	graphical data on CO_2 evolution from four test soils (Dubbs sandy loam, Sharkey clay, Hagerstown silty clay loam, and Memphis silt loam), after application of ^{14}C-carbonyl permethrin, during the incubation period of the test. This approach was used since the actual level of permethrin remaining was only reported for the 28-day timepoint. Conversion of permethrin to CO_2 in the test soils was assumed to be instantaneous and complete (i.e. 100%). Despite a lower rate of CO_2 evolution observed in the San Joaquin sandy loam, this was not considered for further kinetic analysis owing to potential issues surrounding the biological viability of this soil. The assumptions outlined above provide a first tier worst case DT_{50} value assessment for permethrin. The approach used overestimates permethrin levels, leading to longer DT_{50} values, since it is likely that the balance of non-CO_2 material actually consisted of permethrin and some degradation products other than CO_2. After an iterative process to reduce the residual of the sum of the squares, the k value was determined to be 0.01456 d^{-1}, 0.01392 d^{-1}, 0.02207 d^{-1}, and 0.02536 d^{-1} for the Memphis, Sharkey, Dubbs, and Hagerstown test soils, respectively. This resulted in DT_{50} (DT_{90}) values of 47.6 days (158.2 days), 49.8 days (165.4 days), 31.4 days (104.4 days), and 27.3 days (90.8 days), respectievly. The r^2 values for the Memphis, Sharkey, Dubbs, and Hagerstown test soils were determined at 0.992, 0.958, 0.967, and 0.991, respectively, indicating a good fit of the predicted to the observed data. **Figure A7.2.2.1- RMS1** shows the observed and predicted degradation profile of permethrin for one of the test soils (Memphis). It should be noted that owing to the short incubation time (28 days) the degradation parameters derived from this analysis should be treated with some caution, owing to the extrapolation beyond the observed data range during the incubation period. It should also be noted that, strictly speaking, the values obtained represent degradation of lumped non-CO_2 material rather than degradation of permethrin.
Conclusion	Adopt applicant's version with the following addition: **Comments:** (Section 5.3) Study data evaluated by the RMS indicate that, with the exception of the San Joaquin soil, the DT_{50} values of permethrin in a range of soils are between 27.3 days and 49.8 days (when determined using a method based on CO_2 evolution rates).
Reliability	2
Acceptability	acceptable / ~~not acceptable~~ The RMS considers the study acceptable, as despite limited information on the test design, the approach of the authors appears scientifically rigorous. Material balances are good, radiolabelled test material was used, the test system accounted for volatiles/CO_2, and the soil extraction techniques were extensive. Whilst permethrin data are scant, sufficient information from CO_2 evolution during the test is available to provide an estimation of the DT_{50} value for permethrin (as undertaken by the RMS). The information in this study taken in conjunction with the other information presented in Section A.7.2.2.1 is sufficent to assess the rate and route of degradation of permethrin in soil.
Remarks	Four further published, non-GLP journal articles were presented as supporting information. The references are: Chapman, R. A., Tu, C. M., Harris, C. R., and Cole, C., 1981, Persistence of five pyrethroid insecticides in sterile and natural, mineral, and organic soil. *Bulletin of Environmental Contamination and Toxicology*, 26, 513-519. Under the conditions of the test permethrin was observed to degrade more slowly in the sterilised soils than in non-sterilised (mineral and organic) soils with viable microbial populations. Following eight weeks after treatment permethrin was observed in non-sterilised soils at levels of between 6% and 16% of the initial application (1 mg/l) in mineral and organic soils, respectively.

	Kaneko, H., Ohkawa, H., and Miyamoto, J., 1978, Degradation and movement of permethrin isomers in soil. *Journal of Pesticide Science*, 3, 43-51. *Cis*- and *trans*-isomers of permethrin were studied under laboratory conditions in two soil types. Both isomers were observed to degrade rapidly with calculated DT_{50} values of between 6 days and 12 days for *trans*- and *cis*-permethrin, respectively. Lord, K. A., McKinley, M., and Walker, N., 1982, Degradation of permethrin in soils. *Environmental Pollution*, (Series A), 29, 81-90. Under the conditions of the test system permethrin was degraded in a variety of viable soils, with the rate depending upon soil type. Degradation was biological, as permethrin degradation was not observed after heat sterilisation in selected soils. Williams, I. H. and Brown, M. J., 1979, Persistence of permethrin and WL 43775 in soil. *Journal of Agricultural and Food Chemistry*, 27, 1, 130-132. Six soils treated with permethrin were incubated for 16 weeks at alternating temperatures (between 10 °C and 20 °C). At 4 week intervals the soils were sampled and analysed. In five test soils degradation of permethrin proceeded readily resulting in DT_{50} values of approximately 21 days for both *cis*- and *trans*-permethrin. In the other soil, little degradation was observed to take place, with recovery after 16 weeks at ~75% AR for *cis*- and *trans*-permethrin.
	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 A7.2.2.1 - RMS1: Proportions of permethrin determined from the evolution of CO_2 trapped following dosing of permethrin to a range of test soils (Memphis, Sharkey, Dubbs, Hagerstown) at varying sampling points over a 28 day incubation period.

Time (days)	Amount as % radioactivity:							
	Evolved CO_2				Permethrin*			
	M	S	D	H	M	S	D	H
0	-	**0**	**0**	**0**	-	**100**	**100**	**100**
1	**0**	**1**	**3**	**2**	**100**	**99**	**97**	**98**
3	**1**	**4**	**6**	**3**	**99**	**96**	**94**	**97**
5	**4**	**8**	**13**	**9**	**96**	**92**	**87**	**91**
7	**6**	**13**	**19.5**	**16**	**94**	**87**	**80.5**	**84**
9	**9**	**16**	**23**	**20**	**91**	**84**	**77**	**80**
11	**11**	**19**	**27**	**25**	**89**	**81**	**73**	**75**
13	**17**	**21**	**30.5**	**29**	**83**	**79**	**69.5**	**71**
19	**22**	**26**	**38**	**39**	**78**	**74**	**62**	**61**
21	**25**	**28**	**40**	**42**	**75**	**72**	**60**	**58**
24	**28**	**29**	**41.5**	**44**	**72**	**71**	**58.5**	**56**
26	**29**	**29.5**	**42**	**46**	**71**	**70.5**	**58**	**54**
28	**31**	**30**	**43**	**49**	**69**	**70**	**57**	**51**

*** Assuming instantaneous and complete (i.e. 100%) conversion of permethrin to CO_2**
M/S/D/H = Memphis/Sharkey/Dubbs/Hagerstown test soils

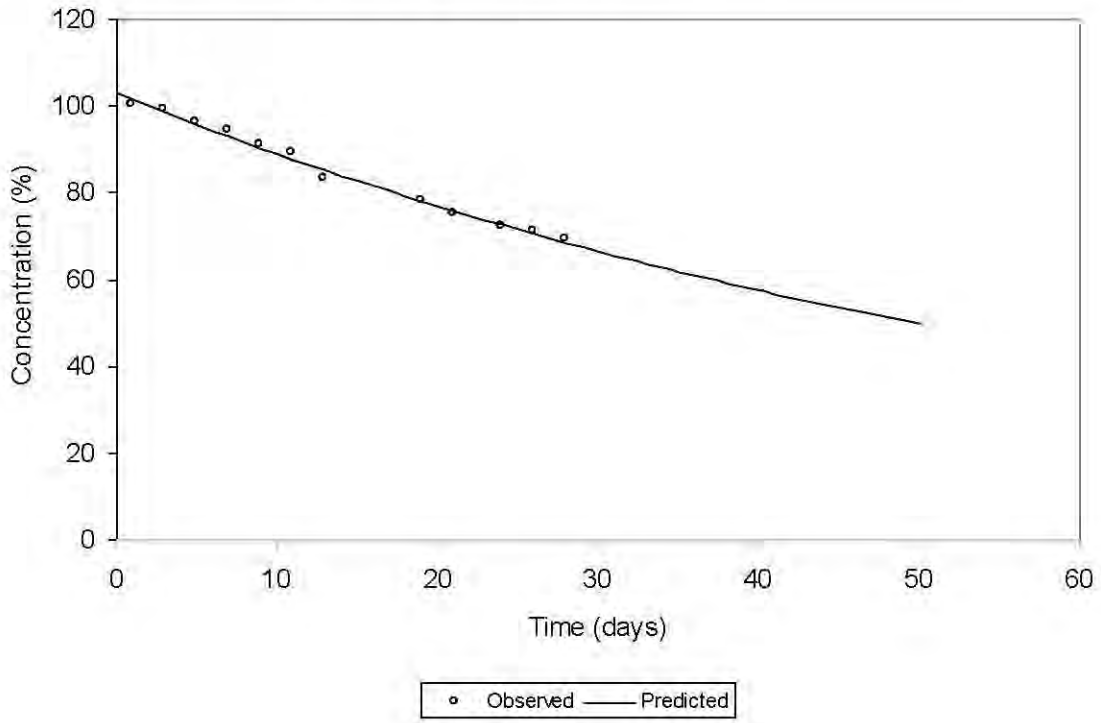


Figure A7.2.2.1 - RMS1: Observed and predicted degradation profile of permethrin following simple first order kinetic analysis and a direct fit approach, and based on CO_2 evolution data from a test conducted on a silt loam soil over a 28 day incubation period (Memphis soil).

Table A7_2_2_1-1: Classification and physico-chemical properties of soils

	Soil 1	Soil 2	Soil 3	Soil 4	Soil 5
Soil order	No data	No data	No data	No data	No data
Soil series	No data	No data	No data	No data	No data
Classification	Silt Loam	Loam	Clay	Silty Clay Loam	Sand Loam
Location	Memphis	Dubbs	Sharkey	Hagerstown	San Joaquin
Horizon	No data	No data	No data	No data	No data
Sand [%]	20.8	48.8	20.8	17.0	48.0
Silt [%]	54.0	44.0	32.0	50.6	42.0
Clay [%]	25.2	7.2	47.2	32.4	9.7
Organic matter [%]	0.7	1.0	6.1	2.3	1.2
Carbonate as $CaCO_3$	No data	No data	No data	No data	No data
insoluble carbonates [%]	No data	No data	No data	No data	No data
pH	5.8	5.9	5.9	7.5	7.2
Cation exchange capacity (MEQ/100 g)	16.3	8.5	33.6	8.8	No data
Extractable cations (MEQ/100 g)	No data	No data	No data	No data	No data

Table A7_2_2_1-2: Test system and conditions

Criteria	**Details**
6.1.8 Test vessels	No data
6.1.9 Number of test vessels/soil	No data
6.1.10 Test temperature	25°C
6.1.11 Light conditions	No data
6.1.12 Test performed in closed vessels due to significant volatility of TS	Yes – flow-through (aerobic) Anaerobic test performed in biometer flasks

Table A7_2_2_1-3: Test 1 - Results

^{14}C label position	^{14}C recovery as:				Total	Total as permethrin
	$^{14}CO_2$	Volatiles	Extractable	Residual		
Carbonyl	64.5	0.2	18.8	27.3	110.8	11.4
Carbonyl + NaN_3	0.3	0.4	71.5	22.9	95.1	65.3
Methylene	58.7	0.1	14.5	25.4	98.7	11.3
Methylene + NaN_3	0.1	0.1	67.7	32.6	100.5	57.7

Table A7_2_2_1-4: Test 1 - Results

^{14}C label position	^{14}C recovery as:				Total	Total as permethrin
	$^{14}CO_2$	Volatiles	Extractable	Residual		
San Joaquin sandy loam	2.2	0.6	86.7	10.6	100.1	6.9
Dubbs fine sandy	46.0	0.7	17.1	38.7	102.5	58.0
Memphis silt	31.5	2.4	18.6	45.0	97.5	15.1
Hagerstown silty clay loam	51.0	0.4	22.5	26.0	99.9	15.5
Sharkey clay	31.1	0.3	40.7	28.5	100.6	27.7

Figure 1: Results from Tests 1 and 3

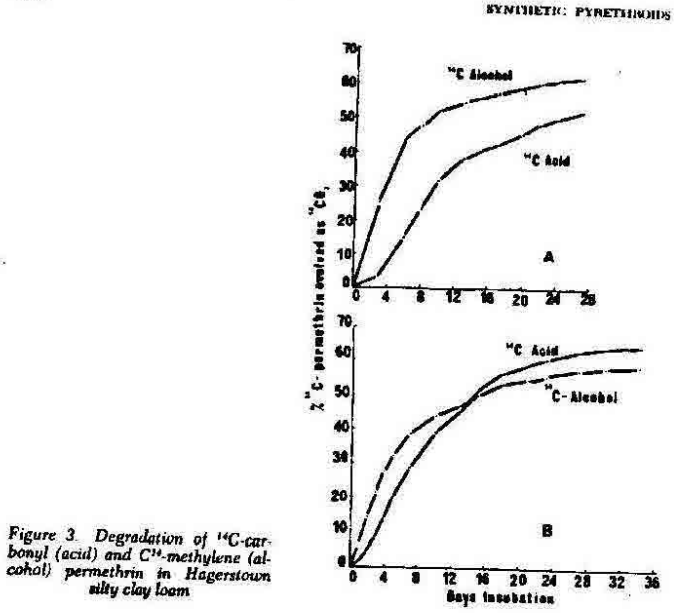


Figure 3. Degradation of ^{14}C-carbonyl (acid) and C^{14}-methylene (alcohol) permethrin in Hagerstown silty clay loam

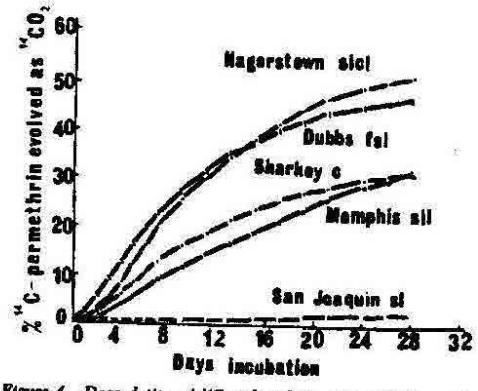


Figure 4. Degradation of ^{14}C-carbonyl permethrin in five soils

Section A7.2.2.1(3) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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

			Official use only
		1 REFERENCE	
1.1	**Reference**	Allen R., 2007 Permethrin: calculation of DT_{50} in aerobic soil. Report No. MEF-07/421 , September, 2007; Not GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Calculation	
2.2	**GLP**	not applicable	
2.3	**Deviations**	None	
		3 METHODS	
3.1	**Procedure**	Two aerobic soil reports Hawkins (1992) and Kaufman *et al.*, (1978) (Doc IIIA, point A.7.2.2.1(1) and A7.2.2.1(2)) are available, from which degradation rates at 25 and 12°C can be determined.	
3.1.1	**Calculation method DT50 at 25°C**	In Hawkins, (1992) the DT_{50} at 25°C was calculated using the data measured and presented in the original report during the first 90 days of the study. In Kaufman *et al.*, (1978) it is not possible to directly calculate the degradation rate with a high degree of confidence. Two sets of data: 1) The % of permethrin remaining after 28 days incubation (half-life assuming first-order kinetics), and 2) The % evolution of $^{14}CO_2$ from soil over the 28 days incubation.	X
3.1.2	**Calculation method DT50 at 12°C**	The DT_{50} at 12°C was then calculated in accordance with FOCUS groundwater framework (FOCUS, 2000), which is the standard guidance used in submissions for plant protection products under 91/414/EC.	
3.1.3	**Assumptions and Equations**	For the temperature normalisation, the incubation temperature T and the reference temperature Tref are compared. The temperature-normalised DT_{50} ($DT_{50,norm}$) is then given by: $DT_{50,norm} = DT_{50} \cdot 2.2^{(T-T_{ref})/10}$ This formula was applied to the DT_{50} values from the two studies to determine a worst-case and mean (realistic worst case) value for use in exposure assessments.	X X
		4 RESULTS	

Section A7.2.2.1(3) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**		**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	
4.1	**DT50 at 25°C**	Hawkins, (1992) the DT_{50} at 25° = 37 days. Kaufman et al., (1978) the measured amounts of permethrin remaining in five soils are given in Table 7.2.2.1(3)-1, along with, the half-life assuming that at day 0, 100% of the applied radioactivity was permethrin. The estimated values of the % permethrin remaining after 28 days and the DT_{50} calculated from the $^{14}CO_2$ evolution curves are given in Table 7.2.2.1(3)-2.	X
4.2	**DT50 at 12°C**	Table 7.2.2.1(3)-3. Worst-case DT_{50}= 103 days, mean DT_{50} = 45 days (n=5)	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	X
5.1	**Materials and methods**	Degradation rates at 25 and 12°C were determined: from two aerobic soil studies (Hawkins, (1992) & Kaufman *et al.*, (1978)). In Hawkins, (1992) the DT_{50} at 25°C was calculated as in the original report, whilst in Kaufman *et al.*, (1978) DT_{50} was calculated via two routes: the % of permethrin remaining after 28 days incubation, and the % evolution of $^{14}CO_2$ from soil over the 28 days incubation. The DT_{50} at 12°C was then calculated in accordance with FOCUS groundwater framework (FOCUS, 2000).	
5.2	**Results and discussion**	Hawkins, (1992) the DT_{50} at 25° = 37 days. Kaufman *et al.*, (1978): DT_{50} based on the measured amounts and $^{14}CO_2$ evolution curves are given in Table A7.2.2.1 (3)-1 & Table A7.2.2.1 (3)-2 respectively. In both studies it is clear that the assumption that there is instantaneous and complete conversion of permethrin to CO_2 is not observed. Other extractable degradation products and non-extracted radioactivity are observed. This can be clearly seen in Figure A7.2.2.1 (3)-1 summarizing the results of Hawkins (1992). During the course of the study the amount of $^{14}CO_2$ evolved is, at most, only half of the amount of permethrin degraded. The other products of degradation include extractable metabolites and non-extractable radioactivity. Therefore an estimate of permethrin degradation rate from carbon dioxide evolution is undoubtedly highly conservative. The data presented by Kaufman *et al* (1978) show a similar pattern to the results of the Hawkins (1992) study (Table A7.2.2.1 (3)-4). After 28 days, between 1.7 and 2.7 molecules of permethrin were degraded for each molecule of carbon dioxide evolved. Therefore these data indicate that the measured amounts of permethrin after 28 days in each of the four soils are comparable with those expected from the corresponding rates of $^{14}CO_2$ evolution. In other words the half-lives shown in Table 7.2.2.1(3)-1 are supported by the corresponding rates of $^{14}CO_2$ evolution Therefore the worst-case DT_{50} degradation in soil at 25°C is that observed in the Frensham sandy loam soil (37 days) from the study (Hawkins 1992). Following calculation in accordance with FOCUS groundwater framework, a worst-case value DT_{50} degradation in soil at 12°C = 103 days (longest DT_{50} value observed) and a mean DT_{50} of 45 days (n=5) Table A7.2.2.1 (2)-3.	X

Section A7.2.2.1(3) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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
5.3 Conclusion	
5.3.1 Reliability	1
5.3.2 Deficiencies	None
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2009

Section A7.2.2.1(3) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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

Materials and Methods

Applicant's version is acceptable with the addition of the following clarifications.

