Section A7.1.1.2.2 Annex Point IIA7.6.1.2	**Biodegradability (ready/inherent)** **Inherent biodegradability**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	• Permethrin has a water solubility of <5 µg l^{-1}. (White D.F, Mullee, D.M; 2004). This would make the undertaking of any biodegradation test technically very difficult, since it would need to be performed at environmentally realistic concentrations.	X
	• A ready biodegradation test on permethrin has shown permethrin to be 'not readily biodegradable' when tested according to existing guidelines.	
	• ^{14}C soil and sediment studies indicate that under environmentally realistic conditions, permethrin is degraded to PBAlc and DCVA. Aerobic degradation is much more rapid than anaerobic.	
	• A ^{14}C STP fate study exists (Caplan, J and Isbister, J; 1979) which indicates that at a level of 100 mg l^{-1} in STP there are no adverse effects on micro-organisms, and that the majority of the applied radioactivity is adsorbed to the activated sludge solids. The test is not to any guidelines and the focus was on the impact on organisms, therefore it is not appropriate to Fraunhofer format. Furthermore, at levels of 100 mg l^{-1}, the bioavailability of permethrin would be difficult to assess.	X X
	• Inherent biodegradability data are only required should releases be direct to STP (Guidance on Data Requirements for Active Substances). More appropriate compartments for releases of permethrin in use as a wood preservative are soil and water.	
	• The EUSES risk assessment in support of the submission indicated that in the default scenario, 2.5 g permethrin per day would enter the STP. This hypothetical emission would be controlled under existing national legislation and assessed for impact under existing legislation, and should inherent biodegradation data be required, it would be highlighted under this risk assessment.	
	Therefore, a justification for non-submission is suggested on the grounds that; i) There is no significant direct emission to STP, and all emissions are already controlled under existing legislation ii) Should there be releases at environmentally relevant concentrations, existing data suggests that all the released permethrin would adsorb strongly to the sludge where it would be susceptible to aerobic degradation.	
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	*7 April 2005 (updated September 2009)*
Evaluation of applicant's justification	The RMS evaluation of the applicants justification agrees that permethrin would be a difficult substance to undertake biodegradation tests owing to its low solubility in water of <5 μg l^{-1}; however, whilst technically difficult this does not make the test impossible and, hence, does not preclude assessment of inherent biodegradation (such as the Modified MITI Test (II)). At issue is the preference for simulation tests instead of new tests on inherent biodegradability if a compound is found to be "not readily biodegradable" following testing of ready biodegradability according to OECD guidelines 301 (A-F) as indicated by the Guidance on Data Requirements for Active Substances and Biocidal Products (Version 4.3.2, October 2000). Such a decision for simulation tests on the active substance is to be based upon the potential risk to specific environmental compartments during the life cycle and use of the biocidal product, which the notifier has undertaken. The OECD Emission Scenario Document for Wood Preservatives (Parts 1-4) indicates that the principal risk of environmental exposure is emissions to soil and surface water from industrial preventative processes (e.g. spraying), treated wood in service, and professional and amateur *in-situ* treatments (both curative and preventive). The notifier has provided water/sediment studies on permethrin under both aerobic and anaerobic conditions, and has provided soil metabolism, degradation, and accumulation studies for permethrin. These provide detailed degradation information for the kinetic behaviour of permethrin in these environmental compartments. The risk of STP contamination from permethrin appears much more limited, but may occur following industrial preventative processes, with wastewater draining to STPs via a facility drain. Not all industrial processing facilities are connected via drains to STPs and, hence, surface water would also be at risk of exposure to permethrin under this emission scenario. The notifier has also stated that under EUSES risk assessment up to 2.5 g of permethrin per day would enter an STP, but has supplied no STP simulation test. The RMS does not agree with the notifier that there are no direct releases of permethrin to STPs. However, the RMS considers that the risk to STP exposure of permethrin to STPs is slight, especially for some MS where official licenses are granted on the basis of on-site sewage treatment sites or contained application facilities. Furthermore, the submitted microorganism inhibition study (Caplan and Isbister, 1979) does cover the effect of permethrin to microorganisms in sewage sludge. Therefore, it is considered acceptable to justify the non-inclusion of an inherent biodegradability study, based on the microorganism inhibition study and limited STP exposure. It should be noted that evidence of inherent biodegradability for permethrin (biodegradation above 20% in a validly conducted test) is available in a dossier supplied by another applicant for this active substance/Product Type combination.
Conclusion	The applicant's justification is acceptable owing to the reasons outlined above. The applicant is not required to provide information on this data point for the purpose of the EU review programme.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.2.3 **Annex Point IIA7.6.1.1** **Annex Point IIA7.6.1.2**	**Biodegradability (ready/inherent)** **Biodegradation in Seawater.**
	Justification for non-submission of data
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [✓]**
Limited exposure [ ]	**Other justification [ ]**
Detailed justification:	**The field of use of permethrin (Product type 8) is in the biological Hazard Classes 1, 2, and 3 (also referred to as Use Classes) see Document I.1, Section 5.1. As permethrin has been not classified for use as a wood preservative in Hazard Class 5 (saltwater) defined in the standard EN 335-1 (CEN, 1992), then a biodegradation study conducted in seawater and covering brackish water is not required for permethrin.**
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	September 2009
Evaluation of applicant's justification	The RMS considers that a study is not required based on the following justification. Uses for wood in Hazard Class 5 (salt water) are not being supported. Therefore a study on biodegradation in seawater is not required.
Conclusion	Study is 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	

Section A7.1.2.1. Annex Point IIIA.XII.2.1	Biological sewage treatment (only headline)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [X]	
Detailed justification:	Headline only – no data requirement	
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	*27 April 2005*
Evaluation of applicant's justification	Not applicable.
Conclusion	Not applicable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.1 Annex Point IIIA.XII.2.1	Biological sewage treatment - Aerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
Detailed justification:	Permethrin has a water solubility of <5 µg l^{-1}. (White D.F, Mullee, D.M; 2004). This would make the undertaking of any biodegradation test technically very difficult, since it would need to be performed at environmentally realistic concentrations. A ready biodegradation test on permethrin has shown permethrin to be 'not readily biodegradable' when tested according to existing guidelines. The Technical Guidance on Data Requirements for Active Substances provides a strategy for testing degradation in relevant compartments. On the flow-chart, the selection for further testing is dependant on direct release to compartment. Releases to Biological sewage treatment Plants are negligible, therefore further testing is inappropriate. More appropriate compartments for releases of permethrin in use as a wood preservative are soil and sediment/water. Therefore, a justification for non-submission is suggested on the grounds that; iii) There is no significant direct emission to STP, and all emissions are already controlled under existing legislation iv) Should there be releases at environmentally relevant concentrations, existing data suggests that all the released permethrin would adsorb strongly to the sludge where it would be susceptible to aerobic degradation.	X X
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	September 2009
Evaluation of applicant's justification	Applicant's justification is not acceptable. The ESD for Product Type 8 identifies direct release to an STP as a possible exposure route via losses during industrial application or losses from a treated noise barrier in service. However, the applicant is not required to provide information on this data point for the purpose of the EU review programme, since evidence of inherent biodegradability for permethrin (biodegradation above 20% in a validly conducted test) is available in a dossier supplied by another applicant for this active substance/Product Type combination. The RMS evaluator considers that reliable evidence of inherent biodegradability obviates the need for an aerobic sewage treatment simulation test in this case. If required, information on the behaviour of permethrin in an STP could perhaps be extrapolated or inferred from the results of the activated sludge metabolism study (Caplan, J.A. and Isbister, J.; 1979) presented in sections A.7.1.1.2.1 and A.7.1.1.2.2.
Conclusion	Applicant's justification is not acceptable. However, the applicant is not required to provide information on this data point for the purpose of the EU review programme, since the RMS evaluator considers that reliable evidence of inherent biodegradability (available in a dossier supplied by another applicant) obviates the need for an aerobic sewage treatment simulation test in this case.
Remarks	This interpretation is based on the guidance given in the note on evaluation of multiple dossiers that was presented at the 33rd Competent Authorities meeting in May 2009 (CA-May09-Doc.8.3).
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.2 Annex Point IIIA.XII.2.1	Biological sewage treatment - Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification [X]**	
Detailed justification:	Permethrin has a water solubility of <5 µg l^{-1}. (White D.F, Mullee, D.M; 2004). This would make the undertaking of any biodegradation test technically very difficult, since it would need to be performed at environmentally realistic concentrations. X A ready biodegradation test on permethrin has shown permethrin to be 'not readily biodegradable' when tested according to existing guidelines. X The Technical Guidance on Data Requirements for Active Substances provides a strategy for testing degradation in relevant compartments. On the flow-chart, the selection for further testing is dependant on direct release to compartment. Releases to Biological sewage treatment Plants are negligible, therefore further testing is inappropriate. More appropriate compartments for releases of permethrin in use as a wood preservative are soil and sediment/water. Therefore, a justification for non-submission is suggested on the grounds that; v) There is no significant direct emission to STP, and all emissions are already controlled under existing legislation vi) Should there be releases at environmentally relevant concentrations, existing data suggests that all the released permethrin would adsorb strongly to the sludge where it would be susceptible to aerobic degradation.	
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	*8 April 2005*
Evaluation of applicant's justification	The applicant's justification does not cover the likelihood of permethrin exposure to anaerobic conditions in the environment, and as a result the notifier's three principal points do not adequately formulate a valid justification. If anaerobic exposure is to be expected a test in accordance with ISO method 11734 would be required, and elimination of a direct route to STPs cannot be justified as above. However, permethrin and its associated biocidal products are unlikely to be present under anaerobic conditions following use as a wood preservative (Product Type 8) with exposure to soil, surface water, groundwater, and air likely to be under aerobic conditions. Furthermore, direct exposure to surface water of permethrin under anaerobic conditions is assessed by the anaerobic water/sediment study (Robinson and Ryan, 1994). Direct exposure to anaerobic conditions, such as may be the case with veterinary hygiene products and biocidal pest control products used in animal housing where release into manure storage facilities is possible, is unlikely to occur. With regard to STPs the predominant degradation of active sludge is through aerobic biodegradation within the aeration tank (as in the case with the model SimpleTreat embedded in EUSES) and, hence, anaerobic biodegradation parameters are not relevant to the environmental risk assessment concerning STPs.
Conclusion	The applicant's justification is not acceptable. However, it is considered that an anaerobic biodegradation test is not required for the environmental assessment of permethrin and that a justification based on the unlikely direct exposure of permethrin to anaerobic conditions in the environment (as stated above) is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.2.1 Annex Point IIIA.XII.2.1	**Biodegradation in Freshwater; Aerobic Aquatic Degradation Study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	• Permethrin has a water solubility of <5 µg l^{-1}. (White D.F, Mullee, D.M; 2004). • Permethrin has an estimated Koc of 25,500 to 404,400. • Aquatic dissipation studies (Hatfield, M.W., 1996) indicates that on release to the aquatic compartment, half-lives in water were between 1.3 and 3.1 days, with rapid adsorption to the sediment compartment. Therefore, a justification for non-submission is suggested on the grounds that; • Should there be releases to the aquatic compartment, a more realistic and appropriate study of degradation should include the sediment compartment.	
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	*12 April 2005*
Evaluation of applicant's justification	Permethrin under aerobic conditions in the water/sediment study (Robinson and Ryan, 1996a) was observed to partition rapidly to the sediment phase up to ~97.3% and ~97.7% for the acid- and alcohol-labelled permethrin, respectively, on Day 0. As a result permethrin remains in the water column for less than a day, owing to the rapid adsorption to sediment. Data from a field aquatic dissipation study (Hatfield, 1996) on two small pond systems at two trial locations in the USA supported the water/sediment study indicated DT_{50} values of permethrin in water ranged from 1.3 to 3.1 days, with similar rapid adsorption of permethrin to the sediment phase. Permethrin has been observed to adsorb rapidly and strongly to five different US soil types in an adsorption/desorption study (Davis, 1991), with K_{foc} values ranging from 28200 to 194000. This is further supported by calculations undertaken using EPIWIN which estimated a permethrin K_{foc} value of 1.78×10^5.
Conclusion	The applicant's justification is acceptable. Should there be releases of permethrin to the aquatic compartment of the environment the active substance is likely to partition quickly from the water phase to the sediment phase as a result of rapid and strong adsorption to the particulate surface.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.2.2 Biodegradation in fresh water: Water/Sediment: Degradation study

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Robinson, R.A & Ryan, J.E.; 1996; Aerobic aquatic metabolism of [14C]Permethrin. XenoBiotic Laboratories, Inc., Plainsboro, NJ. report Ref. Study No. XBL94092, Report Ref. RPT00220.;GLP; Unpublished.	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2	**Companies with a 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. US EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3	X
2.2	**GLP**	Yes.	
2.3	**Deviations**	No.	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	Two separate radiolabelled [^{14}C]permethrin test materials were used in the study, labelled in the cyclopropane position (acid[^{14}C]permethrin) and the benzyl ring (alc[^{14}C]permethrin), as shown in Figure 1. The structures of reference materials used for co-chromatography are shown in Figure 2.	
3.1.1	**Lot/Batch number**	acid[^{14}C]permethrin: Amersham Sample Identification code CFQ8068 alc[^{14}C]permethrin: Sigma Sample Identification code 054H9214	
3.1.2	**Specification**	acid[^{14}C]permethrin: *cis*:*trans* ratio 46:54 alc[^{14}C]permethrin: *cis*:*trans* ratio 53:47	
3.1.3	**Purity**	acid[^{14}C]permethrin: 98.22% alc[^{14}C]permethrin: 99.56%	
3.1.4	**Further relevant properties**	acid[^{14}C]permethrin: Specific activity 7.4 mCi mmol^{-1} alc[^{14}C]permethrin: Specific activity 9.8 mCi mmol^{-1}	
3.1.5	**Composition of Product**	Not applicable	
3.1.6	**TS inhibitory to microorganisms**	No	
3.1.7	**Specific chemical analysis**	$^{14}CO_2$ analysis: Evolved $^{14}CO_2$ was trapped in 1N KOH solution. Traps were changed every 2 weeks, and the solutions analysed for ^{14}C by liquid scintillation counting (LSC). Sediment analysis – Extraction: The extraction process is shown in Figure 3. Duplicate samples were extracted and analysed at each sampling interval. Duplicate treated tubes were centrifuged for approximately 10 minutes at approximately 2500 rpm. The supernatants were decanted and partion extracted (×2) with CH_2Cl_2 and the extracts	

Section A7.1.2.2.2 **Biodegradation in fresh water: Water/Sediment: Degradation study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

combined. The remaining aqueous phase was adjusted to pH approx 1 with HCl, analysed for total radioactivity by LSC and extracted (×2) with CH_2Cl_2. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below).

Following centrifugation, the solids were transferred to Teflon centrifuge tubes with acetonitrile:acidified water (4:1 v/v, water prepared using 1% 1N HCl) and shaken on a wrist-action shaker for approximately 10 minutes. The samples were centrifuged and the process repeated. centrifugates were combined, analysed for total radioactivity by LSC and extracted (×2) with CH_2Cl_2. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below).

Remaining solids were air dried, and aliquots combusted and analysed for total radioactivity by LSC. This radioactivity was considered as 'bound residue' and samples (day 30 only) extracted and analysed as shown in Figure 4, and described below.

Sediment analysis – Bound Residue Extraction: Composit acid- and alcohol-labelled samples from day 30 were prepared (approx. 4 g of each) and heated to reflux in approx. 50 ml 0.25N HCl for approximately 1 hour. The mixture was cooled to room temperature and filtered in vacuo, and the filtrate analysed for total radioactivity by LSC and extracted (×2) with EtOAc. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below). The solids were transferred to a centrifuge tube to which was added 30 ml 0.5N NaOH. The tube was placed on a wrist-action shaker for 24 hours, centrifuged, and the supernatant decanted, acidified with HCl, recentrifuged and the supernatant (fulvic acid) assayed by LSC. The precipitate from the first centrifugation (humin) and the second centrifugation (humic acid) were assayed by combustion/LSC.

Extract analysis: Organosoluble extracts were profiled and analysed qualitatively with normal-phase thin layer chromatography (NP-TLC). Filtrates and organosoluble extracts were analysed quantitatively by reverse-phase high performance liquid chromatography (HPLC). Qulaitative samples were prepared for analysis by HPLC-Mass Spectrometry (HPLC/MS, HPLC/MS/MS to identify two unknown metabolites.

NP-TLC:

Plate:	$Si_{60}F_{254}$ (10×20, 20×20)
Solvent:	Hexane:ether 9:1 or cyclohexane (saturated with formic acid):ether 3:2
Detector:	TLC image detector FUJIX bio-imaging analyser, BAS1000 or AMBIS™ TLC Image scanner, Model 100

HPLC:

Column:	Phenomenex Ultracarb 5ODS(20) 4.6 x 250 mm

Section A7.1.2.2.2 **Biodegradation in fresh water: Water/Sediment: Degradation study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

	Mobile phase	A: 0.01M acetic acid, B: CH_3CN			
	Gradient;	Time	%A	%B	Flow
		0	60	40	1.0
		15	42	48	1.0
		16	10	90	1.0
		36	10	90	1.0
	Detection:	UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 µl glass solid cell			
	HPLC/MS:				
	Column:	Zorbax Rx C18 2.1 x 150 mm			
	Mobile phase	A: Water, B: CH_3OH			
	Gradient;	Time	%A	%B	Flow
		0	95	5	0.3
		1	95	5	0.3
		11	50	50	0.3
		31	10	90	0.3
		36	10	90	0.3
	Detection:	UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 50 µl glass solid cell			
	MS:	Electrospray Ionisation (ESI) –ve ion mode.			
	MSMS Scan	Daughter ion at 15-35 eV			
	Collision gas	Argon			

3.2	**Reference substance**	No
3.3	**Test ing procedure**	
3.3.1	**Sediment/water**	The sediment and pond water used were supplied by American Agricultural Services, North Carolina. Data on the sediment and water are given in Table 1.
3.3.2	**Test system**	The test system for each label consisted of 42 glass centrifuge tubes (50 ml) to whih filtered hydrosoil (approx. 5 g dry weight) and pondwater (approx 10 ml) were added. The flasks tubes were connected in series by dose rate by glass tubes, and air drawn through the series of tubes, and through three volatile traps designed to trap any evolved volatile gases (Figure 5). The tubes were placed in a water bath at 25 ± 1°C for at least 24 hours to equilibrate. Tubes were then removed and treated at 1 or 10 ppm permethrin. Two further tubes were treated with 50 µl acetonitrile to serve as controls. Immediately after dosing, the tubes were reconnected and returned to the water bath. Duplicate tubes were removed at intervals for analysis. The KOH traps were changed at every sampling point.
3.3.3	**Test conditions**	The tubes were stored in the dark, in a water bath set at 25 ± 1°C until sampled for analysis.
3.3.4	**Initial TS concentration**	The experimental design included two nominal dosing levels, 1.0 (16 tubes) and 10 (4 tubes) ppm $^{w}/w$, for both acid and

Section A7.1.2.2.2 **Biodegradation in fresh water: Water/Sediment: Degradation study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

alc[^{14}C]permethrin. The 10 ppm dosing level was included solely to provide sufficient material at the study termination to allow metabolite identification. The rate calculations are all based on vessles dosed at the more realistic 1.0 ppm.

3.3.5 Method of preparation of test solution

acid[^{14}C]permethrin:

Stock solution: Original test material was dissolved in approximately 1.5 ml of acetonitrile and the radioconcentration determined to be 332,000 dpm μl^{-1}, equivalent to 7.9 $\mu g\ \mu l^{-1}$ based on the specific activity (41,962 dpm μg^{-1}).

1.0 ppm dosing solution: A 60 µl aliquot of the stock solution was diluted with acetonitrile to provide the dosing solution. The radioconcentration was determined as 20,257 dpm μl^{-1}, equivalent to 0.483 $\mu g\ \mu l^{-1}$ based on the specific activity (41,962 dpm μg^{-1}).

10 ppm dosing solution: The stock solution was used directly as the dosing solution.

alc[^{14}C]permethrin:

Stock solution: Approximately 1 mCi of original test material was dissolved in approximately 8 ml of acetonitrile and the radioconcentration determined to be 312,000 dpm μl^{-1}, equivalent to 5.6 $\mu g\ \mu l^{-1}$ based on the specific activity (55,601 dpm μg^{-1}).

1.0 ppm dosing solution: A 100 µl aliquot of the stock solution was diluted with 1.86 ml of acetonitrile to provide the dosing solution. The radioconcentration was determined as 15,920 dpm μl^{-1}, equivalent to 0.286 $\mu g\ \mu l^{-1}$ based on the specific activity (55,601 dpm μg^{-1}).

10 ppm dosing solution: The stock solution was used directly as the dosing solution.

3.3.6 Dosing of test systems

A test system was considered to be 15 g in total (10 g pondwater, 5 g sediment).

Two flasks were treated with 50 µl CH_3CN to act as control vessels.

acid[^{14}C]permethrin:

1.0 ppm nominal concentration: 16 flasks were treated at a nominal 1.0 ppm by adding 31 µl of the 1.0 ppm dosing solution to each flask.

10 ppm nominal concentration: 4 flasks were treated at a nominal 10 ppm by adding 19 µl of the 10 ppm dosing solution to each flask.

alc[^{14}C]permethrin:

1.0 ppm nominal concentration: 16 flasks were treated at a nominal 1.0 ppm by adding 52 µl of the 1.0 ppm dosing solution to each flask.

10 ppm nominal concentration: 4 flasks were treated at a nominal 10 ppm by adding 27 µl of the 10 ppm dosing solution to each flask.

3.3.7 Duration of test

30 days (in-life phase)

3.3.8 Analytical parameter

The following parameters were determined;

Evolution of $^{14}CO_2$, loss of permethrin from test systems, formation of DCVA and PBA metabolites.

3.3.9 Sampling

Sampling of the 1.0 ppm flasks was undertaken on days 0, 3, 7, 14,

Section A7.1.2.2.2 **Biodegradation in fresh water: Water/Sediment: Degradation study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

21, 30.

The 10 ppm dosed vessels were sampled on day 30.

3.3.10 Intermediates/ degradation products

The formation of DCVA and PBA metabolites, and other unknown materials were identified from the high dose vessels at the end of the exposure period.

3.3.11 Controls

Two flasks were treated with 50 µl CH_3CN to act as control vessels.

3.3.12 Statistics

The half-life of permethrin was calculated from a plot of log(% permethrin remaining) vs time. From this plot, a linear regression was determined, and the half-life derived using the pseudo first-order kinetic reaction equation;

$T½ = \ln(2)/k$ [$k = -2.303 \times m$, where m is the slope of the plotted line]

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

The loss of *cis*- and *trans*-[^{14}C]permethrin from the test systems are displayed graphically in Figure 6. The log plots are shown in Figure 7. These data were generated by combining the data presented in Tables 4 and 5, which relate to the position of the label, rather than the stereochemistry of the molecule. It is considered *cis*- and *trans*-permethrin data are more pertinent to risk assessment, and these data are presented in Table 6. Log data and statistical analysis data are presented in Table 7.

4.1.2 Total ^{14}C recovery

Tables 2 and 3 show the total recoveries of both acid and alc[^{14}C]permethrin test systems.

The average total recovery for the acid[^{14}C]permethrin was 104.2% with a range of 102.2 to 106.8%.

The average total recovery for the alc[^{14}C]permethrin was 98.5% with a range of 94.2 to 102.5%.

4.1.3 Distribution of radioactivity

Tables 2 and 3 show the distribution of radioactivity in both acid and alc[^{14}C]permethrin test systems.

$^{14}CO_2$ evolution: Over the 30 day study duration, more radioactivity was evolved as $^{14}CO_2$ and other volatile materials in the alcohol labelled permethrin (8.9%), compared to the acid labelled (2.8%).

Supernatant: From day 0, in the acid[^{14}C]permethrin, the amount of radioactivity determined in the pondwater rose to a maximum of 14.9% on day 14, to fall back to 8.9% by the end of the exposure period. In the alc[^{14}C]permethrin, low quantities of radioactivity were found in the pondwater phase (max. 3.84% on day 59).

