Section IIIA 7.1.2.2 **Annex Point XII.2.1**	**Biodegradation in Freshwater** **IIIA 7.1.2.2.1 Aerobic Aquatic Degradation Study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Exposure of aquatic organisms to Permethrin is highly unlikely as Permethrin, according to its recommended use as an insecticide, is to be applied indoors only as a liquid spray. The product may enter drains during cleaning operations following treatment. This presents a possible risk of exposure to STPs and subsequently surface water. However, the quantities entering the STP are thought to be negligible as the use pattern of the product is expected to be localised and of low volume. Furthermore, label recommendations advice against the disposal of the product down drains. A risk assessment carried out on the fate of Permethrin in surface waters following release *via* STP effluent, showed that the risk quotient for Permethrin in surface waters is < 1 indicating no risk to the aquatic compartment. Furthermore, in the unlikely event that Permethrin is released directly into the environment, a distribution study conducted using the Level I Fugacity Model, indicated that Permethrin was predicted to partition predominantly to soil (98.5%) with insignificant amounts distributed to water (0.4%) ("Environmental distribution of Permethrin (Mackay Level I fugacity model)", McManus, K. (2006b) (IIIA 7.3.2)). It is therefore proposed that no further testing on the biodegradation of Permethrin in freshwater is required, as there is no relevant additional scientific information to be gained there from.	
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	26 May 2009	
Evaluation of applicant's justification	The Emission Scenario Document for Product Type 8 identifies that exposure of surface water could occur via a sewage treatment plant (losses during industrial application, losses from a treated noise barrier in service), via rainfall leaching substance from treated wood stored in an uncovered and unpaved area, and through application to a bridge over a pond. However, the RMS agrees with the applicant that an aerobic aquatic degradation study would not provide any	

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Section IIIA 7.1.2.2 **Annex Point XII.2.1**	**Biodegradation in Freshwater** **IIIA 7.1.2.2.1 Aerobic Aquatic Degradation Study**
	additional relevant scientific information. Relevant information on the behaviour of permethrin in surface water bodies can be obtained from the aerobic water/sediment studies provided under annex point IIIA 7.1.2.2.2 (Morlock, G., 2006a and 2006b).
Conclusion	Aerobic aquatic degradation study not required.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Biodegradation in freshwater

IIIA 7.1.2.2.2 Water/sediment degradation

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	~~21~~1 REFERENCE
~~21.1~~1.1 **Reference**	Morlock, G. (2006a), Degradation and metabolism of Permethrin (^{14}C-Vinyl label and ^{14}C-Phenoxyphenyl label) in one water/sediment system (creek) under aerobic conditions - laboratory test, GAB Biotechnologie GmbH & GAB Analytik GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany, unpublished report no.: 20051415/02-CUWS. Dates of experimental work: December 20, 2005 - July 07, 2006
~~21.2~~1.2 **Data protection**	Yes
~~21.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.
~~21.2.2~~1.2.2 Companies with letter of access	Not applicable
~~21.2.3~~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/IA.
	~~22~~2 GUIDELINES AND QUALITY ASSURANCE
~~22.1~~2.1 **Guideline study**	Yes, test method was based on OECD guideline 308 and SETAC 1995.
~~22.2~~2.2 **GLP**	Yes
~~22.3~~2.3 **Deviations**	No, a second water/sediment system (pond) was examined and reported separately (report no. 20051415/01-CUWS).
	~~23~~3 MATERIALS AND METHODS
~~23.1~~3.1 **Test material**	Radiolabelled test item 1: *cis/trans*-[Phenoxyphenyl-U-^{14}C]Permethrin Radiolabelled test item 2: *cis/trans*-[vinyl-2-^{14}C]Permethrin Non radiolabelled test item: Technical Permethrin
~~23.1.1~~3.1.1 Lot/Batch number	Radiolabelled test item 1: CFQ14540 Batch 1 Radiolabelled test item 2: CFQ14539 Batch 1 Non radiolabelled test item: P-37
~~23.1.2~~3.1.2 Specification	Please refer to points 3.1.3 to 3.1.5
~~23.1.3~~3.1.3 Purity	Radiolabelled test item 1: 99.4% (Radiochemical purity)

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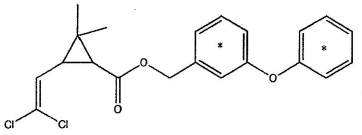
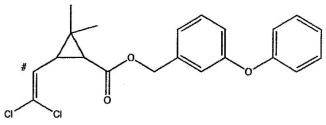
Section A7.1.2.2/1 Annex Point XII 2.1	**Biodegradation in freshwater** **IIIA 7.1.2.2.2 Water/sediment degradation**	
	Radiolabelled test item 2: 99.6% (Radiochemical purity) Non radiolabelled test item: 93.61%	
~~23.1.4~~3.1.4 Specific Activity	Radiolabelled test item 1: 59 mCi/mmol Radiolabelled test item 2: 42 mCi/mmol	
~~23.1.5~~3.1.5 Radiolabeling	 Radiolabelled Test Item 1  Radiolabelled Test Item 2 #*Denotes position of the ^{14}C-label	
~~23.1.6~~3.1.6 Further relevant properties	Cis/Trans ratio: 25.2:74.8 (Test item 1), Cis/Trans ratio: 24.9:75.1 (Test item 2)	
~~23.1.7~~3.1.7 Composition of Product	Not applicable	
~~23.1.8~~3.1.8 TS inhibitory to microorganisms	No	
~~23.1.9~~3.1.9 Specific chemical analysis	None	
~~23.2~~3.2 Reference substance	Non-radiolabeled Permethrin	
Initial concentration of reference substance	Not applicable	
~~23.3~~3.3 Testing procedure		
~~23.3.1~~3.3.1 Test systems	Please refer to Table A7.1.2.2.2-1	
~~23.3.2~~3.3.2 Test conditions	Please refer to Table A7.1.2.2.2-2	X

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Biodegradation in freshwater

IIIA 7.1.2.2.2 Water/sediment degradation

~~23.3.3~~3.3.3 Duration of test	120 days
~~23.3.4~~3.3.4 Analytical procedures	Sediment: Upon removal of the water phase from the test flask the sediment was mixed and samples transferred to a HDPE flask and deep frozen. 40 ml acetonitrile, 40 ml water, Spikemix (1 mg of each metabolite in acetonitrile) and 1 ml acetic acid were added to the aliquot remaining in the incubation fask. The incubation flask was then closed with a carbon dioxide trap to determine the amount of carbon dioxide dissolved in the water phase. The assembly was shaken overnight to allow evolution of the carbon dioxide and the extraction of the sediment. The amount of radioactivity in the carbon dioxide trap was determined by LSC (3 x 1 ml). The extract was then separated from the dispersed sediment by centrifugation. The extraction was repeated three times with 60 ml acetonitrile/water and a further two times with 60 ml pure acetone. The radioactivity in each individual extract as well as in the combined acetonitrile/water extracts was determined by LSC. Where the measured radioactivity was higher than 2.5% of the applied amount, the extract was further processed. 100 ml of this extract was separated and concentrated using a rotary evaporator. The radioactivity in this concentrated phase was characterised by normal and reverse phase TLC. The fractions were co-chromatographed with the available reference compounds. After the final extraction, the sediment was dried prior to combustion. The total amount of non extractable radioactive residues in the sediment after extraction was determined by combustion and LSC (3 x 0.5 g). Water: The radioactivity in the water was determined directly by LSC of an aliquot (3 x 1 g) before it was poured out of the incubation flask. To a further 3 aliquots, 100 µl acetic acid was added and the next day the radioactivity remaining was measured to determine the amount of carbon dioxide which was dissolved in the water phase. An aliquot of the water phase was added to the top of an Extrelute column and extracted with 80 ml acetone. The completeness of the extraction process was checked by LSC. The extract was concentrated using a rotary evaporator and characterised by normal and reverse phase TLC. The fractions were co-chromatographed with the available reference compounds.
~~23.3.5~~3.3.5 Sampling	Two flasks from each system were sampled immediately after application and 24 h, 48 h, 7 d, 14d, 30 d, 62 d, 85 d, 100 d and 120 d after treatment. At each sampling, the height of the sediment and the water layer, the redox potential in water and sediment, the pH in water and the oxygen concentration in water were determined. 120 days after treatment the sediment in the control flasks were analysed for microbial activity, pH and redox potential. The water phase was analysed for pH, redox potential, total N and P, concentration of oxygen and total organic carbon.