Section 3.1.1

Two different methods were used to assess the data from the 1978 study by Kaufman et al., since the level of permethrin present was only reported for the day-28 timepoint. Due to the absence of information on actual permethrin levels at other timepoints, it is not possible to directly calculate the degradation rate of permethrin for this study with a high degree of confidence. Details of the two methods used for kinetic assessment are given below.

Method 1: First-order half-life values were calculated directly from the simple first-order kinetics equation using the reported levels of permethrin at day 28 and assuming a level of 100% applied radioactivity for permethrin at day 0. The results obtained with this method are uncertain since they are only based on measured data for one timepoint.

Method 2: Simple first-order kinetics was applied to levels of permethrin obtained by extrapolation from reported CO_2 levels at various timepoints over the incubation period, assuming that the balance of non-CO_2 material was accounted for exclusively by permethrin. This approach overestimates permethrin levels, leading to longer DT_{50} values, since it is likely that the balance of non-CO_2 material actually consisted of permethrin and some degradation products other than CO_2. Strictly speaking, this method gives half-life values for the degradation of lumped non-CO_2 material rather than for the degradation of permethrin.

Section 3.1.3

Prior to extrapolation to 12 °C, the two sets of half-life values obtained with the different kinetic assessment methods for the four soils in the Kaufman et al. (1978) study were each combined separately with the half-life value for another soil determined by the applicant from the Hawkins (1992) study. Therefore, two sets of half-life values at 25 °C, each containing five values, were separately extrapolated to 12 °C.

The equation used to extrapolate DT_{50} values at 25 °C to 12 °C is different to the one recommended in the EC Technical Guidance Document (section 2.3.6.1). The recommended form of the equation is

$$DT_{50}(12\ °C) = DT_{50}(20) \bullet e^{(0.08\ (20\ -12))}$$

The values have been recalculated at 12 °C by the CA evaluator and mean and maximum values are presented in the section below.

Section A7.2.2.1(3) BPD Data set IIIA/ Annex Point VII.4, XII.1.1	**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

Results and discussion	Applicant's version is acceptable with the addition of the following clarifications and amendments to Table 7.2.2.1(3)-4. Section 4.1 The respective DT_{50} values at 25 ºC obtained for the four soils (Dubbs, Memphis, Hagerstown and Sharkey) in the Kaufman et al. (1978) study are as follows: Method 1 (based on percentage of permethrin present at day 28 timepoint) 7.3, 10.3, 10.4, 15.1 days Method 2 (based on CO_2 evolution rates) 31.4, 47.6, 27.3, 49.8 days The two sets of half-life values at 25 ºC that were separately extrapolated to 12 ºC are as follows: Dataset 1 – 7.3, 10.3, 10.4, 15.1, 37.0 days Dataset 2 – 27.3, 31.4, 37.0, 47.6, 49.8 days Section 4.2 For Dataset 1, extrapolation to 12 ºC gave a maximum DT_{50} value at this temperature of of 105 days and an arithmetic mean of 38 days (n = 5). For Dataset 2, extrapolation to 12 ºC gave a maximum DT_{50} value at this temperature of of 141 days and an arithmetic mean of 106 days (n = 5). Table 7.2.2.1(3)-4 For the Dubbs soil, the percentage of permethrin degraded is 42 (not 93.1). Therefore, for this soil the ratio of permethrin degradation to CO_2 evolution is 0.98 (not 2.2).
Conclusion	Applicant's version is acceptable. The following points should be noted. Overall, the RMS considers that the assessment using DT_{50} values derived from the CO_2 evolution method is a conservative worst case option. The assessment using DT_{50} values derived on the basis of the percentage of permethrin present after 28 days is more realistic. Using a DT_{50} value at 12 ºC of 103 days could represent a realistic worst case situation. Section 5.2 It is stated in relation to the Kaufman et al. (1978) study that after 28 days between 1.7 and 2.7 molecules of permethrin were degraded for each molecule of carbon dioxide evolved. Due to the revision of Table 7.2.2.1(3)-4 noted above, the statement should read that for the four soils kinetically assessed in the Kaufman et al. (1978) study, the number of molecules of permethrin degraded for each molecule of carbon dioxide evolved ranged from 0.98 to 2.7.
Reliability	1
Acceptability	acceptable / not acceptable
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.2.2.1(3) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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
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 7.2.2.1 (3) - 1. Amounts of permethrin measured in soil after 28 days and first-order half-lives (DT50) based upon these amounts (from Kaufman *et al.*,, 1978)

Soil	% permethrin remaining after 28 d[a]	DT50 (d)
Dubbs SL	6.9	7.3
Memphis ZL	15.1	10.3
Hagerstown ZCL	15.5	10.4
Sharkey Clay	27.7	15.1

[a] from Table VIII

Table 7.2.2.1 (3) - 2. . Amounts of permethrin estimated in soil from rate of $^{14}CO_2$ evolution and half-lives based upon these amounts (from Kaufman *et al.*, 1978)

Soil	% $^{14}CO_2$ evolved after 28 d[a]	estimation of % permethrin remaining after 28 d[b]	DT50 (d)
Dubbs SL	43	57	31.4
Memphis ZL	31	69	47.6
Hagerstown ZCL	49	51	27.3
Sharkey Clay	30	70	49.8

[a] from Figure 4

[b] Assuming instantaneous and complete (i.e. 100%) conversion of permethrin to CO_2

Table 7.2.2.1 (3) - 3 Calculation of DT50 values at 12°C

Study	Soil	Temperature	DT50 (days)	DT50 @ 12°C (days)
Hawkins, 1992	Frensham SL	25	37	103
Kaufman et al, 1978	Dubbs SL	25	7.3	20
Kaufman et al, 1978	Sharkey Clay	25	15.1	42
Kaufman et al, 1978	Hagerstown ZCL	25	10.4	29
Kaufman et al, 1978	Memphis ZL	25	10.3	29
			Mean	**45**

Table 7.2.2.1 (3) - 4. Comparison of the residues of permethrin after 28 days and the amount of $^{14}CO_2$ in four soils (from Kaufman, 1978)

Soil	% $^{14}CO_2$ [a]	% permethrin degraded [b]	% permethrin degraded per unit $^{14}CO_2$ evolved
Dubbs SL	43	93.1	2.2
Memphis ZL	31	84.9	2.7
Hagerstown ZCL	49	84.5	1.7
Sharkey Clay	30	72.3	2.4

[a] from Figure 4 [b] from Table VIII

A7.2.2.1(4) BPD Data set IIIA/ Annex Point VII.4, XII.1.1	**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	
	1. REFERENCE	**Official use only**
1.1 Reference	Schäfer, D. and Mikolasch, B. (2004) Kinetic Evaluation of Soil Laboratory Studies with Deltamethrin and its Metabolites D-COOH, Br_2CA and mPBacid to Determine Input Parameters for Model Calculations Bayer CropScience AG, Germany Document; C044585; 8 October 2004; Unpublished	
1.2 Data protection	Yes	
1.2.1 Data owner	Bayer CropScience AG	
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Not applicable	
2.2 GLP	Not applicable	
2.3 Deviations	Not applicable	
	3. MATERIALS AND METHODS	X
3.1 Test material		
3.1.1 Lot/Batch number	Not applicable	
3.1.2 Specification	Not applicable	
3.1.2.1 Description	Not applicable	
3.1.2.2 Purity	Not applicable	
3.1.2.3 Stability	Not applicable	

A7.2.2.1(4) BPD Data set IIIA/ Annex Point VII.4, XII.1.1	**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	
3.2 Test conditions	Experimental data from four laboratory soil degradation studies (Kaufman *et al*, 1978, 1979 a, b; Wang, 1991) were used to quantify the degradation kinetics of deltamethrin and its metabolites D-COOH (AE 0035100). Br_2CA (AE F108565) and mPBacid (AE F109036) in soil. The kinetic evaluation was conducted with the ACSL Optimize software package (ACSL, 1996). The objective was to determine first-order soil DT_{50} values as input parameters for simulation models.	X
	4. RESULTS	
4.1 Materials and methods	The degradation of deltamethrin in soil is a microbial process and the main degradation pathway is ester cleavage, followed by oxidation that leads to the formation of the main metabolites Br_2CA and mPBacid, which are relatively fast mineralised to CO_2. A second degradation route of deltamethrin is the oxidation of the nitrile group, which forms deltamethrin-amide and deltamethrin-carboxylic acid (D-COOH). The latter is subject to ester cleavage and oxidation, again forming the metabolites Br_2CA and mPBacid. The proposed metabolic pathway of deltamethrin in soil is shown in Figure A.7.2.2.1(4)-1. Only the metabolite Br_2CA was found at more than 10% of the applied radioactivity in any soil degradation study, while D-COOH and mPBacid were found at maximum levels between 5% and 10%. The metabolites deltamethrin-amide (D-$CONH_2$) and mPBalcohol never exceeded 0.5% of the applied radioactivity and were not included in the kinetic evaluation. Experimental data from four laboratory soil degradation studies (Kaufman *et al*, 1978, 1979 a, b; Wang, 1991) were used to quantify the degradation kinetics of deltamethrin and its metabolites D-COOH (AE 0035100). Br_2CA (AE F108565) and mPBacid (AE F 109036) in soil. The kinetic evaluation was conducted with the ACSL Optimize software package (ACSL, 1996). The objective was to determine first-order soil DT_{50} values as input parameters for simulation models.	
4.2 Results and discussion	In all cases the chemical reactions could be well described by first-order kinetics and all kinetic parameters passed a significance test. The first-order DT_{50} values were normalised to a reference temperature of 25°C and a reference soil moisture (field capacity), using the standard procedures described in FOCUS (2000). The normalised DT_{50} values for deltamethrin ranged from 11.0 to 26.5 days in four soils (Table A7.2.2.1(4)-1). The three metabolites were found to degrade more rapidly, with DT_{50} values of 4.5 days (D-COOH), 0.7 to 11.6 days (Br_2CA) and 0.6 to 0.9 days (mPBacid). The kinetic evaluation also indicated that on average 31% of the initial degradation of deltamethrin occurs via oxidation of the nitrile group (forming D-COOH), while 69% occurs via ester cleavage (forming Br_2CA and mPBacid).	X

A7.2.2.1(4) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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	
	It can be concluded that deltamethrin is relatively rapidly degraded in soil, with first-order DT_{50} values 11 to 27 days, and forms short-lived metabolites.	
4.3 Conclusion		X
4.3.1 Reliability	1	
4.3.2 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	September 2009
Materials and Methods	Applicant's version is acceptable but the following points should be noted. This study on the route and rate of degradation in soil of deltamethrin and its metabolites was included in the applicant's dossier on permethrin because it contains information on the rate of degradation in soil of the metabolite 3-phenoxybenzoic acid (which is a common metabolite of permethrin, deltamethrin and other pyrethroids). The metabolite is referred to in this study as mPBacid. Section 3.2 Only brief details are given of the kinetic analysis undertaken. It is necessary to refer to the actual study report for a complete description.
Results and discussion	The following amendment should be noted. Section 4.2 The DT_{50} values presented were normalised to a reference temperature of 25 °C. The values should be re-normalised to 12 °C if they are to be used in a biocides exposure assessment. Two DT_{50} values are reported for mPBacid at 25 °C (0.9 days in Dubbs soil, 0.6 days in Hagerstown soil). Re-normalisation to 12 °C, using the equation employed in the Allen (2007) study (Section A.7.2.2.1(3)), results in respective DT_{50} values of 2.5 days and 1.7 days.
Conclusion	The applicant has not included a conclusion. Conclusion should be as follows. Normalised (12 °C) DT_{50} values obtained from the kinetic evaluation for mPBacid (3-phenoxybenzoic acid) are 1.7 days and 2.5 days.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~

A7.2.2.1(4) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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**

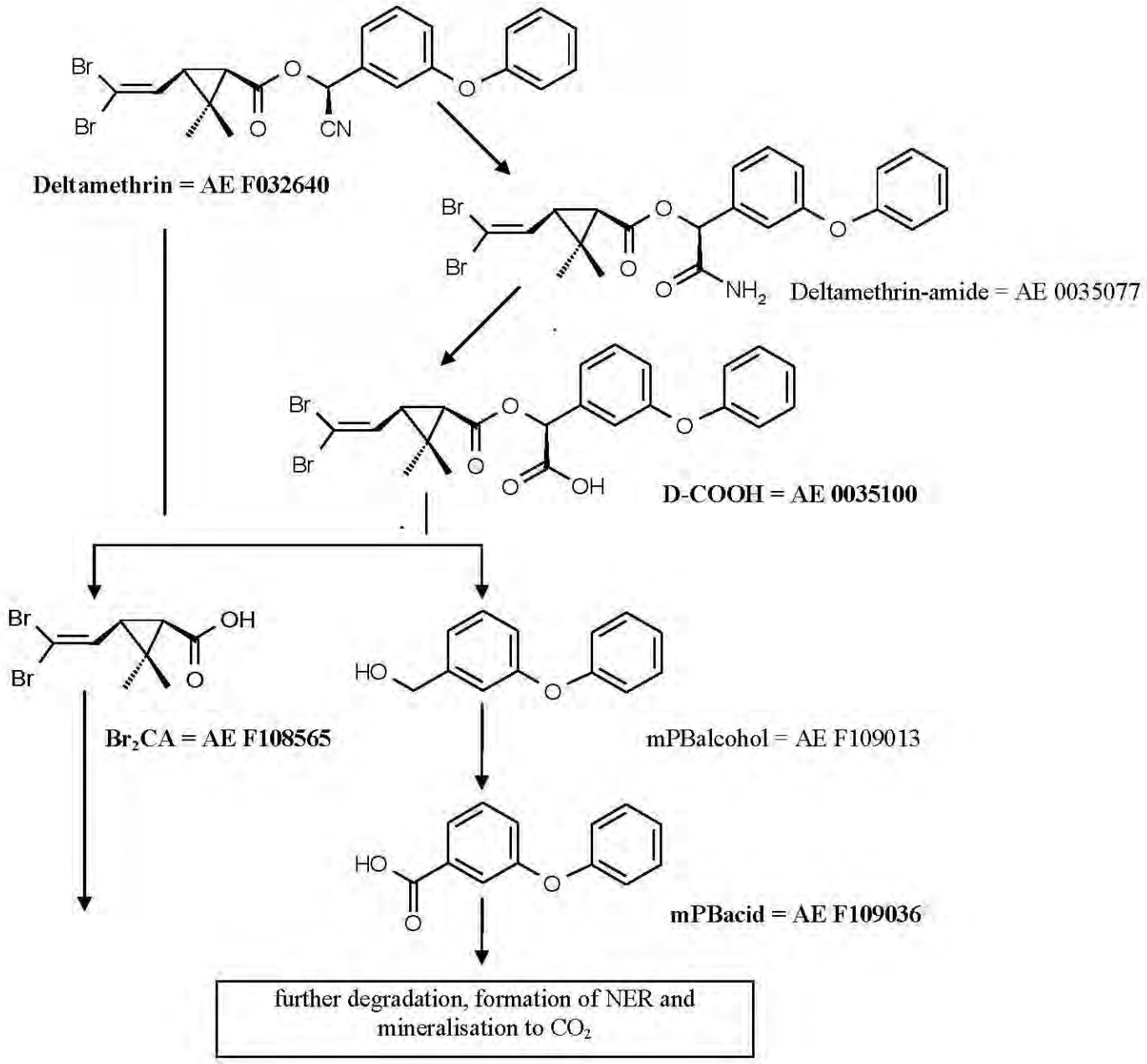
Key Study

Remarks	It should be noted that 3-phenoxybenzoic acid is a common metabolite of a number of pyrethroid substances. In order to decide on the most appropriate soil DT_{50} value for this metabolite, account should also be taken of peer-reviewed values obtained in the EU review programme for pesticides assessed under Directive 91/414/EEC. For example, the EFSA Conclusion on zeta-cypermethrin reports laboratory soil first order DT_{50} values (20 °C, aerobic) for mPBAcid in the range 3-7 days (n = 3). Extrapolated to 12 °C, this range would be 5.6-13.2 days. The EFSA Conclusion also reports field DT_{50} values for this metabolite of 4.8 days (S France, bare soil) and 5.9 days (Italy, bare soil).
	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 A7.2.2.1(4)-1First-order DT_{50} Values of Deltamethrin and its Metabolites D-COOH (AE 0035100), Br_2CA (AE F108565) and mPBacid (AE F109036) in Soil Under Laboratory Conditions, Normalised to 25°C and Field Capacity (they are the geometric means from multiple values for each soil).

Soil	Deltamethrin (days)	D-COOH (days)	Br_2CA (days)	mPBacid (days)
Casa Grand	16.7	-	11.6	-
Dubbs	17.6	4.5	0.9	0.9
Hagerstown	11.0	-	0.7	0.6
Memphis	26.5	-	-	-

Figure 7.2.2.1(4)-1. Proposed Metabolic Pathway of Deltamethrin in Soil.
The compounds in bold were addressed in the kinetic evaluation; none of the other metabolites exceeded 0.5% in any laboratory soil degradation study.