Sediment analysis – Extractable: For both acid[^{14}C]permethrin and alc[^{14}C]permethrin, on day 0 the amount of radioactivity extractable from the sediment was essentially all of the applied radioactivity. After this sampling point, there began a decline in the amount of radioactivity extracted from the sediment, and on the final sampling occasion, day 30, the extractable radioactivity had fallen to 74% (acid[^{14}C]permethrin) and 66% (alc[^{14}C]permethrin)

Sediment analysis – Bound Residue (Unextractable): Initially,

Section A7.1.2.2.2 **Biodegradation in fresh water: Water/Sediment: Degradation study**

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		essentially all of the radioactivity applied was extractable from the sediment. After this sampling point, there began a gradual increase in the amount of radioactivity unextractable from the sediment, and on the final sampling occasion, day 30, the bound residues had risen to 17% (acid[^{14}C]permethrin) and 18% (alc[^{14}C]permethrin)	
4.1.4	**Analyses of organosoluble extracts**	Tables 4 and 5 show the combined data from the analysis of the organosoluble extracts from the supernatant and the sediment analysis distribution of radioactivity in both acid and alc[^{14}C]permethrin test systems, respectively. In the acid[^{14}C]permethrin, the amount of radioactivity determined as permethrin fell from 99.8% to 56.3% of the total applied radioactivity over the duration of the test period. The *trans* isomer (53.8% at day 0 to 22.6% at day 30) appeared to be more susceptible to biodegradation than the *cis* isomer (46.0% at day 0 to 33.7% at day 30). In the alc[^{14}C]permethrin, the amount of radioactivity determined as permethrin fell from 99.9% to 59.5% of the total applied radioactivity over the duration of the test period. The *trans* isomer (45.8% at day 0 to 20.8% at day 30) appeared to be more susceptible to biodegradation than the *cis* isomer (54.1% at day 0 to 38.7% at day 30).	
4.1.5	**Analyses of post extraction solids (PES)**	In the acid[^{14}C]permethrin, the average distribution of radioactivity in the day 30 PES (as a % of total applied radioactivity) was as follows; Hydrolysate EtOAc: 5.1% Hydrolysate aqueous: 0.9% Fulvic acid: 5.2% Humin: 2.9% Humic acid: 3.0% In the alc[^{14}C]permethrin, the average distribution of radioactivity in the day 30 PES (as a % of total applied radioactivity) was as follows: Hydrolysate EtOAc: 1.3% Hydrolysate aqueous: 1.8% Fulvic acid: 5.6% Humin: 4.3% Humic acid: 4.6%	
4.1.6	**Half-life calculations**	Using the data obtained in the study, the half-lives of *cis*- and *trans*-permethrin were calculated to be 63.7 and 27.3 days respectively. The average half-life was 40.4 days.	X
4.1.7	**Intermediates/ degradation products**	In the acid[^{14}C]permethrin, three main metabolites (>1% of applied radioactivity) were identified, *cis*- and *trans*-DCVA (maximum 20.0% of applied) and Metab 1 (maximum 2.6% of applied), identified tentatively as 4-hydroxy permethrin (Figure 7). In the alc[^{14}C]permethrin, two main metabolites (>1% of applied radioactivity) were identified, 3-phenoxybenzoic acid (maximum 5.7% of applied) and Metab 1 (maximum 2.6% of applied), identified tentatively as 4-hydroxy permethrin (Figure 7).	

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The maximum combined amounts of *cis*- plus *trans*-DCVA in the water phase was reached after 14 days (14%) and declined to less than 7% after 30 days. The combined amounts in sediment increased with time and reached a maximum of 15% after 30 days. In the total system the maximum amounts of *cis*- plus *trans*-DCVA were detected after 21 days (24.8%). The results extracted from Table XI of the report (Robinson, R.A & Ryan, J.E.; 1996) are summarised in Table 8 and Figure 9.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was compliant with US EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3. The test design consisted of sacrificial systems prepared in glass tubes. Sediment and water were added to the flasks and allowed to equilibrate under aerobic conditions, after which a known amount of [^{14}C]permethrin was added, and the systems linked via a flow-through system designed to trap evolved gases, which were trapped and quantified. At time intervals, sacrificial systems were removed, extracted and quantified for total permethrin and total applied radioactivity.	X
5.2	**Results and discussion**	Essentially quantitative recovery at every time point was achieved. In the test systems the behaviour of permethrin was relatively easy to follow; Initially, the permethrin binds rapidly to the sediment, remaining in the water column for less than a day, as shown by the amount of radioactivity in the aqueous day 0 samples. Initially the radioactivity is all extractable, but over the course of the study, the radioactivity gets incorporated into the biomass, becoming unextractable by traditional solvent extractions. Extractable radioactivity for the initial period of the test period is present as permethrin, but the ratio of permethrin in the extracts drops over the study, indicating biodegradation is occurring. This is counterbalanced by an increase in $^{14}CO_2$ production, and the appearance of metabolites. Greater $^{14}CO_2$ production in the alcohol labelled permethrin, compared to the acid labelled, indicates the greater stability of the DCVA moiety, compared to the phenoxybenzyl products. The maximum combined amounts of *cis*- plus *trans*-DCVA in the water phase was reached after 14 days (14%) and declined to less than 7% after 30 days. The combined amounts in sediment increased with time and reached a maximum of 15% after 30 days. In the total system the maximum amounts of *cis*- plus *trans*-DCVA were detected after 21 days (24.8%).	
5.3	**Conclusion**	As a fully GLP audited guideline study, this reference is considered to fulfill all required validity criteria.	
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	22 February 2011
Materials and Methods	The applicant's version is considered acceptable, with the addition of the following correction. Section 2.1 (Guideline study) The guideline used for this aerobic water-sediment study was US EPA 162-4, not US EPA 162-3 (which applies to anaerobic water-sediment studies).
Results and discussion	Adopt applicant's version, with the addition of the following information. Section 4.1.6 (Half-life calculations) The measured whole-system DT_{50} values, obtained at 25 ± 1 °C, of 63.7 days for cis-permethrin and 27.3 days for trans-permethrin correspond to equivalent values at 12 °C of 180.2 days and 77.2 days, when extrapolated with the TGD temperature correction equation ($DT_{50}(12\ °C) = DT_{50}(T) \times e^{0.08(T-12)}$).
Conclusion	Adopt applicant's version, with the addition of the following correction. Section 5.1 (Materials and methods) The first sentence in this section should read, "The test was compliant with US EPA Pesticide Assessment Guidelines, Subdivision N, § 162-4."
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	**Comments:** (Section 2.3) In line with current guidelines (e.g. OECD 308) the following deviation(s) were observed: The test was conducted with a single water/sediment system instead of the recommended two test systems. As a result of using a single test system environmental variables are constrained for the assessment of permethrin degradation and behaviour in water/sediment systems. Freshwater characteristics e.g. alkalinity, hardness and NO_3/PO_4 (ratio and individual values) were not reported, as suggested by the guideline. These are considered minor deviations to the current test guideline and do not affect the scientific validity of the study.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 1: Physical and chemical properties of sediment and water

	Sediment	Water
% Sand	62	Not Applicable
% Silt	24	Not Applicable
% Clay	14	Not Applicable
% Organic Matter	7.5	Not Applicable
Cation Exchange Capacity (meq/100 g)	11.5	Not Applicable
pH	5.4	6.04
Bulk Density (g/cc)	0.83	Not Applicable
Class	Sandy Loam	Not Applicable
Dissolved Oxygen (mg/L)	Not Applicable	0.1
Specific Conductance (umhos/cm)	Not Applicable	76

Table 2: Average percent distribution of radioactivity in supernatant and sediment fractions at various intervals (acid label)

	Average: % of Dose					
Fraction ID	0 DAT	3 DAT	7 DAT	14 DAT	21 DAT	30 DAT
Supernatant	3.70	7.34	11.46	14.92	14.09	8.94
CH_2Cl_2-1	2.54	5.86	2.38	5.06	13.04	6.95
Aqueous-1	1.16	1.48	9.08	9.86	1.05	1.99
CH_2Cl_2-2	0.85	1.10	8.54	9.24	0.56	0.79
Aqueous-2	0.31	0.38	0.55	0.63	0.50	1.21
CH_3CN/H_3O+	97.28	93.86	89.54	82.27	77.83	74.27
CH_3CN/CH_2Cl_2	97.28	93.84	89.52	82.24	77.78	74.15
Aqueous-3	0.00	0.02	0.02	0.03	0.05	0.13
PES	1.22	5.45	4.72	6.83	9.15	17.02
Ethylene Glycol	NA	<0.01	<0.01	0.01	0.01	0.01
KOH	NA	0.14	0.26	0.60	1.22	2.78
H_2SO_4	NA	<0.01	<0.01	<0.01	0.01	0.01
Total Volatiles	NA	0.14	0.27	0.61	1.23	2.80
Total Recovery	102.19	106.78	105.99	104.62	102.30	103.02
Average Recovery						104.15

NA = Not Available - i.e., samples were not routinely generated during the analytical procedure except where indicated.

Table 3: Average percent distribution of radioactivity in supernatant and sediment fractions at various intervals (alcohol label)

	Average: % of Dose					
Fraction ID	0 DAT	3 DAT	7 DAT	14 DAT	21 DAT	30 DAT
Supernatant	3.87	2.14	2.40	3.84	4.18	1.31
CH_2Cl_2-1	2.20	1.32	0.59	0.64	2.86	0.64
Aqueous-1	1.67	0.82	1.81	3.20	1.32	0.67
CH_2Cl_2-2	0.85	0.30	0.97	1.88	0.30	NA
Aqueous-2	0.83	0.53	0.84	1.32	1.02	NA
CH_3CN/H_3O+	97.73	92.02	84.85	80.24	71.74	66.35
CH_3CN/CH_2Cl_2	97.71	91.89	84.72	80.09	71.64	66.27
Aqueous-3	0.02	0.13	0.13	0.15	0.10	0.08
PES	0.89	5.84	10.68	11.79	16.62	17.61
Ethylene Glycol	NA	<0.01	0.01	0.02	0.04	0.06
KOH	NA	0.01	1.12	2.24	4.72	8.85
H_2SO_4	NA	<0.01	<0.01	<0.01	<0.01	0.01
Total Volatiles	NA	0.01	1.13	2.26	4.76	8.91
Total Recovery	102.48	100.01	99.05	98.12	97.30	94.18
Average Recovery						98.52

NA = Not Available - i.e., samples were not routinely generated during the analytical procedure except where indicated.

Table 4: Average percent distribution of permethrin and metabolites in supernatant and sediment organosoluble fractions at various intervals (acid label)

Total	Permethrin	cis-Perm	trans-Perm	trans-DCVA	cis-DCVA	Met 1	Met 3	Met 5	Met 7	Total
DAT	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose
0	99.81	46.01	53.81	ND	ND	ND	ND	ND	ND	99.81
3	88.75	45.46	43.29	6.48	0.25	2.23	ND	ND	ND	99.70
7	83.72	43.46	40.27	13.76	0.39	2.56	0.01	ND	ND	100.44
14	75.26	39.91	35.35	17.18	1.78	2.09	0.14	0.09	ND	96.54
21	65.68	36.21	29.47	20.01	2.90	1.52	0.73	ND	ND	90.82
30	56.25	33.68	22.57	18.38	3.70	1.56	0.94	0.23	0.04	81.08

ND = Not Detected

Note: Numbers in table may differ ± 0.01% due to computer rounding

Table 5: Average percent distribution of permethrin and metabolites in supernatant and sediment organosoluble fractions at various intervals (alcohol label)

Total	Permethrin	cis-Perm	trans-Perm	PB-acid	PB-alcohol	Met 1	Met 3	Met 4	Met 6	Total
DAT	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose
0	99 91	54 07	45 84	ND	ND	ND	ND	ND	ND	99 91
3	87 86	50 04	37 82	2 42	0 44	2 50	ND	ND	ND	93 20
7	80 82	47 07	33 76	2 02	0 07	2 05	0 33	0 03	ND	85 32
14	74 93	44 91	30 01	4 44	0 28	2 61	0 21	ND	0 14	82 60
21	66 15	41 09	25 06	5 74	0 14	1 84	0 63	ND	0 02	74 51
30	59 48	38 67	20 81	4 78	0 16	1 78	0 70	ND	0 03	66 91

ND = Not Detected

Note Numbers in table may differ ± 0 01% due to computer rounding

Table 6: Combined data for loss of *cis*- and *trans*-permethrin from test systems (normalised to day 0)

Day No	Total permethrin	*trans*-permethrin	*cis*-permethrin
0	100.00	100.00	100.00
3	88.92	80.45	99.02
7	83.88	74.84	94.46
14	75.40	65.69	86.74
21	65.81	54.77	78.70
30	56.36	41.94	73.20

Table 7: Combined data for loss of *cis*- and *trans*-permethrin from test systems – Log values and statistical data

Day No	Total permethrin	*trans*-permethrin	*cis*-permethrin
0	2.000	2.000	2.000
3	1.947	1.911	1.981
7	1.916	1.871	1.958
14	1.876	1.817	1.929
21	1.820	1.738	1.888
30	1.763	1.640	1.859

R Square value	0.981	0.975	0.991
m	-0.00745	-0.0110	-0.00472
k (rate constant)	0.0172	0.0254	0.0109
T½ (days)	40.4	27.3	63.7

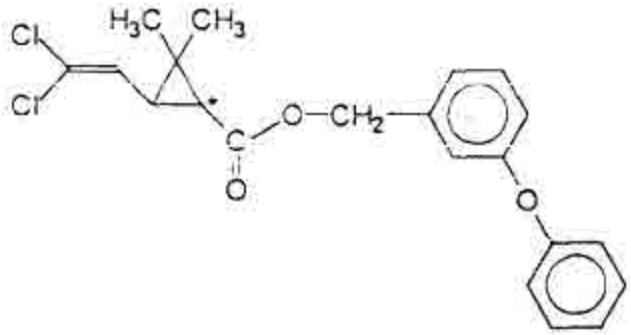
Table 8: Amounts of *cis*- and *trans*-DCVA in aqueous and sediment phases

		Aqueous Phase					Sediment Phase			Total
		$CHCl_2$-1		$CHCl_2$-2			$CHCl_2/CH_3CN$			
Time (days)	Replicate	cis-DCVA	trans-DCVA	cis-DCVA	trans-DCVA	Total DCVA	cis-DCVA	trans-DCVA	Total DCVA	
0	A	0.00	0.00	na	na	0.00	0.00	0.00	0.00	0.00
0	B	0.00	0.00	na	na	0.00	0.00	0.00	0.00	0.00
3	A	0.25	5.85	na	na	6.10	0.00	3.43	3.43	9.53
3	B	0.25	4.55	na	na	4.80	0.00	3.13	3.13	7.93
7	A	0.31	1.73	0.31	6.48	8.83	0.00	3.37	3.37	12.20
7	B	0.15	2.02	0.00	9.86	12.03	0.00	4.06	4.06	16.09
14	A	1.03	3.44	0.59	8.97	14.03	0.00	4.34	4.34	18.37
14	B	1.24	4.13	0.69	7.99	14.05	0.00	5.49	5.49	19.54
21	A	1.50	11.07	na	na	12.57	1.20	7.23	8.43	21.00
21	B	1.61	11.90	na	na	13.51	1.48	9.81	11.29	24.80
30	A	0.93	6.80	na	na	7.73	3.35	12.38	15.73	23.46
30	B	0.72	4.91	na	na	5.63	2.40	12.66	15.06	20.69

na = not analyzed

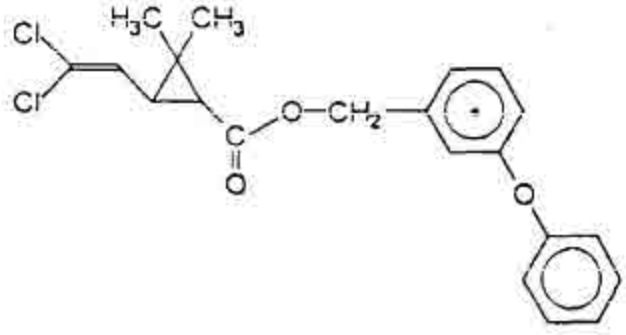
Figure 1: Test materials, indicating the position of the ^{14}C label

Acid label:



* Denotes position of ^{14}C label

Alcohol label:



* Denotes position of ^{14}C label

Figure 2: Reference materials

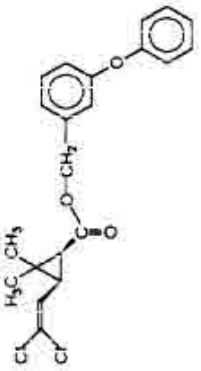
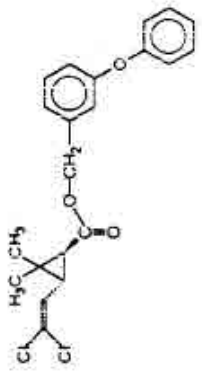
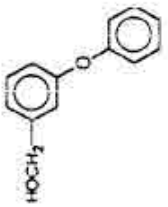
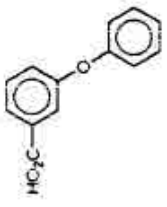
Name	Structure	Source	Lot number	Purity	Expiration Date
cis-Permethrin		FMC Corporation	E6788:90	99.5%	5/95
			E6788:85	99.6%	9/95
trans-Permethrin		FMC Corporation	E6788:91	99.6%	5/95
			E6788:86	99.7%	9/95
3-phenoxybenzyl alcohol		Aldrich	04123EV	98%	4/14/95
		Chem Services	144-119C	99.4%	2/98
3-phenoxybenzoic acid		Aldrich	07727HX	98%	4/18/95
			E6788:84	97.5%	8/95

Figure 2: Reference materials cont'd

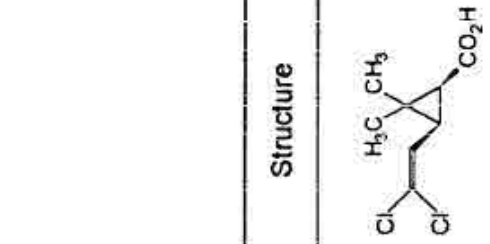
Name	Structure	Source	Lot number	Purity	Expiration Date
cis-dichlorovinyl acid		FMC Corporation	E6788:23	99.3%	5/95
			E6788:23	99.3%	7/96
trans-dichlorovinyl acid		FMC Corporation	E6788:22	99.2%	5/95
			E6788:22	99.2%	7/96

Figure 3: Extraction regime for sediment and water samples

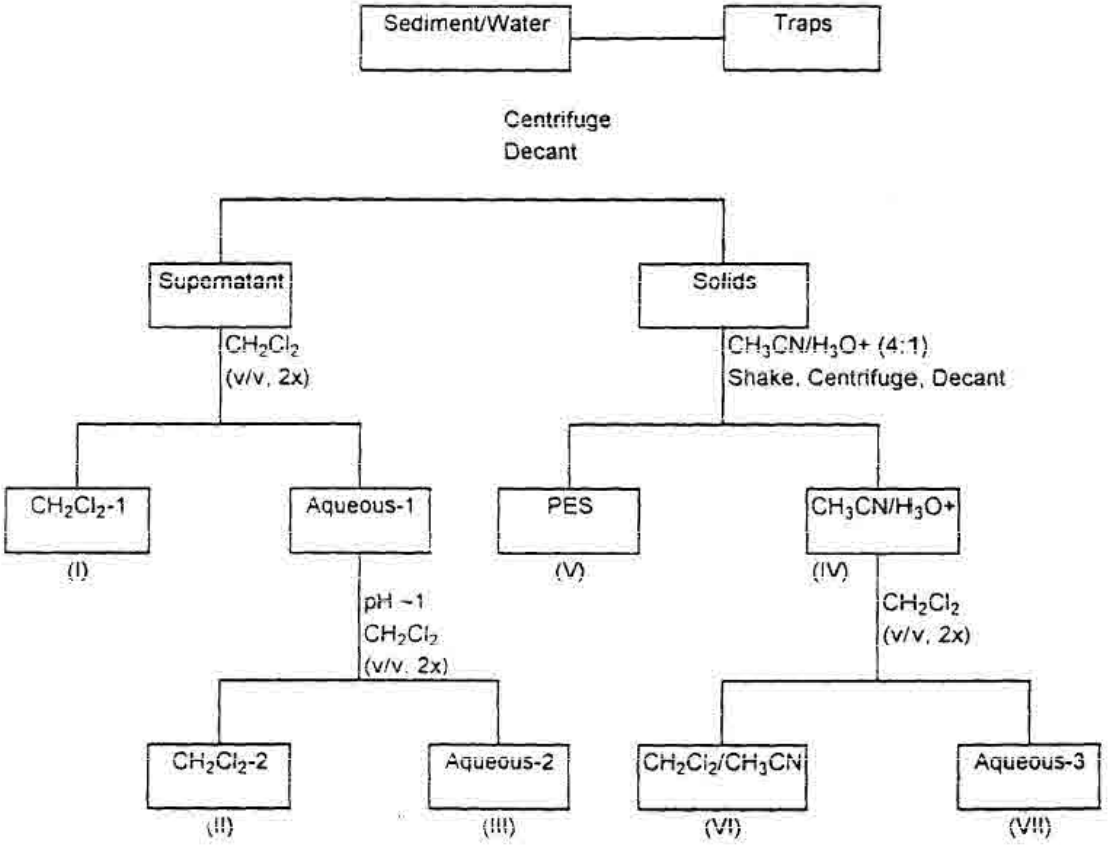


Figure 4: Extraction regime for day 367 PES.