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Biodegradation in freshwater

IIIA 7.1.2.2.2 Water/sediment degradation

~~23.3.6~~3.3.6	Intermediates/ degradation products	Identified		Formatted: Bullets and Numbering
~~23.3.7~~3.3.7	Controls	12 control flasks containing 275 µg of non-radiolabelled test item were used.		Formatted: Bullets and Numbering
~~23.3.8~~3.3.8	Statistics	The half-life of Permethrin in both the phenoxyphenyl and vinyl systems was calculated from a plot of percentage applied radioactivity versus time. The DT_{50} values were calculated by non-linear regression assuming first order degradation of Permethrin.		Formatted: Bullets and Numbering
		~~2~~4 RESULTS		Formatted: Bullets and Numbering
~~24.1~~4.1	**Degradation of test substance**			Formatted: Bullets and Numbering
~~24.1.1~~4.1.1	Distribution of Radiocarbon and Mass Balance	Quantitative recoveries of ^{14}C were obtained throughout the entire testing period and for all samples. For the phenoxyphenyl labelled water/sediment system, the CO_2 trapped from air increased to 22.5 % AR after 120 days. Radioactivity increased in sediment form 2.7 % AR immediately after the treatment to 52.8 % AR after 120 days. The radioactivity in the water phase decreased from the initial 96.8 % AR to 19.9 % AR after 7 days, followed by an increase to 40.3 % AR at day 30 and again a decrease to 1.0 % AR after 120 days. The extractable residues in sediment increased from 2.6 % AR (0 days) to 65.8 % AR after 14 days and then declined to 5.0 % AR after 120 days. The unextractable residues in sediment accounted for a maximum of 47.3 % AR after 120 days. For the vinyl water/sediment system the CO_2 trapped from air increased to 5.4 % AR after 120 days. Radioactivity in sediment increased from 2.6 % AR immediately after the treatment to 67.1 % AR after 14 days. The radioactivity in the water phase decreased from the initial 95.8 % AR to 18.9 % AR after 14 days, followed by an increase to 62.6 % AR after 100 days. The extractable residues in sediment increased from 2.6 % AR (0 days) to 66.5 % AR after 14 days and then declined to 13.0 % AR after 120 days. The unextractable residues in sediment accounted for a maximum of 14.1 % AR after 120 days. The mean recovery of applied radioactivity throughout the study was 95.6% AR for the phenoxyphenyl labelled water/sediment system and 97.3% AR for the vinyl water/sediment system. Please refer to Tables A7.1.2.2.2-5a and b for the distribution of the radioactivity between water, sediment and carbon dioxide in the Phenoxyphenyl and Vinyl labeled water/sediment systems. .		Formatted: Bullets and Numbering
~~24.1.2~~4.1.2	DT_{50}/DT_{90}	The DT_{50} of Permethrin in the phenoxyphenyl labelled system in the water phase was 2.3 days (DT_{90} 7.6 days) and the DT_{50} in the whole	X	Formatted: Bullets and Numbering

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IIIA 7.1.2.2.2 Water/sediment degradation

system was 24.6 days (DT_{90} 81.7 days). The DT_{50} of Permethrin in the vinyl labelled system in the water phase was 1.4 days (DT_{90} 4.5 days) and the DT_{50} in the whole system was 24.3 days (DT_{90} 80.8 days). Please refer to Table A7.1.2.2.2-7a and b for DT_{50} and DT_{90} values of ^{14}C-Phenoxyphenyl and ^{14}C-Vinyl Permethrin in the water phase and complete creek system.

~~2.1.3~~4.1.3 Intermediates/ degradation products

The metabolites formed in the sediment phase and the water phase in the phenoxyphenyl labelled system were, 3-phenoxybenzyl-alcohol (5.5 % AR after 1 day in water, 3.3 % AR after 7 days in sediment) and 3-phenoxybenzoic acid (28.5 % AR after 62 days in water, 16.4 % AR after 62 days in sediment).

The sole metabolite formed in the sediment phase and the water phase in the vinyl labelled system was 3-(2,2-dichlorovinyl)2,2-dimethylcyclopropane carboxylic acid (DCVA) (62.4 % AR after 62 days in water, 21.7 % AR after 62 days in sediment). Please refer to Table A7.1.2.2.2-6a and b for the sum of Permethrin and its metabolites in the total water/sediment system/Phenoxyphenyl and Vinyl labels. Please refer to Figure A7.1.2.2.2-1 for the proposed degradation pathway of Permethrin in the water/sediment system.

~~2.1.4~~4.1.4 Bound Residues

In the phenoxyphenyl labelled system the bound residues increased to a maximum of 47.3 % applied radioactivity (AR) after 120 days. In the vinyl labelled system the bound residues increased to 14.1 % AR after 120 days. Please refer to Table A7.1.2.2.2-5a and b.

~~2.1.5~~4.1.5 Mineralization to CO_2

In the phenoxyphenyl system total mineralization to carbon dioxide was 45.4 % AR after 120 days taking into account the amount of carbon dioxide in the gas phase and dissolved in water and sediment. In the vinyl system the total mineralization to carbon dioxide was 14.1 % AR after 120 days taking into account the amount of carbon dioxide in the gas phase and dissolved in water and sediment. Please refer to Table A7.1.2.2.2-5a and b.

~~2~~5 APPLICANT'S SUMMARY AND CONCLUSION

~~2.1~~5.1 Materials and methods

The degradation time and degradation products of Permethrin in one water/sediment system (creek) with two radiolabels (^{14}C-vinyl and ^{14}C-phenoxyphenyl) under aerobic conditions in the dark was investigated at 20 ± 2°C over a 120 day study period. The applied rate of Permethrin was 1375 g/ha.

This study was conducted according to OECD guideline 308 and is described under point 3.

~~2.2~~5.2 Results and discussion

In the phenoxyphenyl labelled system, $^{14}CO_2$ accounted for 45.4 % of the AR after 120 days. It was trapped from the gas space (22.5 % AR), found dissolved in water (22.5 % AR) and sediment (0.5 % AR). The

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IIIA 7.1.2.2.2 Water/sediment degradation

non volatile radioactivity was found to decrease with time in the water phase (19.9 % AR in water after 7 days incubation) and increased to a maximum of 40.3 % AR after 30 days incubation. The non volatile radioactivity in the sediment increased to a maximum of 65.8 % AR after 14 days and decreased to 5.0 % after 120 days. The bound residues increased to a maximum of 47.3 % AR after 120 days. The majority of the radioactivity in the water phase was Permethrin which declined to zero after 62 days, 3-phenoxybenzyl-alcohol (maximum 5.5 % AR after 1 day, 0 % AR after 62 days) and 3-phenoxybenzoic acid (maximum 28.5 % AR after 62 days, 1.0 % after 120 days). In the sediment phase Permethrin increased from 2.6 % AR at study initiation to 57.1 % AR after 14 days, and then declined to 0 % AR after 100 days. 3-phenoxybenzyl-alcohol appeared at 3.3 % AR after 7 days and 3-phenoxybenzoic acid at a maximum of 16.4 % AR after 62 days. The sole metabolites observed in the sediment phase and the water phase in the phenoxyphenyl labelled system were, 3-phenoxybenzyl-alcohol (5.5 % AR after 1 day in water, 3.3 % AR after 7 days in sediment) and 3-phenoxybenzoic acid (28.5 % AR after 62 days in water, 16.4 % AR after 62 days in sediment). No other metabolites >1% were detected. The decline of Permethrin was fast with a 1st order DT_{50} in the water phase of 2.3 days (DT_{90} 7.6 days) and a DT_{50} in the total system of 24.6 days (DT_{90} 81.7 days). The mean recovery of this test system was 95.6 % AR and no volatile organics were detected.

In the vinyl labelled system, $^{14}CO_2$ accounted for 14.1 % of AR after 120 days. It was trapped from the gas space (5.4 % AR), found dissolved in water (8.5 % AR) and sediment (0.2 % AR). The non volatile radioactivity was found to decrease with time in the water phase (15.4 % AR in water after 7 days incubation) and then increased to a maximum of 62.6 % AR after 100 days incubation. In the sediment the non volatile radioactivity increased to a maximum of 66.5 % AR (extractable) after 14 days and decreased to 13.0 % after 120 days incubation. The bound residues increased to 14.1 % AR after 120 days. The majority of the radioactivity in the water phase was Permethrin which declined to zero after 62 days and 3-(2,2-dichlorovinyl)2,2-dimethylcyclopropane carboxylic acid (DCVA) which increased to 62.6 % AR after 100 days. In the sediment phase Permethrin increased from 2.6 % AR at study initiation to 60.3 % AR after 14 days, and then declined to 0 % AR after 100 days. DCVA increased to 21.7 % AR after 62 days, and then declined to 13.0 % AR after 120 days. The sole metabolite observed in the sediment phase and water phase was DCVA (62.6 % AR after 100 days in water, 21.7 % AR after 62 days in sediment). No other metabolites >1% were detected. The decline of Permethrin in the vinyl labelled system was fast with a 1st order DT_{50} in the water phase of 1.4 days (DT_{90} 4.5 days) and a DT_{50} in the total system of 24.3 days (DT_{90} 80.8 days). The mean recovery of this test system was 97.3 % AR and no volatile organics were detected.