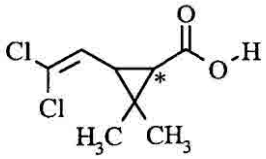
A7.2.2.1(5)
BPD Data set IIIA/ Annex Point VII.4, XII.1.1

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

Official use only

	1 REFERENCE	
1.1	**Reference**	Sakata, S., Mikami, N., and Yamada, H. (1992). Degradation of Pyrethroid Optical Isomers in Soils. J. Pesticide Sci. 17, 169-180. Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd. Bayer AG Report No.: M 9193 BES Ref: M-001653-01-1 Published paper
1.2	**Data protection**	No
1.2.1	Data owner	Published study
1.2.2	Criteria for data protection	No data protection claimed
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No
2.2	**GLP**	No Published paper.
2.3	**Deviations**	None
	3 MATERIALS AND METHODS	
3.1	**Test material**	
3.1.1	Lot/Batch number	Not specified
3.1.2	Specification	DCVA, dichlorovinyl analogue of chrysanthemic acid [(*1RS*)-*cis*, *trans*-3-(2,2-dichlorovinyl)-2, 2-dimethylcyclopropane carboxylate], labelled at the cyclopropyl C-1 carbon.
3.1.3	Purity	The radiochemical purity was >98.5%.
3.1.4	Radiolabelling	 Radiochemical purity >98.5%, 58.0 mCi/mmol
3.1.5	UV/VIS absorption spectra and absorbance value	Not applicable
3.1.6	Further relevant properties	The compound was a mixture of 4 isomers of DCVA, labelled at the cyclopropyl C-1 carbon.
3.2	**Reference substances**	Table 7.2.2.1(5)-1 shows the R*f* values in TLC plates for each of 4 isomers of unlabelled DCVA reference substance. The retention times after separation of the isomers by HPLC are also provided.
3.3	**Test solution**	Soil sample containing *ca* 0.5 ppm radiolabelled DCVA.
3.4	**Testing procedure**	

A7.2.2.1(5) BPD Data set IIIA/ Annex Point VII.4, XII.1.1	**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	
3.4.1 Test system	Test soil samples: characteristics are given in table 7.2.2.1(5)-2 Moisture content: Max. 40% of max. water holding capacity	
3.4.2 Duration of the test	2 weeks incubation	
3.4.3 Conditions of test:	25 ± 2°C, in the dark, during which time each sample was purged with CO_2-free air and the volatile ^{14}C trapped in sodium hydroxide solution. Moisture content was maintained.	
3.4.4 Number of replicates	Two replicates per sampling day.	
3.4.5 Sampling	0, 6, 13, 20. 27 and 42 days after treatment	
3.4.6 Extraction	At each sampling time, incubated soil samples were suspended with HCl and extracted with ethyl acetate. Radioactivity was determined by LSC in the aqueous layer and combined ethyl acetate extracts. After concentration of the extracts, an aliquot was analysed by TLC. The silica gel region corresponding to DCVA on TLC plates was scraped, eluted with ethyl acetate and analysed for 1*R*/1*S* isomerisation.	
3.4.7 Unextractable residues	Dried and combusted to $^{14}CO_2$ and radioactivity determined by LSC. Aliquots were also fractionated into fulvic and humic acids and humin and the fulvic acid fraction extracted with ethyl acetate. The organic layer was concentrated and examined by TLC	
3.4.8 ^{14}C determination and quantification:	Liquid scintillation counting (LSC)	
3.4.9 Identification	Co-chromatography of standards by chiral HPLC (column SUMIPAX-OA 2000 and 4600) with UV detection or on TLC-plates with visualisation under UV-light or by autoradiography.	
	4 RESULTS	
4.1 Screening test	Not performed	
4.2 Degradation rates	For the *trans* isomers of DCVA, degradation rates of the 1*R* isomers degraded faster than the 1*S* isomers in both soils. In the case of the *cis* isomers, there was no significant difference in the degradation rate between 1*R* and 1*S* isomers.	
4.3 Mean balance of radioactivity	More than 97% of the applied radioactivity was recovered from the soils after treatment.	
4.4 Effect of pH	Not applicable	
4.5 Half-life	The half-lives of the 4 isomers of DCVA in aerobic soils ranged from 11.7 to 61.8 days depending on the isomer and are summarised in Table 7.2.2.1(5)-3.	X

A7.2.2.1(5) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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

4.6	**Formation and identity of degradation products**	A major degradation product of DCVA isomers was $^{14}CO_2$, which amounted to *ca* 20% of the applied radioactivity in both soils, 42 days after incubation. The amount of bound radioactivity was *ca* 20% of applied radioactivity for Noichi soil and *ca* 35% for Ushiku soil. In the soil extracts, two unknown degradation products (R*f* 0.66 and 0.33 in solvent system C) were detected in both soils; one (R*f* 0.66) was in trace amounts and the other, a relatively polar compound, possibly a dicarboxylic analogue (COOH-DCVA) of DCVA (R*f* 0.33) amounted to *ca* 15% in the Noichi soil treated with 1*S*, *cis-and* 1*R*, *cis*-DCVA. 1*R*/1*S* isomerisation did not occur in the test soils, as analysed by HPLC in the soil extracts following isolation by preparative TLC.
4.7	**Degradation pathway**	The major degradation pathways of pyrethroids in soils are hydrolysis of the ester linkage and mineralisation of hydrolysis products to CO_2. DCVA undergoes oxidation at one of the methyl groups, yielding the dicarboxylic acid analogue (COOH-DCVA).

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The degradation of four isomers of DCVA was examined in two soils. Samples were incubated in the dark for a period of 2 weeks at 25 ± 2ºC. Samples collected at 0, 6, 13, 20, 27 and 42 days after treatment were suspended with HCl and extracted with ethyl acetate. Radioactivity was determined by LSC in the aqueous layer and combined ethyl acetate extracts. After concentration of the extracts, analysis and identification of the degradation products and determination of 1*R*/1*S* isomerisation was performed by TLC with autoradiography and by chiral HPLC-UV.
5.2	**Results and discussion**	More than 97% of the applied radioactivity was recovered from the soils after treatment. The half-lives of the 4 isomers of DCVA in aerobic soils ranged from 11.7 to 61.8 days depending on the isomer. For the *trans* isomers of DCVA, degradation rates of the 1*R* isomers were faster than the 1*S* isomers in both soils. In the case of the *cis* isomers, there was no significant difference in the degradation rate between 1*R* and *1S* isomers. A major degradation product of DCVA isomers was $^{14}CO_2$, which amounted to *ca* 20% of the applied radioactivity in both soils, 42 days after incubation. 1*R*/1*S* isomerisation did not occur in the test soils, as analysed by HPLC in the soil extracts following isolation by preparative TLC.
5.3	**Conclusion**	The 4 isomers of DCVA degraded relatively rapidly in soil, releasing CO_2 as the major product. Half-lives for the 1*R, trans* isomer were determined to be 11.7 days and 31.4 days while those for the 1*S, trans* isomer were 23.1 days and 61.8 days in the two different soils tested. For the 1*R-cis* isomer, half-lives of 13.5 days and 15.7 days were determined, whereas the 1*S-cis* DCVA showed half-live times of 16.5 days and 16.0 days in the soils tested.
5.3.1	Reliability	2
5.3.2	Deficiencies	None

A7.2.2.1(5) **BPD Data set IIIA/ Annex Point VII.4, XII.1.1**	**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

	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
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Applicant's version is acceptable with the addition of the following comments. Section 4.5 and Table 7.2.2.1(5)-3 The soil half-life values given are aerobic values at 25 °C and at 40% of maximum water-holding capacity. Extrapolation to 12 °C, using the equation in th EC Technical Guidance Document (section 2.3.6.1), results in DT_{50} values ranging from 33.1 days to 175 days.
Conclusion	Applicant's version is acceptable with the addition of the following comments. The aerobic soil half-life values presented for the four isomers of DCVA were determined at 25 °C and at 40% of maximum water-holding capacity. Extrapolation to 12 °C gives half-life values of 33.1 and 88.8 days for the 1*R,trans* isomer, 65.4 and 175 days for the 1*S,trans* isomer, 38.2 and 44.4 days for the 1*R,cis* isomer, and 46.7 and 45.3 days for the 1*S,cis* isomer.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	It should be noted that DCVA (2,2-dimethyl-3-(2,2-dichlorovinyl)cyclopropanecarboxylic acid) is a common metabolite of a number of pyrethroid substances. In order to decide on the most appropriate soil DT_{50} value for this metabolite, account should also be taken of peer-reviewed values obtained in the EU review programme for pesticides assessed under Directive 91/414/EEC. For example, the EFSA Conclusion on zeta-cypermethrin reports laboratory soil first order DT_{50} values (20 °C, aerobic) for *cis*-DCVA in the range 2.7-8 days (n = 3) and for *trans*-DCVA in the range 3.1-11 days (n = 3). Extrapolated to 12 °C, these ranges would respectively be 5.1-15 days and 5.8-21 days. The EFSA Conclusion also gives a field DT_{50} value for *trans*-DCVA of 2.9 days (Italy, bare soil).
	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 7.2.2.1(5)-1: R*f* values in TLC plates and HPLC retention times for isomers of DCVA

Optical isomers	TLC R*f* values			HPLC retention times (min)
	C	D	E	
1*R, trans*-DCVA	0.46	0.33	0.38	25.1
1*R, cis* -DCVA	0.49	0.44	0.45	45.5
1S, *trans*-DCVA	0.46	0.33	0.38	28.3
1S,*cis*-DCVA	0.49	0.44	0.45	48.0

C: n-hexane/toluene/acetic acid (3/15/2); D: n-hexane/acetone (4/1, 2 times);

E: toluene/ethyl ether/acetic acid (75/25/1).

Table A7.2.2.1(5)-2: characteristics of soils used in the experiments

	Ushiku soil	Noichi soil
Texture (* UK ADAS classification system)	Silty loam (*sandy silt loam)	Clay loam (*sandy clay loam)
Sand	43%	55%
Silt	47%	26%
Clay	10%	19%
pH	7.0	7.0
Organic matter	7.6%	3.3%
Max. water holding capacity (g/100 g dry soil)	124.9	67.8

Table 7.2.2.1(5)-3: Half-lives of four isomers of DCVA in aerobic soils

DCVA optical isomers	Half-life (Days)	
	Ushiku soil	Noichi soil
1*R, trans*	11.7	31.4
1*S, trans*	23.1	61.8
1*R, cis*	13.5	15.7
1*s, cis*	16.5	16.0

Section 7.2.2.2 Annex Point XII.1.1, Annex VI, para 85	**Field Soil Dissipation and Accumulation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [✓]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	DT_{50} values calculated from the aerobic degradation investigation conducted on the Frensham soil result in at 32.1 days and 37.0 days, respectively (Hawkins, D.R.; 1992). Kinetic evaluation of permethrin degradation in the Memphis, Dubbs, Sharkey, and Hagerstown soils (Kaufman, D.D., et al.; 1978) was undertaken using simple first order kinetics because of the shorter incubation period (34 days). DT_{50} values were estimated at 47.6, 31.4, 49.8, and 27.3 days from carbon dioxide evolution rates, respectively. This approach is highly conservative as evolved carbon dioxide accounts for, at most, 50% of the degraded permethrin during the course of the study. When the estimation is based upon the percentage of permethrin remaining after 28 d, the resulting DT_{50} are 10.3 7.3, 7.3, 15.1 and 10.4 days at 25°C in the Memphis, Dubbs, Sharkey, and Hagerstown soils, respectively. (Allen, R 2007). DT50 values suggest that permethrin is not expected to persist in soil matrices; hence, the potential for permethrin accumulation in soil is considered low. The degradation of four isomers of DCVA was examined in two soils, under aerobic conditions in the dark at 25°C [Sakata, S., Mikami, N., and Yamada, H. (1992)]. The 4 isomers of DCVA degraded relatively rapidly in soil, releasing CO_2 as the major product. The half-lives of the 4 isomers of DCVA in soils ranged from 11.7 to 61.8 days. The experimental data from laboratory soil degradation studies were used to quantify the degradation kinetics of deltamethrin (another pyrethroid) and its major metabolite Br_2CA and its minor metabolites D-COOH and mPBacid in soil [Schäfer, D. and Mikolasch, B. (2004)]. The kinetic evaluation was conducted with the ACSL Optimize software package (ACSL, 1996). The DT_{50} values of 0.6 to 0.9 days were determined for mPBacid. Based on these experimental data from the laboratory aerobic soil degradation studies, the degradation kinetics of permethrin and its metabolites in soil have been quantified. It has been concluded that permethrin is relatively rapidly degraded in soil and forms short-lived metabolites. Therefore, field soil dissipation and accumulation studies should not be required	
Undertaking of intended data submission [ ]	-	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the	

Section 7.2.2.2 Annex Point XII.1.1, Annex VI, para 85	**Field Soil Dissipation and Accumulation**
	comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2009
Evaluation of applicant's justification	Applicant's justification is acceptable.
Conclusion	Applicant's justification is acceptable. Field soil dissipation and accumulation studies are not required since sufficient information has been presented to characterise the degradation behaviour in soil of permethrin and metabolites formed.
Remarks	Terrestrial field dissipation data on permethrin have previously been reviewed by the US EPA. Permethrin appeared to dissipate in the field (bare ground plots) with half-life values of 17 days for a North Carolina site and 43 days for an Illinois site.
	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 A7.2.2.3 Extent and nature of bound residues

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

Key Study

Official use only

		1 REFERENCE
1.1	**Reference**	Sakata, S., Mikami, N., Yamada, H.; 1992; Degradation of Pyrethroid Optical Isomers in Soil. J. Pesticide. Sci. 17, 169-180; Not GLP; Published
1.2	**Data protection**	No
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC
1.2.2	**Criteria for data protection**	No data protection claimed
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	No
2.2	**GLP**	No: Sumitomo Research Laboratory
2.3	**Deviations**	No: Protocol was not to any guidelines
		3 MATERIALS AND METHODS
3.1	**Test material**	As given in section 2, ^{14}C radiolabelled *cis* and *trans*, R and S 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 98.5%
3.1.4	**Further relevant properties**	Radiolabelled at the methylene Carbon
3.1.5	**Composition of Product**	None
3.1.6	**TS inhibitory to microorganisms**	No
3.1.7	**Specific chemical analysis**	**Sodium hydroxide**; A suitable aliquot was was analysed by LSC for total radioactivity. **Soil**; Samples were extracted by shaking for 10 min consecutively with acetone (60ml x 2) and methanol (60 ml x 1). Extract volumes were reduced to dryness, combined and redissolved in acetone for specific analysis. Unextracted residues were fractionated into fulvic, humic and humin fractions. Average recoveries for samples were >95%. All sample extracts were analysed by TLC: Plate $Si_{60}F_{254}$ System B: Hexane:Ethyl ether 20:1, 2 times System C: Hexane:Toluene:Acetic acid 3:15:2 System D: Hexane:Acetone 4:1
3.2	**Reference substance**	No
3.2.1	**Initial concentration of reference substance**	No
3.3	**Test ing**	

Section A7.2.2.3 Extent and nature of bound residues

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

		Key Study	
	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)	X
3.3.3	**Method of preparation and dosing of test soil**	A stock solution of each isomer of permethrin was prepared such that 100 µl of acetone contained 15 µg of isomer. Soil, equivalent to 15 g on an oven dried basis was placed in a 30 ml beaker and the moisture adjusted to 40% MHC. Soils were preincubated in the dark at 25 ± 2°C, after which 100 µl of the appropriate dosing solution was added to the soil. Each soil was mixed thoroughly , placed in the 3l jar and incubated in the dark until required for analysis.	
3.3.4	**Initial TS concentration**	1.0 mg kg^{-1} on a dry weight basis	
3.3.5	**Duration of test**	16 weeks	
3.3.6	**Analytical parameter**	Specific analysis	X
3.3.7	**Sampling**	0, 1, 2, 4, 8, 12, 16 weeks	
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	**Graph**	See Figure 1	
4.1.2	**Degradation**	Degradation of the isomers and identification of different metabolites after 2 weeks is described in tabular form (see table A7_1_1_2-3) No numerical data on individual time points are presented by the authors to enable calculation of DT50. However, they do provide calculated DT50s based upon their data, and these are given in Table A7_1_1_2-4.	
4.1.3	**Intermediates/ degradation products**	Minor degradation products (see table A7_1_1_2-3, III-1, III-2, VI) were identified as; **III-1**: 3-Hydroxybenzyl (1R)-*cis,trans*-3-(2,2-dichlorvinyl)-2,2-dimethylcyclopropanecarboxylate **III-2**: 3-(4-Hydroxyphenoxy)benzyl (1R)-*cis,trans*-3-(2,2-dichlorvinyl)-2,2-dimethylcyclopropanecarboxylate **VI**: 3-Phenoxybenzoic acid	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, although no measurement of biomass was taken, the inclusion of biomass is not typical in	

Section A7.2.2.3 Extent and nature of bound residues

Annex Point IIA7.6.1.1
Annex Point IIA7.6.1.2

		Key Study	
		research based work. The test system was 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. The analysis was based on TLC, which, while being of a lower resolution than more recent techniques, was capable of resolving *cis*- and *trans*- isomers, although not R, S isomers. Because the permethrin isomers were radiosynthesised and tested separately, this is not considered to be a negative aspect of the test.	
5.2	**Results and discussion**	The results, shown in Table A7_1_1_2-4 indicate that permethrin can be rapidly degraded in the terrestrial environment. In both the R and S configuration, the *cis* is more resistant to biodegradation. Because of the position of the radiolabel, metabolites from the cyclopropyl moiety would not be identified after ester cleavage. However, the metabolites identified were typical of either ester cleavage or phenyl substitution.	X
5.3	**Conclusion**	The test protocol does not compare 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. Since permethrin has such a short half-life, the sampling points are too widespread over the beginning of the test period (days 0, 14) to allow real confidence in the actual derived DT50 values. What can be derived from the results is that the DT50 of permethrin in soil is very short, less than 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	*18 April 2005*
Materials and Methods	The applicant's version is acceptable, with the following revisions: **Comments:** (Section 3.3.6) Non-extractable residues were dried and sampled in duplicate (300 mg) and combusted to CO_2 prior to analysis. Soil samples were extracted into the fulvic acid, humic acid, and humin fractions in the analysis. The fulvic acid fraction was extracted with ethyl acetate (200 ml × 3), and the organic and aqueous fractions were radio-counted. The organic layer was concentrated and examined using TLC. The humic acid and humin fractions were extracted according to a general procedure described under the US Federal Register 40, 26893 (1975).
Results and discussion	Adopt applicant's version with the following revisions: **Comments:** (Section 4.1.3 and 5.2) Addition of the formation percentages next to the degradation products: **III-1**: 3-Hydroxybenzyl (1R)-*cis,trans*-3-(2,2-dichlorvinyl)-2,2-dimethylcyclopropanecarboxylate, reaching a maximum of 12.4% AR following two weeks incubation. **III-2**: 3-(4-Hydroxyphenoxy)benzyl (1R)-*cis,trans*-3-(2,2-dichlorvinyl)-2,2-dimethylcyclopropanecarboxylate, reaching a maximum of 5.7% AR following two weeks incubation. **VI**: 3-Phenoxybenzoic acid, reaching a maximum of 1.6% AR following two weeks incubation. Results indicate formation of two minor metabolites at below 10% of applied radioactivity following two weeks incubation the test soils. Another metabolite (III-1) was observed to reach levels at greater than 10% of the applied radioactivity in both soils following dosing with permethrin. The maximum level of III-1 reached 12.4% AR in the Kodaira soil after two weeks incubation. Aliquots of the bound residues were fractionated into the fulvic, humic, acid fractions and humin. In the Kodaira soil maximum bound radioactivity accounted for between 9.4%, 24.6%, and 6.7% AR in the fulvic, humic, and humin fractions, respectively. Maximum bound radioactivity accounted for between 11.3%, 13.3%, and 8.4% AR in the fulvic, humic, and humin fractions, respectively, of the Azuchi soil. The bound residues were distributed mainly in the humic acid fraction, of which maximum levels were observed in the Kodaira soil, owing to the high organic matter content (15.3%) and clay content (29%) of this soil. Overall, no parent compound was detected in the analysed bound fractions, possibly indicating the complete chemical incorporation of permethrin residues into the soil organic matter.
Conclusion	Include revised version of the conclusion, which fully addresses the data point to be covered, i.e. the extent and nature of NER. **Comments:** (Section 5.3) A published, non-GLP laboratory test on the degradation of pyrethroid isomers, including permethrin, in two soils indicated that permethrin is bound to soils up to a maximum of 39.8% AR after two weeks incubation at a temperature of 25 ± 2°C under dark conditions. Further analysis of the bound soil residue showed that the distribution of the residues was principally in the humic acid fraction (up to 24.6% AR), with maximum levels of radioactivity in the fulvic acid and humin fraction accounting for 11.3% and 8.4%, respectively. NER levels were observed in the largest quantities in the Kodaira soil probably as a result of the high organic matter (15.3%) and clay (29%) contents of this soil and chemical incorporation into the soil organic matter.
Reliability	2

Acceptability	acceptable / ~~not acceptable~~
Remarks	Whilst the test does not comply exactly with any test guidelines and certain points of test detail are not provided, the overall quality of the study remains good. The method employed provided a test system that was incubated that allowed air exchange, structured analysis, radiolabelled test material is used, and a full material balance is established. The test conditions compare favorably to present day guidelines, with dark conditions during the incubation period, a test temperature at 25 ± 2°C, and soil moisture adjusted to 40% MWHC.
	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 «Kodaira»	**Soil 2 «Azuchi»**
Soil order	No data	No data
Soil series	No data	No data
Classification	Light clay	Sandy clay loam
Location	Tokyo metropolis	Shiga prefecture
Horizon	No data	No data
Sand [%]	31	65
Silt [%]	40	18
Clay [%]	29	17
Organic matter [%]	15.3	2.5
Carbonate as $CaCO_3$	No data	No data
insoluble carbonates [%]	No data	No data
pH (1:1 H_2O)	5.5	6.3
Cation exchange capacity (MEQ/100 g)	53.7	13.5
Extractable cations (MEQ/100 g)	No data	No data

Table A7_1_1_2-2: Test system and conditions

Criteria	**Details**
6.1.13 Test vessels	30ml beaker
6.1.14 Number of test vessels/soil	14 beakers, stored in a 3 litre glass jar.
6.1.15 Aeration device	The glass jar was continuously purged with CO_2 free air, which was then passed through 400 ml 0.5M NaOH to trap $^{14}CO_2$.
6.1.16 Measuring equipment	None
6.1.17 Test temperature	25 ± 2°C
6.1.18 Light conditions	Dark
6.1.19 Test performed in closed vessels due to significant volatility of TS	No

Table A7_1_1_2-3: Concentrations of permethrin and degradates in aerobic soil after 2 weeks incubation

Table 9 Concentrations of permethrin (III) isomers and their degradation products in aerobic soils after 2-week incubation.