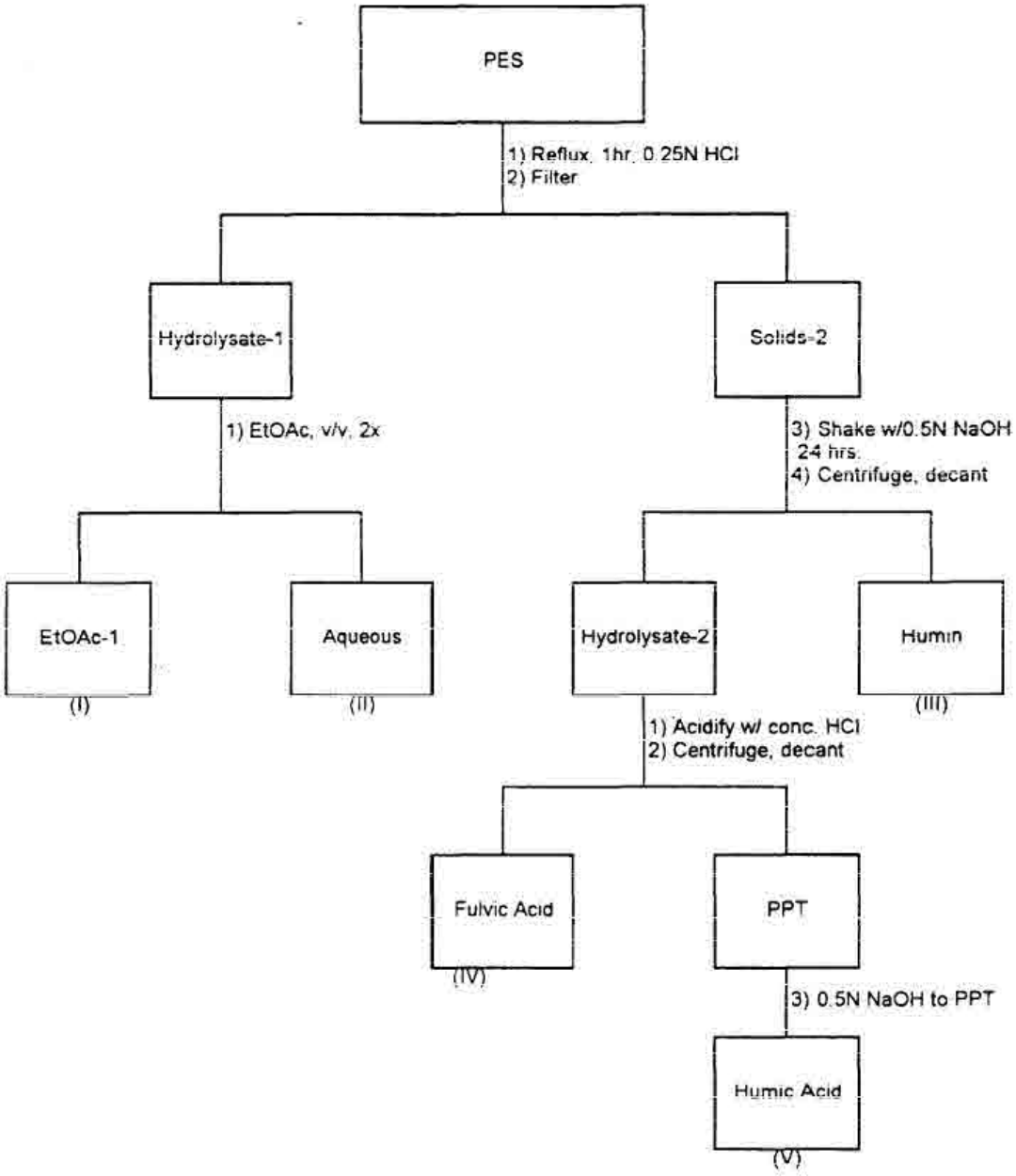


Figure 5: Scematic of test system

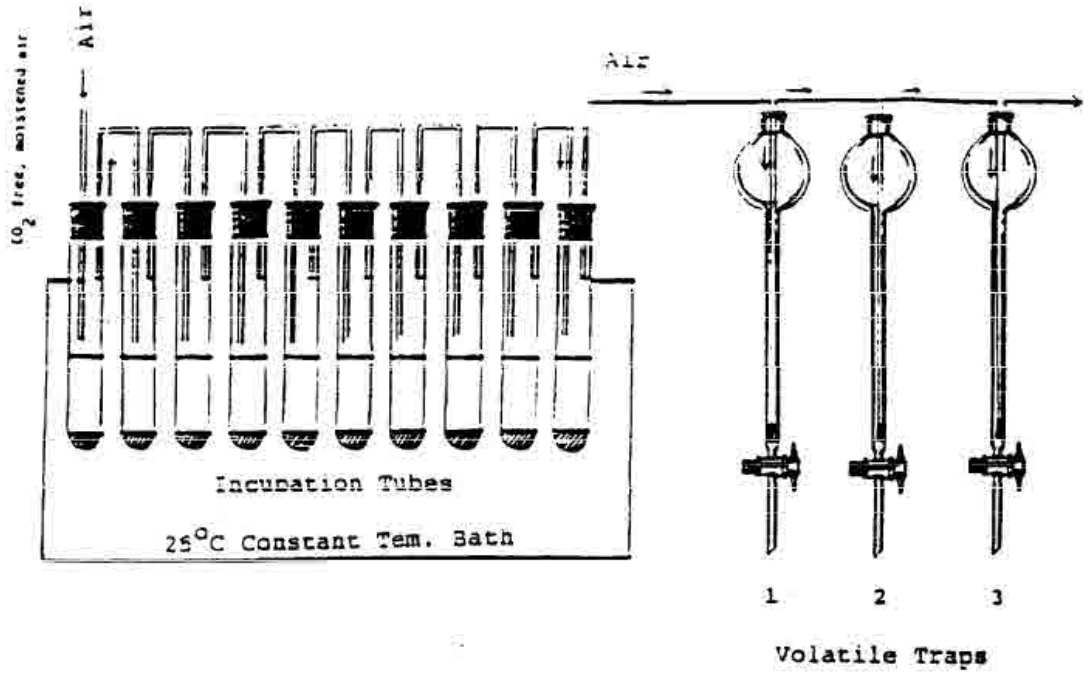


Figure 6: Loss of total, *cis*- and *trans*-permethrin from test systems at various intervals.

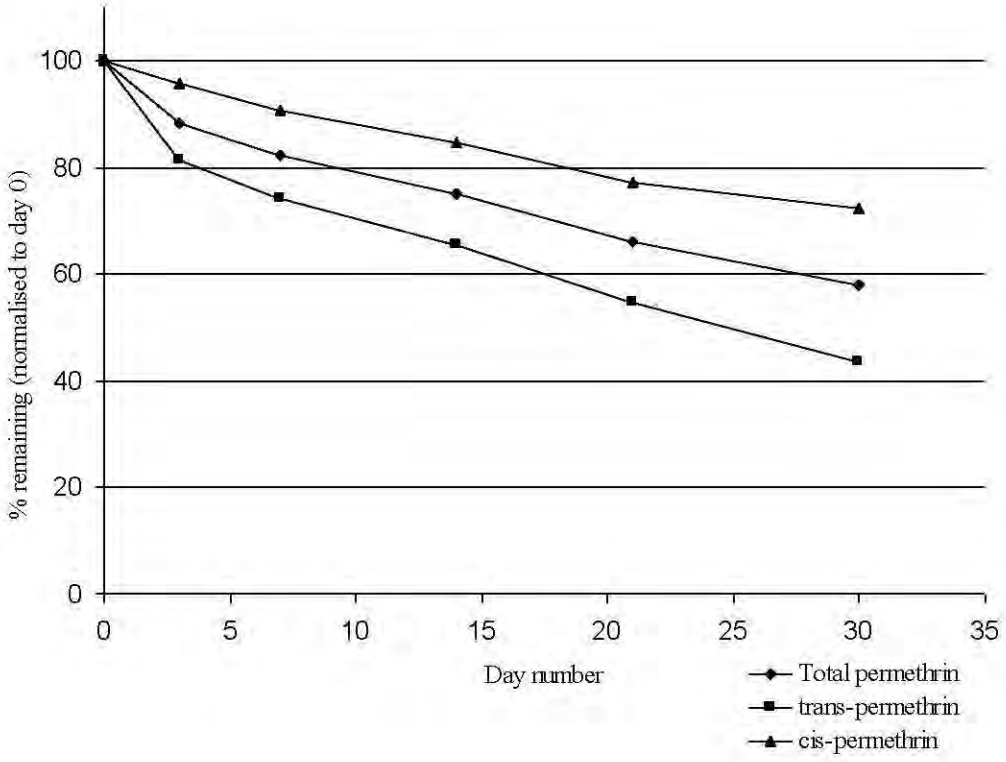


Figure 7: The half-life of total, *cis*- and *trans*-permethrin - plot of log(% permethrin remaining) vs time

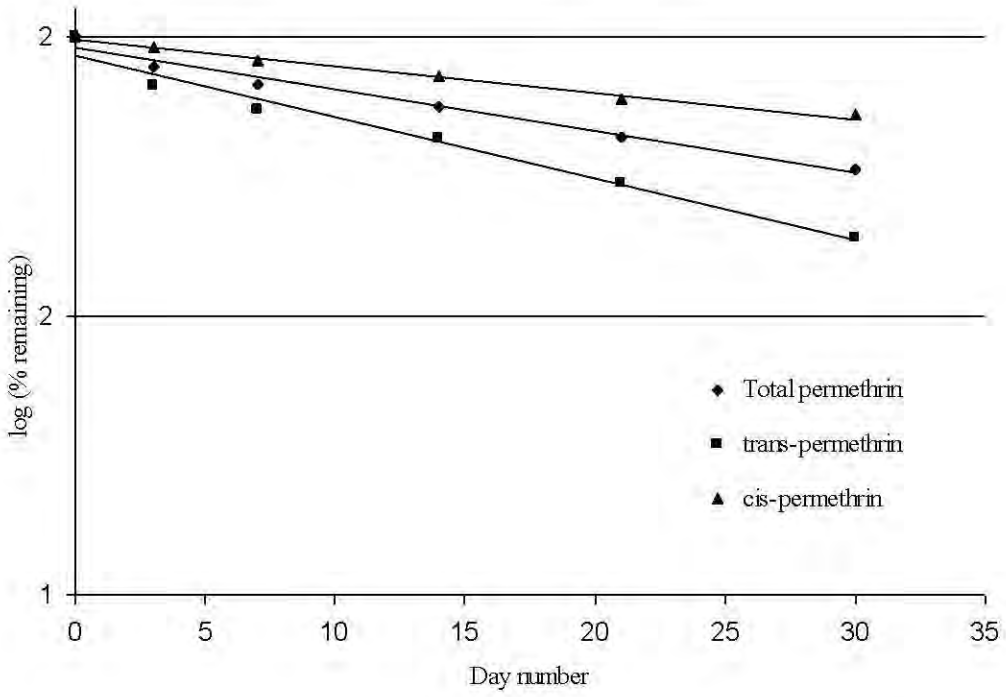
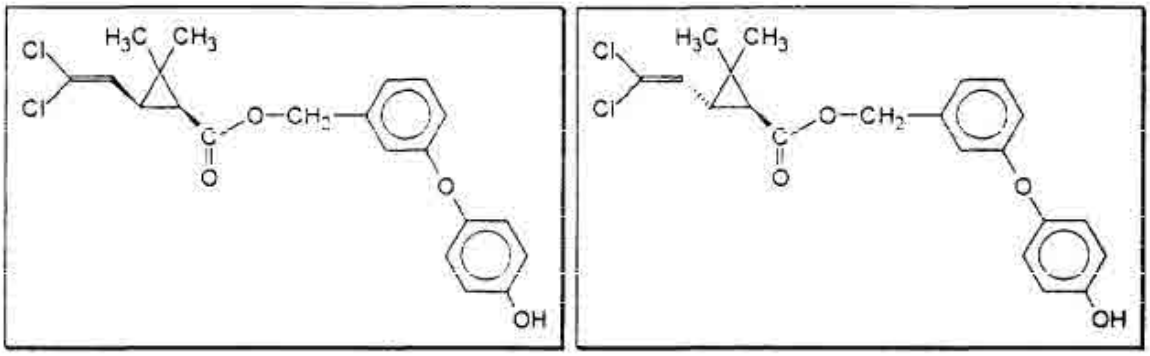


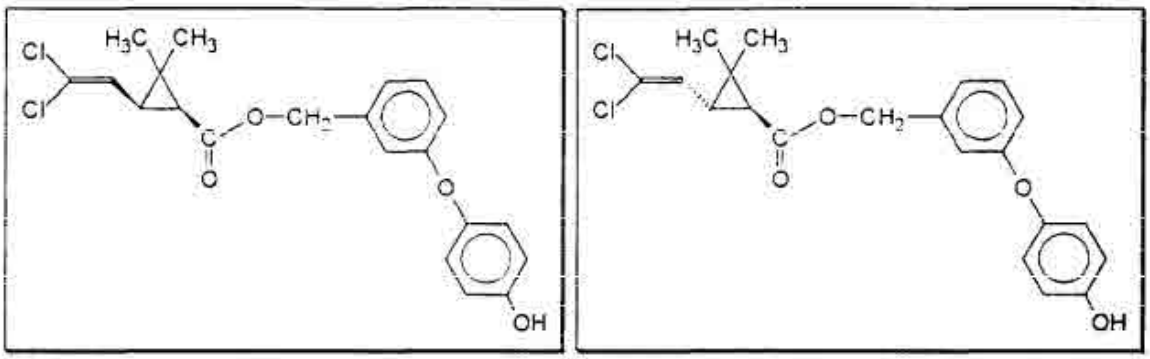
Figure 7: Tentative identity of Metabolite 1.



cis-Metabolite 1
(*cis*-4'-Hydroxy Permethrin)

trans-Metabolite 1
(*trans*-4'-Hydroxy Permethrin)

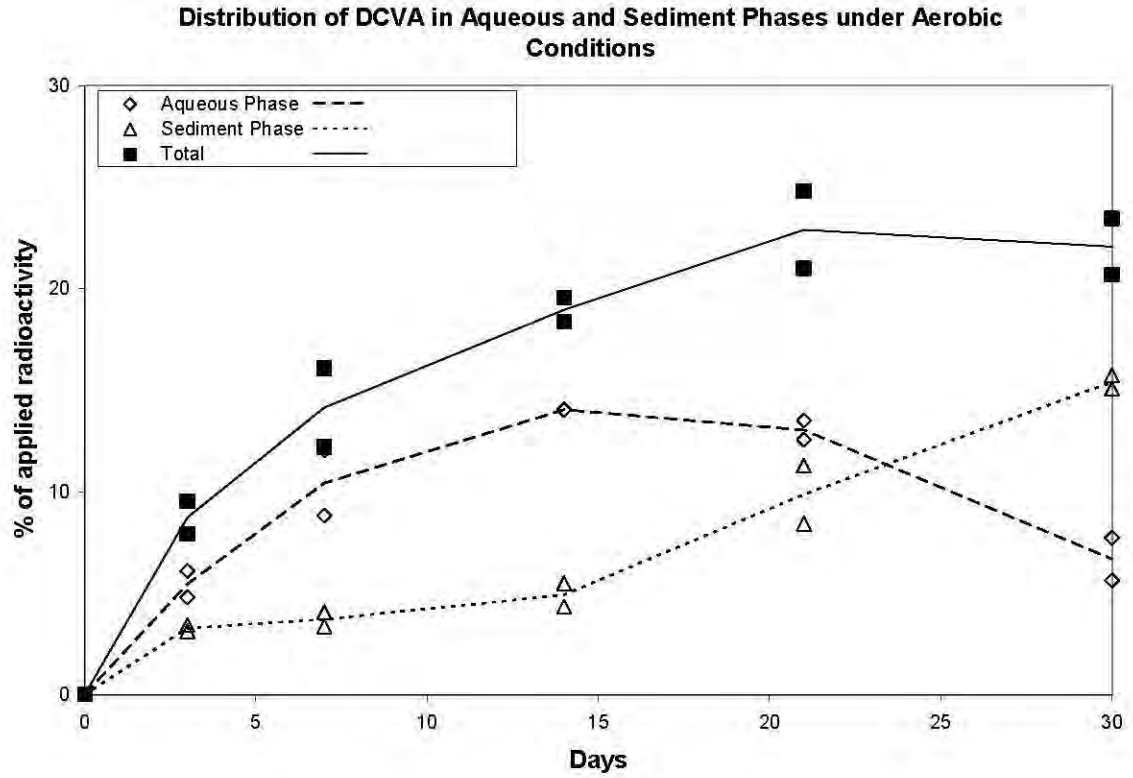
Figure 8: Tentative identity of Metabolite 1.



cis-Metabolite 1
(*cis*-4'-Hydroxy Permethrin)

trans-Metabolite 1
(*trans*-4'-Hydroxy Permethrin)

Figure 9: Formation and decline of *cis*- and *trans*-DCVA in aqueous and sediment phases with time



Section A7.1.2.2.2 (2) **Biodegradation in freshwater: Water/Sediment: Degradation study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Robinson, R.A & Ryan, J.E.; 1996; Anaerobic aquatic metabolism of [14C]Permethrin. XenoBiotic Laboratories, Inc., Plainsboro, NJ. report Ref. Study No. XBL94091, Report Ref. RPT00252; GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2	**Companies with a 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. US EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3	
2.2	**GLP**	Yes.	
2.3	**Deviations**	No.	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	Two separate radiolabelled [^{14}C]permethrin test materials were used in the study, labelled in the cyclopropane position (acid[^{14}C]permethrin) and the benzyl ring (alc[^{14}C]permethrin), as shown in Figure 1. The structures of reference materials used for co-chromatography are shown in Figure 2.	
3.1.1	**Lot/Batch number**	acid[^{14}C]permethrin: Amersham Sample Identification code CFQ8068 alc[^{14}C]permethrin: Sigma Sample Identification code 054H9214	
3.1.2	**Specification**	acid[^{14}C]permethrin: *cis*:*trans* ratio 46:54 alc[^{14}C]permethrin: *cis*:*trans* ratio 53:47	
3.1.3	**Purity**	acid[^{14}C]permethrin: 98.22% alc[^{14}C]permethrin: 99.56%	
3.1.4	**Further relevant properties**	acid[^{14}C]permethrin: Specific activity 7.4 mCi mmol^{-1} alc[^{14}C]permethrin: Specific activity 9.8 mCi mmol^{-1}	
3.1.5	**Composition of Product**	Not applicable	
3.1.6	**TS inhibitory to microorganisms**	No	
3.1.7	**Specific chemical analysis**	$^{14}CO_2$ analysis: Evolved $^{14}CO_2$ was trapped in 1N KOH solution. Traps were changed every 2 weeks, and the solutions analysed for ^{14}C by liquid scintillation counting (LSC). Sediment analysis – Extraction: The extraction process is shown in Figure 3. Duplicate samples were extracted and analysed at each sampling interval. Flasks were filtered in vacuo, and the supernatants analysed by LSC. If the supernatents had >1% of the applied radioactivity, they were adjusted to pH approx 1 with HCl, analysed for total radioactivity by	

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LSC and extracted (×2) with CH_2Cl_2. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below).

Following filtration, the solids were blended in acetonitrile:acidified water (4:1 v/v, water prepared using 1% 1N HCl) for 2 minutes. The samples were filtered and the process repeated. Filtrates were combined, analysed for total radioactivity by LSC and extracted (×2) with CH_2Cl_2. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below).

Remaining solids were air dried, and aliquots combusted and analysed for total radioactivity by LSC. This radioactivity was considered as 'bound residue' and samples (day 367 only) extracted and analysed as shown in Figure 4, and described below.

Sediment analysis – Bound Residue Extraction: Composit acid- and alcohol-labelled samples from day 367 were prepared (approx. 4 g of each) and heated to reflux in approx. 50 ml 0.25N HCl for approximately 1 hour. The mixture was cooled to room temperature and filtered in vacuo, and the filtrate analysed for total radioactivity by LSC and extracted (×2) with EtOAc. The organosoluble extract and the remaining aqueous fraction were analysed for total radioactivity (by LSC) and for permethrin and formed metabolites (see below). The solids were transferred to a centrifuge tube to which was added 30 ml 0.5N NaOH. The tube was placed on a wrist-action shaker for 24 hours, centrifuged, and the supernatant decanted, acidified with HCl, recentrifuged and the supernatant (fulvic acid) assayed by LSC. The precipitate from the first centrifugation (humin) and the second centrifugation (humic acid) were assayed by combustion/LSC.

Extract analysis: Organosoluble extracts were profiled and analysed qualitatively with normal-phase thin layer chromatography (NP-TLC). Filtrates and organosoluble extracts were analysed quantitatively by reverse-phase high performance liquid chromatography (HPLC). Qulaitative samples were prepared for analysis by HPLC-Mass Spectrometry (HPLC/MS, HPLC/MS/MS to identify two unknown metabolites.

NP-TLC:

Plate:	$Si_{60}F_{254}$ (10×20, 20×20)
Solvent:	Hexane:ether 9:1 or cyclohexane (saturated with formic acid):ether 3:2
Detector:	TLC image detector FUJIX bio-imaging analyser, BAS1000 or AMBIS™ TLC Image scanner, Model 100

HPLC:

Column:	Phenomenex Ultracarb 5ODS(20) 4.6 x 250 mm			
Mobile phase	A: 0.01M acetic acid, B: CH_3CN			
Gradient;	Time	%A	%B	Flow
	0	60	40	1.0
	15	42	48	1.0

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	15	10	90	1.0
	36	10	90	1.0

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 µl glass solid cell

HPLC/MS:

Column: Zorbax Rx C8 4.6 x 250 mm

Mobile phase A: 0.01M ammonium acetate, B: CH_3OH

Gradient;

Time	%A	%B	Flow
0	50	50	0.5
1	50	50	0.5
11	20	80	0.5
31	20	80	0.5
37	0	100	0.5

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 50 µl glass solid cell

MS: Electrospray Ionisation (ESI) –ve ion mode; Atmospheric Pressure Chemical Ionisation (APCI) +ve mode; Atmospheric Pressure Ionisation In-source Collision Induced Dissociation (APICID) +ve mode

MSMS Scan: Daughter ion at 15-35 eV

Collision gas: Argon

3.2 Reference substance

No

3.3 Test ing procedure

3.3.1 Sediment/water

The sediment and pond water used were supplied by American Agricultural Services, North Carolina. Data on the sediment and water are given in Table 1.

3.3.2 Test system

The test system for each label consisted of 32 biometer flasks with side arms, to which filtered hydrosoil (approx. 15 g dry weight) and pondwater (approx 55 ml) were added. 0.5 g of glucose was added to each flask. Polyfoam plugs were inserted into the side arms, and flasks purged with N_2 and immediately sealed. The flasks were placed in an incubator at 25 ± 1°C for 32 days to equilibrate. Flasks were then removed and treated at 1 or 10 ppm permethrin. Two further flasks were treated with 50 µl acetonitrile to serve as controls.

Immediately after dosing, the flasks were fitted with a 10 ml KOH trap in the side arm, the flasks swirled by hand, purged with N_2 and stoppered. They were then returned to the incubator and flasks removed at intervals for analysis. The KOH traps were changed every approximately two weeks.

3.3.3 Test conditions

The biometer flasks were stored in the dark, in an incubator set at 25 ± 1°C until sampled for analysis.

3.3.4 Initial TS concentration

The experimental design included two nominal dosing levels, 1.0 and 10 ppm ^{w}/w, for both acid and alc[^{14}C]permethrin. The 10 ppm

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		dosing level was included solely to provide sufficient material at the study termination to allow metabolite identification. The rate calculations are all based on vessles dosed at the more realistic 1.0 ppm.
3.3.5	**Method of preparation of test solution**	**acid[^{14}C]permethrin**: Stock solution: Approximately 1 mCi of original test material was dissolved in approximately 8 ml of acetonitrile and the radioconcentration determined to be 351,690 dpm μl^{-1}, equivalent to 8.4 μg μl^{-1} based on the specific activity (41,962 dpm μg^{-1}). 1.0 ppm dosing solution: A 375 µl aliquot of the stock solution was diluted with 1.38 ml of acetonitrile to provide the dosing solution. The radioconcentration was determined as 80,860 dpm μl^{-1}, equivalent to 1.9 μg μl^{-1} based on the specific activity (41,962 dpm μg^{-1}). 10 ppm dosing solution: The stock solution was used directly as the dosing solution. **alc[^{14}C]permethrin**: Stock solution: Approximately 1 mCi of original test material was dissolved in approximately 8 ml of acetonitrile and the radioconcentration determined to be 314,515 dpm μl^{-1}, equivalent to 5.7 μg μl^{-1} based on the specific activity (55,601 dpm μg^{-1}). 1.0 ppm dosing solution: A 525 µl aliquot of the stock solution was diluted with 0.80 ml of acetonitrile to provide the dosing solution. The radioconcentration was determined as 120,036 dpm μl^{-1}, equivalent to 2.2 μg μl^{-1} based on the specific activity (55,601 dpm μg^{-1}). 10 ppm dosing solution: The stock solution was used directly as the dosing solution.
3.3.6	**Dosing of test systems**	A test system was considered to be 70g in total (55 g pondwater, 15 g dry weight sediment). Two flasks were treated with 50 µl CH_3CN to act as control vessels. **acid[^{14}C]permethrin**: 1.0 ppm nominal concentration: 28 flasks were treated at a nominal 1.0 ppm by adding 36 µl of the 1.0 ppm dosing solution to each flask. 10 ppm nominal concentration: 4 flasks were treated at a nominal 10 ppm by adding 82 µl of the 10 ppm dosing solution to each flask. **alc[^{14}C]permethrin**: 1.0 ppm nominal concentration: 28 flasks were treated at a nominal 1.0 ppm by adding 32 µl of the 1.0 ppm dosing solution to each flask. 10 ppm nominal concentration: 4 flasks were treated at a nominal 10 ppm by adding 124 µl of the 10 ppm dosing solution to each flask.
3.3.7	**Duration of test**	32 days (acclimation) and 367 days (in-life phase)
3.3.8	**Analytical parameter**	The following parameters were determined; Evolution of $^{14}CO_2$, loss of permethrin from test systems, formation of DCVA and PBA metabolites.
3.3.9	**Sampling**	Sampling of the 1.0 ppm flasks was undertaken on days 0, 3, 7, 14,

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30, 59, 90, 120, 181, 269 and 367.

The 10 ppm dosed vessels were sampled on day 367.

3.3.10 Intermediates/ degradation products

The formation of DCVA and PBA metabolites, and other unknown materials were identified from the high dose vessels at the end of the exposure period.

3.3.11 Controls

Two flasks were treated with 50 µl CH_3CN to act as control vessels.

3.3.12 Statistics

The half-life of permethrin was calculated from a plot of log(% permethrin remaining) vs time. From this plot, a linear regression was determined, and the half-life derived using the pseudo first-order kinetic reaction equation;

$T½ = \ln(2)/k$ [$k = -2.303 \times m$, where m is the slope of the plotted line]

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

The loss of *cis*- and *trans*-[^{14}C]permethrin from the test systems are displayed graphically in Figure 5. The log plots are shown in Figure 6. These data were generated by combining the data presented in Tables 4 and 5, which relate to the position of the label, rather than the stereochemistry of the molecule. It is considered *cis*- and *trans*-permethrin data are more pertinent to risk assessment, and these data are presented in Table 6. Log data and statistical analysis data are presented in Table 7.