~~2.3~~5.3 Conclusion

Permethrin degrades at a rapid rate when applied to an aerobic aquatic environment. Degradation of Permethrin involved the formation of three main metabolites; 3-Phenoxybenzyl-Alcohol, DCVA and 3-Phenoxybenzoic-Acid and was accompanied by mineralization and

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IIIA 7.1.2.2.2 Water/sediment degradation

carbon dioxide evolution. A proposed metabolic pathway is presented.

~~25.3.1~~5.3.1	Reliability	1
~~25.3.2~~5.3.2	Deficiencies	None

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

~~27 May 2009~~1 March 2011

Materials and Methods

Applicant's version is acceptable with the following clarification.

Sub-heading 3.3.2 (Table A7.1.2.2.2-2)

Test concentration of 275 µg per flask (containing ~600 mL water) is equivalent to a field application rate of 1375 g/ha and a depth of water in the field of 30 cm.

Results and discussion

Applicant's version is acceptable with the following clarifications.

Sub-heading 4.1.2
Whole-system DT_{50} values represent degradation, whereas DT_{50} values for the water phase represent dissipation.

The reported DT_{50} values were obtained at 20 ± 2 °C. Extrapolation with the TGD temperature correction equation ($DT_{50}(12\ °C) = DT_{50}(T) \times e^{0.08(T-12)}$) gives the following values –

- phenoxyphenyl label: water-phase DT_{50} = 4.4 days, whole-system DT_{50} = 46.7 days;
- vinyl label: water-phase DT_{50} = 2.7 days, whole-system DT_{50} = 46.1 days.

Conclusion

Adopt applicant's version.

Reliability

2

Acceptability

Acceptable

Remarks

This study on a creek-derived water-sediment system and a second study on a pond-derived water-sediment system (Morlock, G., 2006b) have both been presented under this data point to meet the requirement of the guidance followed for testing on two systems. Consequently, both studies are key studies for this data point.

It is noted that OECD Guideline 308 recommends that one of the sediments used should have a high organic carbon content (2.5-7.5%) and that the other should have a low organic carbon content (0.5-2.5%), with the difference in the organic carbon contents normally being at least 2%. Both of the sediments used for this data point were of low organic carbon content (0.44% and 1.76%). The RMS evaluator has assigned both water-sediment studies a reliability rating of 2, since neither used sediment with a high organic carbon content.

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IIIA 7.1.2.2.2 Water/sediment degradation

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

Table A7.1.2.2.2-1: Description of test system

Criteria	Details
Glassware and equipment	Closed gas flow system: flasks used were 1000ml all-glass metabolism flasks (inner diameter: 10.1 cm; surface: 80 cm^2) Combustion of soil samples was performed using an oxidiser OX-500 with oxygen support regulator, Zinser, Germany. Radioassays of solutions were performed on a liquid scintillation counter 1409, Wallac, Finland.
Measurement of Volatiles	To determine evolved organic volatiles, glass tubes filled with Tenax absorbent were used as volatile traps (350 mg). They were analysed for radioactivity at each sampling. The radioactive carbon dioxide evolved in the test system was trapped by a sodium hydroxide solution in a separate reservoir, which was connected to the flask (30 ml). Traps for radioactive carbon dioxide were analysed at intervals of about 4 weeks.

Table A7.1.2.2.2-2: Description of test conditions

Criteria	Details
Purity of water	Water was sampled from a creek, known not to be influenced by effluents or human activity. The data of the exact location, date of sampling and conditions of water and sediment at sampling time were recorded and archived in the testing facility. The sampling was performed at Dentelbach in D-71579 Spiegelberg, Germany. Water was sampled from the top 5 to 10 cm of the surface of the water. The sampling site was located 1 to 2 m from firm land. The water was sieved through a 0.2 mm sieve and stored at temperatures between 15°C and 20°C under aeration. At the time of sampling the oxygen concentration was measured just below the water surface. Hardness, ammonia, nitrite, nitrate, temperature, oxygen and redox potential were determined immediately before sampling. Please refer to Tables A7.1.2.2.2-3 and A7.1.2.2.2-4 for characterisation of the water used.
Soil	Sediment was sampled from a creek, known not to be influenced by effluents or human activity. The data of the exact location, date of sampling and conditions of water and sediment at sampling time were recorded and archived in the testing facility. The sampling was performed at Dentelbach in D-71579 Spiegelberg, Germany. Sediment was sampled from the top 5 to 10 cm of the surface of the sediment. The sampling site was located 1 to 2 m from firm land. The sediment was sieved through a 2 mm sieve and stored at temperatures between 15°C and 20°C under aeration. At the time of sampling the oxygen concentration was measured just below the water surface. Hardness, ammonia, nitrite, nitrate, temperature, oxygen and redox potential were determined immediately before sampling. Please refer to Tables A7.1.2.2.2-3 and A7.1.2.2.2-4 for characterisation of the sediment used.
Preparation of flasks	After storage of water and sediment for a period of one day approximately 350 g of wet sediment was transferred into metabolism flasks to establish a layer of 2.5 cm. The flasks were then filled to 7.5 cm (approximately 500 ml) with water. The flasks were then incubated at 20°C ± 2°C in the dark under aerobic conditions until an equilibrium based on measured variables was reached. During this acclimatisation period each system was aerated by a slight orbital movement of the test vessel on an orbital shaker which did not disturb the surface of the sediments. Any organic volatiles were trapped by glass tubes filled with Tenax and any carbon dioxide generated was trapped by an attached sodium hydroxide reservoir. The oxygen content inside the

	test vessels was determined by a pressure transducer system on two biomass flasks. If a reduction of more than 10 % of the initial oxygen content occurred the system was aerated.
Preparation of test chemical solution and application to soil and water	The test items were applied in 500 µl of ethanol using a pipette to the surface. The concentration of the solvent did not exceed 0.1 % of the amount of water present.
Test concentrations (mg a.s. /L)	22 flasks contained 275µg of ^{14}C-Vinyl labelled test item 2. Radioactivity of 10 µCi was applied to each flask. Assuming a specific activity of 42 mCi/mmol, this corresponded to 93.5 µg of test item. Therefore the application rate was 93.5 µg of labelled test item and 181.5 µg of non-labelled test item per vessel. 22 flasks contained 275 µg of ^{14}C-Phenoxyphenyl labelled test item 1. Radioactivity of 10 µCi was applied to each flask. Assuming a specific activity of 59 mCi/mmol, this corresponded to 66.7 µg of test item. Therefore the application rate was 66.7 µg of labelled test item and 208.3 µg of non-labelled test item per vessel.
Test system	Incubated in the dark under aerobic conditions
Temperature (°C)	20 ± 2°C
Replicates	22
Sterilisation	Not documented

Table A7.1.2.2.2-3: Characterization of water and sediment at the time of sampling

		Creek (Dentelbach)
Water	Total P [mg/l]:	0.14
	Ca/Mg/Na/K [mg/l]	42/19/18/4.4
	Total N [mg/l]:	7.0
	Total organic carbon [mg/l]:	1.76
	Temperature [°C]*	0.1
	pH*	7.67
	Oxygen [mg/l]*	13.99
	Redox potential [mV]*	+219
	Water hardness (total) [°dH]*	15 (268 mg $CaCO_3$/L)
	Water hardness (carbonate) [°dH]*	10 (178 mg $CaCO_3$/L)
Sediment	Total P [mg/kg]	45.7
	Total N [mg/kg]	204
	pH	6.8
	Total Organic carbon [%]	0.44
	Sand/silt/clay [%]	97.7/2.1/0.2
	Cation exchange capacity [mval/100g]	3.17
	Redox potential [mV]*	+255

* determined at sampling site; all other values are taken after sieving of sediment and water

Table A7.1.2.2.2-4: Characterization of water and sediment at the beginning of the study and after 120 days

		Creek (Dentelbach)
Water	Total P [mg/l]:	
	Beginning of the study	0.19
	After 120 days	0.14
	Total N [mg/l]:	
	Beginning of the study	<1
	After 120 days	<1
	Organic carbon [mg/l]:	
	Beginning of the study	5.9
	After 120 days	5.2
Sediment	Total P [mg/kg]	45.7
	Total N [mg/kg]	204
	pH	6.8
	Organic carbon [%]	0.44
	Particle size distribution Sand/silt/clay [%]	97.7/2.1/0.2
	Sediment Classification	Sand
	Cation exchange capacity [mval/100g]	3.17
	Microbial biomass [µg C/g dry matter]:	
	Beginning of the study	11.9
	After 120 days	11.2