	% of the applied ^{14}C							
	Kodaira soil				Azuchi soil			
	1*R* isomers		1*S* isomers		1*R* isomers		1*S* isomers	
	trans	*cis*	*trans*	*cis*	*trans*	*cis*	*trans*	*cis*
NaOH soln. ^{14}C	36.3	9.4	42.7	9.3	50.3	15.2	58.4	21.3
Extract ^{14}C	18.9	50.1	20.6	57.5	20.8	52.8	14.4	43.1
trans-III	13.2	<0.1	10.8	<0.1	15.1	<0.1	10.3	<0.1
cis-III	<0.1	30.9	<0.1	36.2	<0.1	35.8	<0.1	26.0
III-1	1.5	10.7	3.3	12.4	1.9	11.4	0.8	8.7
III-2	1.3	3.6	2.1	4.0	1.2	2.5	1.2	5.7
VI	0.7	1.0	1.6	0.6	1.5	0.4	1.2	0.3
Others	2.2	3.9	2.8	4.3	1.1	2.7	0.9	2.4
Bound ^{14}C	39.8	36.4	37.3	31.6	28.6	27.3	25.9	32.3
Fulvic acid	9.4	7.1	7.8	5.5	11.3	10.9	8.5	10.6
Humic acid	24.6	23.1	23.5	19.4	11.6	10.4	11.4	13.3
Humin	5.8	6.2	6.0	6.7	5.7	6.0	6.0	8.4
Total ^{14}C	95.0	95.9	100.6	98.4	99.7	95.3	98.7	96.7

Table A7_1_1_2-4: Half-life of permethrin in aerobic soils (days)

Isomer	Kodaira soil	Azuchi soil
1*R*, *trans*	4.1	3.9
1*R*, *cis*	8.1	6.4
1*S*, *trans*	3.1	2.5
1*S*, *cis*	9.8	5.8

Figure 1: Degradation of isomers in soil

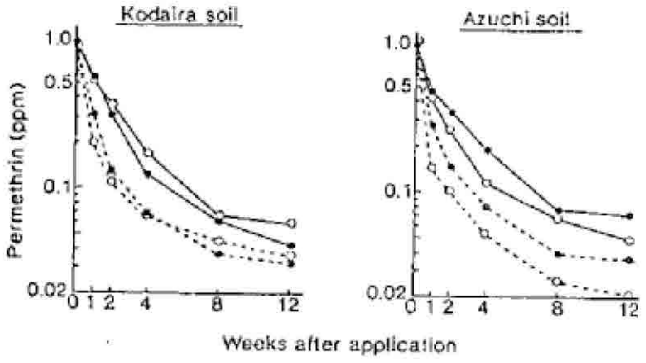


Fig. 4 The concentrations of permethrin (III) isomers in soils under aerobic conditions.

●···●, 1*R*, *trans*; ○···○, 1*S*, *trans*; ●—●, 1*R*, *cis*; ○—○, 1*S*, *cis*.

Section A7.2.2.4	**Other soil degradation studies**
Annex Point IIIA, VII.4 **Annex Point IIIA,XII.1.1**	**Phototransformation on soil including identity of transformation products**

		Key Study	Official use only
		1 REFERENCE	
1.1	**Reference**	Brown, P.M and Leahey, J.P; 1987; Permethrin: Photolysis on a soil surface. Report No. RJ0581B, 29 April 1987; Not GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Syngenta	
1.2.2	**Companies 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: Guidelines not available at time of testing	
2.2	**GLP**	No	
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 methylene (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: Batch 86-J28 alc[^{14}C]permethrin: Batch 86-J29	
3.1.2	**Specification**	acid[^{14}C]permethrin: *cis*:*trans* ratio 49:51 alc[^{14}C]permethrin: *cis*:*trans* ratio 49:51	
3.1.3	**Purity**	acid[^{14}C]permethrin: 95.0% alc[^{14}C]permethrin: 93.4%	
3.1.4	**Radiolabelling**	As shown in Figure 1	
3.1.5	**UV/VIS absorption spectra and absorbance value**	As shown in Figure 3 (from Amos, R. and Donelan, R. B 1987)	
3.1.6	**Further relevant properties**	acid[^{14}C]permethrin: Specific activity 1.02 GBq mmol^{-1} alc[^{14}C]permethrin: Specific activity 2.32 GBq mmol^{-1}	
3.1.7	**Preparation of test chemical solution**	Radiochemical stock solutions were prepared in hexane, such that the solutions contained 5 µg permethrin per 100 µl hexane (on 1 cm^2 area of soil, 100 µl dosing solution is equivalent to an overspray of 0.5 kg ha^{-1}).	
3.2	**Reference substances**	None	
3.3	**Soil type**	See table A7_1_1_2-1	

Section A7.2.2.4	Other soil degradation studies
Annex Point IIIA, VII.4 Annex Point IIIA,XII.1.1	Phototransformation on soil including identity of transformation products

		Key Study
3.4	Testing procedure	
3.4.1	Test system	See table A7_1_1_2-2, Figure 4.
3.4.2	Properties of light source	See table A7_1_1_2-2, Figure 5
3.4.3	Determination of irradiance	See table A7_1_1_2-2, Figure 5
3.4.4	Temperature	Temperature was maintained at 25 ± 5°C throughout the exposure period, by a flow of water and air.
3.4.5	pH	Not recorded
3.4.6	Duration of the test	33 days 3 hours (Florida autumn sunlight equivalents)
3.4.7	Number of replicates	2 replicates per time point, per radiolabel
3.4.8	Sampling	Nominal irradiation period; 0, 5, 15, 20, 30 (Florida autumn sunlight equivalents) Actual irradiation period; See Results Table 1.
3.4.9	Analytical methods	The soil was scraped into a 10 ml graduated tube and the plate area washed with 5 ml acetonitrile, into the tube. The tube was then ultrasonicated for 10 minutes, then centrifuged, the supernatant being transferred to a 25 ml volumetric flask. This was repeated with 1 x acetonitrile and 3 x methanol, and the extracts combined and analysed by LSC. The soil was air dried, and subsamples combusted for LSC analysis. Polyurethane bungs from the inlet and outlet arms were refluxed in acetonitrile (25 ml, 1 hr) and assayed by LSC to determine loss of volatile materials. Silicone tubing joining the vessels were allowed to stand in methanol (4 hours), which was subsequently assayed by LSC. Trapping solutions were assayed by LSC at time of sampling. Extracts were analysed by thin layer chromatography (TLC). TLC was carried out using either pre-coated normal phase $Si_{60}F_{254}$ silica gel plates or pre-coated reverse phase C18 silica gel plates, under the following conditions; Solvent system 1: Hexane:Diethyl ether 20:1 v/v Solvent system 2: Hexane (sat'd w acetonitrile) Solvent system 3: Cyclohexane (sat'd w formic acid):Diethyl ether 3:2 Solvent system 4: Chloroform:acetonitrile:formic acid 90:10:0.2 Samples were co-chromatographed alongside reference standards of permethrin and metabolites as shown in Figure 2.
3.5	Transformation products	No
3.5.1	Method of analysis for transformation products	No

Section A7.2.2.4	**Other soil degradation studies**
Annex Point IIIA, VII.4 **Annex Point IIIA,XII.1.1**	**Phototransformation on soil including identity of transformation products**

Key Study

4 RESULTS

4.1	**Screening test**	Not performed
4.2	**Actinometer data**	Not used
4.3	**Controls**	Control samples stored in the dark yielded quantitative recovery of applied radioactivity, all of which was present as parent material (Results Table 2).
4.4	**Photolysis data**	
4.4.1	**Concentration values**	Recovery data (as % of applied) are tabulated in Results Table 2, and shown graphically in Figures 6 and 7.
4.4.2	**Mass balance**	Total recovery of radiolabelled test substance are shown in Table 2. Individual isomer and total permethrin data are also included.
4.4.3	**k^c_p**	See 4.4.8
4.4.4	**Kinetic order**	See 4.4.8
4.4.5	**k^c_p / k^a_p**	See 4.4.8
4.4.6	**Reaction quantum yield (ϕ^c_E)**	See 4.4.8
4.4.7	**k_{pE}**	See 4.4.8
4.4.8	**Half-life ($t_{1/2E}$)**	Low losses of permethrin (7.9% of applied ^{14}Cacid, 21.1% of applied ^{14}Calcohol) over the exposure period does not allow an accurate assessment of the kinetics of photodegradation of permethrin to be made. From the data, the overall half-life of permethrin on soil appears to be in the region of approximately 200 days (Florida autumn sunlight equivalents).
4.5	**Specification of the transformation products**	Up to 9 by-products of degradation were observed, the greatest of which being 4.9% of the applied radioactivity.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was performed on steel plates, which allowed light from the Xenon Arc lamp to fully irradiated the soils. Temperature was controlled by flowthrough water and air. Sacrificial samples were removed at time intervals and solvent extracted. The extracts were then analysed by TLC (four different systems) and *cis* and *trans* isomers identified.
5.2	**Results and discussion**	Losses of permethrin were observed for both (7.9% of applied ^{14}Cacid, 21.1% of applied ^{14}Calcohol) radiolabelled materials, although the rate of disappearance is so low as to prohibit any accurate estimate of half-life or reaction kinetics. Variability between measurements makes differentiating between isomers unreliable. The half-life appeared to be in the region of approximately 200 days.
5.2.1	**k^c_p**	See 4.4.8
5.2.2	**K_{pE}**	See 4.4.8
5.2.3	**ϕ^c_E**	See 4.4.8
5.2.4	**$t_{1/2E}$**	See 4.4.8

Section A7.2.2.4	**Other soil degradation studies**
Annex Point IIIA, VII.4 **Annex Point IIIA,XII.1.1**	**Phototransformation on soil including identity of transformation products**

		Key Study	
5.3	**Conclusion**	Since permethrin had such a long half-life in the test system, the sampling points were not widespread enough to cover the measured half life. This does not allow an accurate assessment of the kinetics of photodegradation of permethrin to be made, which does not allow real confidence in the derived DT50 value.	X
5.3.1	**Reliability**	2	
5.3.2	**Deficiencies**	Yes The study was not completed to recognised GLP procedures; however the testing protocol, although not to any recognised guidelines, incorporated essential elements necessary to enable some confidence in the output. The test system was designed to allow for mass balance determinations, which were high throughout the course of the study, indicating no material was lost and some confidence can be placed in the results. Existing data indicates permethrin to be rapidly degraded in most soil types. The minimal losses observed in this study would indicate that at some stage during the soil preparation/treatment the soil underwent an element of biomass change, reducing it's functionality. It is possible that the soil biomass, sampled in Spring in the UK, being placed in a light box at a minimum of 25°C under intense light, underwent change which temporarily reduced its ability to biodegrade the permethrin.	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*19 April 2005*
Materials and Methods	The applicant's version is acceptable.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version, with the following revision: **Comments:** (Section 5.3) Whilst there is the possibility that minimal losses of permethrin in the test soil, in contrast to existing degradation permethrin data in soil, were the result of soil preparation and test system treatment, the losses of permethrin (between 7.9% and 21.1% AR) also indicate the relative photostability of the permethrin compound. In addition the number of transformation products (up to 9) are an indication that permethrin is subject to facile photoisomerism in which photo-induced molecular species are formed.
Reliability	2
Acceptability	Acceptable / ~~not acceptable~~
Remarks	**Comments:** (Section 2.3) In line with current guidelines (e.g. SETAC 1995) the following deviation was observed: The test temperature for the soil photolysis study was maintained at 25 °C ± 5 °C, instead of 20 °C ± 3 °C. This is considered a minor deviation to current test guidelines and does 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 A7_1_1_2-1: Classification and physico-chemical properties of soils used as adsorbents

Classification	Loam
Location	"18-Acres", Jealott's Hill
Horizon	10 – 25 cm
Sand [%]	47.1
Silt [%]	28.1
Clay [%]	24.8
Organic matter [%]	4.53
pH (1:1 H_2O)	6.75
Cation exchange capacity (MEQ/100 g)	19.1

Table A7_1_1_2-2: Description of test system

Criteria	**Details**
Laboratory equipment	Samples were irradiated with a Hanau NXe 4500 xenon arc lamp (Heraeus Instruments). A slurry of sieved soil in water was prepared and applied in 1mm layers, to stainless steel plates. Soil was then removed to leave two 1x1cm areas on each plate, to act as duplicates for each sampling point. Twenty such plates were then treated with permethrin, ten per radiolabel. Once the solvent had evaporated six plates per label were placed in the photolysis apparatus (Figure 4) and irradiation begun. One plate was kept for day 0 analysis, the remaining plates were stored as dark controls. The exuent air was drawn through a series of traps to remove any volatile ^{14}C by-products. The vessel had a thermocouple inserted for temperature monitoring. See Figure 4.
Test apparatus	Samples were irradiated with a Hanau NXe 4500 xenon arc lamp (Heraeus Instruments).
Properties of artificial light source:	
Nature of light source	Xenon Arc Lamp
Emission wavelength spectrum	See Figure 5
Light intensity	Light intensity was measured using an international Light IL500A Research Radiometer in conjunction with an SEE 038 broad band silicon detector. Narrow and wide band filters wewre used to monitor intensity in the following regions. NBS 297 peak wavelength 297 ± 2 nm } narrow NBS 365 peak wavelength 365 ± 2 nm } band WBS 375 peak transmission 280-420 nm } wide WBS 500 peak transmission 430-700 nm } band Intensity at each vessel position was measured at the start and on sampling. These values were transformed into standard Florida autumn sunshine equivalent days.

Results Table 1: Irradiation period

Radiolabel	Intensity ($W\ cm^2$)	Hrs irradiation	Equivalent days of Florida autumn sunlight
Cyclopropane0A	-	-	-
Cyclopropane0B	-	-	-
Cyclopropane6A	0.111	20.8	5.9
Cyclopropane6B	0.106	20.8	5.6
Cyclopropane15A	0.114	53.3	15.3
Cyclopropane15B	0.110	53.3	14.8
Cyclopropane21A	0.110	76.7	21.4
Cyclopropane21B	0.107	76.7	20.8
Cyclopropane30A	0.118	111.4 ± 3.5	33.4 ± 1.0
Cyclopropane30B	0.112	111.4 ± 3.5	31.6 ± 1.0
CyclopropaneDCA	-	-	-
CyclopropaneDCB	-	-	-
Methylene0A	-	-	-
Methylene0B	-	-	-
Methylene6A	0.113	20.8	6.0
Methylene6B	0.119	20.8	6.3
Methylene16A	0.120	53.3	16.2
Methylene16B	0.123	53.3	16.6
Methylene23A	0.120	76.7	23.3
Methylene23B	0.123	76.7	23.9
Methylene30A	0.120	111.4 ± 3.5	33.8 ± 1.0
Methylene30B	0.120	111.4 ± 3.5	34.1 ± 1.0
MethyleneDCA	-	-	-
MethyleneDCB	-	-	-

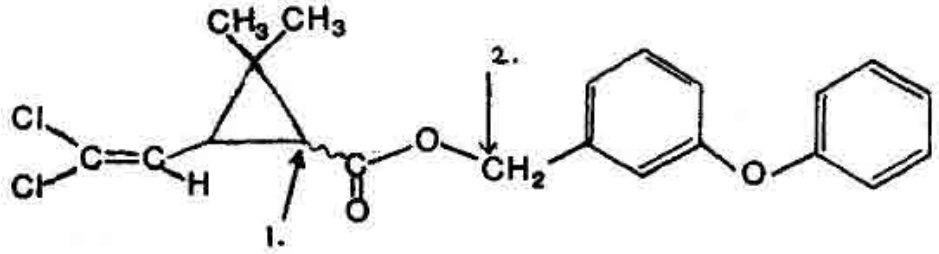
Results Table 2: Recovery data

Radiolabel	Equivalent days of Florida autumn sunlight	Total % recovery	% *cis*-permethrin	% *trans*-permethrin	% Total permethrin
Cyclopropane0A	-	94.5	42.1	40.3	82.4
Cyclopropane0B	-	95.9	42.3	43.0	85.2
Cyclopropane6A	5.9	100.6	36.6	41.1	77.7
Cyclopropane6B	5.6	97.0	39.0	37.1	76.1
Cyclopropane15A	15.3	-[a]	-[a]	-[a]	-[a]
Cyclopropane15B	14.8	104.7	43.2	42.3	85.5
Cyclopropane21A	21.4	99.1	37.9	40.9	78.8
Cyclopropane21B	20.8	101.2	38.3	42.4	80.7
Cyclopropane30A	33.4 ± 1.0	96.9	33.6	37.5	71.1
Cyclopropane30B	31.6 ± 1.0	100.7	38.9	41.8	80.7
CyclopropaneDCA	-	97.0	46.5	41.1	87.6
CyclopropaneDCB	-	96.6	45.4	41.2	86.6
Methylene0A	-	98.8	45.0	44.8	89.7
Methylene0B	-	99.3	45.3	45.2	90.5
Methylene6A	6.0	100.9	41.5	42.8	84.3
Methylene6B	6.3	99.7	43.0	45.4	88.4
Methylene16A	16.2	103.7	32.4	37.3	69.7
Methylene16B	16.6	101.2	34.1	34.9	69.0
Methylene23A	23.3	97.8	30.3	31.5	61.8
Methylene23B	23.9	101.1	28.2	31.0	59.2
Methylene30A	33.8 ± 1.0	100.1	34.1	36.9	71.0
Methylene30B	34.1 ± 1.0	102.6	31.7	35.2	67.0
MethyleneDCA	-	101.2	46.0	46.4	92.4
MethyleneDCB	-	101.3	46.3	47.4	93.7

a Not dosed, in error.

DC Dark controls

Figure 1: Permethrin structure, showing position of the radioisotope

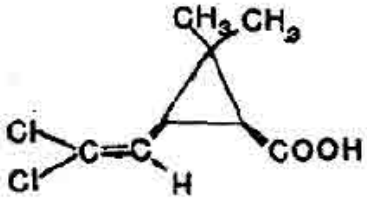


1. ^{14}C-cyclopropane-labelled permethrin, batch no. 86-J28, specific activity 1.02 GBq mmol^{-1}.