4.1.2 Total ^{14}C recovery

Tables 2 and 3 show the total recoveries of both acid and alc[^{14}C]permethrin test systems.

The average total recovery for the acid[^{14}C]permethrin was 98.4% with a range of 93.3 to 102.2%.

The average total recovery for the alc[^{14}C]permethrin was 98.9% with a range of 91.1 to 103.0%.

4.1.3 Distribution of radioactivity

Tables 2 and 3 show the distribution of radioactivity in both acid and alc[^{14}C]permethrin test systems.

$^{14}CO_2$ evolution: Over the 367 day study duration, approximately twice as much radioactivity was evolved as $^{14}CO_2$ and other volatile materials in the alcohol labelled permethrin (43%), compared to the acid labelled (24%).

Supernatant: From day 0, in the acid[^{14}C]permethrin, the amount of radioactivity determined in the pondwater rose to a maximum of 22% on day 90, to fall back to 5% by the end of the exposure period. In the alc[^{14}C]permethrin, negligible radioactivity was found in the pondwater phase (max. 2.7% on day 59).

Sediment analysis – Extractable: For both acid[^{14}C]permethrin and alc[^{14}C]permethrin, on day 0 the amount of radioactivity extractable from the sediment was essentially all of the applied radioactivity. This remained the case up to day 14. After this sampling point, there began a decline in the amount of radioactivity extracted from the sediment, and on the final sampling occasion, day 367, the extractable radioactivity had fallen to 31% (acid[^{14}C]permethrin) and 17% (alc[^{14}C]permethrin)

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		Sediment analysis – Bound Residue (Unextractable): Initially, essentially all of the radioactivity applied was extractable from the sediment. This remained the case up to day 14. After this sampling point, there began a gradual increase in the amount of radioactivity unextractable from the sediment, and on the final sampling occasion, day 367, the bound residues had risen to 34% (acid[^{14}C]permethrin) and 31% (alc[^{14}C]permethrin)	
4.1.4	**Analyses of organosoluble extracts**	Tables 4 and 5 show the combined data from the analysis of the organosoluble extracts from the supernatant and the sediment analysis distribution of radioactivity in both acid and alc[^{14}C]permethrin test systems, respectively. In the acid[^{14}C]permethrin, the amount of radioactivity determined as permethrin fell from 97.1% to 24.0% of the total applied radioactivity over the duration of the test period. The *trans* isomer (52.3% at day 0 to 9.0% at day 367) appeared to be more susceptible to biodegradation than the cis isomer (44.8% at day 0 to 15.0% at day 367). In the alc[^{14}C]permethrin, the amount of radioactivity determined as permethrin fell from 100.4% to 14.5% of the total applied radioactivity over the duration of the test period. The *trans* isomer (47.1% at day 0 to 3.7% at day 367) appeared to be more susceptible to biodegradation than the cis isomer (53.3% at day 0 to 10.9% at day 367).	
4.1.5	**Analyses of post extraction solids (PES)**	In the acid[^{14}C]permethrin, the average distribution of radioactivity in the day 367 PES (as a % of total applied radioactivity) was as follows; Hydrolysate EtOAc: 6.0% Hydrolysate aqueous: 3.0% Fulvic acid: 10.1% Humin: 6.9% Humic acid: 7.9% In the alc[^{14}C]permethrin, the average distribution of radioactivity in the day 367 PES (as a % of total applied radioactivity) was as follows; Hydrolysate EtOAc: 1.1% Hydrolysate aqueous: 4.3% Fulvic acid: 7.9% Humin: 8.3% Humic acid: 9.1%	
4.1.6	**Half-life calculations**	Using the data obtained in the study, the half-lives of *cis*- and *trans*-permethrin were calculated to be 179.4 and 114.5 days respectively. The average half-life was 144.7 days.	X
4.1.7	**Intermediates/ degradation products**	In the acid[^{14}C]permethrin, three main metabolites (>1% of applied radioactivity) were identified, DCVA (maximum 27.3% of applied), Metab A (maximum 2.0% of applied), identified tentatively as cyclopropanecarboxylic acid, 3-(2,2-dichlorethenyl)-2,2-dimethyl-(3-hydroxyphenyl)methyl ester and Metab B (maximum 2.6% of applied), identified tentatively as 4-hydroxy permethrin (Figure 7).	

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The maximum combined amounts of *cis*- plus *trans*-DCVA in the water phase was reached after 90 days (average 20%) and declined to about 2% after 367 days. The combined amounts in sediment increased with time and reached a maximum of 9% after 269 days declining to ca. 4% at the end of the study. In the total system the maximum amounts of *cis*- plus *trans*-DCVA were detected after 90 days (average 27%) and declined to an average of 6% after 367 days. The results extracted from Table XI of the report are summarised in Table 8 and Figure 8.

In the alc[^{14}C]permethrin, three main metabolites (>1% of applied radioactivity) were identified, 3-phenoxybenzoic acid (maximum 3.2% of applied), Metab A (maximum 3.5% of applied), identified tentatively as cyclopropanecarboxylic acid, 3-(2,2-dichlorethenyl)-2,2-dimethyl-(3-hydroxyphenyl)methyl ester and Metab B (maximum 3.1% of applied), identified tentatively as 4-hydroxy permethrin (Figure 7).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was compliant with US EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3. The test design consisted of sacrificial systems prepared in glass biometer flasks. Sediment and water were added to the flasks and allowed to equilibrate under anaerobic conditions, after which a known amount of [^{14}C]permethrin was added, and the systems again made anaerobic. Evolved gasses were trapped and quantified. At time intervals, sacrificial systems were removed, extracted and quantified for total permethrin and total applied radioactivity.

5.2 Results and discussion

Essentially quantitative recovery at every time point was achieved.

In the test systems the behaviour of permethrin was relatively easy to follow; Initially, the permethrin binds rapidly to the sediment, remaining in the water column for less than a day, as shown by the amount of radioactivity in the aqueous day 0 samples. Initially the radioactivity is all extractable, but over the course of the study, the radioactivity gets incorporated into the biomass, becoming unextractable by traditional solvent extractions. Extractable radioactivity for the initial period of the test period is present as permethrin, but the ratio of permethrin in the extracts drops over the study, indicating biodegradation is occurring. This is counterbalanced by an increase in $^{14}CO_2$ production, and the appearance of metabolites.

Greater $^{14}CO_2$ production in the alcohol labelled permethrin, compared to the acid labelled, indicates the greater stability of the DCVA moiety, compared to the phenoxybenzyl products.

The maximum combined amounts of *cis*- plus *trans*-DCVA in the water phase was reached after 90 days (average 20%) and declined to about 2% after 367 days. The combined amounts in sediment increased with time and reached a maximum of 9% after 269 days declining to ca. 4% at the end of the study. In the total system the maximum amounts of *cis*- plus *trans*-DCVA were detected after 90 days (average 27%) and declined to an average of 6% after 367 days

5.3 Conclusion

As a fully GLP audited guideline study, this reference is considered

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to fulfill all required validity criteria.

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	22 February 2011
Materials and Methods	The applicant's version is considered acceptable of the materials and methods used in this test.
Results and discussion	Adopt applicant's version, with the addition of the following information. Section 4.1.6 (Half-life calculations) The measured whole-system DT_{50} values, obtained at 25 ± 1 °C, of 179.4 days for cis-permethrin and 114.5 days for trans-permethrin correspond to equivalent values at 12 °C of 507.6 days and 323.9 days, when extrapolated with the TGD temperature correction equation ($DT_{50}(12\ °C) = DT_{50}(T) \times e^{0.08(T-12)}$).
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	**Comments:** (Section 2.3) In line with current guidelines (e.g. OECD 308) the following deviation(s) were observed: The test was conducted with a single water/sediment system instead of the recommended two test systems. As a result of using a single test system environmental variables are constrained for the assessment of permethrin degradation and behaviour in water/sediment systems. Freshwater characteristics e.g. alkalinity, hardness and NO_3/PO_4 (ratio and individual values) were not reported, as suggested by the guideline. These are considered minor deviations to the current test guideline and do not affect the scientific validity of the study.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 1: Physical and chemical properties of sediment and water

	Sediment	Water
% Sand	62	Not Applicable
% Silt	24	Not Applicable
% Clay	14	Not Applicable
% Organic Matter	7.5	Not Applicable
Cation Exchange Capacity (meq/100 g)	11.5	Not Applicable
pH	5.4	5.68
Bulk Density (g/cc)	0.83	Not Applicable
Class	Sandy Loam	Not Applicable
Dissolved Oxygen (mg/L)	Not Applicable	0.1
Specific Conductance (µmhos/cm)	Not Applicable	76

Table 2: Average percent distribution of radioactivity in supernatant and sediment fractions at various intervals (acid label)

	Average: % of Dose										
Fraction ID	0	3	7	14	30	59	90	120	181	269	367
Supernatant	0.74	0.57	0.57	1.26	6.70	16.07	22.18	12.62	14.61	7.75	4.99
CH_2Cl_2-1	NA	NA	NA	1.15	6.28	15.00	20.43	11.94	11.76	6.38	2.41
Aqueous-1	NA	NA	NA	0.11	0.42	1.07	1.75	0.69	2.85	1.37	2.58
CH_3CN/H_3O+	97.09	97.64	99.49	96.20	89.69	78.06	62.18	78.84	52.42	44.56	30.78
CH_3CN/CH_2Cl_2	97.07	97.58	99.30	96.20	89.67	78.02	62.12	78.82	52.32	44.44	30.62
Aqueous-2	0.03	0.06	0.19	<0.01	0.02	0.04	0.06	0.02	0.10	0.12	0.17
PES	0.28	0.45	0.54	1.35	3.59	7.52	8.39	7.81	20.22	33.10	33.86
KOH	NA	0.04	0.05	0.05	0.16	0.47	1.65	1.47	7.34	13.20	23.37
Foam Plug	NA	0.08	0.12	0.11	0.26	0.09	0.19	0.22	0.43	0.50	0.32
Total Volatiles	NA	0.12	0.16	0.15	0.42	0.56	1.83	1.68	7.77	13.69	23.69
Recovery	98.11	98.77	100.75	98.95	100.39	102.20	94.57	100.95	95.01	99.09	93.31

NA = Not Available - i.e., samples were not routinely generated during the analytical procedure except where indicated.

Table 3: Average percent distribution of radioactivity in supernatant and sediment fractions at various intervals (alcohol label)

	Average: % of Dose										
Fraction ID	0	3	7	14	30	59	90	120	181	269	367
Supernatant[1]	0.36	0.27	0.21	0.27	2.51	2.69	0.66	1.33	0.74	0.09	0.08
CH_2Cl_2-1	NA	NA	NA	NA	2.38	2.18	0.25	1.09	NA	NA	NA
Aqueous-1	NA	NA	NA	NA	0.13	0.51	0.30	0.14	NA	NA	NA
CH_3CN/H_3O+	100.37	102.29	100.89	100.46	96.88	86.39	60.08	62.62	62.71	12.41	17.26
CH_3CN/CH_2Cl_2	100.35	102.26	100.88	100.45	96.86	86.34	59.98	62.54	62.64	12.28	17.13
Aqueous-2	0.03	0.03	0.01	0.01	0.02	0.06	0.11	0.08	0.08	0.13	0.13
PES	0.53	0.45	0.75	2.11	3.27	7.87	18.92	17.51	13.92	32.14	30.71
KOH	NA	0.02	0.03	0.03	0.35	5.32	17.26	14.42	20.55	46.54	42.99
Foam Plug	NA	0.01	0.16	0.03	0.02	0.13	0.03	0.05	0.19	0.09	0.06
Total Volatiles	NA	0.03	0.18	0.05	0.37	5.45	17.29	14.46	20.74	46.63	43.05
Recovery	101.26	103.04	102.02	102.88	103.03	102.39	96.94	95.91	98.11	91.27	91.09

NA = Not Available - i.e., samples were not routinely generated during the analytical procedure except where indicated.

[1] Day 0 Rep. A Supernatant was combined w/CH_3CN/H_3O+ extract and assayed as one fraction.

Table 4: Average percent distribution of permethrin and metabolites in supernatant and sediment organosoluble fractions at various intervals (acid label)

Total	Permethrin	trans-Perm	cis-Perm	trans-DCVA	cs-DCVA	Met. A	Met. B	Met. C	Met. D	Met. F	Met. I	Total
		Rt ~31	Rt ~32	Rt ~16.5	Rt ~18.5	Rt ~25	Rt ~26	Rt ~4.5	Rt ~7	Rt ~14.5	Rt ~8.5	
Day	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose
0	97.07	52.27	44.80	ND	ND	ND	ND	ND	ND	ND	ND	97.07
3	97.58	53.92	43.66	ND	ND	ND	ND	ND	ND	ND	ND	97.58
7	99.30	53.45	45.86	ND	ND	ND	ND	ND	ND	ND	ND	99.30
14	95.58	50.85	44.73	1.33	0.21	0.16	ND	0.02	0.01	ND	ND	97.34
30	87.56	46.29	41.28	6.31	0.63	0.38	0.89	0.01	0.09	0.10	ND	95.95
59	71.84	35.15	36.68	14.85	2.40	1.34	2.38	ND	0.24	ND	ND	93.04
90	50.93	22.09	28.84	20.75	6.57	1.39	2.64	ND	0.27	ND	ND	82.55
120	71.88	33.79	38.09	15.14	1.52	0.60	1.47	ND	0.15	ND	ND	90.75
181	42.55	18.51	24.04	14.03	4.65	1.06	1.39	0.12	0.18	0.10	0.03	64.08
269	32.92	13.10	19.83	9.99	4.21	2.04	0.85	0.05	0.61	0.05	0.10	50.82
367	24.04	9.04	15.01	5.43	0.86	1.61	0.85	ND	ND	ND	0.24	33.03

ND = Not Detected

Note Numbers in table may differ ± 0.01% due to computer rounding

Table 5: Average percent distribution of permethrin and metabolites in supernatant and sediment organosoluble fractions at various intervals (alcohol label)

Total	Permethrin	trans-Perm	cis-Perm	PB-alcohol	FB-acid	Met. A	Met. B	Met. C	Met. E	Met. G	Met. H	Total
		Rt ~31	Rt ~32	Rt ~15	Rt ~17.5	Rt ~25	Rt ~26	Rt ~4.5	Rt ~9	Rt ~14.5	Rt ~22.5	
Day	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose	% of Dose
0	100.35	47.09	53.26	ND	ND	ND	ND	ND	ND	ND	ND	100.35
3	101.87	47.43	54.44	ND	0.39	ND	ND	ND	ND	ND	ND	102.26
7	100.88	47.77	53.12	ND	ND	ND	ND	ND	ND	ND	ND	100.88
14	100.07	45.42	54.65	0.33	ND	ND	ND	ND	ND	ND	ND	100.45
30	95.09	42.84	52.25	0.45	3.19	0.01	0.26	ND	0.27	ND	ND	99.25
59	83.86	32.99	50.87	0.01	2.86	0.52	1.01	0.01	0.23	0.01	0.02	88.52
90	53.67	20.99	32.68	ND	ND	3.24	3.08	ND	ND	ND	ND	59.98
120	54.88	20.63	34.25	ND	0.69	3.45	2.75	ND	0.94	ND	ND	62.70
181	59.65	20.66	38.99	ND	ND	1.31	1.69	ND	ND	ND	ND	62.64
269	10.50	2.83	7.67	ND	ND	0.96	0.71	ND	ND	ND	ND	12.16
367	14.53	3.69	10.85	ND	ND	1.78	0.83	ND	ND	ND	ND	17.13

ND = Not Detected

Note: Numbers in table may differ ± 0.01% due to computer rounding

Table 6: Combined data for loss of *cis*- and *trans*-permethrin from test systems

Day No	Total permethrin	*trans*-permethrin	*cis*-permethrin
0	100.00	100.00	100.00
3	101.02	101.94	99.84
7	101.41	101.85	101.05
14	99.09	96.87	101.23
30	92.48	89.77	95.12
59	78.79	68.66	88.69
90	52.98	43.42	62.87
120	64.37	54.23	74.66
181	51.64	39.64	63.43
269	22.19	15.54	29.33
367	19.62	12.57	26.94

Table 7: Combined data for loss of *cis*- and *trans*-permethrin from test systems – Log values and statistical data

Day No	Total permethrin	*trans*-permethrin	*cis*-permethrin
0	2.000	2.000	2.000
3	2.004	2.008	1.999
7	2.006	2.008	2.005
14	1.996	1.986	2.005
30	1.966	1.953	1.978
59	1.896	1.837	1.948
90	1.724	1.638	1.798
120	1.809	1.734	1.873
181	1.713	1.598	1.802
269	1.346	1.191	1.467
367	1.293	1.099	1.430

R Square value	0.952	0.962	0.938
m	-0.00208	-0.00263	-0.00168
k (rate constant)	0.00479	0.00605	0.00386
T½ (days)	144.7	114.5	179.4

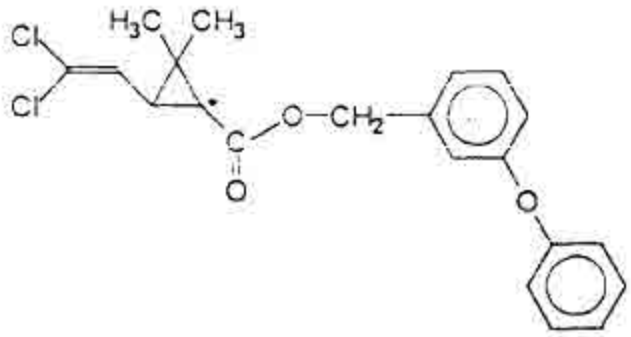
Table 8: Amounts of *cis*- and *trans*-DCVA in aqueous and sediment phases

		Aqueous Phase			Sediment Phase			Total
		$CHCl_2$-1			$CHCl_2/CH_3CN$			
Time (days)	Replicate	cis-DCVA	trans-DCVA	Total DCVA	cis-DCVA	trans-DCVA	Total DCVA	
0	A	na	na	0.00	0.00	0.00	0.00	0.00
0	B	na	na	0.00	0.00	0.00	0.00	0.00
3	A	na	na	0.00	0.00	0.00	0.00	0.00
3	B	na	na	0.00	0.00	0.00	0.00	0.00
7	A	na	na	0.00	0.00	0.00	0.00	0.00
7	B	na	na	0.00	0.00	0.00	0.00	0.00
14	A	0.11	1.31	1.42	0.00	0.68	0.68	2.10
14	B	0.07	0.64	0.71	0.23	0.12	0.35	1.06
30	A	1.08	9.20	10.28	0.00	1.27	1.27	11.55
30	B	0.17	1.71	1.88	0.00	0.44	0.44	2.32
59	A	1.36	9.99	11.35	0.26	1.26	1.52	12.87
59	B	2.40	16.03	18.43	0.78	2.42	3.20	21.63
90	A	2.47	11.87	14.34	2.05	5.25	7.30	21.64
90	B	6.31	19.97	26.28	2.31	4.43	6.74	33.02
120	A	0.78	7.97	8.75	0.72	7.13	7.85	16.60
120	B	1.53	13.37	14.90	0.00	1.80	1.80	16.70
181	A	1.73	5.20	6.93	5.23	7.86	13.09	20.02
181	B	2.34	13.81	16.15	0.00	1.18	1.18	17.33
269	A	1.32	3.09	4.41	4.65	3.92	8.57	12.98
269	B	0.98	5.92	6.90	1.46	7.04	8.50	15.40
367	A	0.00	0.03	0.03	0.43	0.04	0.47	0.50
367	B	0.58	3.73	4.31	0.71	7.06	7.77	12.08

na = not analysed

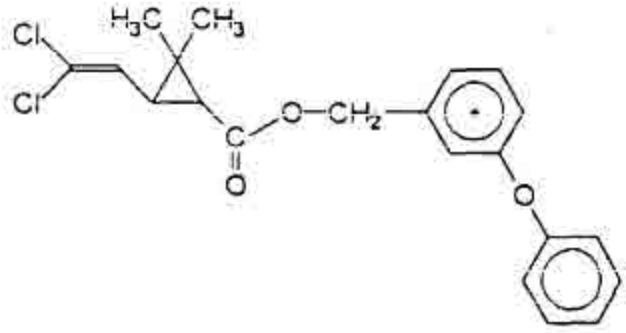
Figure 1: Test materials, indicating the position of the ^{14}C label

Acid label:



* Denotes position of ^{14}C label

Alcohol label:



* Denotes position of ^{14}C label

Figure 2: Reference materials

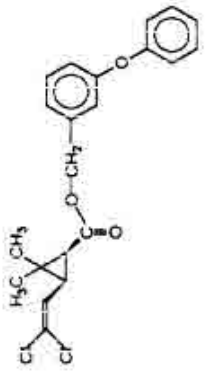
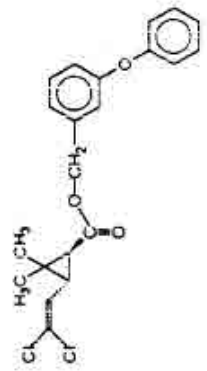
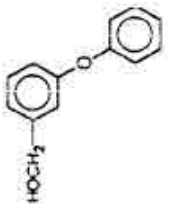
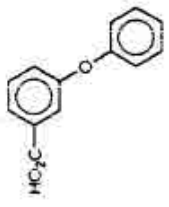
Name	Structure	Source	Lot number	Purity	Expiration Date
cis-Permethrin		FMC Corporation	E6788:90	99.5%	5/95
			E6788:85	99.6%	9/95
trans-Permethrin		FMC Corporation	E6788:91	99.6%	5/95
			E6788:86	99.7%	9/95
3-phenoxybenzyl alcohol		Aldrich	04123EV	98%	4/14/95
		Chem Services	144-119C	99.4%	2/98
3-phenoxybenzoic acid		Aldrich	07727HX	98%	4/18/95
			E6788:84	97.5%	8/95

Figure 2: Reference materials cont'd

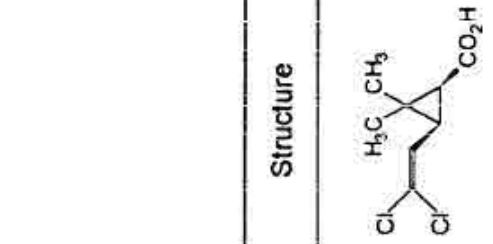
Name	Structure	Source	Lot number	Purity	Expiration Date
cis-dichlorovinyl acid		FMC Corporation	E6788:23	99.3%	5/95
			E6788:23	99.3%	7/96
trans-dichlorovinyl acid		FMC Corporation	E6788:22	99.2%	5/95
			E6788:22	99.2%	7/96

Figure 3: Extraction regime for sediment and water samples

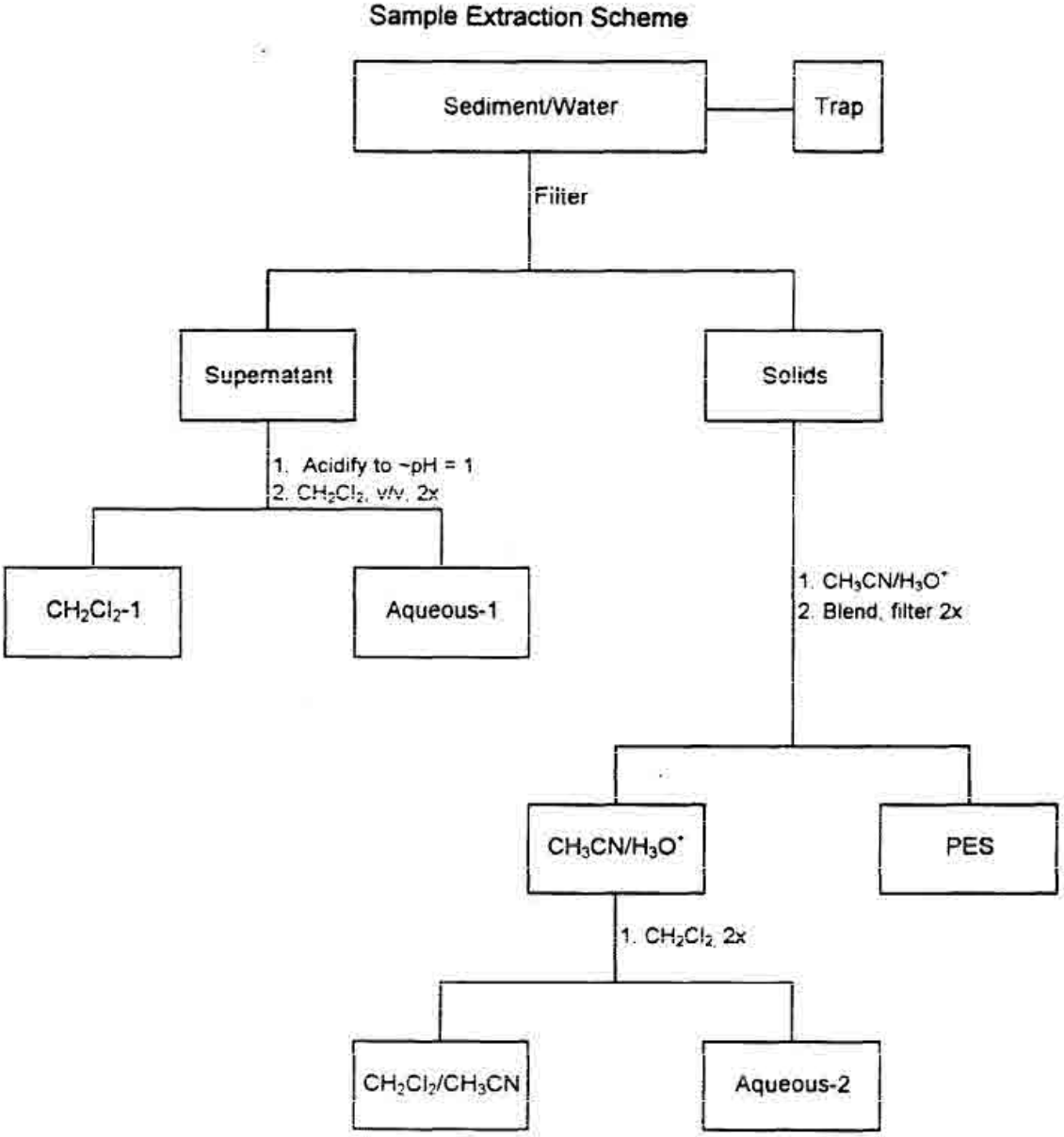


Figure 4: Extraction regime for day 367 PES.