Table A7.1.2.2.2-5a: Distribution of the radioactivity between water, sediment and carbon dioxide, in the water/sediment system with the Phenoxyphenyl label (% of the applied radioactivity)

Time [days]	Total CO_2 [%AR]	CO_2 trapped directly [%AR]	Water Phase			Sediment				Sum [a] Recovery [%AR]
			Total after sampling [%AR]	SNV (soluble but not volatile after acid treatment) [%AR]	CO_2 evolved after acid treatment [%AR]	Extract [%AR]	CO_2 from sediment [%AR]	Bound Residues [%AR]	Total in sediment [%AR]	
0	6.8	0.0	103.6	96.8	6.8	2.6 [b]	0.0	0.1 [b]	2.7	106.3
1	2.1	0.0	90.4	88.4	2.1	13.3 [b]	0.0	0.3 [b]	13.6	104.1
2	3.7	0.0	57.7	54.1	3.7	36.6 [b]	0.0	0.4 [b]	40.0	94.8
7	5.9	0.0	25.6	19.9	5.9	60.0 [c]	0.0	0.9 [c]	60.9	86.7
14	5.0	0.0	26.8	22.1	5.0	65.8 [b]	0.0	1.4 [b]	67.2	94.3
30	2.8	0.1	43.0	40.3	2.7	45.7 [b]	0.0	2.0 [b]	47.7	90.8
62	17.2	4.3	41.2	28.5	12.8	23.0 [c]	0.2	27.3 [c]	50.5	96.0
85	32.5	12.6	36.3	16.8	19.5	9.3 [c]	0.4	35.6 [c]	45.3	94.2
100	39.4	17.3	32.1	10.5	21.7	6.7	0.5	33.7	40.9	90.3
120	45.4	22.5	23.5	1.0	22.5	5.0	0.5	47.3	52.8	98.7

[a] Values have been calculated from the raw data and therefore there maybe slight differences between these values and calculations performed using the rounded values. [b] Values are only from one vessel due to inhomogeneity of the sediment, therefore for one of the duplicate vessels the complete sediment was extracted and not only an aliquot. [c] Complete sediment of both parallel vessels were extracted and not only an aliquot.

Table A7.1.2.2.2-5b: Distribution of the radioactivity between water, sediment and carbon dioxide, in the water/sediment system with the Vinyl label (% of the applied radioactivity)

Time [days]	Total CO_2 [%AR]	CO_2 trapped directly [%AR]	Water Phase			Sediment				Sum[a] Recovery [%AR]
			Total after sampling [%AR]	SNV (soluble but not volatile after acid treatment) [%AR]	CO_2 evolved after acid treatment [%AR]	Extract [%AR]	CO_2 from sediment [%AR]	Bound Residues [%AR]	Total in sediment [%AR]	
0	5.5	0.0	101.3	95.8	5.5	2.6[b]	0.0	0.0[b]	2.6	103.9
1	8.7	0.0	74.4	65.8	8.7	31.8[b]	0.0	0.3[b]	32.1	106.6
2	2.3	0.0	36.2	34.1	2.2	53.3[b]	0.1	0.3[b]	53.7	90.0
7	5.0	0.0	20.4	15.4	5.0	63.7[c]	0.0	0.4[c]	64.1	84.5
14	4.3	0.1	23.1	18.9	4.2	66.5[b]	0.0	0.6[b]	67.1	90.3
30	2.9	0.3	42.6	40.0	2.6	49.1[b]	0.0	1.1[b]	50.2	93.1
62	6.1	1.2	67.3	62.4	4.9	23.3	0.1	13.9[d]	37.3	105.7
85	10.7	3.0	69.0	61.3	7.7	15.0	0.1	13.0	28.1	100.0
100	9.0	2.7	68.8	62.6	6.2	16.3	0.2	11.2	27.7	99.1
120	14.1	5.4	67.1	58.5	8.5	13.0	0.2	14.1	27.3	99.7

[a] Values have been calculated from the raw data and therefore there maybe slight differences between these values and calculations performed using the rounded values. [b] Values are only from one vessel due to inhomogeneity of the sediment, therefore for one of the duplicate vessels the complete sediment was extracted and not only an aliquot. [c] Both vessels were completely extracted instead of only an aliquot. [d] Value only from one vessel due to outlier.

Table A7.1.2.2.2-6a: Sum of Permethrin and its metabolites in the total water/sediment system/Phenoxyphenyl label (% of the applied radioactivity)

Time [days]	% dissipation in total system			Sum [%]
	Permethrin	Metabolite 1	Metabolite 2	
0	99.4	0.0	0.0	99.4
1	89.3	5.6	6.8	101.7
2	86.3	3.3	1.2	90.8
7	59.6	4.5	15.9	80.0
14	65.9	1.8	20.3	88.0
30	59.2	3.0	23.9	86.1
62	6.6	0.0	44.9	51.5
85	3.6	0.2	22.3	26.1
100	0.0	0.0	17.2	17.2
120	0.0	0.0	6.0	6.0

Metabolite 1 = 3-Phenoxybenzyl-Alcohol, Metabolite 2 = 3-Phenoxybenzoic-Acid

Table A7.1.2.2.2-6b: Sum of Permethrin and its metabolites in the total water/sediment system/Vinyl label (% of the applied radioactivity)

Time [days]	% dissipation in total system		Sum [%]
	Permethrin	Metabolite 1	
0	98.4	0	98.4
1	93.7	3.9	97.6
2	83.2	4.2	87.4
7	67.2	11.9	79.1
14	72.2	13.2	85.4
30	60.2	28.9	89.1
62	1.6	84.1	85.7
85	0.5	75.8	76.3
100	0	78.9	78.9
120	0	71.5	71.5

Metabolite 1 = DCVA

Table A7.1.2.2.2-7a: DT_{50} and DT_{90} values of ^{14}C-Phenoxypenyl Permethrin in the water phase and the complete creek system

^{14}C-Phenoxyphenyl Permethrin		R^2	DT_{50} [days]			DT_{90} [days]		
				LL	UL		LL	UL
Creek	Total	0.9336	24.6	18.9	35.4	81.7	62.7	117.5
	Water	0.9642	2.3	1.8	3.2	7.6	5.9	10.7

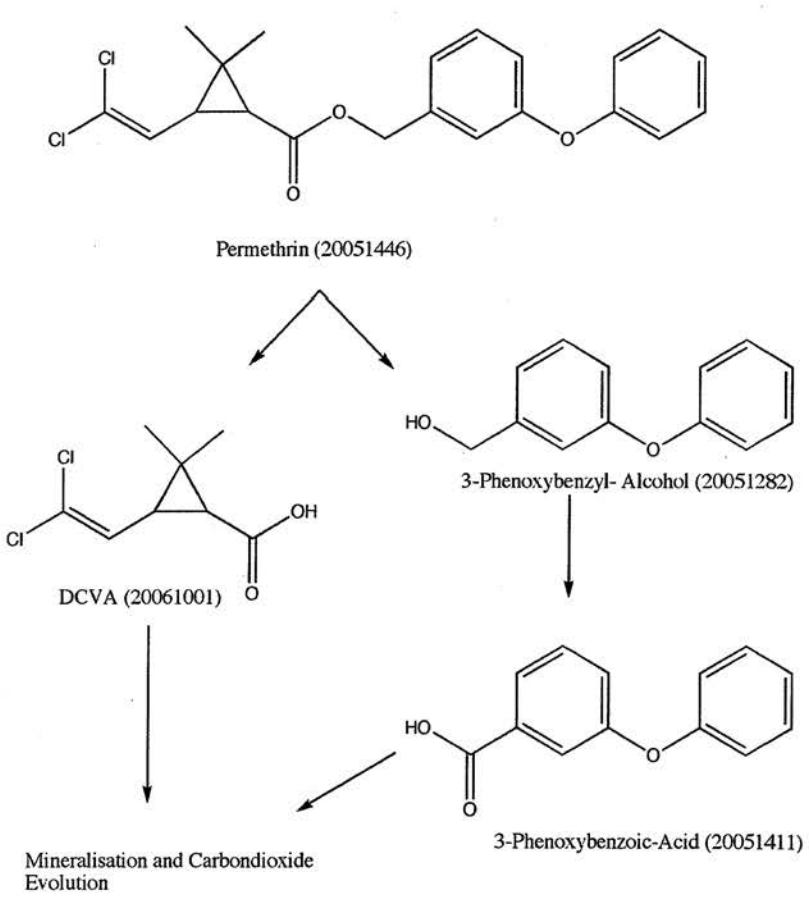
LL = Lower Limit, UL = Upper Limit (95% confidence limits)