2. ^{14}C-methylene-labelled permethrin, batch no. 86-J29, specific activity 2.32 GBq mmol^{-1}.

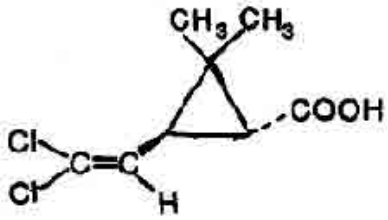
Figure 2: Reference materials

Compound I



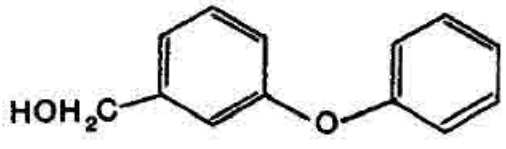
(1RS)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylic acid

Compound II



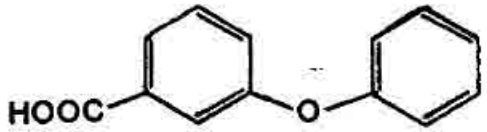
(1RS)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane-carboxylic acid

Compound III



3-phenoxybenzyl alcohol

Compound IV



3-phenoxybenzoic acid

Figure 3: UV-vis spectrum of permethrin

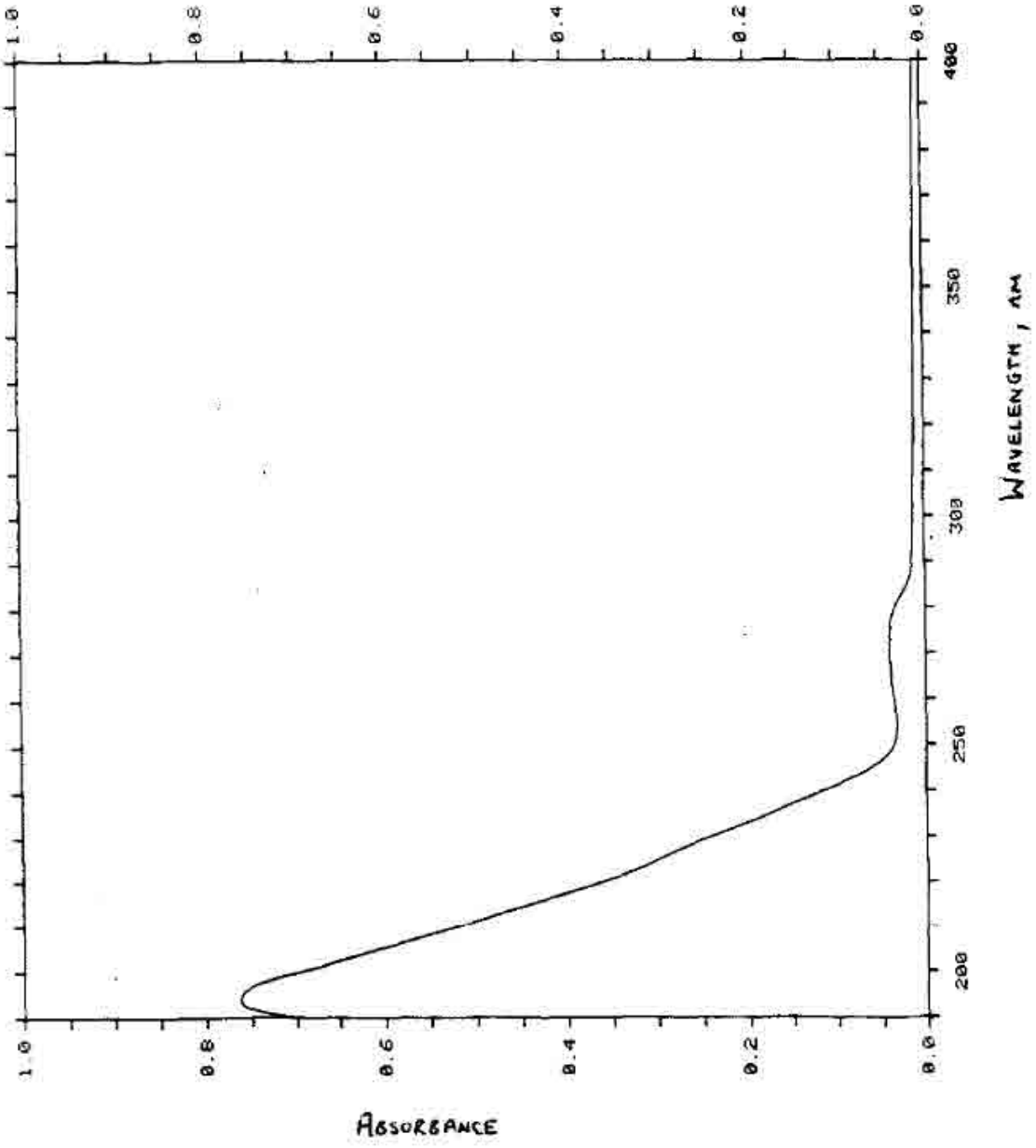


Figure 4: Test system (vessel)

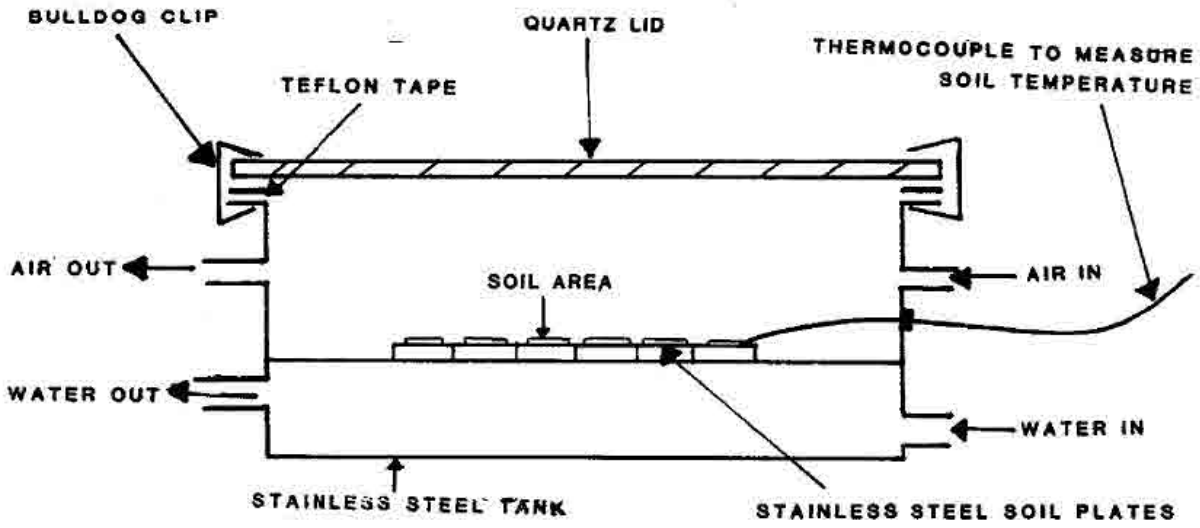


Figure 5: Properties of light source – Comparison of spectral distribution with D65 radiation

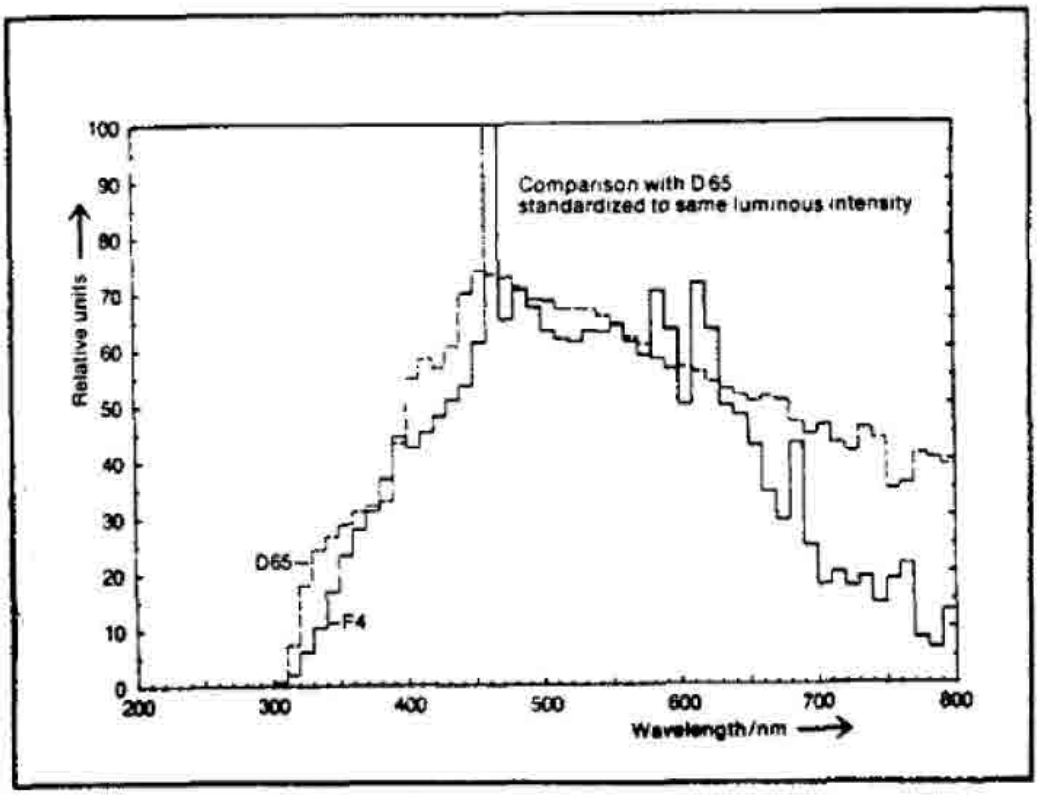


Figure 6: % recovered [^{14}C]permethrin radiolabelled in the cyclopropane (acid[^{14}C]permethrin) position

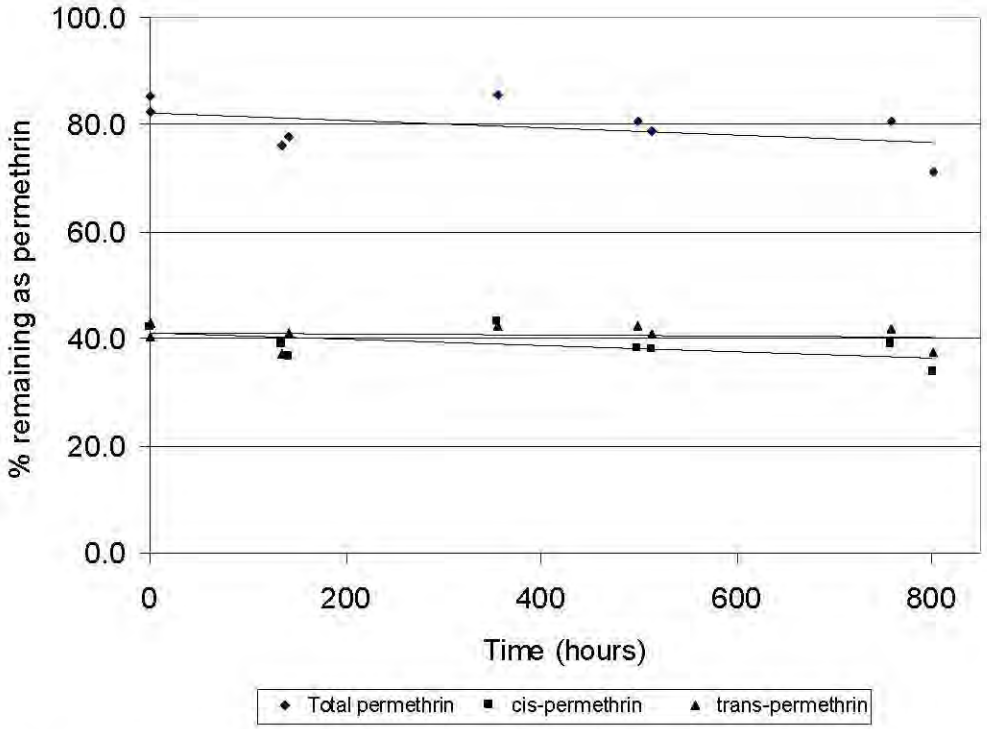
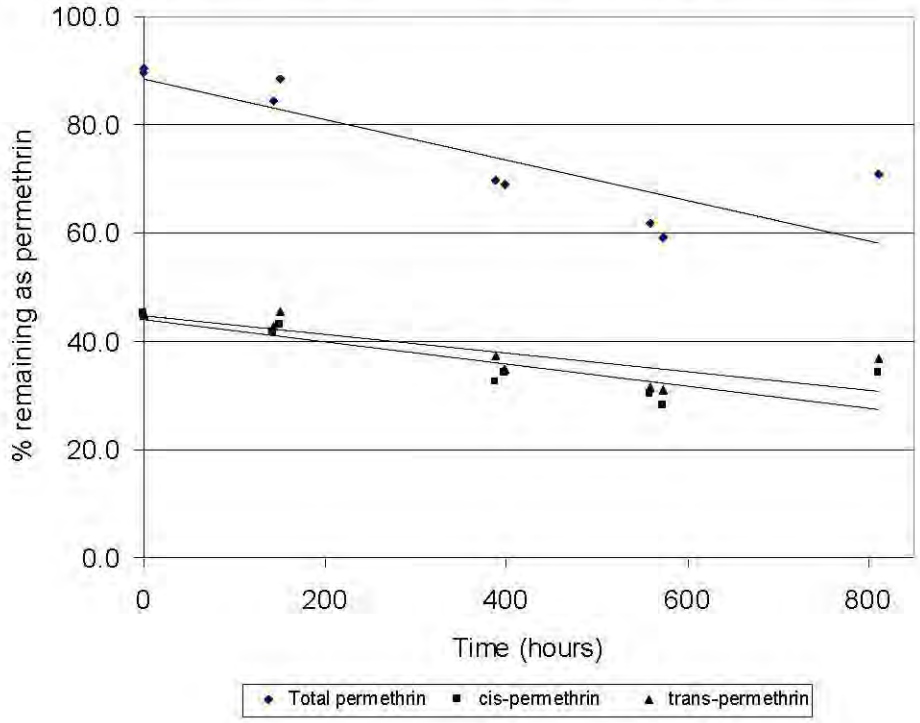


Figure 7: % recovered [^{14}C]permethrin radiolabelled in the methylene (alc[^{14}C]permethrin) position



Section A7.2.3 **Annex Point IIIA.XII.2.2**	**Adsorption and mobility in soil, further studies**	
	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	
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 A7.2.3.1 Adsorption and mobility in soil, further studies

Annex Point IIIA, XII.1.2-3.

Key Study

			Official use only
		1 REFERENCE	
1.1	**Reference**	Davis, M. L.; 1991; Sorption/Desorption of 14C-Permethrin on Soils by the Batch Equilibrium Method. Battelle Memorial Institute. Report No. Sc900199; GLP; Unpublished	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC	
1.2.2	**Companies 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**	Yes. US EPA Pesticide Assessment Guidelines 40 CFR Part 160, Subdivision N, Section 163-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2, ^{14}C labelled	
3.1.1	**Lot/Batch number**	Isotope #193, FMC	
3.1.2	**Specification**	Deviating from specification given in section 2 as follows ^{14}C-radiolabelled material was synthesised by a commercial company for the purposes of this test.	
3.1.3	**Purity**	96.3%	
3.1.4	**Further relevant properties**	Specific activity 16.7 mCi $mmol^{-1}$	
3.1.5	**Method of analysis**	Samples were analysed by radiochemical techniques to determine total radioactivity in solutions. Thin layer chromatographic analysis of solutions adsorption equilibrium was performed.	X
3.2	**Degradation products**	Degradation products tested: Yes	
3.2.1	**Method of analysis for degradation products**	Thin layer chromatographic analysis of solutions adsorption equilibrium was performed. Reference (non-labelled) standards of known metabolites were run concurrently, and degradation products identified by co-chromatography.	X
3.3	**Reference substance**	No	
3.3.1	**Method of analysis for reference substance**		
3.4	**Soil types**	In tabular form (see table A7.2.3.1(1)-1)	
3.5	**Testing procedure**		
3.5.1	**Test system**	Tests were conducted in Teflon 50 ml centrifuge tubes with tight-fitting screw caps. The soils and test solutions were mixed using a	

Section A7.2.3.1 **Adsorption and mobility in soil, further studies**

Annex Point IIIA, XII.1.2-3.

Key Study

		rolling mill housed in a temperature controlled walk-in chamber maintained at 25°C.
3.5.2	**Test solution and Test conditions**	Soils were partially air dried, sieved through a 2mm sieve and stored at approximately 4°C in closed containers. Moisture contents were determined immediately prior to study initiation. Soils were weighed out to reflect weights on a dry weight basis. The maximum concentration was determined by the solubility of the test substance in test media. Preliminary test concentration was 0.5 mg l^{-1} Definitive test concentrations were 0.55, 0.35, 0.19, 0.05 mg l^{-1} Test solutions were prepared in situ. Stock solutions prepared in acetonitrile, such that the final concentration of co-solvent in the test solutions would be 5% in all cases. Appropriate volumes were dispensed into the teflon tubes, and 0.01M $CaCl_2$ added to make a final solvent weight of 35 g (preliminary test) or 40 g (definitive test). Soils were added to the test tubes to provide a 5:1 (preliminary test) or 20:1 (definitive test) solution:soil ratio.
3.6	**Test performance**	
3.6.1	**Preliminary test**	According to (a)"OECD 106": No The preliminary test was performed to determine the extent of adsorption to the container wall, and equilibrium times for adsorption and desorption. Test solutions were prepared in the individual tubes and allowed to reach equilibrium for 30 minutes. Triplicate samples were removed for analysis by liquid scintillation counting (LSC) to verify initial concentration, prior to soil addition. Appropriate weights of each soil in duplicate were added to tubes to give a solution:soil ratio of approximately 5:1. All relevant weights were recorded. The soil was dispersed and the sealed tubes tumbled on the rolling mill. Control test solutions (without soil) and blanks (no permethrin added) were run concurrently. At approximately 2, 4, 8 hours, all tubes were centrifuged, and triplicate 1 ml aliquots of the supernatant removed for LSC analysis. After each sampling the soil pellet was broken up, and the tubes replaced on the rollers. After 8 hours, the supernatant was removed following centrifugation, and the weight of the pellet plus tube was recorded. Sufficient 0.01M $CaCl_2$ was added to each tube to match the original weight, the soil pellets were resuspended and the tubes placed back on the roller. 2.0 ml aliquots were removed for LSC analysis at 10, 24 and 48 hours. At the end of the desorption period, the supernatant was decanted post-centrifugation, the pellets removed and frozen, and the tubes rinsed with solvent to determine the amount of permethrin adsorbed to the tubes.
3.6.2	**Screening test: Adsorption**	According to (a)"OECD 106": No Test solutions at 0.55, 0.35, 0.19 and 0.05 mg l^{-1} were prepared in the individual tubes and allowed to reach equilibrium for 30 minutes. Triplicate samples were removed for analysis by liquid scintillation counting (LSC) to verify initial concentration, prior to soil addition. All tubes plus soil were equilibrated for 2 hours, as defined in the

Section A7.2.3.1 **Adsorption and mobility in soil, further studies**

Annex Point IIIA, XII.1.2-3.