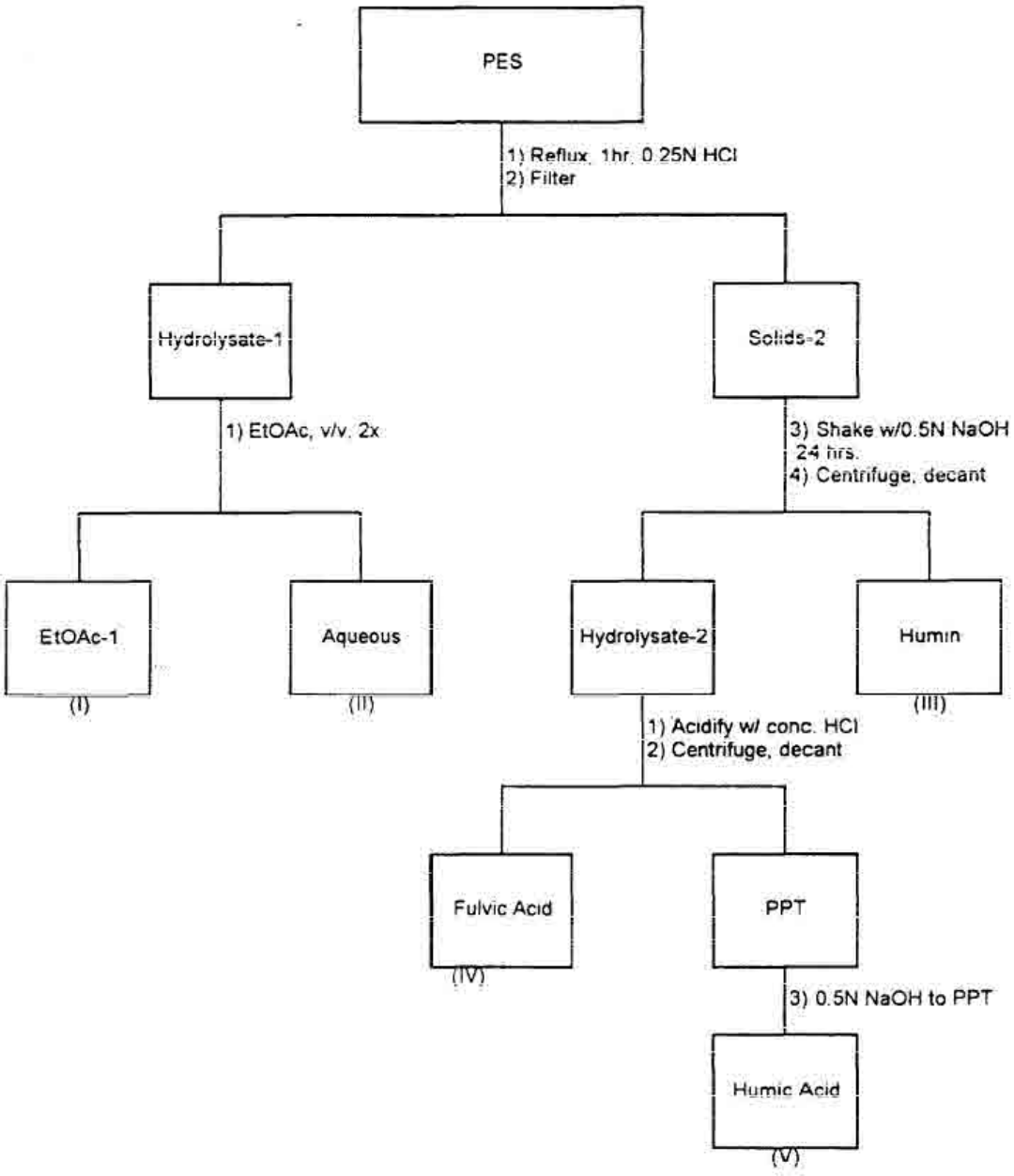


Figure 5: Loss of total, *cis*- and *trans*-permethrin from test systems at various intervals.

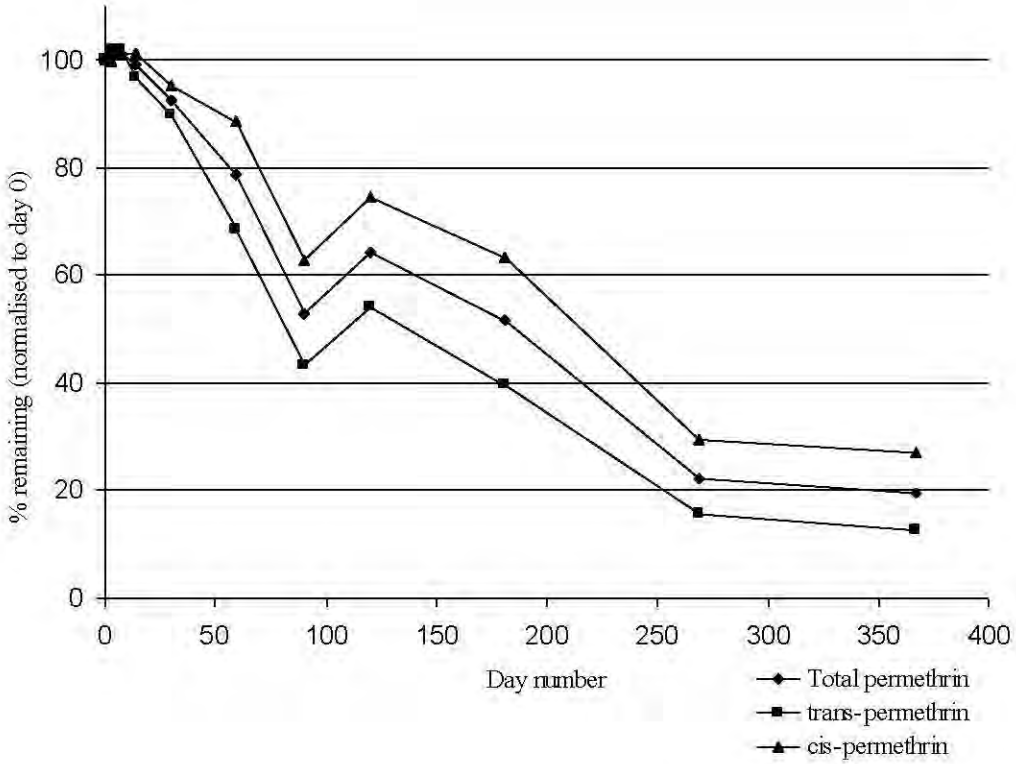


Figure 6: The half-life of total, *cis*- and *trans*-permethrin - plot of log(% permethrin remaining) vs time

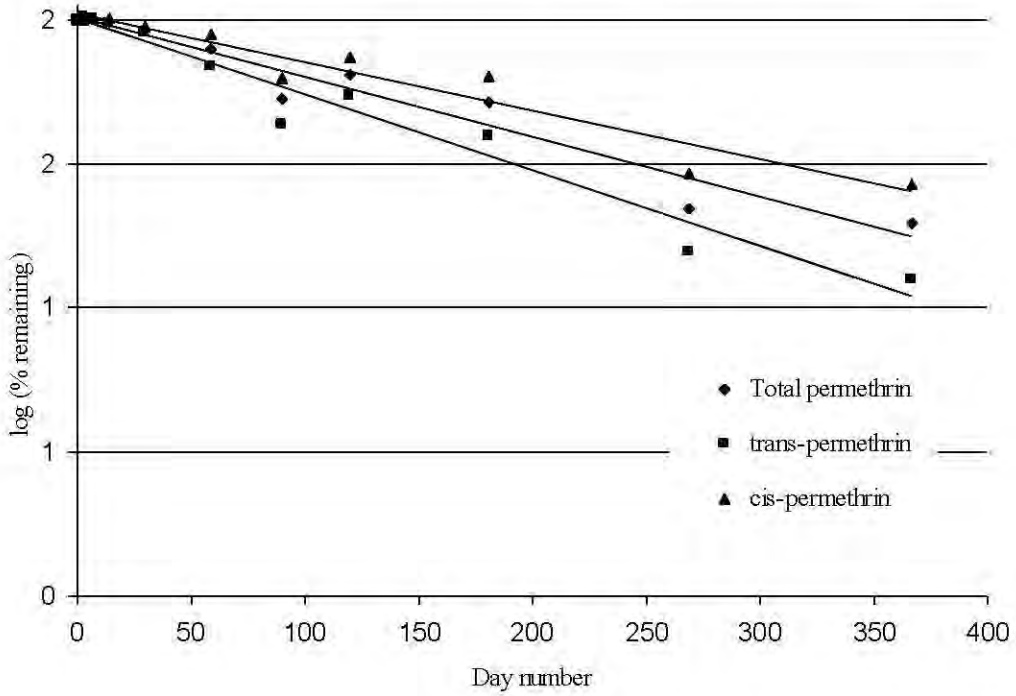
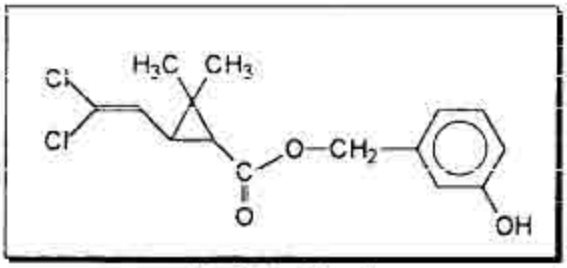
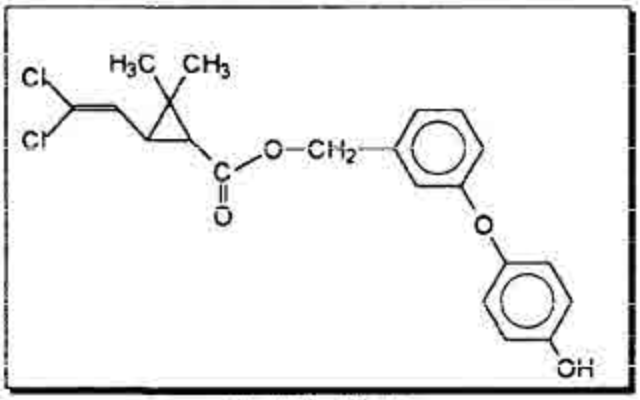


Figure 7: Tentative identities of Metabolites A and B.

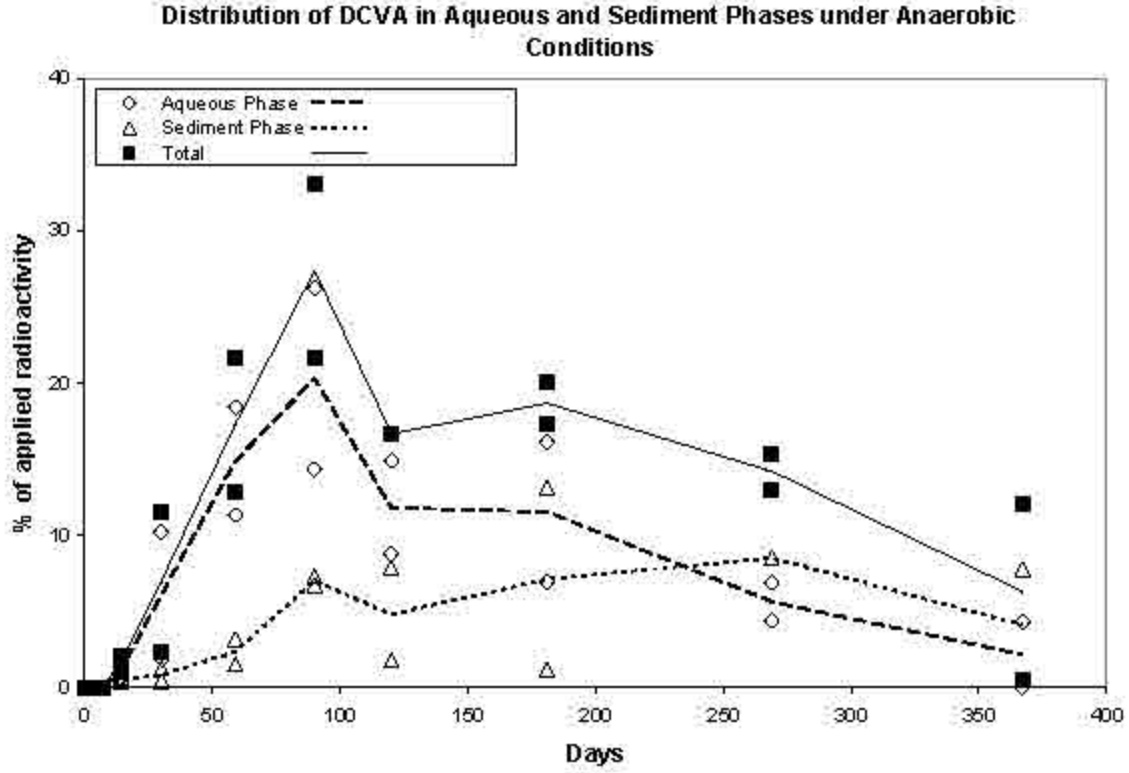


Metabolite A



Metabolite B
(4'-Hydroxy Permethrin)

Figure 8: Formation and decline of *cis*- and *trans*-DCVA in aqueous and sediment phases with time



Section A7.1.3 **Annex Point IIIA.XII.2.1**	**Adsorption/Desorption screening test**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	An EPIWIN calculation of Log Koc returns a value of 5.25 and a Koc of 1.78×10^5. This is largely supported by the results of the full Sorption/Desorption study undertaken in four soils and one sediment (Davis M.L, 1991) which gave a range of Koc values from 2.7×10^4 to 4×10^5. Therefore a justification for non-submission of data is suggested on the grounds that existing data more than adequately cover this data requirement.	
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	*13 April 2005*	
Evaluation of applicant's justification	The RMS agrees with the applicant's justification that existing data, such as the adsorption/desorption batch equilibrium test presented for Annex Point 7.2.3 and supporting information using the EPIWIN model remove the need for an adsorption/desorption screening test. Both the laboratory data and model calculations provide K_{foc} values of a similar order of magnitude as outlined in the above justification. Furthermore, the batch equilibrium test (Davis, 1991) provided a full assessment of the adsorption/desorption characteristics of permethrin on both soil (four types) and sediment (one type) as part of the testing regime.	
Conclusion	The applicant's justification is acceptable. Existing information is supplied and presented (under Annex Point 7.2.3) that provides detailed assessment of the adsorption/desorption properties of permethrin.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.4 Annex Point IIIA.XII.2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary**

Key Study

Official use only

		1 REFERENCE
1.1	**Reference**	Hatfield, M.W; 1996; Aquatic dissipation of permethrin in California and North Carolina. American Agricultural Services Report on Study No. AA940907; GLP; Unpublished
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Bayer CropScience AG
1.2.2	**Companies with a letter of access**	None
1.2.3	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	No guidelines are available. The study was designed to fulfil the EPA 40 CFR 158 requirements for registration of pesticides, specifically Pesticide Assessment Guidelines
2.2	**GLP**	Yes
2.3	**Deviations**	No: Protocol was not to any guidelines
		3 MATERIALS AND METHODS
3.1	**Test material**	Permanone (permethrin formulated product)
3.1.1	**Lot/Batch number**	18382
3.1.2	**Specification**	No data
3.1.3	**Purity**	10.1% Active Ingredient
3.1.4	**Composition of Product**	No data
3.2	**Test ing procedure**	In March 1995, an aquatic dissipation study was initiated in North Carolina (NC) and California (CA) to investigate the water and sediment residue dissipation and mobility of permethrin and its major metabolites, *cis*-DCVA, *trans*- DCVA, and Phenoxybenzoic acid (PBA) in an aquatic environment. The aquatic study was established in small ponds, and ten applications of the test substance were made. Permanone was first applied at 0.07 pounds active ingredient per acre (lb ai/A) on May 5, 1995 (NC) and June 12, 1995 (CA) by broadcast spray to the ponds. A total of 10 applications were made to each treated pond. The total test substance applied was 0.7 lb ai/A and was in excess of the maximum seasonal application rate. Soil/Sediment and pond water samples were collected at specified pre- and post-application timings and were shipped frozen under chain of custody to the analytical lab. Processing consisted of sectioning soil cores, compositing replicates, grinding core sections, and splitting resultant samples into residue and archive subsamples. Processing was not required for water samples. The Soil/Sediment samples were analyzed for *cis*- permethrin, *trans*-

Section A7.1.4 Annex Point IIIA.XII.2.2	Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary

		Key Study	
		permethrin, *cis*-DCVA, *trans*-DCVA, and PBA through 359 (CA) and 361 (NC) days after the last application. The analytical method used was FMC report p.2703M (effective date August 30, 1993 – not reported), entitled "Analytical method for the determination of permethrin, Dichlorovinyl Acid and m-Phenoxybenzoic Acid Residues in/on Soil". The method was validated for *cis*-permethrin, *trans*- permethrin, *cis*-DCVA, *trans*-DCVA, and PBA in soil, with recoveries of 94, 94, 100, 92, and 98%, respectively. Recoveries of 106, 106, 105, 108, and 110% were obtained for sediment validation. The limit of quantitation (L.O.Q.) was 10 parts per billion (ppb). The analytical method was determined to be suitable for analyses of Soil/Sediment in the study. The pond water samples were analyzed under method ACG No. 280 (effective date of July 14, 1993 – not reported). The method is entitled Determination of permethrin in Water (Hexane Extraction). The water method was validated for *cis*-permethrin, *trans*-permethrin, PBA, *cis*-DCVA, and *trans*-DCVA with recoveries of 97, 90, 94, 94, and 95%, respectively. The L.O.Q. was 0.5 ppb. **4 RESULTS**	
4.1	**Dissipation of test substance**	Under aquatic environmental conditions, *cis*-permethrin and *trans*-permethrin were relatively immobile, remaining primarily in the sediment fraction (0-5 cm). One minor detection of *cis*/*trans*-DCVA was found in sediment fractions at 0DA9A* from the NC site. No metabolite detections were noted in CA. The metabolites *trans*-DCVA and PBA were detected in water samples immediately after the second application in both study sites. Cis-DCVA residues were obtained after 0DA5A (CA) and 0DA6A (NC) and disappeared by 90DA10A in NC and 120DA10A in CA. Sediment residues in CA declined from 0.153 ppm at ODA10A to 0.017 ppm at 90DA10A. Sediment residues were 0.042 ppm at 0DA10A and declined to 0.013 ppm at 272DA10A in NC. Average sediment residue of 0.052 ppm for *cis*-permethrin and 0.013 ppm for *trans*-permethrin was determined for 361DA10A in NC. Half-lives in sediment were calculated to be 256 and 62 days for *cis*-permethrin and *trans*-permethrin at the NC site. Half-lives in pond water were 3.1 and 1.3 days in NC. Likewise in CA, sediment half-lives for *cis*- permethrin and *trans*-permethrin were 118 and 18 days, respectively. Half lives in pond water were 1.8 and 1.4 in CA. *0DA9A indicates 0 Days After 9th Application. This nomenclature is continued throughout the report.	X
4.2	**Degradation products**	There were no detections of *cis*/*trans*-DCVA or PBA in CA and NC sediment. The metabolites *trans*-DCVA and PBA were detected in water samples immediately after the second application in both study sites. Cis-DCVA residues were obtained after 0DA5A (CA) and 0DA6A (NC) and disappeared by 90DA10A in NC and 120DA10A in CA. Metabolite half-lives for *cis*-DCVA, *trans*-DCVA, and PBA were also calculated for the water matrices only. Half-lives in CA were	X

Section A7.1.4 Annex Point IIIA.XII.2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary**	
	Key Study	
	28, 22, and 7.5 days for *cis*-DCVA, *trans*-DCVA, and PBA, respectively. The half-life of each metabolite in NC water was very similar to the CA water dissipation (Figure 13). Halflives of 33, 23, and 14 days were reported for the metabolites in NC water.	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study investigates the fate of permethrin in sediment and pond-water after 10 consecutive applications (made over 10 consecutive days) at an application rate of 0.7 lb ai/A. Ponds in California and North Carolina were treated, and water and sediment samples removed for analysis. The fate of permethrin was traced over the course of 270 days (following the last application), with frequent sampling and analysis of samples for permethrin and it's major metabolites, DCVA and PBA. The methodology is reported in detail, as are environmental conditions, climate, soil/pondwater characteristics. The study was undertaken and audited according to the requirements of GLP.	X
5.2 Results and discussion	The results indicate; • The half-life in pond water is 1.3 to 3.1 days, and it is so short as to make distinction between loss rates due to environmental conditions difficult to predict. • The half-life in sediment ranges from 18 to 256 days, the *cis*-isomer being significantly more resistant to degradation than the *trans*-isomer. Loss in the CA site was significantly quicker than the NC site. • Metabolites were detected only in the water compartment and disappeared by 90DA10A in NC and 120DA10A in CA, respectively.	X
5.3 Conclusion	This report describes a very detailed investigation into the behaviour of permethrin in real environmental scenarios. The rapid losses of permethrin from the aqueous phase, followed by degradation in the sediment compartment fully support the findings of laboratory based tests.	
5.3.1 Reliability	1	
5.3.2 Deficiencies	Not applicable	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*18 April 2005 (amended September 2009)*
Materials and Methods	The applicant's version is acceptable.