Table A7.1.2.2.2-7b: DT_{50} and DT_{90} values of ^{14}C-Vinyl Permethrin in the water phase and the complete creek system

^{14}C-Vinyl Permethrin		R^2	DT_{50} [days]			DT_{50} [days]		
				LL	UL		LL	UL
Creek	Total	0.9388	24.3	18.7	34.8	80.8	62.1	115.7
	Water	0.9626	1.4	1.1	1.9	4.5	3.6	6.2

LL = Lower Limit, UL = Upper Limit

Figure A 7.1.2.2.2-1: Proposed degradation pathway of Permethrin in the water/sediment system



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	~~2~~6~~1~~ REFERENCE
~~26.1~~1.1 **Reference**	Morlock, G. (2006b), Degradation and metabolism of Permethrin (^{14}C-Vinyl label and ^{14}C-Phenoxyphenyl label) in one water/sediment system (pond) under aerobic conditions - laboratory test, GAB Biotechnologie GmbH & GAB Analytik GmbH, Eutinger Str. 24, D-75223 Niefern-Öschelbronn, Germany, unpublished report no.: 20051415/01-CUWS. Dates of experimental work: December 20, 2005 - May 17, 2006
~~26.2~~1.2 **Data protection**	Yes
~~26.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.
~~26.2.2~~1.2.2 Companies with letter of access	Not applicable
~~26.2.3~~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/IA.
	~~2~~7~~2~~ GUIDELINES AND QUALITY ASSURANCE
~~27.1~~2.1 **Guideline study**	Yes, test method was based on OECD guideline 308 and SETAC 1995.
~~27.2~~2.2 **GLP**	Yes
~~27.3~~2.3 **Deviations**	No, a second water/sediment system (creek) was examined and reported separately (report no. 20051415/02-CUWS).
	~~2~~8~~3~~ MATERIALS AND METHODS
~~28.1~~3.1 **Test material**	Radiolabelled test item 1: *cis/trans*-[Phenoxyphenyl-U-^{14}C]Permethrin Radiolabelled test item 2: *cis/trans*-[vinyl-2-^{14}C]Permethrin Non radiolabelled test item: Technical Permethrin
~~28.1.1~~3.1.1 Lot/Batch number	Radiolabelled test item 1: CFQ14540 Batch 1 Radiolabelled test item 2: CFQ14539 Batch 1 Non radiolabelled test item: P-37
~~28.1.2~~3.1.2 Specification	Please refer to points 3.1.3 to 3.1.5

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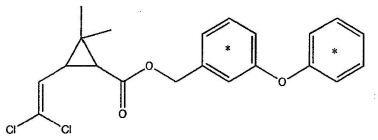
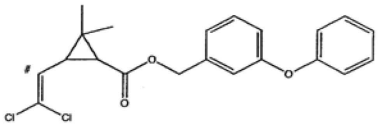
~~28.1.3~~3.1.3 Purity	Radiolabelled test item 1: 99.4% (Radiochemical purity) Radiolabelled test item 2: 99.6% (Radiochemical purity) Non radiolabelled test item: 93.61%
~~28.1.4~~3.1.4 Specific Activity	Radiolabelled test item 1: 59 mCi/mmol Radiolabelled test item 2: 42 mCi/mmol
~~28.1.5~~3.1.5 Radiolabeling	 Radiolabelled Test Item 1  Radiolabelled Test Item 2 #*Denotes position of the ^{14}C-label
~~28.1.6~~3.1.6 Further relevant properties	Cis/Trans ratio: 25.2:74.8 (Test item 1), Cis/Trans ratio: 24.9:75.1 (Test item 2)
~~28.1.7~~3.1.7 Composition of Product	Not applicable
~~28.1.8~~3.1.8 TS inhibitory to microorganisms	No
~~28.1.9~~3.1.9 Specific chemical analysis	None
~~28.2~~3.2 **Reference substance**	Non-radiolabeled Permethrin
Initial concentration of reference substance	Not applicable

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~~28.3~~3.3 Testing procedure	
~~28.3.1~~3.3.1 Test systems	Please refer to Table A7.1.2.2.2-1
~~28.3.2~~3.3.2 Test conditions	Please refer to Table A7.1.2.2.2-2
~~28.3.3~~3.3.3 Duration of test	120 days
~~28.3.4~~3.3.4 Analytical procedures	Sediment: Upon removal of the water phase from the test flask the sediment was mixed and samples transferred to a HDPE flask and deep frozen. To the sediment remaining in the flask, 40 ml acetonitrile, 40 ml water, Spikemix (1 mg of each metabolite in acetonitrile) and 1 ml of acetic acid were added. The flask was then closed with a carbon dioxide trap to determine the amount of carbon dioxide dissolved in the water phase. The assembly was shaken overnight to allow evolution of the carbon dioxide and the extraction of the sediment. The amount of radioactivity in the carbon dioxide trap was determined by LSC (3 x 1 ml). The extract was then separated from the dispersed sediment by centrifugation. The extraction was repeated three times with 60 ml acetonitrile/water and a further two times with 60 ml pure acetone. The radioactivity in each individual extract as well as in the combined acetonitrile/water extracts was determined by LSC. When the measured radioactivity was higher than 2.5% of the applied amount, the extract was further processed. 100 ml of this extract was separated and concentrated using a rotary evaporator. The radioactivity in this concentrated phase was characterised by normal and reverse phase TLC. The fractions were co-chromatographed with the available reference compounds. After the final extraction, the sediment was dried prior to combustion. The total amount of non extractable radioactive residues in sediment after extraction was determined by combustion and LSC (3 x 0.5 g). Water: The radioactivity in the water was determined directly by LSC of an aliquot (3 x 1 g) before it was poured out of the incubation flask. To a further 3 aliquots 100 µl acetic acid was added and the next day the radioactivity remaining was measured to determine the amount of carbon dioxide which was dissolved in the water phase. An aliquot of the water phase was added to the top of an Extrelute column and extracted with 80 ml acetone. The completeness of the extraction process was checked by liquid scintillation counting. The extract was concentrated using a rotary evaporator and characterised by normal and reverse phase TLC. The fractions were co-chromatographed with the available reference compounds.
~~28.3.5~~3.3.5 Sampling	Two flasks from each system were sampled immediately after application and 24 h, 48 h, 7 d, 14 d, 30 d, 62 d, 86 d, 100 d and 120 d after treatment. At each sampling, the height of the sediment and the water layer, the redox potential in water and sediment, the pH in water

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and the oxygen concentration in water were determined. 120 day after treatment the sediment in the control flasks was analysed for microbial activity, pH and redox potential. The water phase were analysed for pH, redox potential, total N and P, concentration of oxygen and total organic carbon.

~~28.3.6~~3.3.6 Intermediates/ degradation products — Identified

~~28.3.7~~3.3.7 Controls — 10 control flasks containing 275 µg of non-radiolabelled test item were used

~~28.3.8~~3.3.8 Statistics — The half-life of Permethrin in both the phenoxyphenyl and vinyl systems was calculated from a plot of percentage applied radioactivity versus time. The DT_{50} values were calculated by non-linear regression assuming first order degradation of Permethrin.

~~29~~4 **RESULTS**

~~29.1~~4.1 **Degradation of test substance**

~~29.1.1~~4.1.1 Distribution of Radiocarbon and Mass Balance — Quantitative recoveries of ^{14}C were obtained throughout the entire testing period and for all samples.

For the phenoxyphenyl labelled water/sediment system, the CO_2 trapped from air increased to 16.1 % AR after 120 days. Radioactivity increased in sediment from 3.9 % AR immediately after the treatment to 71.9 % AR after 7 days. The radioactivity in the water phase decreased from the initial 89.8 % AR to 25.9 % AR after 7 days, followed by an increase to 37.3 % AR at day 30 and again a decrease to 23.6 % AR after 120 days. The extractable residues in sediment increased from 3.8 % AR (0 days) to 70.6 % AR after 7 days and then declined to 9 % AR after 120 days. The unextractable residues in sediment accounted for a maximum of 55.0 % AR after 86 days.

For the vinyl water/sediment system, the CO_2 trapped from air increased to 4.3 % AR after 120 days. Radioactivity in sediment increased from 3.8 % AR immediately after the treatment to 66.1 % AR after 7 days. The radioactivity in the water phase decreased from the initial 97.9 % AR to 24.7 % AR after 7 days, followed by an increase to 65.5 % AR after 120 days. The extractable residues in sediment increased from 3.7 % AR (0 days) to 65.0 % AR after 7 days and then declined to 14.3 % AR after 120 days. The unextractable residues in sediment accounted for a maximum of 19.1 % AR after 86 days.