Key Study

		preliminary test. After 2 hours, the tubes were centrifuged and triplicate aliquots removed for LSC analysis. The adsorption solution was removed, and the weight of pellet plus tube recorded to determine the amount of remaining interstitial water.	
3.6.3	**Screening test: Desorption**	Filter sterilised 0.01M $CaCl_2$ was added to each tube to match the original weight, the soil pellets were resuspended and the tubes placed back on the roller for 48 hours. After this time, the tubes were centrifuged, the supernatant removed for LSC analysis, and the weight of pellet plus tube recorded to determine the amount of remaining interstitial water. Soil pellets were removed, air dried and ground for determination of remaining radioactivity by combustion/LSC.	
3.6.4	**HPLC-method**	No	
3.6.5	**Other test**	No	
		4 RESULTS	
4.1	**Preliminary test**	Summarized results in tabular form (see table A7.2.3.1(1)--2)	
4.2	**Screening test: Adsorption**	Summarized results in tabular form (see table A7.2.3.1(1)--3)	
4.3	**Screening test: Desorption**	Summarized results in tabular form (see table A7.2.3.1(1)--4)	
Calculations		Insufficient data are presented in the report to support the adsorption-desorption kinetics as described in the report. However, kinetics and Freundlich isotherms are presented graphically in Figures 1 to 6.	
4.3.1	**Ka , Kd**	Summarised in table A7.2.3.1(1)--5	
4.3.2	**Ka_{oc} , Kd_{oc}**	Summarised in table A7.2.3.1(1)--5	
4.4	**Degradation product(s)**	Only one degradation product was identified by radio-TLC. This was characterised as DCVA, and was present in quantities ranging from 0.4% (sand) to 7.6% (aquatic sediment). Significant unidentified radioactivity remained unresolved at the origin (0.2% for controls, to 16.6% for aquatic sediment)	X
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The guidelines and the methods used and reported were suitable for the determination of the adsorption-desorption of permethrin. The low concentrations employed, and the inclusion of 5% acetonitrile as a co-solvent, suggest that true solution was achieved, and the mass balance data indicate all applied test material was accounted for, further validating the results.	
5.2	**Results and discussion**	The data and results presented are in agreement with all other available data on permethrin, in that they show it rapidly and irreversibly binds to soil or sediment matrices.	
5.2.1	**Adsorbed a.s. [%]**	Summarised in table A7.2.3.1(1)--5	
5.2.2	**K_a**	Summarised in table A7.2.3.1(1)--5	
5.2.3	**K_d**	Summarised in table A7.2.3.1(1)--5	
5.2.4	**Ka_{oc}**	Summarised in table A7.2.3.1(1)--5	
5.2.5	**Ka/Kd**	Summarised in table A7.2.3.1(1)--5	

Section A7.2.3.1 Adsorption and mobility in soil, further studies

Annex Point IIIA, XII.1.2-3.

Key Study

5.2.6	**Degradation products (% of a.s.)**	Only one degradation product was identified by radio-TLC. This was characterised as DCVA, and was present in quantities ranging from 0.4% (sand) to 7.6% (aquatic sediment). Significant unidentified radioactivity remained unresolved at the origin (0.2% for controls, to 16.6% for aquatic sediment)
5.3	**Conclusion**	The study was performed to GLP standards, according to guidelines relevant at the time, therefore the valididty criteria are considered fulfilled. Based on the findings of the report, permethrin has the potential to be immobile in the soil textural classes studied
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	*19 April 2005*
Materials and Methods	The applicant's version is acceptable with the following revisions: **Comments:** (Section 3.1.5 and 3.2.1) TLC was used for the analysis the solutions adsorption equilibrium. Whilst, this method is not recommended under OECD 106, TLC analysis was performed by co-chromatography with test solutions run concurrently with reference standards of the test material and known metabolites. Overall, material balances were good for 4 out of the 5 soil types, with mass balances within the range of 90% and 110% of the nominal AR.
Results and discussion	Adopt applicant's version with the following revisions: **Comments:** (Section 4.4) Include: Whilst no numerical data is presented for the adsorption kinetics of DCVA, the authors of the test report state that permethrin binds more tightly to soil than its degradates, which are more polar than permethrin and consequently are likely to remain in solution. This supports the observation of lower proportions of permethrin to its degradates in solutions of soils with more organic matter, which points to an artefact of the affinity of permethrin to organic matter.
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	acceptable / ~~not acceptable~~
Remarks	**Comments:** (Section 2.3) In line with current guidelines (OECD 106) the following deviation was observed: The use of TLC as a method for sorption measurements is not recommended, owing to the reliability of their measurements especially when compared to more robust methods which utilise one or more stationary phases to determine sorption measurements, such as HPLC, GC-MS, or HPLC-MS. However, independent of the analytical method, the TLC method used in this study provided suitable recoveries for four out of five soil types between 90% and 110% of the nominal AR. This is considered to represent a minor deviation and does not affect the scientific validity of this study. The results are considered reliable enough to conclude that permethrin was essentially immobile in the soils tested.
	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 A7.2.3.1(1)--1: Classification and physico-chemical properties of soils used as adsorbents

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

TABLE I: SOIL CHARACTERIZATION

Soil Source	% Sand	% Silt	% Clay	% OM	pH	CEC meq/100g	Textural Class
Lake County, Florida[a]	94	2	4	0.4	6.0	0.6	sand
Merrimac, Wisconsin[a]	76	13	11	1.8	6.9	5.2	sandy loam
Porterville, California[b]	32.5	34.4	33.1	2.07	7.8	30.0[c]	clay loam
West Jefferson, Ohio[b]	15.3	64.3	20.4	2.10	5.8	18.9	silt loam
Meigs, Georgia[a]	78.1	15.4	6.5	2.7	6.8	5.7	sediment, sandy loam

OM = Organic Matter Content = 1.724 x % Organic Carbon[d]
CEC = Cation Exchange Capacity
Soil analysis by: [a] A & L Agricultural Laboratories, Memphis TN
[b] Ohio Soil Characterization Laboratory, Department of Agronomy, Columbus, OH
[c] Agvise, Northwood ND

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Table A7.2.3.1(1)–2: Results of preliminary test:

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

TABLE II: PRELIMINARY TEST KINETICS RESULTS OF (A) PERCENT ^{14}C-PERMETHRIN ADSORBED AND (B) PERCENT ^{14}C-PERMETHRIN DESORBED

TABLE IIA: PRELIMINARY ADSORPTION TEST RESULTS

SOIL ID	0 HR AVG DPM/g	0 HR AVG ug/g	2 HR AVG DPM/g	2 HR AVG ug/g	2 HR % ADS	2 HR AVG % ADS	4 HR AVG DPM/g	4 HR AVG ug/g	4 HR % ADS	4 HR AVG % ADS	8 HR AVG DPM/g	8 HR AVG ug/g	8 HR % ADS	8 HR AVG % ADS
CONTROL SOLN	48497	0.512	22067	0.233	54.5	57.2	16604	0.175	65.8	69.9	7238	0.076	85.1	87.3
	49578	0.521	19865	0.210	59.8		13848	0.136	74.0		5246	0.055	89.4	
SAND, FL	51330	0.542	3968	0.042	92.3	92.4	3856	0.040	92.5	92.7	3612	0.038	93.0	93.1
	50853	0.537	3835	0.041	92.4		3593	0.038	92.9		3487	0.037	93.1	
SANDY LOAM,UI	50745	0.536	3006	0.032	94.1	94	2804	0.030	94.5	94.2	3211	0.034	93.7	93.7
	48794	0.515	3954	0.031	93.9		2962	0.031	93.9		3074	0.032	93.7	
CLAY LOAM, CA	50877	0.537	2829	0.030	94.4	94.5	2831	0.030	94.4	94.4	2956	0.031	94.2	94.1
	50900	0.538	2812	0.030	94.5		2834	0.030	94.4		2989	0.032	94.1	
SILT LOAM, OH	50688	0.535	2536	0.027	95.0	95	2629	0.028	94.8	94.8	2777	0.029	94.5	94.6
	52143	0.550	2675	0.028	95.0		2712	0.029	94.8		2831	0.030	94.6	
SEDIMENT, GA	51463	0.543	941	0.010	98.2	98.2	865	0.009	98.3	98.3	792	0.008	98.5	98.5
	51423	0.543	939	0.010	98.2		876	0.009	98.3		794	0.008	98.5	

Spec. Act. = 1.06E-05 ug/DPM = 1 ug/94746 DPM

TABLE IIB: PRELIMINARY DESORPTION TEST RESULTS

SOIL ID	10 HR AVG DPM/mL	10 HR AVG ug/mL	10 HR % DES	24 HR AVG DPM/mL	24 HR AVG ug/mL	24 HR % DES	48 HR AVG DPM/mL	48 HR AVG ug/mL	48 HR % DES	ACN AVG DPM/mL	ACN AVG ug/mL	ACN % DES
CONTROL	2637	0.0278	6.09	32529	0.3433	74.64	33999	0.3588	77.94	162317	1.7132	22.58
SAND, FL	649	0.0068	1.26	975	0.0103	1.91	671	0.0071	1.33	21173	0.2235	2.62
SANDY LOAM, UI	654	0.0069	1.32	1179	0.0124	2.34	2676	0.0282	5.34	6772	0.0715	0.87
CLAY LOAM, CA	867	0.0092	1.54	1586	0.0167	2.79	3318	0.0350	5.84	3896	0.0411	0.46
SILT LOAM, OH	971	0.0102	1.79	2136	0.0225	3.92	5660	0.0597	10.39	3964	0.0418	0.46
SEDIMENT, GA	336	0.0035	0.58	343	0.0036	0.61	330	0.0035	0.55	1243	0.0131	0.14

Table A7.2.3.1(1)--3: Results of screening test - adsorption:

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

TABLE V: MASS BALANCE OF ^{14}C-PERMETHRIN AT DESORPTION EQUILIBRIUM FOR EACH SOIL

SOIL TYPE (Location)	A TOTAL APPLIED (ug)	B Removed after Ads (ug)	C Removed after DES (ug)	D ug in Desorbed Soil	E Adsorbed to Tube (ug)	B+C+D+E TOTAL RECOVERED (ug)	% OF TOTAL APPLIED	AVG % TOTAL Std Dev RSD
SAND, FL	21.51	1.97	0.64	9.04	4.36	16.91	78.6	79
	21.63	2.06	0.69	9.81	4.42	16.98	78.5	12.4
	22.80	2.04	0.67	11.87	2.03	16.61	74.5	15.7
	13.89	1.48	0.44	7.82	1.81	11.55	83.6	
	14.10	1.46	0.34	4.16	1.77	7.73	54.8	
	13.99	1.48	0.44	6.76	2.18	10.83	77.4	
	7.50	0.89	0.28	3.97	0.88	6.02	80.3	
	7.45	0.98	0.27	2.89	0.98	4.32	60.7	
	7.43	0.91	0.27	3.44	1.18	5.80	78.2	
	1.96	0.33	0.08	1.17	0.86	1.83	91.4	
	1.89	0.30	0.08	1.22	0.29	1.89	100.0	
	1.89	0.31	0.08	1.16	0.12	1.67	88.6	
SANDY LOAM, NJ	21.77	1.65	1.78	17.61	0.69	21.73	99.8	107.7
	22.36	1.65	1.60	17.29	0.64	21.18	94.6	10
	21.88	1.64	1.85	17.57	0.63	21.72	99.3	9.3
	13.88	1.07	1.66	11.49	0.37	14.59	105.1	
	13.50	1.08	1.76	11.06	0.34	14.24	105.5	
	13.65	1.07	1.46	11.13	0.46	14.32	104.9	
	7.38	0.99	0.98	5.86	0.20	7.61	103.1	
	7.34	0.59	0.99	5.90	0.20	7.68	104.6	
	7.33	0.60	1.05	5.94	0.24	7.83	107.0	
	1.96	0.18	0.43	1.64	0.03	2.29	118.0	
	1.86	0.18	0.35	1.77	0.06	2.36	126.9	
	1.88	0.18	0.34	1.75	0.06	2.33	123.9	
CLAY LOAM, CA	21.71	1.42	1.21	19.23	0.25	22.11	101.8	109.5
	21.14	1.39	1.12	18.74	0.31	21.56	102.0	8
	21.88	1.47	1.20	19.76	0.41	22.84	104.4	7.3
	13.57	0.93	0.90	12.38	0.15	14.36	107.3	
	13.84	0.92	0.88	12.87	0.20	14.87	107.4	
	14.01	0.91	0.83	12.73	0.23	14.70	104.9	
	7.35	0.50	0.55	6.72	0.11	7.88	107.2	
	7.30	0.50	0.53	6.82	0.10	7.95	108.0	
	7.41	0.49	0.56	6.69	0.08	7.82	105.5	
	1.92	0.16	0.18	1.98	0.03	2.33	122.4	
	1.80	0.15	0.18	1.85	0.04	2.22	123.3	
	1.92	0.15	0.17	1.97	0.04	2.33	121.4	

A: Average of triplicate LSC analysis of initial dose solution.
B: Average of triplicate LSC analysis of adsorption supernatant.
C: Average of triplicate LSC analysis of desorption supernatant.
D: Average of triplicate combustion radioanalysis of soil.
E: Average of triplicate LSC analysis of organic solvent rinse (acetonitrile).

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Table A7.2.3.1(1)--4: Results of screening test - desorption: Mass balance at desorption equilibreum

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

TABLE V: MASS BALANCE OF ^{14}C-PERMETHRIN AT DESORPTION EQUILIBRIUM FOR EACH SOIL

(Continued)

SOIL TYPE (Location)	A TOTAL APPLIED (ug)	B Removed after ADS (ug)	C Removed after DES (ug)	D ug in Desorbed Soil	E Adsorbed to Tube (ug)	B+C+D+E TOTAL RECOVERED (ug)	% OF TOTAL APPLIED	AVG % TOTAL Std Dev RSD
SILT LOAM, OH	22.09	1.30	2.86	16.01	0.44	22.81	103.3	109.6
	22.19	1.53	3.01	16.06	0.34	22.93	103.3	7.19
	22.02	1.47	2.96	16.11	0.39	22.73	103.3	7.2
Ohio								
	13.92	0.96	2.02	11.58	0.26	14.87	106.8	
	14.03	1.06	1.84	11.64	0.25	14.80	106.0	
	13.94	0.99	2.16	11.25	0.24	14.61	104.8	
	7.34	0.53	1.44	5.77	0.10	7.84	106.8	
	7.47	0.54	1.45	5.84	0.35	8.18	109.5	
	7.31	0.54	1.49	5.74	0.00	7.86	104.7	
	1.94	0.16	0.34	1.60	0.03	2.33	120.1	
	1.89	0.16	0.32	1.59	0.04	2.31	122.2	
	1.85	0.16	0.33	1.57	0.04	2.30	124.3	
SEDIMENT, GA	22.23	0.78	0.15	23.93	0.14	25.03	112.6	108.9
	21.99	0.80	0.13	22.97	0.28	24.10	109.6	8
	21.98	0.82	0.15	21.85	0.14	22.96	104.5	7.3
	14.07	0.51	0.10	13.93	0.09	14.63	104.0	
	13.76	0.54	0.09	13.74	0.10	13.47	97.9	
	13.73	0.53	0.10	14.21	0.10	14.94	108.8	
	7.65	0.30	0.07	7.26	0.04	7.76	101.4	
	7.50	0.48	0.07	7.28	0.04	7.81	104.1	
	7.58	0.39	0.07	7.43	0.04	7.93	104.6	
	2.09	0.14	0.02	2.12	0.02	2.30	113.3	
	1.97	0.11	0.02	2.13	0.02	2.28	121.9	
	1.97	0.11	0.02	2.16	0.02	2.33	124.6	
CONTROLS	21.83	19.46	0.20	0.00	2.91	22.54	103.3	93.8
	22.22	15.37	0.28	0.00	5.47	21.12	99.1	8.9
	23.00	18.72	0.37	0.00	7.47	21.46	97.6	9.3
	14.19	4.37	1.25	0.00	6.13	11.63	82.0	
	13.72	3.47	0.40	0.00	8.66	12.55	91.5	
	14.19	4.39	0.36	0.00	8.97	13.84	97.5	
	7.28	1.73	0.71	0.00	5.16	7.62	105.0	
	7.30	2.07	1.25	0.00	3.73	6.84	93.7	
	7.62	2.38	0.73	0.00	3.87	6.26	82.4	
	1.79	0.60	0.28	0.00	1.03	1.91	106.7	
	1.73	0.66	0.28	0.00	0.94	1.88	108.7	
	1.88	0.43	0.15	0.00	0.89	1.47	88.8	

A: Average of triplicate LSC analysis of initial dose solution.
B: Average of triplicate LSC analysis of adsorption supernatant.
C: Average of triplicate LSC analysis of desorption supernatant.
D: Average of triplicate combustion radioanalysis of soil.
E: Average of triplicate LSC analysis of organic solvent rinse (acetonitrile).

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Table A7.2.3.1(1)--5: Summarised Adsorption/Desorption constants for ^{14}C Permethrin

Soil type	%OC	Phase	Kd	K	Koc	1/n	R^2
Sand, FL	0.23	Adsorption	140	446	194000	1.32	0.9940
		Desorption	276	287	125000	1.01	0.9898
Sandy loam, WI	1.04	Adsorption	217	355	34100	1.12	0.9991
		Desorption	112	265	25500	1.23	0.9824
Clay loam, CA	1.20	Adsorption	246	378	31500	1.10	0.9983
		Desorption	250	600	50000	1.21	0.9898
Silt loam, OH	1.22	Adsorption	236	344	28200	1.09	0.9988
		Desorption	87.5	330	27000	1.42	0.9911
Sediment, GA	1.57	Adsorption	401	1517	96600	1.29	0.9861
		Desorption	2413	6349	404400	1.15	0.9768

Figure 1: Kinetic plots for (A) Adsorption and (B) Desorption

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FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 1: Kinetics Plots of Concentration Equilibrium for (A) Adsorption and (B) Desorption of ^{14}C-Permethrin

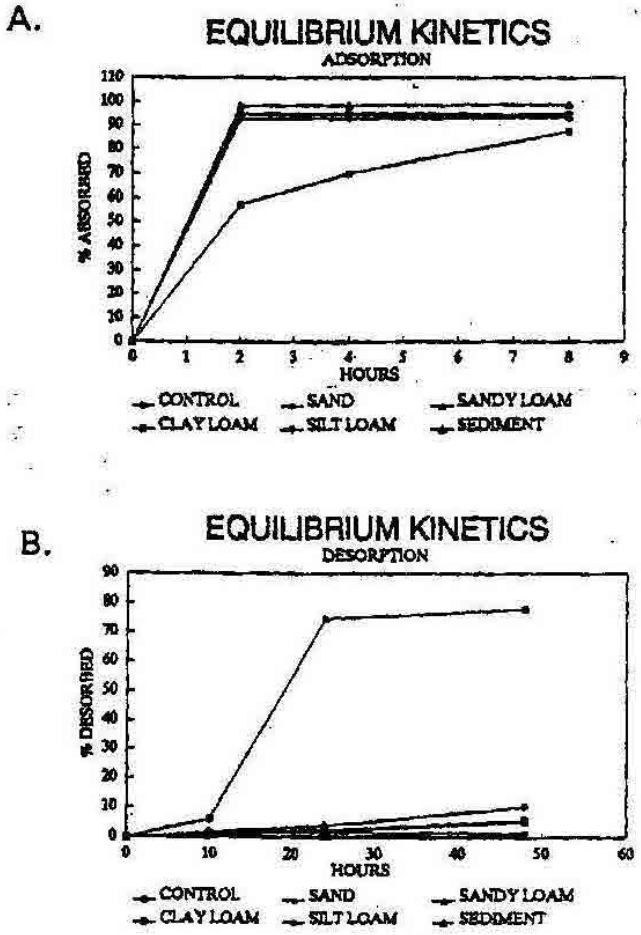

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Figure 2: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) on Florida Sand

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 2: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) of ^{14}C-Permethrin on Florida Sand at 25°C.