Section A7.1.4 Annex Point IIIA.XII.2.2	**Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary**

	Key Study
Results and discussion	Applicant's version is acceptable but the following points should be noted. Section 4.1, Section 4.2 Presumably the half-life values in water and sediment reported for parent and metabolites reflect the overall result of transfer processes on each compartment and are not degradation-only values. Section 4.2 (Degradation products) It is stated that there were no detections of cis/trans-DCVA or PBA in sediment from the test sites. However, according to Section 4.1 (Dissipation of test substance), there was one minor detection of cis/trans-DCVA in sediment from the North Carlina site at 0 days after the ninth application.
Conclusion	Applicants's version is acceptable but the following points should be noted. Section 5.1 (Materials and methods) It is stated that the fate of permethrin was traced over 270 days following the last application but according to Section 3.2 (Testing procedure), samples from the California site were analysed through 359 days after the last application, and samples from the North Carolina site were analysed through 361 days after the last application. Section 5.2 (Results and discussion) It is stated that metabolites were only detected in the water compartment. However, according to Section 4.1 (Dissipation of test substance), there was one minor detection of cis/trans-DCVA in sediment from the North Carlina site at 0 days after the ninth application. Overall, the results indicate rapid loss of permethrin from water to the sediment compartment, where degradation occurs. The metabolites formed (cis/trans-DCVA and PBA) were found mainly in the water compartment. The findings are in broad agreement with the results of the water/sediment studies reported in Section A.7.1.2.2.2.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	

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

Section A7.1.4.1 Annex Point IIIA.XII.2.2	Field studies on accumulation in sediment	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	Field studies on accumulation in sediment are only required if non-extractable residues are formed exceeding 70% of the initial dose in the water sediment system, or if the mineralisation rate is less than 5% in 100 days (The Technical Guidance on Data Requirements for Active Substances). In Robinson & Ryan (1996[1]), CO_2 production in an aerobic aquatic sediment study achieved 5.9% in 30 days. In Robinson & Ryan (1996[1]), non-extractable residues in an aerobic aquatic sediment study were 18% in 30 days. Since neither of the required criteria are met, further investigation is not 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	*13 April 2005*
Evaluation of applicant's justification	The aerobic water/sediment study (Robinson and Ryan, 1996a) indicate that the required criteria for a field study on accumulation in sediment were not met under aerobic conditions and that a field study on the accumulation of permethrin is not required. In addition, the anaerobic water/sediment study (Robinson and Ryan, 1996b) shows that maximum CO_2 levels of between 23.4% and >98% of applied radioactivity were observed by the end of the study. NER levels in the sediment reached a maximum of between 30.7% and 33.9% for both radiolabelled substances by the end of the incubation period. Therefore, following a water/sediment study under both aerobic and anaerobic conditions a field study on the accumulation of permethrin is not required.
Conclusion	The applicant's justification is acceptable, with the addition of the anaerobic water/sediment study as supporting information.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.1 Aerobic Degradation in Soil, initial study

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hawkins, D.R.; 1992; The aerobic soil metabolism of 14C - Permethrin. Report number HRC/ISN 251/911499; GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Syngenta	
1.2.2	**Companes with letter of access**	Bayer Environmental Science	
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**	Yes	
2.3	**Deviations**	Yes: Degradation was only assessed in one soil.	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	Two separate radiolabelled [^{14}C]permethrin test materials were used in the study, labelled in the cyclopropyl position (acid[^{14}C]permethrin) and phenyl (alc[^{14}C]permethrin), as shown in Figure 1. The structures of reference materials used for co-chromatography are shown in Figure 2.	
3.1.1	**Lot/Batch number**	Both synthesised in-house at ICI Plant Protection division, Jealott's Hill Research Station. acid[^{14}C]permethrin: Batch90-J19 alc[^{14}C]permethrin: Batch 90-J8	
3.1.2	**Specification**	acid[^{14}C]permethrin: *cis*:*trans* ratio nominal 50:50 alc[^{14}C]permethrin: *cis*:*trans* ratio nominal 40:60	
3.1.3	**Purity**	acid[^{14}C]permethrin: minimum 98.1% alc[^{14}C]permethrin: minimum 97.4%	
3.1.4	**Further relevant properties**	acid[^{14}C]permethrin: Specific activity 1.957 GBq mmol^{-1} alc[^{14}C]permethrin: Specific activity 1.980 GBq mmol^{-1}	
3.1.5	**Composition of Product**	None	
3.1.6	**TS inhibitory to microorganisms**	No	
3.1.7	**Specific chemical analysis**	**Hydroxide solutions from traps**; A suitable aliquot was was analysed by LSC for total radioactivity. **Soil**; All samples were extracted by shaking for 30 min consecutively with acetonitrile (approx 60ml x 2). All samples except day 0 samples were also heated under reflux with acetonitrile/water (7/3) for 3 hours. After each extraction, samples were centrifuged, and the supernatant separated from the soils. The cold extract supernatants were combined and analysed by LSC, to provide extract recovery data. A portion was then concentrated by	

Section A7.2.1 **Aerobic Degradation in Soil, initial study**

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

rotary evaporation under nitrogen to 1 to 2 ml and duplicate aliquots (25 µl) radioassayed. Recovery from the concentration process was >95% in all cases, and was assumed to be quantitative. Extracts were then analysed by TLC and HPLC

Reflux extracts were concentrated by rotary evaporation to an aqueous residue which was then radioassayed. The pH was adjusted to pH2 with HCl and an aliquot added to a pre-conditioned C8 bondelut column. The column was washed with a pH2 buffer, and eluted with acetonitrile. Aliquots were measured by LSC where required, mass balance data obtained, and aliquots analysed by TLC. The total proportions of radioactivity applied to the soil did not exceed 1.8%.

The soil was air dried, and subsamples combusted for LSC analysis.

Extract analysis: were analysed by thin layer chromatography (TLC) and high performance liquid chromatography (HPLC).

TLC was carried out using pre-coated normal phase $Si_{60}F_{254}$ silica gel plates, under the following conditions;

Solvent system 1: Hexane:Diethyl ether 10:1 v/v

Solvent system 2: Chloroform:ethyl acetate:methanol 6:3:1

Solvent system 3: Toluene:hexane:acetic acid 15:13:2

Solvent system 4: Hexane:toluene:triethylamine 3:3:1 (2/3 times)

HPLC was carried out under the following conditions;

HPLC 1: Radiochemical purity

Column: Zorbax ODS 4.6 x 250 mm

Mobile phase Acetonitrile:water 85:15 @ 2 ml min^{-1}

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 or 400 µl CaF_2 solid cell. A fraction collector was used to collect column eluate for quantification.

HPLC 2: Extract analysis

Column: Zorbax ODS 4.6 x 250 mm

Mobile phase A: Water, B: CH_3CN

Gradient;

Time	%A	%B	Flow
0	15	85	2.0
22	15	85	2.0
23	0	100	2.0
30	0	100	2.0

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 or 400 µl CaF_2 solid cell. A fraction collector was used to collect column eluate for quantification.

Samples were co-chromatographed alongside reference standards of permethrin and metabolites as shown in Figure 2.

3.2 Reference substance No

3.2.1 Initial No

Section A7.2.1 Aerobic Degradation in Soil, initial study

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

	concentration of reference substance		
3.3	**Testing procedure**		
3.3.1	**Soil types**	Described in tabular form (see table A7_1_1_2-1)	
3.3.2	**Test system and conditions**	Described in tabular form (see table A7_1_1_2-2) Soil samples were incubated aerobically under sterile conditions (90 days) and non-sterile conditions (365 days). They were maintained in darkness at 25°C in flow through systems (Figure 3) to trap volatile radiolabelled compounds including $^{14}CO_2$. The soil water content was maintained at 75%.	
3.3.3	**Method of preparation and dosing of test soil**	A stock solution of each isomer of permethrin was prepared such that 500 µl of methanol/water (1/4 v/v) was equivalent to an application rate of 1.6 mg kg^{-1}. Soil was dosed as in table A7_1_1_2-2.	
3.3.4	**Initial TS concentration**	1.6 mg kg^{-1} on a dry weight basis	
3.3.5	**Duration of test**	365 days	
3.3.6	**Analytical parameter**	Specific analysis	
3.3.7	**Sampling**	Non-sterile: days 0, 1, 3, 7, 14, 30, 60, 90, 120, 181, 275, 365 Sterile: days 7, 30, 90	
3.3.8	**Intermediates/ degradation products**	Identified (See 4.1.3)	
3.3.9	**Controls**	None	
		4 RESULTS	
4.1	**Degradation of test substance**		
4.1.1	**Recovery of radioactivity**	Total recoveries of radioactivity in non-sterile soils ranged from 80-105%. Total recoveries of radioactivity in sterile soils ranged from 91-99%. Results are shown in Table A7_1_1_2-3 to A7_1_1_2-6.	
4.1.2	**Degradation**	The amount of permethrin in extracts (mean of 4 samples characterised using TLC and HPLC methods) is given in tabular form (see table A7_1_1_2-7). CO_2 evolution achieved >40% by the end of the test period. These data are shown graphically in Figure 4. In sterile soils, after 90 days the amount of permethrin remaining was approximately 80%, indicating 20% loss which could be accounted for by physical degradation processes.	X
4.1.3	**Intermediates/ degradation products**	Minor degradation products were identified, and a route of degradation was described (Figure 5); the two main metabolites (>5% of applied at some stage of the exposure period) were identified as DCVA and PBA.	X

Section A7.2.1 Aerobic Degradation in Soil, initial study

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The testing protocol, although not to any recognised guidelines, incorporated essential elements necessary to enable confidence in the output. The soil was characterised, including description of biomass. The test system was an enclosed flowthrough system designed to allow for mass balance determination, which were high throughout the course of the study, indicating no material was lost and confidence can be placed in the results. Soils were prepared and dosed as individual sacrificial vessels, allowing total contents analysis, which excluded any losses or variation due to sub-sampling. The inclusion of sterile soils enabled estimation of the impact of physical processes such as hydrolysis. The analysis was based on TLC and HPLC, which was capable of resolving *cis-* and *trans-* isomers.
5.2	**Results and discussion**	The results, shown in Table A7_1_1_2-7 indicate that permethrin can be rapidly degraded in the terrestrial environment. The degradation appeared to be bi-phasic, with the initial rapid phase seeing a reduction from 95.5% applied radiation to 16.4% applied radiation after 90 days. After 365 days the permethrin accounted for 3.6% of the applied radiation. The slow-down in the degradation probably reflects the decreasing microbial activity inherent in sieved soils in closed test systems. Based on data from the first 90 day period, the half-life of permethrin in soil was 37 days, assuming first order kinetics. The half-life of permethrin in sterile soil would be in excess of 300 days, based on the reported data. This loss could be accounted for by physical degradation, such as hydrolysis. The metabolites identified were typical of either ester cleavage or phenyl substitution, the two main metabolites (>5% of applied at some stage of the exposure period) were identified as DCVA and PBA.
5.3	**Conclusion**	The test protocol does not compare with current guidelines for testing soil degradation, being performed in a single soil. However, it is designed to minimise loss of test material, allow derivation of DT50, and allow for characterisation of metabolites. The sampling points were sufficient over the beginning of the test period to allow real confidence in the derived DT50 values.
5.3.1	**Reliability**	1
5.3.2	**Deficiencies**	Test was only performed in one soil type.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1 March 2011
Materials and Methods	The applicant's version is acceptable.
Results and discussion	Adopts applicant's version, with the following revision: **Comments:** (Section 4.1.2) The following should be added: Under non-sterile conditions permethrin was observed to decline biphasically to about 16% AR after 90 days incubation and continued to decline to 4% after 365 days. The initial DT_{50} of permethrin in a sandy loam soil was calculated to be 37 days, assuming first order kinetics over the first 90 days. The applicant's summary only gives data for total permethrin (cis and trans isomers combined) and does not give information on the behaviour of the individual isomers. However, the original study report shows that the cis-isomer degraded more slowly than the trans-isomer. For ^{14}C-phenyl-labelled permethrin, the ratio of cis/trans isomers changed from 40/60 at day 0 to 50/50 at day 30 to 78/22 by day 365. (Section 4.1.3) The following should be added: The main metabolites identified above 10% of the applied radioactivity following the metabolism of permethrin were *trans*-DCVA (up to 11.3% AR) and PBA (up to 15% AR) after 14-30 days. These metabolites declined towards the end of the incubation period to ~3% after 365 days. A further minor metabolite, 3-(2,2-dichlorovinyl)-2-methylcyclopropane-1,2-dicarboxylic acid, was observed at a maximum of 7% AR after 14-30 days.
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	**Comments:** (Section 2.3) In line with current guidelines (OECD 307, SETAC 1995) the following deviations were observed: The test temperature for the aerobic soil degradation study was maintained at 25 °C ± 2 °C, instead of 20 °C ± 2 °C. The test soil moisture was not reported in the study. These deviations are considered minor deviations to current test guidelines, which do not affect the scientific validity of the study. The observed biphasic degradation profile, with a much slower phase occurring after about 90 days, might have been an experimental artefact due to low initial levels of microbial biomass and its further decline over the incubation period. The microbial biomass by the end of the study was less than 1% of total organic carbon, which is an indication of poor microbial status. Also, permethrin was incubated for 365 days in this laboratory study, which is far beyond the limit of 120 days normally recommended for such studies (e.g. OECD TG 307). A decrease in soil microbial activity would be expected after 120 days in an artificial laboratory system isolated from natural replenishment. The RMS evaluator is of the opinion that only data from the first 90 days of the study can be considered to be reliable.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*

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

Table A7_1_1_2-1: Classification and physico-chemical properties of soils

	Soil 1 «Frensham»
Soil order	No data
Soil series	No data
Classification	Sandy loam
Location	Frensham, Surrey, UK
Horizon	No data
Sand [%]	75
Silt [%]	19
Clay [%]	5
Organic matter [%]	2.1
Carbonate as $CaCO_3$	No data
insoluble carbonates [%]	No data
pH (1:1 H_2O)	6.63
Cation exchange capacity (MEQ/100 g)	6.7
Extractable cations (MEQ/100 g)	No data
Microbial biomass at Day 0 At Day 365	32.8 mg C/100g 5.3 mg C/100g

Table A7_1_1_2-2: Test system and conditions

Criteria	Details
6.1.1 Test vessels	Approx. 60 g (dry weight) soil was weighed into 5.4 cm diameter glass crystallising dishes. Depending on required samples, 6 or 12 dishes were placed in glass columns, as shown in Figure 3.
6.1.2 Number of test vessels	[Per radioisotope] 24 non-sterile, 6 sterile. Total vessel analysis per replicate, 2 replicates analysed per time point.
6.1.3 Aeration device	Negative pressure pump system, closed system with exuent air drawn through a series of traps to remove, and thus quantify, any volatile materials.
6.1.4 Measuring equipment	None
6.1.5 Test temperature	25 ± 2°C
6.1.6 Light conditions	Dark
6.1.7 Test performed in closed vessels due to significant volatility of TS	No – flowthrough aeration to trap evolved volatile products

Table A7_1_1_2-3: Extraction and recovery of radioactivity from non-sterile Frensham sandy loam soil after application of ^{14}C–cyclopropyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
0	7(A)	97.3	-	97.3	0.3	-	97.6
	18(B)	100.1	-	100.1	0.3	-	100.4
1	8(A)	93.6	3.1	96.7	0.2	0.1	97.0
	23(B)	91.4	3.9	95.3	0.5	0.04	95.8
3	70(A)	83.4	8.4	91.8	3.3	0.4	95.5
	15(B)	87.1	6.5	93.6	2.6	0.2	96.4
7	6(A)	86.4	7.8	94.2	1.4	1.8	97.4
	25(B)	84.3	7.8	92.1	1.1	0.8	94.0
14	13(A)	80.5	9.7	90.2	1.8	4.6	96.6
	20(B)	86.6	7.8	94.4	0.9	2.4	97.7
30	69(A)	33.0	19.0	52.0	17.7	10.2	79.9
	21(B)	54.5	16.8	71.3	6.3	7.8	85.4
60	11(A)	50.1	18.8	68.9	14.7	18.8	102.4
	16(B)	32.4	21.1	53.5	24.1	17.6	95.2
90	80(A)	20.3	13.9	34.2	37.0	25.1	96.3
	28(B)	26.8	16.4	43.2	29.1	25.8	98.1
120	5(A)	33.5	14.8	48.3	25.9	30.8	105.0
	19(B)	19.7	15.8	35.5	24.0	31.8	91.3
181	14(A)	25.5	12.5	38.0	26.0	37.9	101.9
	24(B)	26.4	14.3	40.7	18.3	40.9	99.9
275	9(A)	9.9	10.0	19.9	34.3	44.6	98.8
	17(B)	11.9	12.1	24.0	31.2	46.1	101.3
365	79(A)	4.8	7.1	11.9	42.6	48.6	103.1
	27(B)	13.0	12.5	25.5	20.2	50.3	96.0

Table A7_1_1_2-4: Extraction and recovery of radioactivity from non-sterile Frensham sandy loam soil after application of ^{14}C–phenyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
0	42(D)	98.2	-	98.2	0.2	-	98.4
	58(E)	99.8	-	99.8	0.2	-	100.0
1	36(D)	92.3	4.1	96.4	0.6	0.1	97.1
	55(E)	95.7	3.6	99.3	0.4	0.1	99.8
3	35(D)	92.3	5.0	97.3	0.7	0.3	98.3
	60(E)	90.7	5.4	96.1	0.8	0.3	97.2
7	46(D)	84.4	7.1	91.5	3.5	1.2	96.2
	59(E)	77.9	8.6	86.5	7.3	1.5	95.3
14	38(D)	69.2	9.5	78.7	8.5	3.5	90.7
	50(E)	70.8	9.5	80.3	5.0	4.8	90.1
30	48(D)	73.2	12.0	85.2	4.0	9.7	98.9
	52(E)	63.6	12.2	75.8	7.0	11.6	94.4
60	40(D)	41.2	7.9	49.1	23.2	20.4	92.7
	56(E)	48.1	7.8	55.9	20.9	16.9	93.7
90	37(D)	34.4	9.0	43.4	28.1	27.9	99.4
	49(E)	22.0	7.6	29.6	34.3	22.2	86.1
120	45(D)	19.6	7.1	26.7	33.2	33.2	93.1
	61(E)	24.5	7.8	32.3	27.5	27.7	87.5
181	43(D)	11.9	6.5	18.4	25.0	39.8	83.2
	57(E)	21.1	9.1	30.2	27.9	34.4	92.5
275	39(D)	13.7	7.5	21.2	28.8	44.0	94.0
	54(E)	21.8	8.2	30.0	34.6	40.1	104.7
365	41(D)	10.0	5.9	15.9	26.6	46.5	89.0
	51(E)	12.5	8.0	20.5	24.8	42.5	87.8

Table A7_1_1_2-5: Extraction and recovery of radioactivity from sterile Frensham sandy loam soil after application of ^{14}C–cyclopropyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
7	31(C)	95.3	2.0	97.3	0.1	0.02	97.4
	33(C)	93.5	2.6	96.1	0.1	0.02	96.2
30	29(C)	90.9	6.0	96.9	0.3	0.1	97.3
	32(C)	92.1	5.7	97.8	0.3	0.1	98.2
90	30(C)	83.2	7.0	90.2	0.8	0.2	91.2
	34(C)	86.3	7.0	93.3	0.8	0.2	94.3

Table A7_1_1_2-6: Extraction and recovery of radioactivity from sterile Frensham sandy loam soil after application of ^{14}C–phenyl permethrin at a rate of 1.6 mg kg^{-1}

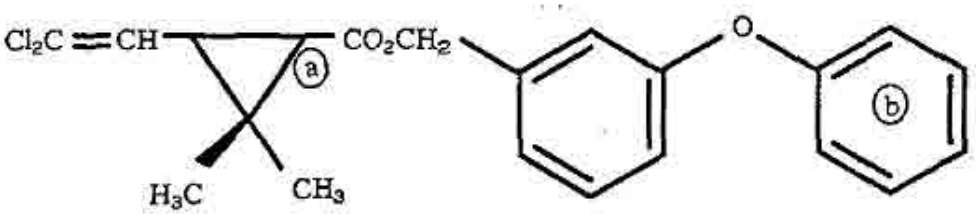
Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
7	64(F)	96.1	1.9	98.0	0.1	0.01	98.1
	67(F)	95.5	3.3	98.8	0.1	0.01	98.9
30	63(F)	92.4	4.7	97.1	0.2	0.1	97.4
	68(F)	90.6	6.9	97.5	0.3	0.1	97.9
90	65(F)	85.2	7.6	92.8	1.0	0.1	93.9
	66(F)	83.4	9.2	92.6	1.0	0.1	93.7

Table A7_1_1_2-7: Loss of permethrin in aerobic soils and CO_2 evolution

Time (days)	Permethrin remaining (%)	$^{14}CO_2$ evolution (%)
0	95.4	
1	91.1	0.1
3	83.3	0.3
7	74.5	1.3
14	65.4	3.8
22		6.9
30	44.5	9.8
36		11.7
44		14.0
52		16.3
60	30.6	18.4
76		22.3
90	16.4	25.2
105		28.5
120	12.5	30.9
135		33.0
150		35.2
164		36.9
181	9.8	38.2
196		39.3
211		40.4
226		41.3
241		42.1
255		42.8
275	6.2	43.7
290		44.4
304		44.9
314		45.3
329		45.7
346		46.3
365	3.6	47.0

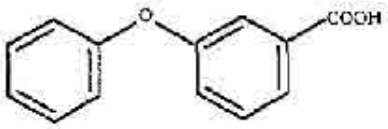
Figure 1: Permethrin structure, showing position of the radioisotope



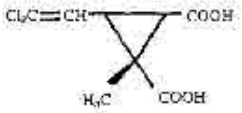
a Denotes position of ^{14}C–cyclopropyl label

b Denotes position of ^{14}C–phenyl label

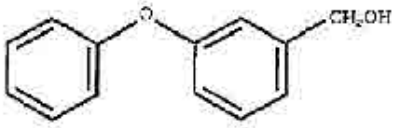
The following reference substances were supplied by ICI Agrochemics



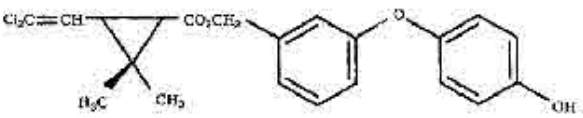
3–Phenoxybenzoic acid (3–PBA)
(R41207)



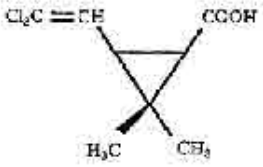
3–(2,2–dichlorovinyl)–2–methylcyclopropane
1,2–dicarboxylic acid
(ICIA0557/66/03)



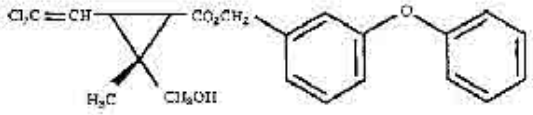
3–Phenoxybenzyl alcohol (3PBAlc)
(R79406)



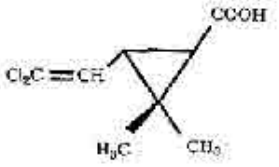
4'–Hydroxypermethrin
(R251537)



cis–3–(2,2–dichlorovinyl)–
2,2–dimethylcyclopropanecarboxylic acid
(*cis*–DCVA)



Hydroxypermethrin
(R252022)



trans 3–(2,2–dichlorovinyl)–
2,2–dimethylcyclopropanecarboxylic acid
(*trans*–DCVA)