The average percent recovery of applied radioactivity throughout the study was 97.1% AR for the phenoxyphenyl labelled water/sediment system and 98.0% AR for the vinyl water/sediment system. Please refer

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to Tables A7.1.2.2.2-5a and b for the distribution of the radioactivity between water, sediment and carbon dioxide in the Phenoxyphenyl and Vinyl labeled water/sediment systems.

~~29.1.2~~4.1.2 DT_{50}/DT_{90}

The DT_{50} of Permethrin in the phenoxyphenyl labelled system in the water phase was 2.2 days (DT_{90} 7.3 days) and the DT_{50} in the whole system was 24.6 days (DT_{90} 81.7 days). The DT_{50} of Permethrin in the vinyl labelled system in the water phase was 2.2 days (DT_{90} 7.4 days) and the DT_{50} in the whole system was 14.3 days (DT_{90} 47.6 days). Please refer to Tables A7.1.2.2.2-7a and b for DT_{50} and DT_{90} values of ^{14}C-Phenoxyphenyl and ^{14}C-Vinyl Permethrin in the water phase and complete pond system.

~~29.1.3~~4.1.3 Intermediates/ degradation products

The metabolites formed in the sediment phase and the water phase in the phenoxyphenyl labelled system were, 3-phenoxybenzyl-alcohol (38.2 % AR after 2 days in water, 2.6 % AR after 30 days in sediment) and 3-phenoxybenzoic acid (28.8 % AR after 30 days in water, 12.5 % AR after 100 days in sediment). The sole metabolite formed in the sediment and water phases in the vinyl labelled system was 3-(2,2-dichlorovinyl)2,2-dimethylcyclopropane carboxylic acid (DCVA) (62.5 % AR after 100 days in water, 17 % AR after 86 days in sediment). Please refer to Tables A7.1.2.2.2-6a and b for the sum of Permethrin and its metabolites in the total water/sediment system/Phenoxyphenyl and Vinyl labels. Please refer to Figure A7.1.2.2.2-1 for the proposed degradation pathway of Permethrin in the water/sediment system.

~~29.1.4~~4.1.4 Bound Residues

In the phenoxyphenyl labelled system the bound residues increased to a maximum of 55.0 % applied radioactivity (AR) after 86 days and decreased to 43.4 % AR after 120 days. In the vinyl labelled system the bound residues increased to a maximum of 19.1 % AR after 86 days and decreased to 15.0 % AR after 120 days. Please refer to Table A7.1.2.2.2-5a and b.

~~29.1.5~~4.1.5 Mineralization to CO_2

In the phenoxyphenyl system total mineralization to carbon dioxide was 30.1 % AR after 120 days taking into account the amount of carbon dioxide in the gas phase and dissolved in water and sediment. In the vinyl system the mineralization to carbon dioxide was 8.4 % AR after 120 days taking into account the amount of carbon dioxide in the gas phase and dissolved in water and sediment. Please refer to Table A7.1.2.2.2-5a and b.

~~30~~5 APPLICANT'S SUMMARY AND CONCLUSION

~~30.1~~5.1 Materials and methods

The degradation time and degradation products of Permethrin in one water/sediment system (pond) with two radiolabels (^{14}C-vinyl and ^{14}C-phenoxyphenyl) under aerobic conditions in the dark was investigated at 20 ± 2°C over a 120 day study period. The applied rate of Permethrin was 1375 g/ha.

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This study was conducted according to OECD guideline 308 and SETAC 1995 and is described under point 3.

~~30.2~~5.2 Results and discussion

In the phenoxyphenyl labelled system, $^{14}CO_2$ accounted for 30.1 % of the AR after 120 days. It was trapped from the gas space (16.1 % AR), found dissolved in water (13.4 % AR) and sediment (0.7 % AR). The non volatile radioactivity was found to decrease with time in the water phase (24.1 % AR in water after 7 days incubation) and increased to a maximum of 33.5 % AR after 30 days incubation. The non volatile radioactivity in the sediment increased to a maximum of 70.6 % AR after 7 days and decreased to 9.0 % after 120 days. The bound residues increased to a maximum of 55.0 % AR after 86 days and decreased to 43.4 % AR after 120 days. The majority of the radioactivity in the water phase was Permethrin which declined to zero after 62 days, 3-phenoxybenzyl-alcohol (maximum 38.2 % AR after 2 days, 0 % AR after 30 days) and 3-phenoxybenzoic acid (maximum 28.8 % AR after 30 days, 10.3 % after 120 days). In the sediment phase Permethrin increased from 3.8 % AR at study initiation to 67.0 % AR after 7 days, and then declined to 0 % AR after 100 days. 3-phenoxybenzyl-alcohol appeared at 2.6 % after 30 days and 3-Phenoxybenzoic acid at a maximum of 12.5 % AR after 100 days. The sole metabolites observed in the sediment phase and the water phase in the phenoxyphenyl labelled system were, 3-phenoxybenzyl-alcohol (38.2 % AR after 2 days in water, 2.6 % AR after 30 days in sediment) and 3-phenoxybenzoic acid (28.8 % AR after 30 days in water, 12.5 % AR after 100 days in sediment). No other metabolites >1% were detected. The decline of Permethrin was fast with a 1st order DT_{50} in the water phase of 2.2 days (DT_{90} 7.3 days) and a DT_{50} in the total system of 24.6 days (DT_{90} 81.7 days). The mean recovery of this test system was 97.1 % AR and no volatile organics were detected.

In the vinyl labelled system, $^{14}CO_2$ accounted for 8.4 % of AR after 120 days. It was trapped from the gas space (4.3 % AR), found dissolved in water (4.0 % AR) and sediment (0.1 % AR). The non volatile radioactivity was found to decrease with time in the water phase (24.3 % AR in water after 7 days incubation) and then increased to a maximum of 62.5 % AR after 100 days incubation. In the sediment the non volatile radioactivity increased to a maximum of 65.0 % AR (extractable) after 7 days and decreased to 14.3 % after 120 days incubation. The bound residues increased to a maximum of 19.1 % AR after 86 days and decreased to 15.0 % after 120 days. The majority of the radioactivity in the water phase was Permethrin which declined to zero after 30 days and 3-(2,2-dichlorovinyl)2,2-dimethylcyclopropane carboxylic acid (DCVA) which increased to 62.5 % AR after 100 days. In the sediment phase Permethrin increased from 3.6 % AR at study initiation to 62.5 % AR after 7 days, and then declined to 0 % AR after 86 days. DCVA increased from 0.1 % AR at study initiation to 17 % AR after 86 days, and then declined to 14.4 % AR after 120 days. The sole metabolite observed in the sediment phase and water phase was DCVA (62.5 % AR after 100 days in water, 17 % AR after 86 days in sediment). No other metabolites >1% were detected. The decline of Permethrin in the vinyl labelled system was fast with a 1st order DT_{50} in

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	the water phase of 2.2 days (DT_{90} 7.4 days) and a DT_{50} in the total system of 14.3 days (DT_{90} 47.6 days). The mean recovery of this test system was 97.9 % AR and no volatile organics were detected.
~~30.3~~5.3 Conclusion	Permethrin degrades at a rapid rate when applied to an aerobic aquatic environment. Degradation of Permethrin involved the formation of three main metabolites; 3-Phenoxybenzyl-Alcohol, DCVA and 3-Phenoxybenzoic-Acid and was accompanied by mineralization and carbon dioxide evolution. A proposed metabolic pathway is presented.
~~30.3.1~~5.3.1 Reliability	1
~~30.3.2~~5.3.2 Deficiencies	None

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Evaluation by Competent Authorities	
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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	29 May 2009
Materials and Methods	Applicant's version is acceptable with the following clarification. Sub-heading 3.3.2 (Table A7.1.2.2.2-2) Test concentration of 275 µg per flask (containing ~600 mL water) is equivalent to a field application rate of 1375 g/ha and a depth of water in the field of 30 cm.
Results and discussion	Applicant's version is acceptable with the following clarifications. Sub-heading 4.1.2 Whole-system DT_{50} values represent degradation, whereas DT_{50} values for the water phase represent dissipation. The reported DT_{50} values were obtained at 20 ± 2 °C. Extrapolation with the TGD temperature correction equation ($DT_{50}(12\ °C) = DT_{50}(T) \times e^{0.08(T-12)}$) gives the following values – phenoxyphenyl label: water-phase DT_{50} = 4.2 days, whole-system DT_{50} = 46.7 days; vinyl label: water-phase DT_{50} = 4.2 days, whole-system DT_{50} = 27.1 days. Sub-heading 4.1.4 According to Table A7.1.2.2.2-5b, the level of bound residues at day 120 in the system treated with vinyl-radiolabelled substance was 14.1% AR (not 15.0 %AR).
Conclusion	Adopt applicant's version.
Reliability	2