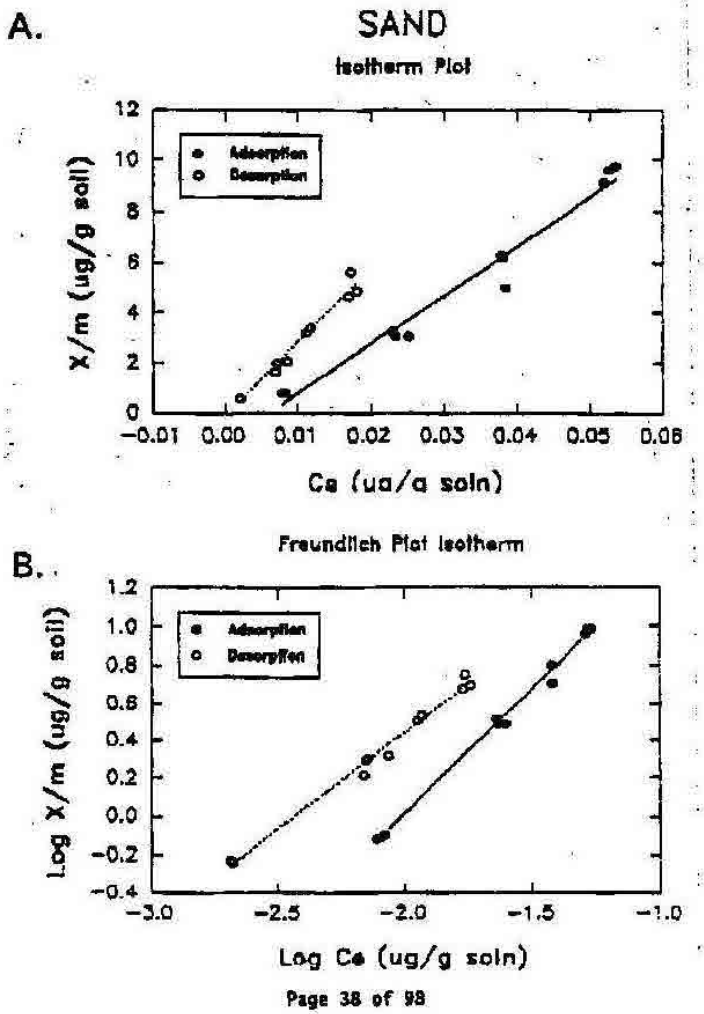

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Figure 3: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) on Wisconsin Sandy Loam

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 3: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) of ^{14}C-Permethrin on Wisconsin Sandy Loam at 25°C.

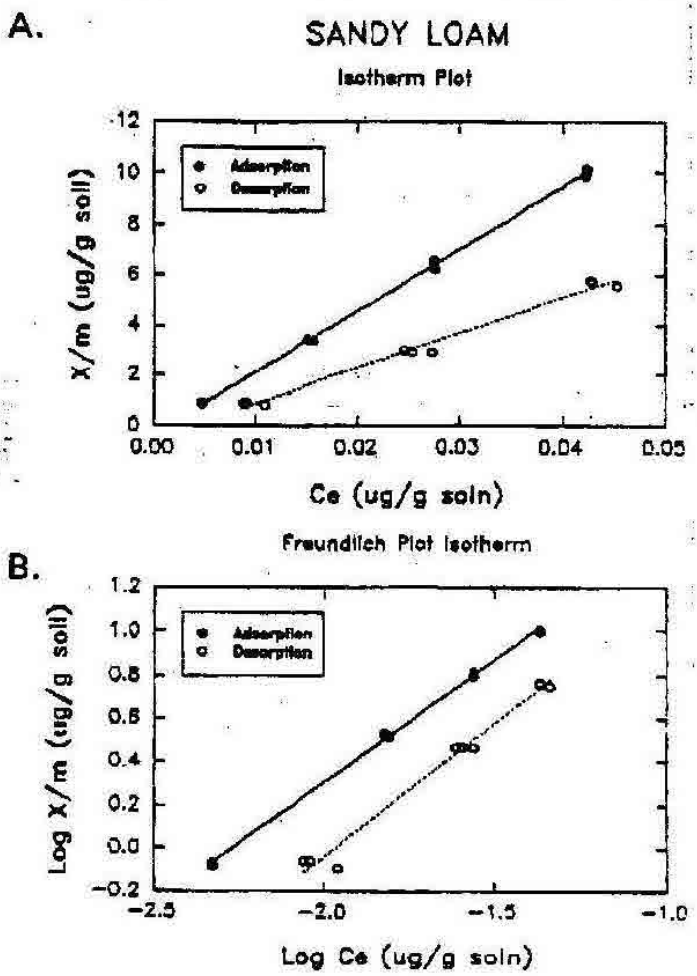

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Figure 4: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) on California Clay Loam

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 4: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) of ^{14}C-Permethrin on California Clay Loam at 25°C.

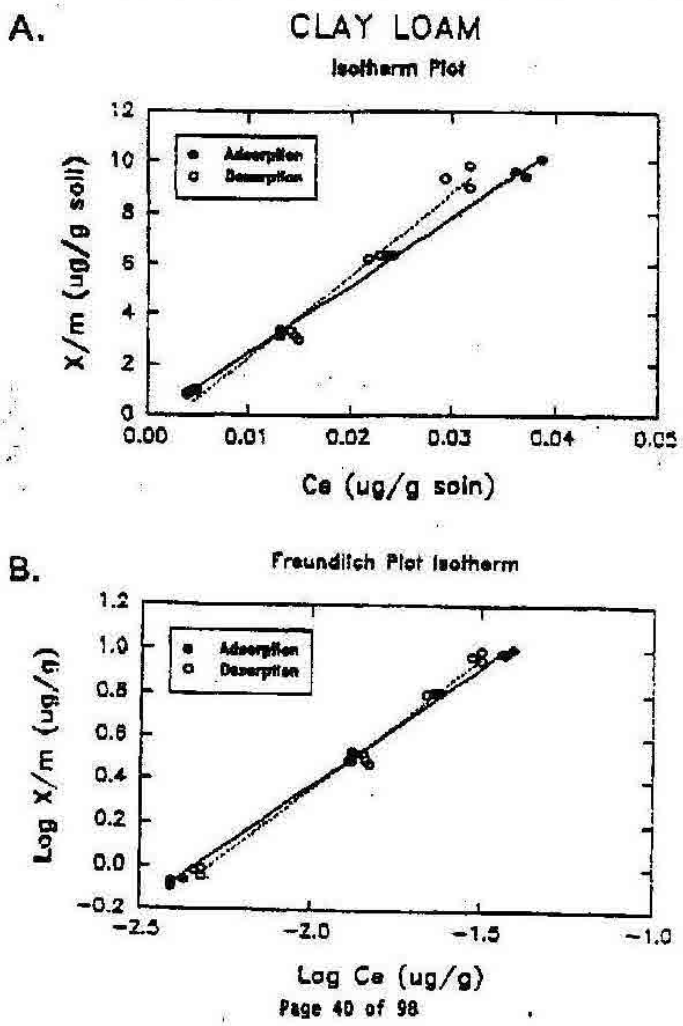

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Figure 5: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) on Ohio Silt Loam

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FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 5: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) of ^{14}C-Permethrin on Ohio Silt Loam at 25°C.

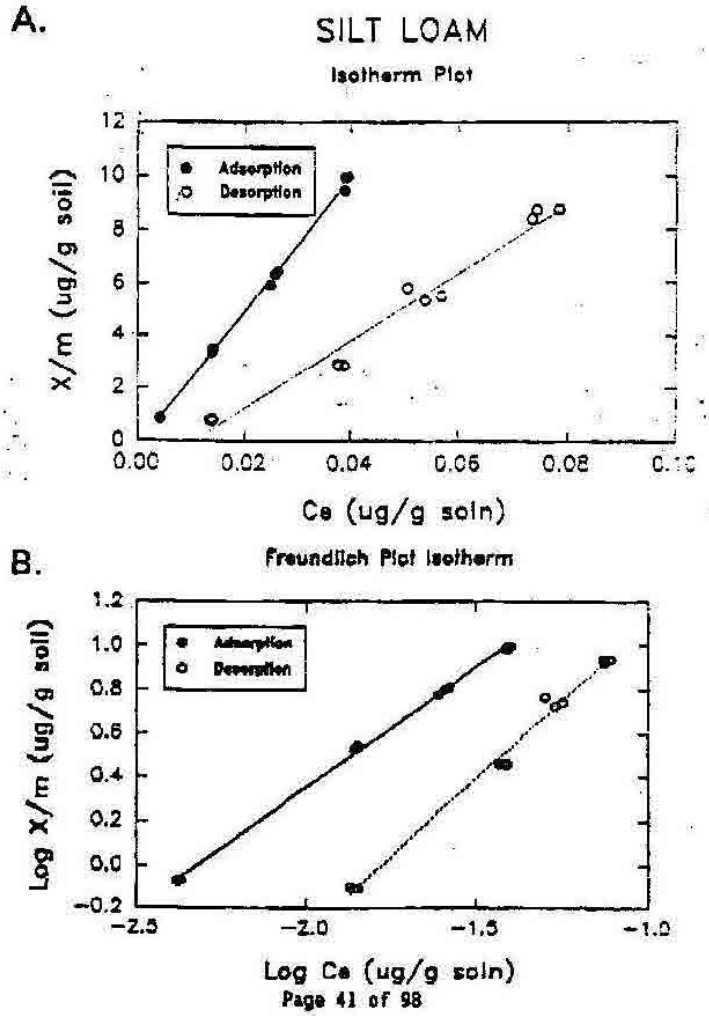

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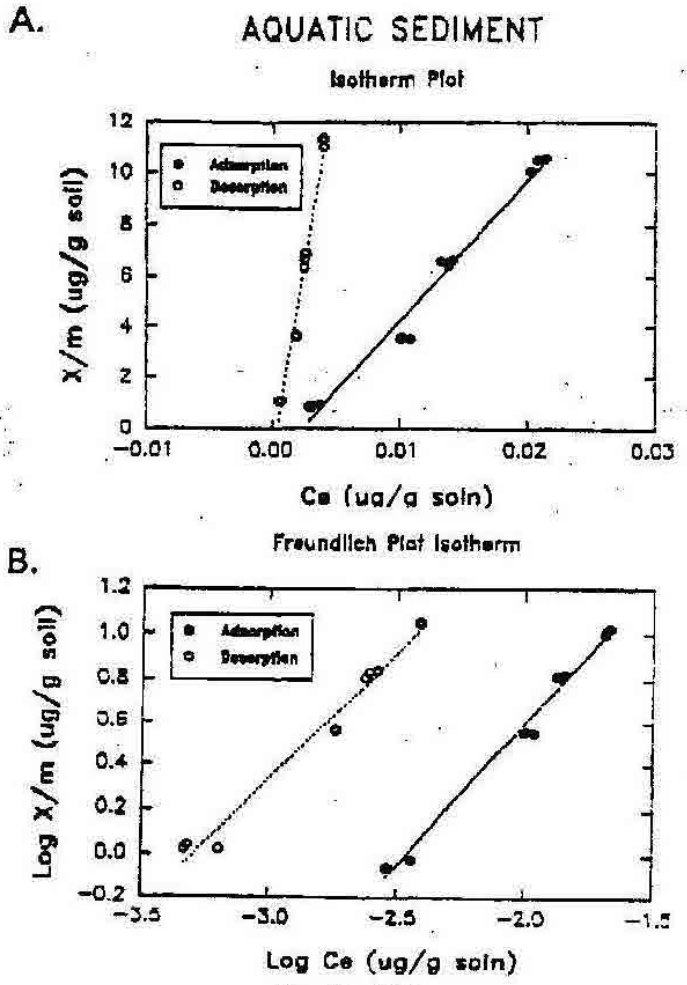
Figure 6: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) on Georgia Sediment

FMC Corporation
Study #138E3290E1

FMC Report No.: PC-0156
Battelle Study No. SC900199

Figure 6: Adsorption/Desorption Isotherms (A) and Freundlich Plots (B) of ^{14}C-Permethrin on Georgia Aquatic Sediment at 25°C.



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Section 7.2.3.1 (2) **BPD Data Set IIA/ Annex Point VII.7.7**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

		KEY STUDY	
		1. REFERENCE	**Official use only**
1.1	Reference	Reynolds, J.L. (1992); Adsorption and Desorption of ^{14}C-m-Phenoxybenzoic Acid in Four Soils; XenoBiotic Laboratories Inc, USA; Document A71037 ; 18 November 1992; Unpublished	
1.2	Data protection	Yes	
1.2.1	**Data owner**	Bayer CropScience AG	
1.2.2	**Companies with letter of access**	Sumitomo Chemical (UK) PLC	
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 163-1	
2.2	GLP	Yes	
2.3	Deviations	No	
		3. MATERIALS AND METHODS	
3.1	Test material	Labelled and unlabelled mPBacid	
3.1.1	**Lot/Batch number**	Labelled: X6975A Unlabelled: 7B0237B	
3.1.2	**Specification**	m-Phenoxybenzoic acid (mPBacid)	
3.1.2.1	**Description**	^{14}C-labelled at the benzylic carbon	
3.1.2.2	**Purity**	Labelled: 100% with a specific activity of 20 mCi/mMole Unlabelled: 100 %	
3.1.2.3	**Stability**	Stable	
3.2	Test conditions		
3.2.1	**Type of study**	Batch equilibrium	
3.2.2	**Number of soils**	Four	

Section 7.2.3.1 (2) **BPD Data Set IIA/ Annex Point VII.7.7**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

KEY STUDY

3.2.3	**Description of soils**	See Table A7.2.3.1(2)-1
3.2.4	**Concentrations**	0.05, 0.09, 0.68 and 1.36 mg/l
3.2.5	**Vehicle**	Acetonitrile
3.2.6	**Test system**	Individually-labelled 50 ml Teflon® centrifuge tubes, each containing ~5 g of soil, were prepared as described in the previous section. A total of 12 tubes, 2 tubes per soil type and 2 positive controls (blank tubes with only ~25 ml of treatment solution) and 2 negative control tubes (soil and untreated $CaCl_2$ solution), were prepared for the four treatment rates. Approximately 25 ml of the $CaCl_2$ solution was then added to each soil tube using a pipette. The appropriate amount of radiolabelled chemical was then added to each tube. All tubes were capped securely and placed on a Wrist Action® Shaker and shaken under ambient conditions. Samples were assayed at 48 hours post-treatment (the optimum equilibration time determined from the preliminary study). After the 48-hour shaking period, all sample tubes were centrifuged for about 10 minutes as described in the previous section. Following centrifugation, the supernatants (adsorption solutions, typically ~22 – 25 ml each) were aliquoted in duplicate for LSC. Each supernatant was then decanted to minimize its binding to the glassware and the resultant loss of the chemical; the total volume was recorded. Upon completion of the adsorption procedure, approximately 25 ml of fresh, untreated, 0.01 M $CaCl_2$ solution was added to all of the tubes to initiate the desorption process. All tubes were then returned to the shaker and shaken again under ambient conditions for an additional 48 hours. After shaking, the soil-solution samples were centrifuged as described above. The supernatants (desorption solutions, approximately 25 ml each) were assayed by LSC, decanted, and their volumes recorded. The desorbed soils were removed, air dried, and subsampled for combustion analyses.
3.2.7	**Desorption time**	48 hours
3.2.8	**Replicates**	Two
3.3	Reference substance	
3.3.1	**Analytical method**	Combustion followed by scintillation counting; HPLC
3.3.2	**Other**	-

Section 7.2.3.1 (2) **BPD Data Set IIA/ Annex Point VII.7.7**		**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**	
		KEY STUDY	
3.4 remarks	Further	The Freundlich isotherm equation was used for data evaluation	
		4. RESULTS	X
4.1 time	Equilibrium		
4.2 balance	Material	The average recoveries in the definitive study were 103.33 (control), 100.54% (AZ #3 clay), 100.13% (MS silty clay loam), 97.39% (MD sandy loam), and 101.53% (MI clay loam).	
4.3	K_{oc}	The K_{oc} values determined for the adsorption of m-phenoxybenzoic acid in the four soils were as follows: 287.76 (AZ #3), 189.90 (MS), 105.03 (MD), and 50.65 (MI).	
4.4	$K_{ads} - K_{des}$	K_{ads} values of m-phenoxybenzoic acid based on the total radioactivity in the four soils were as follows: 0.67 (AZ clay); 1.54 (MS silty clay loam); 2.68 (MD sandy loam) and 1.34 (MI clay loam). For the desorption process of m-phenoxybenzoic acid from the soil matrices, the K_{des} values were as follows: 0.87 (AZ #3 clay); 3.00 (MS silty clay loam); 4.21 (MD sandy loam) and 1.85 (MI clay loam).	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods	Adsorption/desorption of mPBacid (m-phenoxybenzoic acid), ^{14}C-labelled at the benzylic carbon (radiopurity 100%), was studied in accordance with US EPA Guideline 163-1. Characteristics of the four soils used are shown in Table A7.2.3.1-3. A preliminary study was performed to determine the proper soil:solution ratio and equilibration time (assay after 0, 2, 4, 24, 48 and 72 hours). Test concentrations in the definitive study were 0.050, 0.085, 0.68 and 1.4 mg/L, in 0.01 M $CaCl_2$ solution, with < 1% acetonitrile and toluene as co-solvent. Test tubes were prepared in duplicate. Soil:solution ratio was 1:5 (25 ml solution and 5 g soil), and equilibration time 48 hours. After the adsorption step, a 48-h desorption step followed. Soil-less and mPBacid-free controls were included in the study. To minimise binding to centrifuge tubes, these were precoated with unlabelled mPBacid dissolved in methylene chloride. Supernatants were analysed with LSC. After the desorption step soil aliquots were combusted for analysis of $^{14}CO_2$. Selected supernatant samples were also analysed with HPLC. Freundlich isotherm equation was used to determine adsorption constants, K_d. Adsorption was also expressed as K_{oc}.	

