytical methods	Extraction: with acetonitrile:water (7:3 v/v), filtration, 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 or SL40 counter. Thin layer chromatography (TLC): Merck silica gel F_{254} plates and various solvent systems; location and quantification of radioactive sites by a radio-scanner and autoradiography. Radio-HPLC (samples up to 28 weeks): PAC Partisil-5, 100 or 200 × 4.5 mm I.D. column; various mobile phases, as appropriate: (a) 1% dioxan + 0.1% v/v acetic acid in petroleum spirit (b) 5% v/v ethanol + 0.5% v/v acetic acid in petroleum spirit (c) 20% dichloromethane (50% water saturated) in petroleum spirit. 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. Mass spectrometry: Using a Finnigan 3200F GC-MS.

Section A7.2.1 Aerobic degradation in soil, initial study

Annex Points IIIA 7.4 and IIIA 12.1.1

3.2	**Degradation products**		
3.2.1	Method of analysis for degradation products	$^{14}CO_2$ was trapped from the exhaust air by 10% w/v Potassium hydroxide solution and submitted to LSC. Quantification of volatile and extractable degradation products as described under 3.1.5 above. Bound residues: After extraction with aqueous acetonitrile the soil was treated with 0.5N hydrochloric acid and heated to 60 °C for 5 minutes. The mixture was cooled and filtered and the soil was washed again with 0.5N hydrochloric acid in the same way. The soil residuum was then shaken with 0.5N sodium hydroxide at ambient temperature for 24 hours and centrifuged. The supernatant liquid was radio-counted to give the amount of radioactivity associated in total with the humic acid and fulvic acid fractions. After acidification with 6N-hydrochloric acid, the humic acid precipitate was separated by centrifugation and the supernatant liquid was again radio-counted to give the amount of radioactivity associated with the soluble fulvic acid fraction. The fulvic acid fraction was extracted with ethyl acetate (2 x 50 ml), the organic and aqueous extracts then being radio-counted. The organic solution was concentrated, radio-counted again and examined by TLC. The humic acid precipitate was refluxed with 6N hydrochloric acid at 100°C for 2 hours. The mixture was cooled and centrifuged. The acidic solution was radio-counted and extracted twice with ethyl acetate. The aqueous and organic extracts were radio-counted, and the latter was concentrated and examined by TLC. Identification of degradation products (i) by comparison with reference substances and by MS.	
3.3	**Reference substance**	Yes Unlabelled references substances as specified in Table 1 of the study report were used.	
3.3.1	Method of analysis for reference substance	As described in 3.1.5 above.	
3.4	**Soil types**	The physical-chemical properties of the test soils are presented in Table A7.2.2.1- 3.	X
3.5	**Testing procedure**	The test was divided in four different trial designs, targeted at different purposes, as described in detail in Table A7.2.2.1- 4.	
3.5.1	Test substance concentration	Nominal dose rate in all test setups: 2.5 mg a.i./kg soil	
3.5.2	Solvent	Acetonitrile	
3.5.3	Method of application	Dropwise addition to soil from micro-syringes, mixing by rotation of the test vessels.	
3.5.4	Testing apparatus	See Table A7.2.2.1- 4.	

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4 and IIIA 12.1.1

3.5.5	Incubation period	26 weeks 52 weeks (prolonged study, reference A7.2.2.1/04)
3.5.6	Incubation temperature	25 ± 2 °C
3.5.7	Moisture	Aerobic conditions: 15.6% (=54% field capacity) Anaerobic conditions: Submerged Balance study: 19.6% Isomer comparison (Biometer study): 18.4%
3.5.8	Sampling	Soil extracts: 0, 2, 4, 8, and 16 weeks; CO_2: at regular intervals, however varying among test designs, over 26 weeks; for details please refer to the study report. Biomass measurement: 3, 60 and 120 days.

4 RESULTS

4.1	**Degradation**	<u>Aerobic:</u> Unchanged parent compound decreased from 92.7–95.5% recovered radioactivity at the start of the experiments to 4.2–9.5% recovered radioactivity after 16 weeks. The degradation curve was relatively consistent across isomer mixtures and labelling positions. <u>Anaerobic:</u> Up to 160 days after treatment the major metabolite was PBA (comprising 73% of the applied radioactivity). At this stage minor metabolites and bound residues accounted for less than 6% and 14% respectively of the applied radioactivity.
4.2	**Disappearance time**	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 in Leiston sandy loam and between 8 and 16 weeks in Los Palacios clay.

Section A7.2.1 **Aerobic degradation in soil, initial study**

Annex Points IIIA 7.4 and IIIA 12.1.1

4.3 Degradation products

The major route of degradation was hydrolysis of the ester linkage to form 3-phenoxybenzoic acid (PBA) and 2,2-dimethyl-3-(2^1,2^1-dichlorovinyl) cyclopropane carboxylic acid (DCVA). Under aerobic conditions PBA reached a maximum concentration of 23%, 60% and 2% respectively of the applied radioactivity at 2–4 weeks after treatment in sandy clay, clay and sandy loam soils. The DCVA reached a maximum concentration of 51% of the applied radioactivity after 4 weeks in sandy clay soil, after which its concentration declined. The other soils were not treated with a radiolabel in the cyclopropyl group. A minor route of metabolism was hydroxylation of the phenoxy ring to form a hydroxy derivative of cypermethrin (maximum concentration 3% of the applied radioactivity). Analysis of samples stored for 52 weeks after treatment with [^{14}C]-Cypermethrin or its isomers showed the presence of 2-methyl-2-carboxy-3(2^1,2^1-dichlorovinyl) cyclopropane carboxylic acid in one soil (6% of the applied radioactivity, reference A7.2.2.1/04). In a separate experiment in that study it was shown that this metabolite could be formed directly from DCVA. Unextracted (bound) radioactivity accounted for up to 38% and 27%, respectively, of the applied radioactivity by the end of the study (52 weeks after treatment) from the [^{14}C-benzyl] and [^{14}C-cyclopropyl]-cypermethrin treatments.

When the sandy clay soil was treated with [^{14}C-benzyl]-Cypermethrin, 52% of the applied radioactivity was converted to $^{14}CO_2$ over 26 weeks after treatment. Extensive mineralisation was also found from the [^{14}C-cyclopropyl]-Cypermethrin isomers, with 28% and 35% of the applied dose being trapped as $^{14}CO_2$, from the *cis* and *trans*-isomers, respectively, after 22 weeks.

The "bound" residues from the 16 week samples in the sandy clay were further characterized by extraction with acid followed by alkali extraction. Most of the "bound" radiolabelled material was released by this procedure, with the radioactivity being distributed between the humic acid, fulvic acid and humin fractions. Small amounts of PBA and DCVA (<2% and 4–9%, respectively) were found in the fulvic acid fractions, indicating that these metabolites can become strongly bound to soil.

The proposed degradation pathway is presented in Figure A7.2.2.1- 1.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The route of aerobic degradation of Cypermethrin was studied in three soils (Los Palacios and Brenes, Spain, and Leiston, UK) as a non-guideline study, prior to the issuing of agreed guidelines on this endpoint.

Cypermethrin (cis/trans-ratio = 3:7) as well as isolated cis- and trans-isomers, ^{14}C-labelled either in the benzyl or in the cyclopropyl ring, were applied to soil and exposed to aerobic or anaerobic conditions. Evolved $^{14}CO_2$ was trapped and quantified by LSC; soil extracts were analysed for parent compound and degradation products by various radio-analytical techniques.