Section A7.1.2.2/2 Annex Point XII 2.1	**Biodegradation in freshwater** **IIIA 7.1.2.2.2 Water/sediment degradation**
Acceptability	Acceptable
Remarks	This study on a pond-derived water-sediment system and another study on a creek-derived water-sediment system (Morlock, G., 2006a) have both been presented under this data point to meet the requirement of the guidance followed for testing on two systems. Consequently, both studies are key studies for this data point. It is noted that OECD Guideline 308 recommends that one of the sediments used should have a high organic carbon content (2.5-7.5%) and that the other should have a low organic carbon content (0.5-2.5%), with the difference in the organic carbon contents normally being at least 2%. Both of the sediments used for this data point were of low organic carbon content (1.76% and 0.44%). The RMS evaluator has assigned both water-sediment studies a reliability rating of 2, since neither used sediment with a high organic carbon content.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remark	

Table A7.1.2.2.2-1: Description of test system

Criteria	Details
Glassware and equipment	Closed gas flow system: flasks used were 1000ml all-glass metabolism flasks (inner diameter: 10.1 cm; surface: 80 cm^2) Combustion of soil samples was performed using an oxidiser OX-500 with oxygen support regulator, Zinser, Germany. Radioassays of solutions were performed on a liquid scintillation counter 1409, Wallac, Finland.
Measurement of Volatiles	To determine evolved organic volatiles, glass tubes filled with Tenax absorbent were used as volatile traps (350 mg). They were analysed for radioactivity at each sampling. The radioactive carbon dioxide evolved in the test system was trapped by a sodium hydroxide solution in a separate reservoir, which was connected to the flask (30 ml). Traps for radioactive carbon dioxide were analysed at intervals of about 4 weeks.

Table A7.1.2.2.2-2: Description of test conditions

Criteria	Details
Purity of water	Water was sampled from a pond, known not to be influenced by effluents or human activity. The data of the exact location, date of sampling and conditions of water and sediment at sampling time are recorded and archived in the testing facility. The sampling was performed at "Ernst Maurer See" in D-75428 Illingen, Germany. Water was sampled from the top 5 to 10 cm of the surface of the water. The sampling site was located 1 to 2 m from firm land. The water was sieved through a 0.2 mm sieve and stored at temperatures between 15°C and 20°C under aeration. Hardness, ammonia, nitrite, nitrate, temperature, oxygen and redox potential were determined immediately before sampling. Please refer to Table A7.1.2.2.2-3 and A7.1.2.2.2-4 for characterisation of the water used.
Soil	Sediment was sampled from a pond, known not to be influenced by effluents or human activity. The data of the exact location, date of sampling and conditions of water and sediment at sampling time are recorded and archived in the testing facility. The sampling was performed at "Ernst Maurer See" in D-75428 Illingen, Germany. Sediment was sampled from the top 5 to 10 cm of the surface of the sediment. The sampling site was located 1 to 2 m from firm land. The sediment was sieved through a 2 mm sieve and stored at temperatures between 15°C and 20°C under aeration. Hardness, ammonia, nitrite, nitrate, temperature, oxygen and redox potential were determined immediately before sampling. Please refer to Table A7.1.2.2.2-3 and A7.1.2.2.2-4 for characterisation of the sediment used.
Preparation of flasks	After storage of water and sediment for a period of two days approximately 250 g of wet sediment was transferred into metabolism flasks to establish a layer of 2.5 cm. The flasks were then filled to 7.5 cm (approximately 500 ml) with water. The flasks were then incubated at 20°C ± 2°C in the dark under aerobic conditions until an equilibrium based on measured variables was reached. During this acclimatisation period each system was aerated by a slight orbital movement of the test vessel on an orbital shaker which did not disturb the surface of the sediments. Any organic volatiles were trapped by glass tubes filled with Tenax and any carbon dioxide generated was trapped via an attached sodium hydroxide reservoir. The oxygen content inside the test vessels was determined by a pressure transducer system on two biomass flasks. If a reduction of more than 10 % of the initial oxygen content occurred the system was aerated.

Preparation of test chemical solution and application to soil and water	The test items were applied in 500 µl of ethanol using a pipette to the surface. The concentration of the solvent did not exceed 0.1 % of the amount of water present.
Test concentrations (mg a.s. /L)	22 flasks contained 275µg of ^{14}C-Vinyl labelled test item 2. Radioactivity of 10 µCi was applied to each flask. Assuming a specific activity of 42 mCi/mmol, this corresponded to 93.5 µg of test item. Therefore the application rate was 93.5 µg of labelled test item and 181.5 µg of non-labelled test item per vessel. 22 flasks contained 275 µg of ^{14}C-Phenoxyphenyl labelled test item 1. Radioactivity of 10 µCi was applied to each flask. Assuming a specific activity of 59 mCi/mmol, this corresponded to 66.7 µg of test item. Therefore the application rate was 66.7 µg of labelled test item and 208.3 µg of non-labelled test item per vessel.
Test system	Incubated in the dark under aerobic conditions
Temperature (°C)	20 ± 2°C
Replicates	22
Sterilisation	Not documented

Table A7.1.2.2.2-3: Characterization of water and sediment at the time of sampling

		Pond (Illingen)
Water	Total P [mg/l]:	<0.1
	Ca/Mg/Na/K [mg/l]	89/92/22/4.8
	Total N [mg/l]:	<1
	Total organic carbon [mg/l]:	6.65
	Temperature [°C]*	8.0
	pH*	7.77
	Oxygen [mg/l]*	8.34
	Redox potential [mV]*	+232
	Water hardness (total) [°dH]*	36 (643 mg $CaCO_3$/L)
	Water hardness (carbonate) [°dH]*	23 (411 mg $CaCO_3$/L)
Sediment	Total P [mg/kg]	466
	Total N [mg/kg]	1027
	pH*	7.25
	Total Organic carbon [%]	1.76
	Sand/silt/clay [%]	32.8/59.7/7.5
	Cation exchange capacity [mval/100g]	41.7
	Redox potential [mV]*	-107

* determined at sampling site; all other values are taken after sieving of sediment and water

Table A7.1.2.2.2-4: Characterization of water and sediment at the beginning of the study and after 120 days

		Pond (Illingen)
Water	Total P [mg/l]:	
	Beginning of the study	<0.1
	After 120 days	<0.1
	Total N [mg/l]:	
	Beginning of the study	<1
	After 120 days	<1
	Organic carbon [mg/l]:	
	Beginning of the study	6.65
	After 120 days	4.03
Sediment	Total P [mg/kg]	466
	Total N [mg/kg]	1027
	pH	7.6
	Organic carbon [%]	1.76
	Particle size distribution Sand/silt/clay [%]	32.8/59.7/7.5
	Sediment Classification	Sandy silt
	Cation exchange capacity [mval/100g]	41.7
	Microbial biomass [µg C/g dry matter]:	
	Beginning of the study	1420
	After 120 days	779

Table A7.1.2.2.2-5a: Distribution of the radioactivity between water, sediment and carbon dioxide, in the water/sediment system with the Phenoxyphenyl label (% of the applied radioactivity)

Time [days]	Total CO_2 [%AR]	CO_2 trapped directly [%AR]	Water Phase			Sediment				Sum [a] Recovery [%AR]
			Total after sampling [%AR]	SNV (soluble but not volatile after acid treatment) [%AR]	CO_2 evolved after acid treatment [%AR]	Extract [%AR]	CO_2 from sediment [%AR]	Bound Residues [%AR]	Total in sediment [%AR]	
0	0.0	0.0	89.8	89.8	0.0	3.8 [b]	0.0	0.1 [b]	3.9	93.7
1	0.0	0.0	87.6	87.6	0.0	12.4 [b]	0.0	0.2 [b]	12.6	100.2
2	1.4	0.0	98.8	87.6	11.3	14.3 [b]	0.0	0.3 [b]	14.6	103.6
7	1.9	0.0	25.9	24.1	1.9	70.6 [b]	0.0	1.3 [b]	71.9	97.9
14	1.1	0.0	27.3	26.9	1.1	57.2	0.0	1.8	59.0	87.0
30	4.3	0.4	37.3	33.5	3.9	48.0	0.1	17.9	66.0	103.7
62	19.1	5.7	31.0	18.2	12.8	16.1	0.6	40.7	57.4	94.1
86	26.4	11.0	22.0	7.5	14.6	10.0	0.9	55.0	65.9	98.9
100	27.3	12.5	28.3	14.2	14.1	12.5	0.8	44.6	57.9	98.6
120	30.1	16.1	23.6	10.3	13.4	9.0	0.7	43.4	53.1	92.8

[a] Values have been calculated from the raw data and therefore there may be slight differences between these values and calculations performed using the rounded values. [b] Values are only from one vessel due to inhomogeneity of the sediment, therefore for one of the duplicate vessels the complete sediment was extracted and not only an aliquot.