Figure 3: Test design

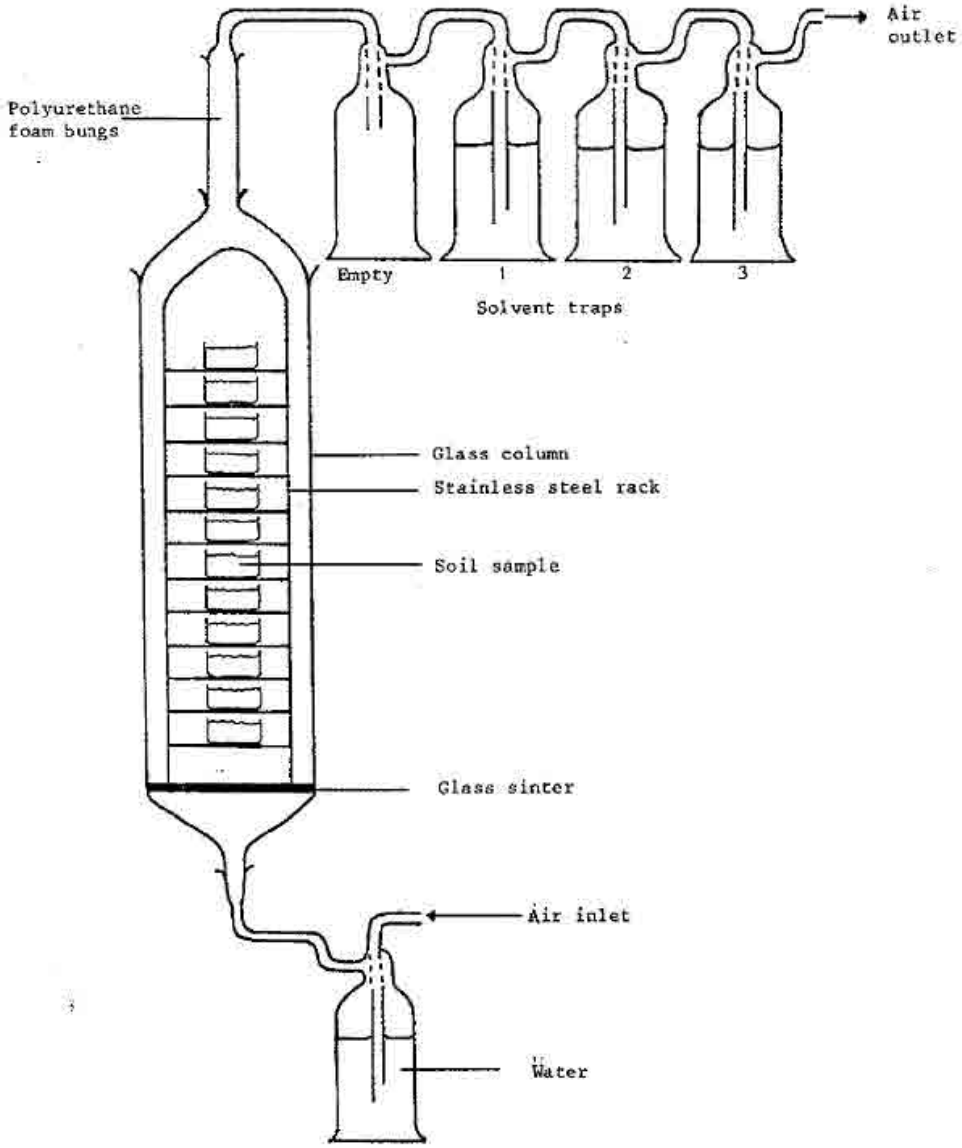


Figure 4: Loss of permethrin in aerobic soils and CO_2 evolution

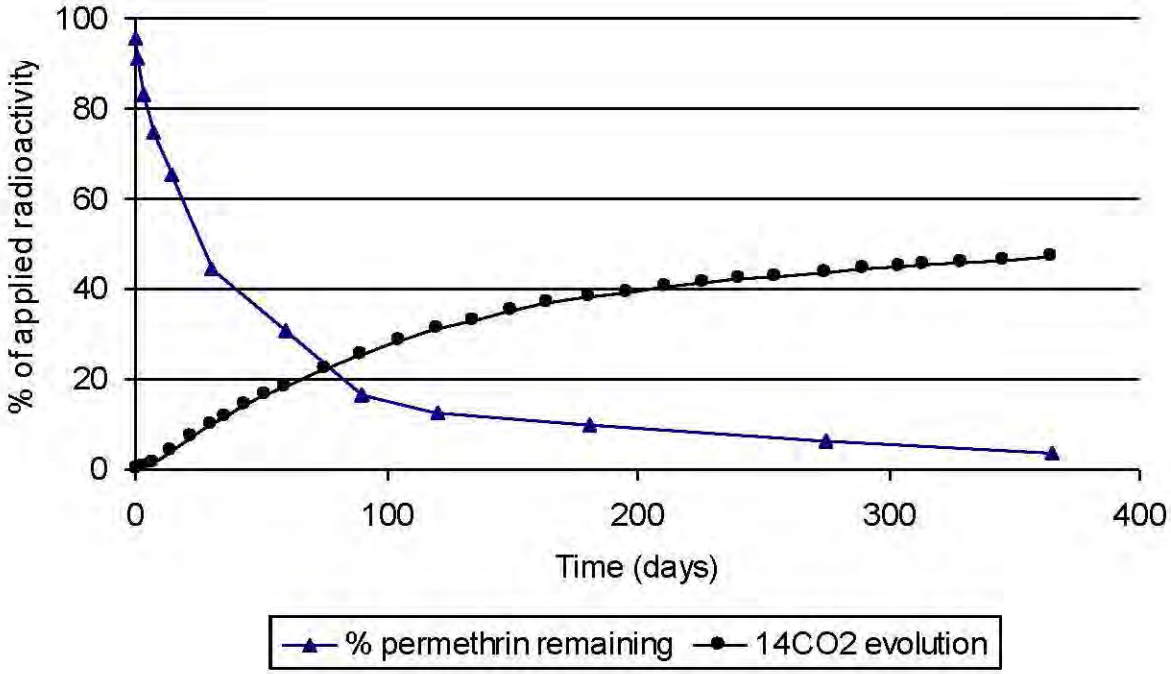
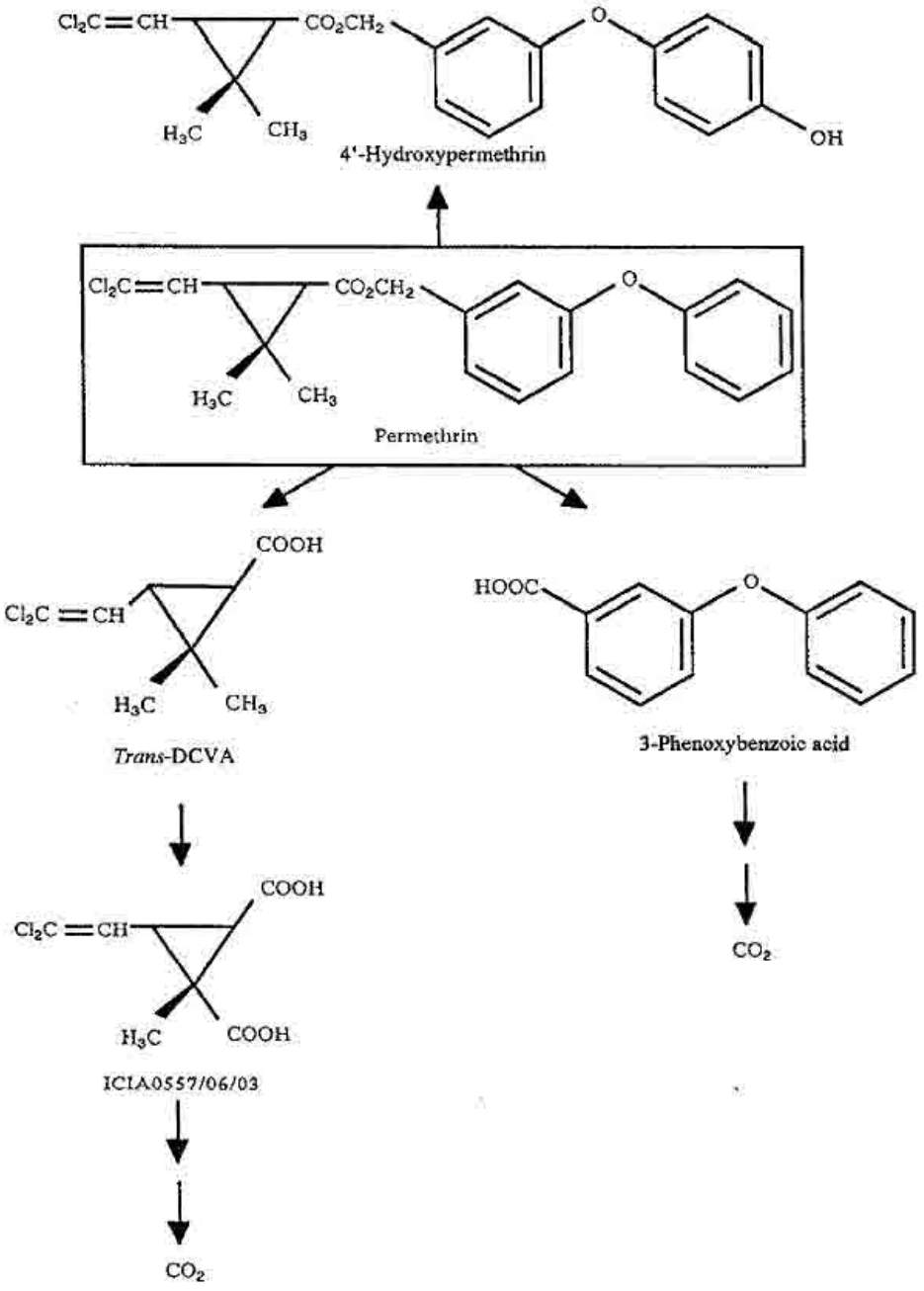


Figure 5: Proposed degradation pathway for permethrin in soil



Section A7.2.2 **Annex Point IIIA.XII.2.2**	**Aerobic degradation in soil, further study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	
Detailed justification:	Headline only	
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 **Evaluation of applicant's justification** **Conclusion** **Remarks**		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Give date of comments submitted *Discuss if deviating from view of rapporteur member state* *Discuss if deviating from view of rapporteur member state* **Remarks**		

Section A7.2.2.1	**The rate and route of degradation**
Annex Point IIA7.6.1.1 **Annex Point IIA7.6.1.2**	**including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Hawkins, D.R.; 1992; The aerobic soil metabolism of 14C - Permethrin. Report number HRC/ISN 251/911499; GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Syngenta	
1.2.2	**Companes with letter of access**	Bayer Environmental Science	
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**	Yes	
2.3	**Deviations**	Yes: Degradation was only assessed in one soil.	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	Two separate radiolabelled [^{14}C]permethrin test materials were used in the study, labelled in the cyclopropyl position (acid[^{14}C]permethrin) and phenyl (alc[^{14}C]permethrin), as shown in Figure 1. The structures of reference materials used for co-chromatography are shown in Figure 2.	
3.1.1	**Lot/Batch number**	Both synthesised in-house at ICI Plant Protection division, Jealott's Hill Research Station. acid[^{14}C]permethrin: Batch90-J19 alc[^{14}C]permethrin: Batch 90-J8	
3.1.2	**Specification**	acid[^{14}C]permethrin: *cis*:*trans* ratio nominal 50:50 alc[^{14}C]permethrin: *cis*:*trans* ratio nominal 40:60	
3.1.3	**Purity**	acid[^{14}C]permethrin: minimum 98.1% alc[^{14}C]permethrin: minimum 97.4%	
3.1.4	**Further relevant properties**	acid[^{14}C]permethrin: Specific activity 1.957 GBq mmol^{-1} alc[^{14}C]permethrin: Specific activity 1.980 GBq mmol^{-1}	
3.1.5	**Composition of Product**	None	
3.1.6	**TS inhibitory to microorganisms**	*No*	

3.1.6 Specific chemical analysis

Hydroxide solutions from traps; A suitable aliquot was was analysed by LSC for total radioactivity.

Soil; All samples were extracted by shaking for 30 min consecutively with acetonitrile (approx 60ml x 2). All samples except day 0 samples were also heated under reflux with acetonitrile/water (7/3) for 3 hours. After each extraction, samples were centrifuged, and the supernatant separated from the soils.

The cold extract supernatants were combined and analysed by LSC, to provide extract recovery data. A portion was then concentrated by rotary evaporation under nitrogen to 1 to 2 ml and duplicate aliquots (25 µl) radioassayed. Recovery from the concentration process was >95% in all cases, and was assumed to be quantitative. Extracts were then analysed by TLC and HPLC

Reflux extracts were concentrated by rotary evaporation to an aqueous residue which was then radioassayed. The pH was adjusted to pH2 with HCl and an aliquot added to a pre-conditioned C8 bondelut column. The column was washed with a pH2 buffer, and eluted with acetonitrile. Aliquots were measured by LSC where required, mass balance data obtained, and aliquots analysed by TLC. The total proportions of radioactivity applied to the soil did not exceed 1.8%.

The soil was air dried, and subsamples combusted for LSC analysis.

Extract analysis: were analysed by thin layer chromatography (TLC) and high performance liquid chromatography (HPLC).

TLC was carried out using pre-coated normal phase $Si_{60}F_{254}$ silica gel plates, under the following conditions;

Solvent system 1: Hexane:Diethyl ether 10:1 v/v

Solvent system 2: Chloroform:ethyl acetate:methanol 6:3:1

Solvent system 3: Toluene:hexane:acetic acid 15:13:2

Solvent system 4: Hexane:toluene:triethylamine 3:3:1 (2/3 times)

HPLC was carried out under the following conditions;

HPLC 1: Radiochemical purity

Column: Zorbax ODS 4.6 x 250 mm

Mobile phase Acetonitrile:water 85:15 @ 2 ml min^{-1}

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 or 400 µl CaF_2 solid cell. A fraction collector was used to collect column eluate for quantification.

HPLC 2: Extract analysis

Column: Zorbax ODS 4.6 x 250 mm

Mobile phase A: Water, B: CH_3CN

Gradient;

Time	%A	%B	Flow
0	15	85	2.0
22	15	85	2.0
23	0	100	2.0
30	0	100	2.0

Detection: UV at 254 nm and ^{14}C Raytest Ramona-5-LS radioactivity analyser with a 200 or 400 µl CaF_2 solid cell. A fraction collector was used to collect column eluate for quantification.

Samples were co-chromatographed alongside reference standards of permethrin and metabolites as shown in Figure 2.

3.2	**Reference substance**	No	
3.2.1	**Initial concentration of reference substance**	No	
3.3	**Testing procedure**		
3.3.1	**Soil types**	Described in tabular form (see table A7_1_1_2-1)	
3.3.2	**Test system and conditions**	Described in tabular form (see table A7_1_1_2-2) Soil samples were incubated aerobically under sterile conditions (90 days) and non-sterile conditions (365 days). They were maintained in darkness at 25°C in flow through systems (Figure 3) to trap volatile radiolabelled compounds including $^{14}CO_2$. The soil water content was maintained at 75%.	
3.3.3	**Method of preparation and dosing of test soil**	A stock solution of each isomer of permethrin was prepared such that 500 µl of methanol/water (1/4 v/v) was equivalent to an application rate of 1.6 mg kg^{-1}. Soil was dosed as in table A7_1_1_2-2.	
3.3.4	**Initial TS concentration**	1.6 mg kg^{-1} on a dry weight basis	
3.3.5	**Duration of test**	365 days	
3.3.6	**Analytical parameter**	Specific analysis	
3.3.7	**Sampling**	Non-sterile: days 0, 1, 3, 7, 14, 30, 60, 90, 120, 181, 275, 365 Sterile: days 7, 30, 90	
3.3.8	**Intermediates/ degradation products**	Identified (See 4.1.3)	
3.3.9	**Controls**	None	
		4 RESULTS	
4.1	**Degradation of test substance**		
4.1.1	**Recovery of radioactivity**	Total recoveries of radioactivity in non-sterile soils ranged from 80-105%. Total recoveries of radioactivity in sterile soils ranged from 91-99%. Results are shown in Table A7_1_1_2-3 to A7_1_1_2-6.	
4.1.2	**Degradation**	The amount of permethrin in extracts (mean of 4 samples characterised using TLC and HPLC methods) is given in tabular form (see table A7_1_1_2-7). CO_2 evolution achieved >40% by the end of the test period. These data are shown graphically in Figure 4. In sterile soils, after 90 days the amount of permethrin remaining was approximately 80%, indicating 20% loss which could be accounted for by physical degradation processes.	X
4.1.3	**Intermediates/ degradation products**	Minor degradation products were identified, and a route of degradation was described (Figure 5); the two main metabolites (>5% of applied at some stage of the exposure period) were identified as DCVA and PBA.	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	

5.1	**Materials and methods**	The testing protocol, although not to any recognised guidelines, incorporated essential elements necessary to enable confidence in the output. The soil was characterised, including description of biomass. The test system was an enclosed flowthrough system designed to allow for mass balance determination, which were high throughout the course of the study, indicating no material was lost and confidence can be placed in the results. Soils were prepared and dosed as individual sacrificial vessels, allowing total contents analysis, which excluded any losses or variation due to sub-sampling. The inclusion of sterile soils enabled estimation of the impact of physical processes such as hydrolysis. The analysis was based on TLC and HPLC, which was capable of resolving *cis-* and *trans-* isomers.
5.2	**Results and discussion**	The results, shown in Table A7_1_1_2-7 indicate that permethrin can be rapidly degraded in the terrestrial environment. The degradation appeared to be bi-phasic, with the initial rapid phase seeing a reduction from 95.5% applied radiation to 16.4% applied radiation after 90 days. After 365 days the permethrin accounted for 3.6% of the applied radiation. The slow-down in the degradation probably reflects the decreasing microbial activity inherent in sieved soils in closed test systems. Based on data from the first 90 day period, the half-life of permethrin in soil was 37 days, assuming first order kinetics. The half-life of permethrin in sterile soil would be in excess of 300 days, based on the reported data. This loss could be accounted for by physical degradation, such as hydrolysis. The metabolites identified were typical of either ester cleavage or phenyl substitution, the two main metabolites (>5% of applied at some stage of the exposure period) were identified as DCVA and PBA.
5.3	**Conclusion**	The test protocol does not compare with current guidelines for testing soil degradation, being performed in a single soil. However, it is designed to minimise loss of test material, allow derivation of DT50, and allow for characterisation of metabolites. The sampling points were sufficient over the beginning of the test period to allow real confidence in the derived DT50 values.
5.3.1	**Reliability**	1
5.3.2	**Deficiencies**	Test was only performed in one soil type.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2 March 2011
Materials and Methods	The applicant's version is acceptable.
Results and discussion	Adopts applicant's version, with the following revisions: **Comments:** (Section 4.1.2) The following should be added: Under non-sterile conditions permethrin was observed to decline biphasically to about 16% AR after 90 days incubation and continued to decline to 4% after 365 days. The initial DT_{50} of permethrin in a sandy loam soil was calculated to be 37 days, assuming first order kinetics over the first 90 days. The applicant's summary only gives data for total permethrin (cis and trans isomers combined) and does not give information on the behaviour of the individual isomers. However, the original study report shows that the cis-isomer degraded more slowly than the trans-isomer. For ^{14}C-phenyl-labelled permethrin, the ratio of cis/trans isomers changed from 40/60 at day 0 to 50/50 at day 30 to 78/22 by day 365. (Section 4.1.3) The following should be added: The main metabolites identified above 10% of the applied radioactivity following the metabolism of permethrin were *trans*-DCVA (up to 11.3% AR) and PBA (up to 15% AR) after 14-30 days. These metabolites declined towards the end of the incubation period to ~3% after 365 days. A further minor metabolite, 3-(2,2-dichlorovinyl)-2-methylcyclopropane-1,2-dicarboxylic acid, was observed at a maximum of 7% AR after 14-30 days.
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~ The information in this study and another four studies presented in Section A.7.2.2.1 is sufficent to assess the rate and route of degradation of permethrin (including identification of processes involved and identification of main transformation products) in a range of soil types under various conditions.
Remarks	**Comments:** (Section 2.3) In line with current guidelines (OECD 307, SETAC 1995) the following deviations were observed: The test temperature for the aerobic soil degradation study was maintained at 25 °C ± 2 °C, instead of 20 °C ± 2 °C. Only one test soil is reported in the study. (Information from additional soils is available in the following four studies presented in Section A.7.2.2.1). The test soil moisture was not reported in the study. These deviations are considered minor deviations to current test guidelines, which do not affect the scientific validity of the study. The observed biphasic degradation profile, with a much slower phase occurring after about 90 days, might have been an experimental artefact due to low initial levels of microbial biomass and its further decline over the incubation period. The microbial biomass by the end of the study was less than 1% of total organic carbon, which is an indication of poor microbial status. Also, permethrin was incubated for 365 days in this laboratory study, which is far beyond the limit of 120 days normally recommended for such studies (e.g. OECD TG 307). A decrease in soil microbial activity would be expected after 120 days in an artificial laboratory system isolated from natural replenishment. The RMS evaluator is of the opinion that only data from the first 90 days of the study can be considered to be reliable.

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

Table A7_1_1_2-1: Classification and physico-chemical properties of soils

	Soil 1 «Frensham»
Soil order	No data
Soil series	No data
Classification	Sandy loam
Location	Frensham, Surrey, UK
Horizon	No data
Sand [%]	75
Silt [%]	19
Clay [%]	5
Organic matter [%]	2.1
Carbonate as $CaCO_3$	No data
insoluble carbonates [%]	No data
pH (1:1 H_2O)	6.63
Cation exchange capacity (MEQ/100 g)	6.7
Extractable cations (MEQ/100 g)	No data
Microbial biomass at Day 0 At Day 365	32.8 mg C/100g 5.3 mg C/100g

Table A7_1_1_2-2: Test system and conditions

Criteria	Details
Test vessels	Approx. 60 g (dry weight) soil was weighed into 5.4 cm diameter glass crystallising dishes. Depending on required samples, 6 or 12 dishes were placed in glass columns, as shown in Figure 3.
Number of test vessels	[Per radioisotope] 24 non-sterile, 6 sterile. Total vessel analysis per replicate, 2 replicates analysed per time point.
Aeration device	Negative pressure pump system, closed system with exuent air drawn through a series of traps to remove, and thus quantify, any volatile materials.
Measuring equipment	None
Test temperature	25 ± 2°C
Light conditions	Dark
Test performed in closed vessels due to significant volatility of TS	No – flowthrough aeration to trap evolved volatile products

Table A7_1_1_2-3: Extraction and recovery of radioactivity from non-sterile Frensham sandy loam soil after application of ^{14}C–cyclopropyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
0	7(A)	97.3	-	97.3	0.3	-	97.6
	18(B)	100.1	-	100.1	0.3	-	100.4
1	8(A)	93.6	3.1	96.7	0.2	0.1	97.0
	23(B)	91.4	3.9	95.3	0.5	0.04	95.8
3	70(A)	83.4	8.4	91.8	3.3	0.4	95.5
	15(B)	87.1	6.5	93.6	2.6	0.2	96.4
7	6(A)	86.4	7.8	94.2	1.4	1.8	97.4
	25(B)	84.3	7.8	92.1	1.1	0.8	94.0
14	13(A)	80.5	9.7	90.2	1.8	4.6	96.6
	20(B)	86.6	7.8	94.4	0.9	2.4	97.7
30	69(A)	33.0	19.0	52.0	17.7	10.2	79.9
	21(B)	54.5	16.8	71.3	6.3	7.8	85.4
60	11(A)	50.1	18.8	68.9	14.7	18.8	102.4
	16(B)	32.4	21.1	53.5	24.1	17.6	95.2
90	80(A)	20.3	13.9	34.2	37.0	25.1	96.3
	28(B)	26.8	16.4	43.2	29.1	25.8	98.1
120	5(A)	33.5	14.8	48.3	25.9	30.8	105.0
	19(B)	19.7	15.8	35.5	24.0	31.8	91.3
181	14(A)	25.5	12.5	38.0	26.0	37.9	101.9
	24(B)	26.4	14.3	40.7	18.3	40.9	99.9
275	9(A)	9.9	10.0	19.9	34.3	44.6	98.8
	17(B)	11.9	12.1	24.0	31.2	46.1	101.3
365	79(A)	4.8	7.1	11.9	42.6	48.6	103.1
	27(B)	13.0	12.5	25.5	20.2	50.3	96.0