Section 7.2.3.1 (2) **BPD Data Set IIA/ Annex Point VII.7.7**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

KEY STUDY

5.2	Results and discussion	The average recovery in the definitive study ranged from 97 to 103%. In soil-less controls with the higher test concentration approximately 18 – 27% of the test substance adsorbed to the walls or caps of the centrifuge tubes, whereas no adsorption was observed at the lower concentrations. The test substance was the only substance detected with HPLC. Adsorption constants ranged from 0.67 (AZIII clay) to 2.7 (MD sandy loam). K_{oc} values ranged from 51 (MI clay loam) to 288 (AZIII clay). Coefficients of determination were ≥ 0.98, and the slopes of the lines (1/n) ranged from 0.92 to 1.0. Desorption constants, K_{des}, ranged from 0.87 (AZIII clay) to 4.2 (MD sandy loam). The author concluded that the results indicate that mPBacid is mobile and readily desorbed from soil.
5.3	Conclusion	
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	September 2009
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Adopt applicant's version but the following points should be noted. It is necessary to refer to the study report to check the presented results. In order to avoid confusion, Freundlich coefficients should be denoted by K_F. The term K_d should be reserved for simple distribution coefficients.
Conclusion	Adopt applicant's version (as presented in Section 5.2).
Reliability	1
Acceptability	acceptable / ~~not acceptable~~
Remarks	It should be noted that 3-phenoxybenzoic acid (also known as m-phenoxybenzoic acid or mPBacid) is a common metabolite of a number of pyrethroid substances. In order to decide on the most appropriate adsorption values for this metabolite, account should also be taken of peer-reviewed values obtained in the EU review programme for pesticides assessed under Directive 91/414/EEC. For example, the EFSA Conclusion on zeta-cypermethrin reports the following for mPBAcid: K_{Foc} = 118-215 (mean 151.67, 1/n = 0.65-0.67, 3 soils).

	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section 7.2.3.1 (2) **BPD Data Set IIA/ Annex Point VII.7.7**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

KEY STUDY

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 A7.2.3.1(2)-1 Characteristics of Soils Used in Study on Adsorption/Desorption of mPBacid (prior to testing the soils were sieved [∅ 2 mm])

	Sand %	Silt %	Clay %	OM %	pH %	FMC % [1]	CEC meq/100g
Arizona III Clay	32	25	43	0.4	7.6	26.8	23.9
Mississippi Silty Clay Loam	14	47	39	1.4	6.5	32.1	17.1
Maryland Sandy loam	76	13	11	4.4	6.4	12.9	9.4
Michigan Clay loam	35	33	32	4.6	6.8	25.9	17.1

[1] = Field Moisture Capacity at 1/3 bar

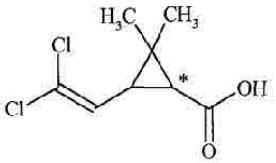
Section 7.2.3.1(3)
BPD Data Set IIA/ Annex Point VII.7.7

Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,

Adsorption and desorption of metabolites and degradation products

Key Study

Official use only

	1 REFERENCE	
1.1	**Reference**	Slangen, P (1999), Adsorption/desorption of FCR 1272-permethric acid on soil, NOTOX B.V.Hambakenwetering 3, 5231 DD `s-Hertogenbosch, The Netherlands.Bayer AG, Bayer Report No.: IM 1983, BES Ref: M-015423-01-1.Report date: 30 August 1999Unpublished
1.2	**Data protection**	Yes
1.2.1	Data owner	Bayer CropScience AG
1.2.2	Companies with letters of access	Sumitomo Chemical (UK) PLC
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD Guideline 106 (1997, draft), EPA Guideline § 163-1 Leaching and Adsorption/ Desorption Studies, EC Commission Directive 95/35 EC, SETAC, 1995
2.2	**GLP**	Yes , Ministry of Health, Welfare and Sport, State Supervisory Public Health Service,Veterinary Public Health Inspectorate, Rijswijk, The Netherlands
2.3	**Deviations**	None
	3 MATERIALS AND METHODS	
3.1	**Test material**	
3.1.1	Lot/Batch number	The test materials were:
3.1.2	Specification	1) cyclopropane-l-^{14}C FCR 1272-permethric acid
3.1.3	Purity	[cyclopropane-l-^{14}C]3-(2,2-dichlorovinyl)-2,2-dimethyl-cyclopropane carboxylic acid (DCVA), with radiochemical purity >99 %, isomer ratio of 53.7 % *cis*/46.3 % *trans*, specific activity of 3.22 MBq/mg
3.1.4	Further relevant properties	 * = position of ^{14}C label
		2) non-labelled FCR 1272-permethric acid, purity >98.9 % and isomer ratio of 51.1 % *cis*/47.8 % *trans*
3.1.5	Method of analysis	Radioactive purity was checked by TLC before the tests and stability of permethric acid was checked during the tests
3.2	**Degradation products**	Not tested.
3.2.1	Method of analysis	Not applicable

Section 7.2.3.1(3) BPD Data Set IIA/ Annex Point VII.7.7	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

Key Study

	for degradation products			
3.3	**Soil characteristics**	Soils characteristic are given in Table A7.2.3.1(3)-1		
3.4	**Testing procedure**			
3.4.1	Test system	Application solution:	0.01 M CaCl2	
		Test conditions: for adsorption kinetics:	Concentration: 1.00/1.02 µg/ml, soil/water ratio: 1 : 2 at 22°C, 1 : 1 at 20 °C 50 ml polypropylene tubes, shaking periods 4 ... 72 h	
		Test conditions: for adsorption-desorption isotherms:	Concentrations: 0.04, 0.1, 0.5, 1.0 µg/ml soil/water ratio: 1 : 1 at 20 °C 50 ml polypropylene tubes, shaking period 24 h	
		Sampling:	2 replicates	
		Analysis by TLC:	Silica-60 F254 Chloroform : methanol: acetic acid (90:10:1 v/v/v)	
		14C determinations	liquid scintillation (fluids) Electronic autoradiography instant imager	
3.5	**Test performance**	The study was performed according the OECD Guideline No. 106, as stated in the addendum of the monograph from the PPP dossier.		
3.5.1	Preliminary test	Not performed		
3.5.2	Screening test: Adsorption	According to (a)"OECD 106": Yes		
3.5.3	Screening test: Desorption	According to (a)"OECD 106": Yes		
3.5.4	HPLC-method	According to (a)" OECD-HPLC-method"[1]: No		
3.5.5	Other test			
		4 RESULTS		X
4.1	**Adsorption kinetics:**	The adsorption equilibrium was reached in all soils within 24 h and was comparable for both soil/water ratios.		
4.2	**Adsorption-Desorption isotherms:**	A significant adsorption-desorption hysteresis effect was observed in the adsorption and desorption isotherms. The isotherms could be described by the Freundlich equation. Correlation coefficients for the adsorption isotherm were >0.99 for all soils.		

[1] OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient (K_{OC}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999).

Section 7.2.3.1(3) **BPD Data Set IIA/ Annex Point VII.7.7**		**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**	
		Key Study	
4.3	**Calculations**	The Freundlich adsorption isotherm parameters are given in Table A7.2.3.1(3)-2: The Freundlich desorption isotherm parameters are given in Table A7.2.3.1(3)-3.	
4.4	**Degradation product(s)**	Permethric acid was stable during the experiment and hence no degradation products were formed.	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The adsorption behaviour of FCR 1272-permethric acid was investigated in three soils. Adsorption studies used the batch equilibrium method. Adsorption and desorption isotherms were determined over a range of concentrations of 0.04-1 µg/ml. Adsorption kinetics experiments at soil:solution ratio 1:2 were carried out at 22ºC; all other adsorption-desorption experiments were carried out at 20ºC.	
5.2	**Results and discussion**	The adsorption equilibrium was reached in all soils within 24 h and was comparable for both soil/water ratios. A significant adsorption-desorption hysteresis effect was observed in the adsorption and desorption isotherms. The isotherms could be described by the Freundlich equation. Correlation coefficients for the adsorption isotherm were >0.99 for all soils.	
5.3	**Conclusion**	FCR 1272-permethric acid can be considered to be moderately mobile in Speyer 2.1 soil and Cranfield 115 soil. In Cranfield 230 soil, FCR 1272-permethric acid is considered to be immobile, according to the classification scheme by Mensink, *et.al* .The mean $K_{f,oc}^{ads}$ was 133.71 (1/n = 0.904)	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	None	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2009
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Adopt applicant's version but the following point should be noted. It is necessary to refer to the study report to check the presented results.

Section 7.2.3.1(3) **BPD Data Set IIA/ Annex Point VII.7.7**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant,** **Adsorption and desorption of metabolites and degradation products**

	Key Study
Conclusion	Applicant's version should be amended in Section 5.3 in regard to the use of a mobility classification scheme. The applicant refers to a classification scheme propsed by Mensink et al., on the basis of which the test material is classified as moderately mobile in Speyer 2.1 and Cranfield 115 soils and immobile in Cranfield 230 soil. However, using the well known McCall classification system*, the test material would be classified as showing very high mobility in the Speyer 2.1 and Cranfield 115 soils, and as showing medium mobility in the Cranfield 230 soil. Since there is no agreed soil mobility classification system that is universally used, it would perhaps be better not to assign any mobility classes but instead just present the actual mobility values obtained. *McCall P.J., Swann R.L., Laskowski D.A., Unger S.M., Vrona S.A., and Dishburger, H.J., (1980), "Estimation of Chemical Mobility in Soil from Liquid Chromatographic Retention Times". Bull. Environm Contam. Toxicol. 24, 190-195. The following point should also be noted. Adsorption appears to depend on soil pH – mobility increases with soil pH. The highest K_{Foc} was obtained with the most acidic soil, and the lowest K_{Foc} was obtained with the most alkaline soil.
Reliability	1
Acceptability	acceptable / ~~not acceptable~~
Remarks	It should be noted that FCR 1272-permethric acid (2,2-dimethyl-3-(2,2-dichlorovinyl)cyclopropanecarboxylic acid [DCVA]) is a common metabolite of a number of pyrethroid substances. In order to decide on the most appropriate adsorption values for this metabolite, account should also be taken of peer-reviewed values obtained in the EU review programme for pesticides assessed under Directive 91/414/EEC. For example, the EFSA Conclusion on zeta-cypermethrin reports the following for *trans*-DCVA: K_{Foc} = 18-48 (mean 28.33, 1/n = 0.56-0.81, 3 soils).
	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 A7.2.3.1(3)-1: Classification and physico-chemical properties of soils used as adsorbents
Soil types and characteristics

Soil	Speyer 2.1	Cranfield ll5	Cranfield 230
Source	Rheinland-Pfalz/ Germany	Netherton, Goodham/ UK	Tickvall, Derbyshire/ UK
Soil type	sand	Clay loam	Sandy loam
Horizon (cm)	0-20	0-20	10-20
Clay/silt/sand (%) (USDA)	2.5/8.0/89.5	32.2/23.1/44.9	10/18.9/71.2
pH $H_2O/CaCl_2$	6.9/6.0	8.1/7.5	5.1/4.3
Organic Carbon (%)	0.59	1.6	0.8
CEC (meq/l00g)	4	25.9	10.6

Table A7.2.3.1(3)-2: Freundlich adsorption isotherm parameters

Soil	**K_f^{ads} (cm^3/g)**	**$K_{f,oc}^{ads}$(cm^3/g)**	**l/n**
Speyer 2.1	0.184	31.05	0.884
Cranfield 115	0.224	13.95	0.871
Cranfield 230	2.893	356.15	0.957
Mean	**1.100**	**133.71**	**0.904**

Table A7.2.3.1(3)-3: Freundlich desorption isotherm parameters

Soil	**K_f^{des} (cm^3/g)**	**$K_{f,oc}^{des}$(cm^3/g)**
Speyer 2.1	0.676	114.19
Cranfield 115	0.498	31.11
Cranfield 230	5.678	699.17
Mean	**2.284**	**281.49**

Section A7.2.3.2 **Annex Point IIIA, XII.1.2-3.**	**Adsorption and mobility in soil, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	Some data have been submitted on the mobility in soil, but the reference only applies to one soil (Smith & Willis, 1985). Other data are available on permethrin which give supplementary information on its movement in several soil and sediment types (Davis ML, 1991; Sharom & Solomon, 1981) which indicate that the findings of Smith & Willis, 1985 are indicative of the behaviour of permethrin in all soil types, namely no significant movement. Therefore a justification for non-submission of further data is proposed on the grounds that sufficient data exist to indicate negligible movement of permethrin once it has adsorbed onto an organic surface.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted*	
Date **Evaluation of applicant's justification**	**EVALUATION BY RAPPORTEUR MEMBER STATE** *19 April 2005* The RMS considers the applicants justification to be valid for permethrin owing to the supporting information outlined above by the notifier. However, a more detailed justification is considered appropriate. Permethrin is known to become readily and tightly bound to both soil and sediment, and to show considerable hysteresis during the desorption phase as permethrin is not readily desorbed from soil or sediment surfaces. In the adsorption/desorption study (Davis, 1991) K_{foc} values determined for the adsorption phase in five soil types ranged from 28200 to 194000, indicating considerable adsorption. Furthermore, in the water/sediment study conducted under aerobic conditions (Robinson and Ryan, 1996a) permethrin was observed to partition rapidly to the sediment phase by 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. Supporting 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 and indicated a similar rapid adsorption of permethrin to the sediment phase. It is considered unlikely that permethrin would reach groundwater under normal use conditions of this biocidal product and, therefore, poses a very limited contamination risk to groundwater.	

Section A7.2.3.2 **Annex Point IIIA, XII.1.2-3.**	**Adsorption and mobility in soil, further studies**
Conclusion	The applicant's justification is acceptable with the additional information as outlined above by the RMS.
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 A7.2.3.2 Annex Point IIIA, XII.1.2-3	**Adsorption and mobility in soil, further studies**

Additionnal information

			Official use only
		1 REFERENCE	
1.1	**Reference**	Smith, S. & Willis, G.H.; 1985; Movements of pesticides in soil columns as affected by anhydrous ammonia. Env. Tox. Chem, 4, 425-434; Not GLP; Published	
1.2	**Data protection**	No	
1.2.1	**Data owner**	Sumitomo Chemical (UK) PLC	
1.2.2	**Criteria for data protection**	No data protection claimed	
6.2		**2 GUIDELINES AND QUALITY ASSURANCE**	
2.1	**Guideline study**	No	
2.2	**GLP**	No: Pesticide Degradation Laboratory (US Department of Agriculture owned Research Facility)	
2.3	**Deviations**	No: Protocol was not to any guidelines	
6.3		**3 MATERIALS AND METHODS**	
3.1	**Test material**		X
3.1.1	**Lot/Batch number**	No data	
3.1.2	**Specification**	Supplied by FMC	
3.1.3	**Purity**	94.5%	
3.1.4	**Further relevant properties**	No data	
3.1.5	**Composition of Product**	No data	
3.1.6	**TS inhibitory to microorganisms**	No	
3.1.7	**Specific chemical analysis**	Leachate Extraction: 500 ml of leachate (in duplicate) was stirred with 150 ml benzene on a magnetic stirrer for 1.5 h. The mixture was quantitatively transferred to to a 1L separating funnel, and the aqueous layer discarded. The benzene was dried over anhydrous sodium sulphate and analysed for permethrin. Extraction efficiencies were >96%. Soil Extraction: Pewrformed in duplicate per zone per column. 25 g of air-dried soil was soxhlet extracted with 200 ml benzene:methanol (60.5:39.5) for 3 hours. The extract was washed with water to remove the methanol, dried over anhydrous sodium sulphate and reduced to a suitable volume for analysis for permethrin Analysis: A MicroTec model DSS162 GC with ^{63}Ni ECD detector was used. The separation was performed on a 120cm x 4 mmid glass column, packed with 3% SP2401 on 100-120 mesh Supelcoport. N_2 carrier gas flow was 180 ml/min, Col. temp 200°C, Inj. temp 270°C, Det. temp 245°C.	
3.2	**Reference substance**	No	
3.3	**Testing procedure**		
3.3.1	**Soil type**	Described in tabular form (see Table 1)	
3.3.2	**Test system and**	Six soil columns were prepared in cast acrylic tubing (10.2 cmid,	

Section A7.2.3.2 Annex Point IIIA, XII.1.2-3	**Adsorption and mobility in soil, further studies**

Additionnal information

	conditions	11.4 cmod, 50.8 cm long) fitted with a buchner funnel (containing a circle of Whatman No. 41 filter paper) at one end. The soil was uniformly packed to a depth of 40 cm using a vibration-continuous filling technique. The top 5 cm of each column was removed and stored. The next 5cm were then removed and mixed with sufficient permethrein in hexane to allow a soil concentration of 5 μg g^{-1}. The soils were mixed on a rolling mill for approximately 16 hours, and then replaced onto the columns. The initial 2.5 cm layers were then placed on the top of the columns and covered with a circle of filter paper. Each soil column was brought to –33 kPa matric water potential (21% moisture by weight) by the addition of 772 ml distilled water, and allowed to equilibrate overnight. The centre of the permethrin fortified zone in the columns were injected with anhydrous NH_3 in duplicate to simulate 0, 50 and 150 kg N per hectare. After approx. 24 hours, the soil columns were eluted with three pore volumes of distilled water added at an average rate of 20 ml h^{-1}. Leachate was collected for analysis, and the columns segmented and air-dried for extraction and analysis.
3.3.3	**Initial TS concentration**	5 μg g^{-1} in top layer
3.3.4	**Duration of test**	Columns were leached with three pore volumes (1500 ml), added at an average rate of 20 ml h^{-1}
3.3.5	**Analytical parameter**	Permethrin specific analysis
3.3.6	**Sampling**	Leachate: Collected by pore volume (500 ml) and stored for analysis. Soil: After leaching, each column was segmented into zones (0-2.5, 2.5-7.5, 7.5-12.5, 12.5-17.5, 17.5-22.5, 22.5-27.5, 27.5-32.5, 32.5-37.5 cm) for air drying, followed by extraction and analysis.
3.3.7	**Intermediates/ degradation products**	No data
		4 RESULTS
4.1	**Movement of test substance**	
4.1.1	**Graph**	The data for *cis* and *trans* permethrin are presented graphically in Figures 1 and 2.
4.1.2	**Movement**	<0.1% of the applied radioactivity appeared in the leachate. No numerical data are presented to quantify the leaching of permethrin, however a visual inspection of the graphically presented data would indicate that permethrin is essentially immobile in soil.
4.1.3	**Intermediates/ degradation products**	No data
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	No data on the isomer ratio are given, however because data are presented as a percentage of initial dose, this is not considered to

Section A7.2.3.2 Annex Point IIIA, XII.1.2-3	**Adsorption and mobility in soil, further studies**	
		Additionnal information
		affect the general conclusions drawn from the test. The methodology only employs one soil, and no numerical data are presented, therefore the results can only be considered indicative. However, good mass balance data (albeit presented graphically) tends towards the conclusion that the results are reliable.
5.2	**Results and discussion**	<0.1% of the applied radioactivity appeared in the leachate. No numerical data are presented to quantify the leaching of permethrin, however a visual inspection of the graphically presented data would indicate that permethrin is essentially immobile in soil.
5.3	**Conclusion**	The test protocol does not compare with current guidelines for testing soil column leaching. However, it's design does allow an assessment of movement on a soil column in the presence of increased NH_3-N. There are not enough data and inadequate placing of sampling points over the test period to allow derivation of leaching rates, and only one soil was used. However the data are supportive of a high soil-water partition ratio.
5.3.1	**Reliability**	2
5.3.2	**Deficiencies**	Not applicable