Table A7.1.2.2.2-5b: Distribution of the radioactivity between water, sediment and carbon dioxide, in the water/sediment system with the Vinyl label (% of the applied radioactivity)

Time [days]	Total CO_2 [%AR]	CO_2 trapped directly [%AR]	Water Phase			Sediment				Sum [a] Recovery [%AR]
			Total after sampling [%AR]	SNV (soluble but not volatile after acid treatment) [%AR]	CO_2 evolved after acid treatment [%AR]	Extract [%AR]	CO_2 from sediment [%AR]	Bound Residues [%AR]	Total in sediment [%AR]	
0	0.0	0.0	97.9	97.9	0.0	3.7 [b]	0.0	0.1	3.8	101.7
1	0.0	0.0	92.3	92.3	0.0	9.8 [b]	0.0	0.1	9.9	102.2
2	2.0	0.0	90.7	90.7	2.0	10.5 [b]	0.0	0.2	10.7	103.4
7	1.4	0.0	24.7	24.3	1.4	65.0 [b]	0.0	1.1	66.1	91.8
14	4.0	0.0	36.6	32.6	4.0	53.6 [b]	0.1	1.1	54.7	91.3
30	3.7	0.3	53.9	50.6	3.4	25.7 [b]	0.1	11.0	36.8	91.0
62	4.1	1.4	64.7	62.1	2.6	20.9	0.1	11.0	32.0	98.1
86	6.9	3.5	60.2	56.9	3.3	16.9	0.2	19.1	36.3	99.9
100	4.6	2.7	64.3	62.5	1.8	16.3	0.2	18.0	34.5	101.4
120	8.4	4.3	65.5	61.5	4.0	14.3	0.1	14.1	29.5	98.4

[a] Values have been calculated from the raw data and therefore there may be slight differences between these values and calculations performed using the rounded values. [b] Values are only from one vessel due to inhomogeneity of the sediment, therefore for one of the duplicate vessels the complete sediment was extracted and not only an aliquot.

Table A7.1.2.2.2-6a: Sum of Permethrin and its metabolites in the total water/sediment system/Phenoxyphenyl label (% of the applied radioactivity)

Time [days]	% dissipation in total system			Sum [%]
	Permethrin	Metabolite 1	Metabolite 2	
0	93.6	0.0	0.0	93.6
1	71.8	27.6	0.7	100.1
2	63.3	38.5	0.2	102.0
7	75.0	14.0	5.1	94.1
14	60.0	1.4	22.9	84.3
30	45.0	2.6	33.8	81.4
62	6.9	0.0	27.4	34.3
86	0.6	0.0	16.9	17.5
100	0.0	0.0	26.7	26.7
120	0.0	0.0	19.3	19.3

Metabolite 1 = 3-Phenoxybenzyl-Alcohol, Metabolite 2 = 3-Phenoxybenzoic-Acid

Table A7.1.2.2.2-6b: Sum of Permethrin and its metabolites in the total water/sediment system/Vinyl label (% of the applied radioactivity)

Time [days]	% dissipation in total system		Sum [%]
	Permethrin	Metabolite 1	
0	98.0	3.6	101.6
1	71.1	31.1	102.2
2	71.4	29.9	101.3
7	62.5	26.9	89.4
14	56.6	29.6	86.2
30	10.1	66.2	76.3
62	4.2	78.8	83.0
86	0.0	73.9	73.9
100	0.0	78.8	78.8
120	0.0	75.9	75.9

Metabolite 1 = DCVA

Table A7.1.2.2.2-7a: DT_{50} and DT_{90} values of ^{14}C-Phenoxypenyl Permethrin in the water phase and the complete pond system

^{14}C-Phenoxyphenyl	R^2	DT_{50} [days]	DT_{90} [days]

Permethrin				LL	UL		LL	UL
Pond	Total	0.9236	24.6	18.4	36.9	81.7	61.2	122.5
	Water	0.9717	2.2	1.8	2.9	7.3	5.9	9.7

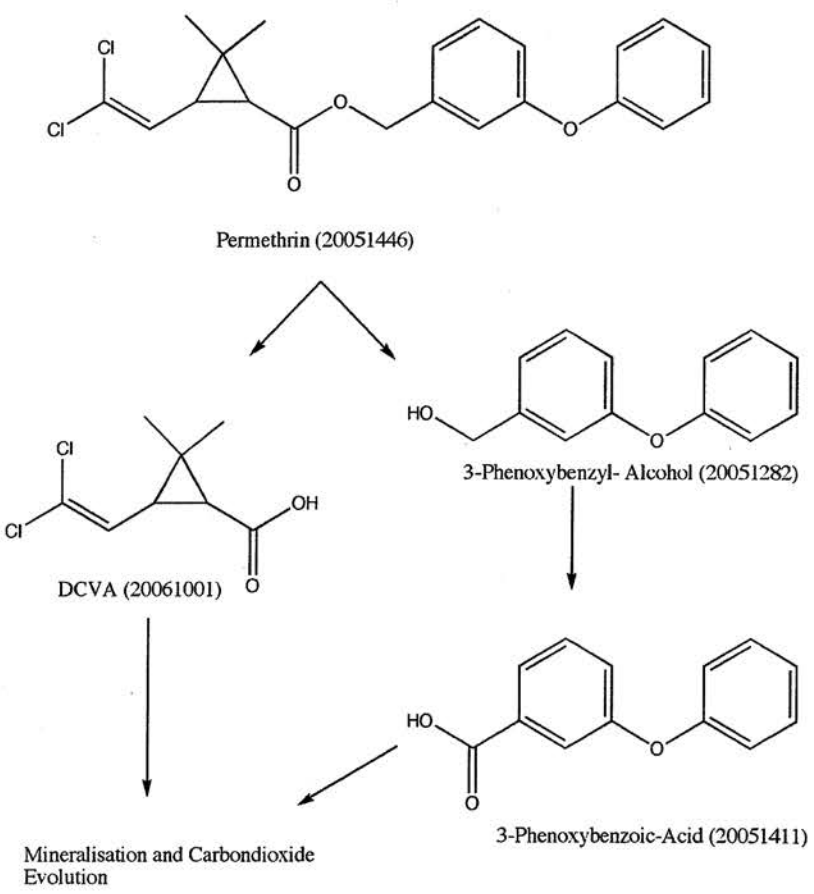
LL = Lower Limit, UL = Upper Limit (95% confidence limits)

Table A7.1.2.2.2-7b: DT_{50} and DT_{90} values of ^{14}C-Vinyl Permethrin in the water phase and the complete pond system

^{14}C-Vinyl Permethrin		R^2	DT_{50} [days]			DT_{50} [days]		
				LL	UL		LL	UL
Pond	Total	0.9444	14.3	10.9	20.9	47.6	36.1	69.6
	Water	0.9637	2.2	1.7	3.1	7.4	5.8	10.2

LL = Lower Limit, UL = Upper Limit

Figure A7.1.2.2.2-1: Proposed degradation pathway of Permethrin in the water/sediment system



Section A7.1.2.2.2/01 Water/sediment degradation study

Annex Point IIIA-XII.2.1

		6 REFERENCE
6.1	**Reference**	Stangelj, A. (2011): Calculations of environmental fate endpoints in water-sediment systems for Permethrin and metabolites according to recommendations of the FOCUS working group on degradation kinetics GAB Consulting GmbH, Lamstedt, Germany unpublished report number: 158250-A3-0701020202-01
6.2	**Data protection**	Yes
6.2.1	Data owner	Tagros Chemicals India Ltd.
6.2.2	Companies with letter of access	Not applicable.
6.2.3	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/IA of Directive 98/8/EC.
		7 GUIDELINES AND QUALITY ASSURANCE
7.1	**Guideline study**	Modelling and persistence endpoints for Permethrin and its main metabolites in water-sediment systems investigated in two studies were re-calculated according to the FOCUS kinetics guidance (FOCUS, 2006)[1].
7.2	**GLP**	No
7.3	**Deviations**	None
		8 MATERIALS AND METHODS
8.1	**Test material**	Not relevant, the study is a model calculation.
8.1.1	Lot/Batch number	Not relevant, the study is a model calculation.
8.1.2	Specification	Not relevant, the study is a model calculation.
8.1.3	Purity	Not relevant, the study is a model calculation.
8.1.4	Further relevant properties	Not relevant, the study is a model calculation.
8.1.5	Composition of Product	Not relevant, the study is a model calculation.
8.1.6	TS inhibitory to microorganisms	Not relevant, the study is a model calculation.
8.1.7	Specific chemical analysis	Not relevant, the study is a model calculation.
8.2	**Reference**	Not relevant, the study is a model calculation.

[1] FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

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