Table A7_1_1_2-4: Extraction and recovery of radioactivity from non-sterile Frensham sandy loam soil after application of ^{14}C–phenyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
0	42(D)	98.2	-	98.2	0.2	-	98.4
	58(E)	99.8	-	99.8	0.2	-	100.0
1	36(D)	92.3	4.1	96.4	0.6	0.1	97.1
	55(E)	95.7	3.6	99.3	0.4	0.1	99.8
3	35(D)	92.3	5.0	97.3	0.7	0.3	98.3
	60(E)	90.7	5.4	96.1	0.8	0.3	97.2
7	46(D)	84.4	7.1	91.5	3.5	1.2	96.2
	59(E)	77.9	8.6	86.5	7.3	1.5	95.3
14	38(D)	69.2	9.5	78.7	8.5	3.5	90.7
	50(E)	70.8	9.5	80.3	5.0	4.8	90.1
30	48(D)	73.2	12.0	85.2	4.0	9.7	98.9
	52(E)	63.6	12.2	75.8	7.0	11.6	94.4
60	40(D)	41.2	7.9	49.1	23.2	20.4	92.7
	56(E)	48.1	7.8	55.9	20.9	16.9	93.7
90	37(D)	34.4	9.0	43.4	28.1	27.9	99.4
	49(E)	22.0	7.6	29.6	34.3	22.2	86.1
120	45(D)	19.6	7.1	26.7	33.2	33.2	93.1
	61(E)	24.5	7.8	32.3	27.5	27.7	87.5
181	43(D)	11.9	6.5	18.4	25.0	39.8	83.2
	57(E)	21.1	9.1	30.2	27.9	34.4	92.5
275	39(D)	13.7	7.5	21.2	28.8	44.0	94.0
	54(E)	21.8	8.2	30.0	34.6	40.1	104.7
365	41(D)	10.0	5.9	15.9	26.6	46.5	89.0
	51(E)	12.5	8.0	20.5	24.8	42.5	87.8

Table A7_1_1_2-5: Extraction and recovery of radioactivity from sterile Frensham sandy loam soil after application of ^{14}C–cyclopropyl permethrin at a rate of 1.6 mg kg^{-1}

Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
7	31(C)	95.3	2.0	97.3	0.1	0.02	97.4
	33(C)	93.5	2.6	96.1	0.1	0.02	96.2
30	29(C)	90.9	6.0	96.9	0.3	0.1	97.3
	32(C)	92.1	5.7	97.8	0.3	0.1	98.2
90	30(C)	83.2	7.0	90.2	0.8	0.2	91.2
	34(C)	86.3	7.0	93.3	0.8	0.2	94.3

Table A7_1_1_2-6: Extraction and recovery of radioactivity from sterile Frensham sandy loam soil after application of ^{14}C–phenyl permethrin at a rate of 1.6 mg kg^{-1}

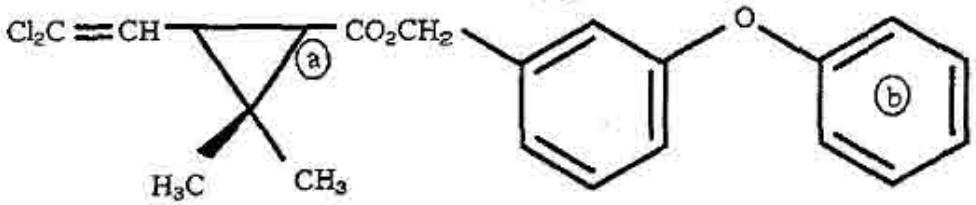
Results are expressed as % applied radioactivity

Time after application (days)	Sample no. (storage column)	Extracted			Not extracted	Volatiles	Total recovery
		Ambient	Reflux	Total			
7	64(F)	96.1	1.9	98.0	0.1	0.01	98.1
	67(F)	95.5	3.3	98.8	0.1	0.01	98.9
30	63(F)	92.4	4.7	97.1	0.2	0.1	97.4
	68(F)	90.6	6.9	97.5	0.3	0.1	97.9
90	65(F)	85.2	7.6	92.8	1.0	0.1	93.9
	66(F)	83.4	9.2	92.6	1.0	0.1	93.7

Table A7_1_1_2-7: Loss of permethrin in aerobic soils and CO_2 evolution

Time (days)	Permethrin remaining (%)	$^{14}CO_2$ evolution (%)
0	95.4	
1	91.1	0.1
3	83.3	0.3
7	74.5	1.3
14	65.4	3.8
22		6.9
30	44.5	9.8
36		11.7
44		14.0
52		16.3
60	30.6	18.4
76		22.3
90	16.4	25.2
105		28.5
120	12.5	30.9
135		33.0
150		35.2
164		36.9
181	9.8	38.2
196		39.3
211		40.4
226		41.3
241		42.1
255		42.8
275	6.2	43.7
290		44.4
304		44.9
314		45.3
329		45.7
346		46.3
365	3.6	47.0

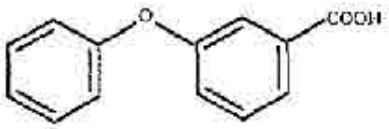
Figure 1: Permethrin structure, showing position of the radioisotope



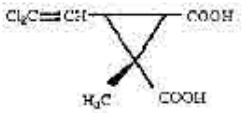
a Denotes position of ^{14}C–cyclopropyl label

b Denotes position of ^{14}C–phenyl label

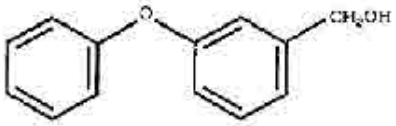
The following reference substances were supplied by ICI Agrochemica



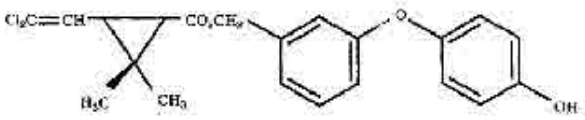
3–Phenoxybenzoic acid (3–PBA)
(R41207)



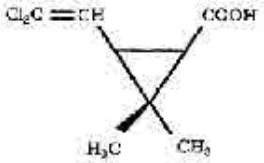
3–(2,2–dichlorovinyl)–2–methylcyclopropane–
1,2–dicarboxylic acid
(ICIA0557/06/03)



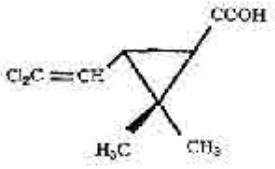
3–Phenoxybenzyl alcohol (3PBAlc)
(R79406)



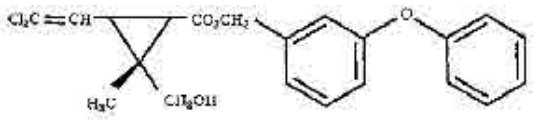
4'–Hydroxypermethrin
(R251557)



cis–3–(2,2–dichlorovinyl)–
2,2–dimethylcyclopropanecarboxylic acid
(*cis*–DCVA)



trans 3–(2,2–dichlorovinyl)–
2,2–dimethylcyclopropanecarboxylic acid
(*trans*–DCVA)



Hydroxypermethrin
(R233022)

Figure 3: Test design

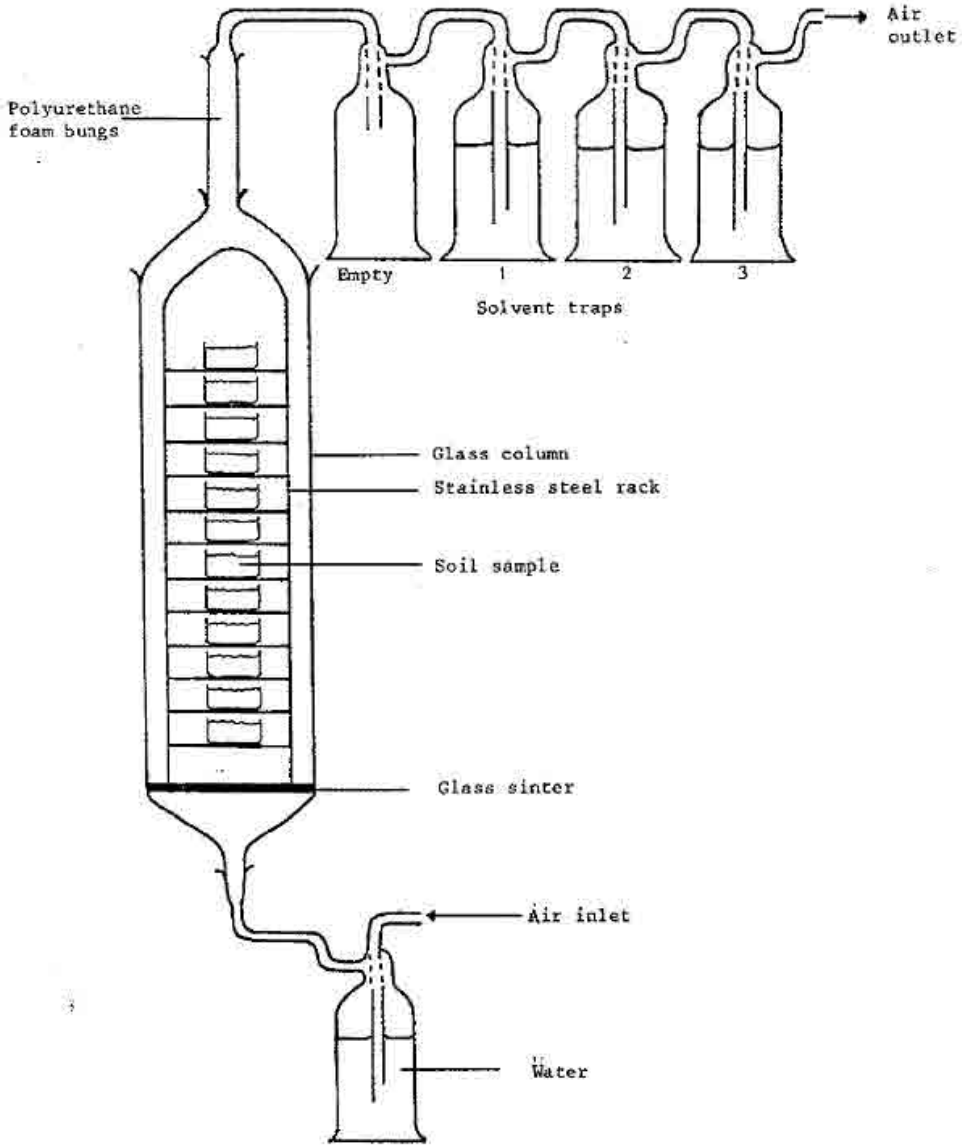


Figure 4: Loss of permethrin in aerobic soils and CO_2 evolution

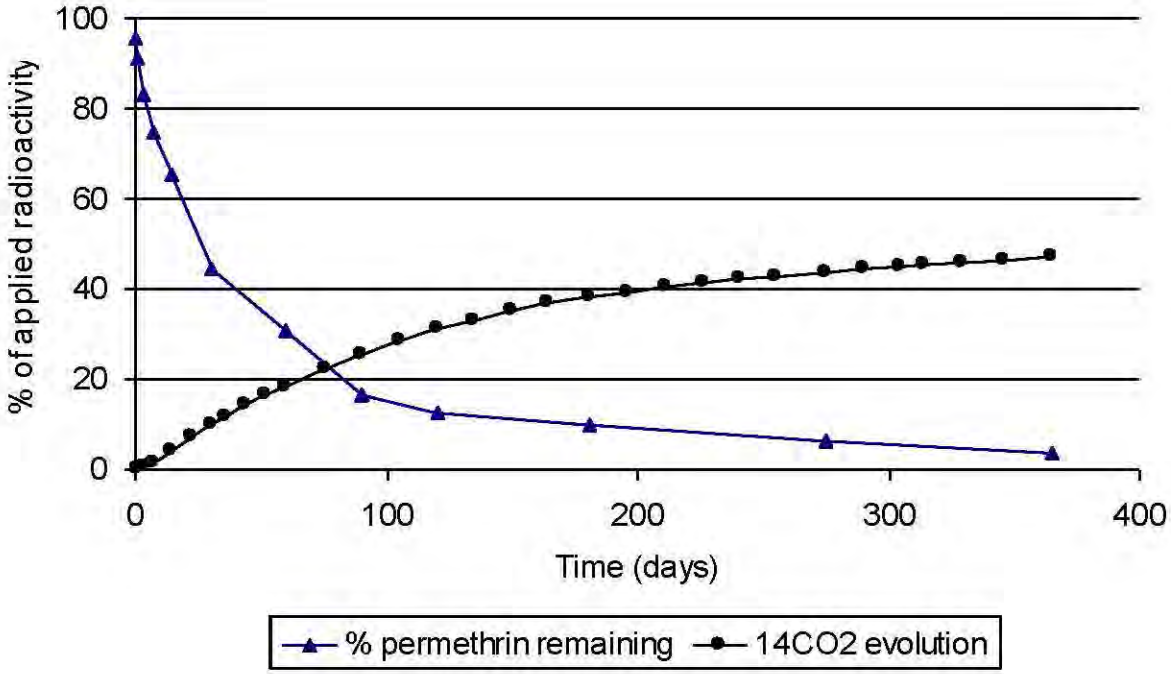
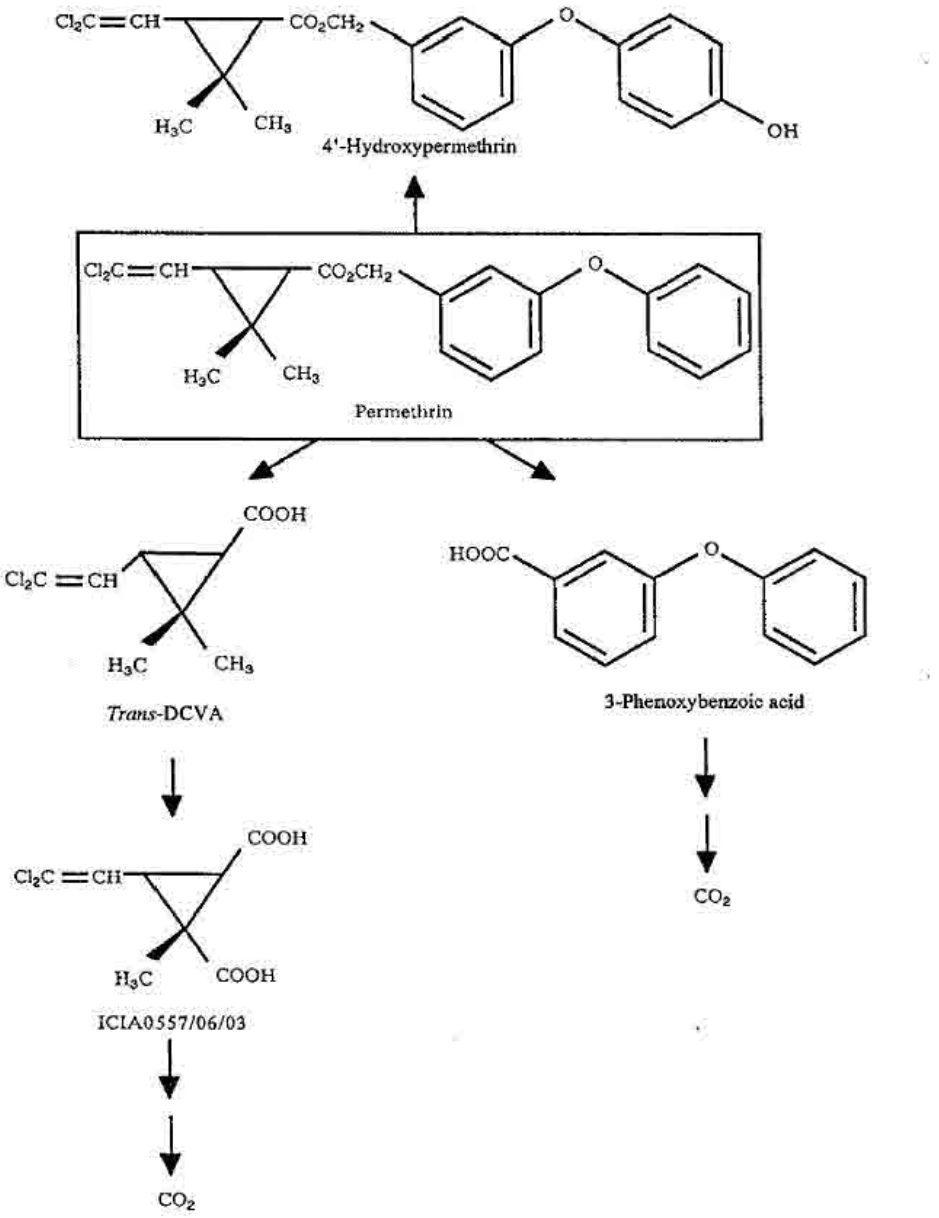


Figure 5: Proposed degradation pathway for permethrin in soil



Section A7.2.2.1(2)	**The rate and route of degradation**
Annex Point IIA7.6.1.1 **Annex Point IIA7.6.1.2**	**including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Kaufman, D.D., Clark Haynes; S., Jordan, E.G, Kayser, A.J.; 1978; Permethrin Degradation in Soil and Microbial Cultures. In Synthetic Pyrethroids; Not GLP; Published	
1.2	**Data protection**		
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC	
1.2.2	**Companes with letter of access**	No data protection claimed	
1.2.3	**Criteria for data protection**	No data protection claimed	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No: University research	
2.3	**Deviations**	No: Protocol was not to any guidelines	X
		3 MATERIALS AND METHODS	X
3.1	**Test material**	As given in section 2; ^{14}C radiolabelled *cis* and *trans* isomers.	
3.1.1	**Lot/Batch number**	Not available	
3.1.2	**Specification**	Specific activity 28.8 mCi $mmol^{-1}$	
3.1.3	**Purity**	At least %	X
3.1.4	**Composition of Product**	Radiolabelled at the methylene (alcohol) and carbonyl (acid) Carbon	
3.1.5	**TS inhibitory to microorganisms**	No	
3.1.6	**Specific chemical analysis**	Yes, two-dimensional TLC using hexane:benzene:acetone (7:3:0.1) x3, and benzene (formate saturated):ether (10:3) x1.	
3.2	**Reference substance**	No	
3.3	**Test ing procedure**		
3.3.1	**Soil types**	Described in tabular form (see table A7_2_2_1-1)	
3.3.2	**Test system and conditions**	Three tests were conducted: 1. Aerobic soil degradation in one soil (Hagerstown) using biotic and sterile soils (repeated) 2. Anaerobic degradation in one soil using biotic flooded soil (Hagerstown) 3. Aerobic soil degradation in five soils Little detail is supplied on the test systems; data provided are given in table A7_2_2_1-2	
3.3.3	**Method of preparation of test solution**	All tests (1, 2, 3): A mixture of *cis/trans* isomers was prepared in benzene. ^{14}C carbonyl was 46:54 *cis:trans* ratio, ^{14}C alcohol was 22:78 *cis:trans* ratio	
3.3.4	**Initial TS**	All tests (1, 2, 3): Materials were applied to soils in 0.1 ml of	

Section A7.2.2.1(2) **Annex Point IIA7.6.1.1** **Annex Point IIA7.6.1.2**		**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**	
		Key Study	
	concentration	benzene to simulate an application rate of 0.2 lb/A	
3.3.5	**Duration of test**	Test 1: 28 (34) days Test 2: 60 days Test 3: 28 days	
3.3.6	**Analytical parameter**	Test 1: $^{14}CO_2$ production, parent analysis, degradation product analysis Test 2: $^{14}CO_2$ production, parent analysis, degradation product analysis Test 3: $^{14}CO_2$ production, parent analysis, degradation product analysis	
3.3.7	**Sampling**	Test 1 [extra sampling on repeat]: $^{14}CO_2$ production -days [1, 2], 3, [4, 5] 6, [7], 8, 10, 12, 16, 20, 24, 27 [30, 34], parent analysis, degradation product analysis day 27 [34] Test 2: $^{14}CO_2$ production, parent analysis, degradation product analysis days 30, 60 Test 3: $^{14}CO_2$ production – days 1, 2, 3, 4, 5, 7, 9, 11, 13, 15, 17, 19, 21, 24, 26, 28, parent analysis, degradation product analysis day 28	
3.3.8	**Intermediates/ degradation products**	Identified by TLC	
3.3.9	**Nitrate/nitrite measurement**	No	
3.3.10	**Controls**	No	
3.3.11	**Statistics**	No	
		4 RESULTS	
4.1	**Degradation of test substance**		
4.1.1	**Graph**	Test 1 and Test 3 data are presented graphically in Figure 1.	
4.1.2	**Degradation**	Test 1: Results from the original and repeat experiment are presented in the first two graphs of Figure 1. The numerical mass balance data from the repeat test are given in Table A7_2_2_1-3. Test 2: After 30 days incubation, carbonyl/methylene labelled permethrin had degraded to 38.0/25.5% of original radioactivity. By day 60 this had further reduced to 16.0/10.7%. Test 3: Results are presented in the third graph of Figure 1. The numerical mass balance data from the test are given in Table A7_2_2_1-4.	X
4.1.3	**Intermediates/ degradation products**	Degradation products were identified as; Dichlorvinyl acid (DCVA) 3-Phenoxybenzoic acid (PBA) 3-Phenoxybenzyl alcohol	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and**	Little detail is provided on the experimental design. However, good	

Section A7.2.2.1(2) **Annex Point IIA7.6.1.1** **Annex Point IIA7.6.1.2**		**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**	
		Key Study	
	methods	recovery data indicate the closed systems employed were suitable for control of losses from a radiolabelled study. The most pertinent element of a soil degradation study, the soil itself, is described in detail.	
5.2	**Results and discussion**	The results, shown in Table A7_1_1_2-3 and 4 indicate that permethrin can be rapidly degraded in a wide variety of soils describing the aerobic terrestrial environment. In the San Joaquin soil, although $^{14}CO_2$ production was low, only 58% of the applied radioactivity was present as permethrin, and this value was the lowest by over 30%. Although no biomass data are presented, based upon the rapid degradation observed in all other soils, it may be that the San Joaquin soil was not biologically viable, and the loss observed was due to abiotic means such as hydrolysis. Metabolites identified were typical of either ester cleavage or phenyl substitution, and the authors present a tentative degradation pathway.	
5.3	**Conclusion**	The test design does not provide enough detail to allow comparison with current guidelines for testing soil degradation. However, it is designed to minimise loss of test material, allow derivation of DT50, and allow for characterisation of metabolites. The data indicate permethrin is rapidly degraded in the terrestrial environment, with DT50 values, based on CO_2 production, of approximately 2 weeks.	X
5.3.1	**Reliability**	2	
5.3.2	**Deficiencies**	Not applicable	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*3 May 2005*
Materials and Methods	The applicants version is acceptable, with the following revisions. **Comments:** Information on the test design is limited. The percentage purity of the test compound is not reported in the study. The provenance, collection and treatment of test soils were not documented in the report. No biomass characterisation was performed on the test soils. Parent and metabolite data are not reported for each sampling timepoint. With regard to characterisation of radioactivity, specifically for permethrin, this appears to have been undertaken only at the end of the incubation period of the aerobic degradation tests. The method used to determine the approximate DT_{50} value of permethrin involved graphical examination of the formation of $^{14}CO_2$ over the incubation period (see **Figure 1**), assuming 100% and instantaneous formation of CO_2 from permethrin in the test soils.
Results and discussion	Adopts applicant's version, with the following revisions: **Comments:** (Section 4.1.2) According to the notifier, results from the study indicate that the DT_{50} value for permethrin is relatively short, being in the order of approximately 2 weeks. However, the study author notes that more detailed testing is required to more accurately determine the permethrin DT_{50} value, especially over the range of tested soils. In addition the number of sampling points throughout the incubation period for characterisation of permethrin from applied radioactivity are not sufficient for detailed kinetic analysis of permethrin degradation directly, and instead use of the CO_2 evolution for the test soils is employed to determine approximate DT_{50} values of permethrin. (Section 4.1.3) Whilst identification of the main metabolites was undertaken by TLC analysis, with DCVA, PBA and 3-phenoxybenzyl alcohol being identified, the amounts formed as a percentage of applied radioactivity are generally not reported. The report only states that these degradation products, along with the parent material appeared as the predominant radioactive products on TLC plates. DCVA, PBA, and 3-phenoxybenzyl alcohol are reported to represent between 2-20% of applied radioactivity. Furthermore, the solvent systems used were only partially capable of separating the PBA and 3-phenoxybenzyl alcohol, and the DCVA which comprised of category D on the TLC plates. Thus, potentially and as indicated by the initial aerobic soil study (Hawkins, 1992), these metabolites, especially DCVA and PBA are likely to reach levels greater than 10% of the applied radioactivity. Furthermore, no kinetic analysis of these main degradation products was undertaken. Evaluation by the RMS of the graphical test data (**Figure 1** [Figure 3]) was undertaken to assess the degradation of permethrin using simple first order kinetics, of the equation described below, in order to determine DT_{50} and DT_{90} values: $C(t) = C_0 e^{-kt}$ where k is the rate constant and C_0 is the concentration of permethrin at time (t) 0. **Table A7.2.2.1 – RMS1** summarises the data obtained from the graphical test data. The concentration of permethrin was derived from the