Section A7.2.3.1/02 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

the study. The competent authority evaluator notes that adsorption studies on a further four soils are available for this 3-phenoxybenzoic acid in the dossier supplied by the applicant Bayer-Sumitomo.

Sub-headings 4.2 and 5.2

The parameters K^{ads}_{Foc} and K^{des}_{Foc} presented here have been evaluated in the study from the intercept of the Freundlich isotherm with the y-axis. Some of these intercept values are negative numbers but have been reported as positive numbers in error. Therefore the subsequently evaluated equilibrium constants are incorrect. The corrected values are included in the table at the bottom of this section.

	Soil:	LUFA 2.1	LUFA 2.2	LUFA 2.4
Adsorption	$K_{d(ads)}$*	0.72	3.27	6.04
	1/n	0.8098	0.9467	0.6426
	log K^{ads}_{F}	-0.2172	0.3396	0.5128
	K^{ads}_{F}	0.6065	2.1857	3.2569
	r^2	0.9928	0.9708	0.97
	% OC	0.86	1.72	2.07
	K^{ads}_{Foc}	70.5	127.1	157.3
Desorption	$K_{d(des)}$*	6.96	4.44	n.d.
	1/n	0.5795	0.633	n.d.
	log K^{des}_{F}	-0.1438	0.1553	n.d.
	K^{des}_{F}	0.7181	1.4299	n.d.
	r^2	0.9966	0.9608	n.d.
	% OC	0.86	1.72	n.d.
	K^{des}_{Foc}	83.5	83.1	n.d.

* from Tier 1/2 studies.

Conclusion The results presented in the study are of good quality. The average (arithmetic mean) K^{ads}_{Foc} is 118.3 mg/l.

Reliability 1

Acceptability Acceptable

Remarks The average (arithmetic mean) K^{ads}_{Foc} is 118.3 ml/g. This is comparable to the arithmetic mean K^{ads}_{Foc} value of 158.4 ml/g reported in the Bayer-Sumitomo dossier for permethrin.

COMMENTS FROM ...

Date

Section A7.2.3.1/02 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

Section A7.2.3.1/02 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

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

Soil description	LUFA 2.1	LUFA 2.2	LUFA 2.4
Batch No.	F2.10209	F2.23708	F2.44209
pH ($CaCl_2$)	5.67	5.74	7.04
Organic carbon [%]	0.86	1.72	2.07
Maximum water holding capacitiy [g/100g]]	32.2	42.6	43.7
Cation exchange capacity [meq/100 g]	3.4	9.4	24.9
Soil density [g/L]	1524	1271	1310
Soil type [a]	loamy sand	loamy sand	loam
Particle size [%] [a]			
<0.002 mm	2.4	4.7	26.9
0.002-0.05 mm	8.0	11.1	39.0
0.05-2.00 mm	89.6	84.2	34.1

a USDA. classification system

Table A7.2.3.1-2: Analytical methods used for soil samples

HPLC/MS-MS	Instrument	HPLC with MS/MS detector – Shimazu / API 4000
	Column	Phenomenex Synergi Fusion-RP 80A, 50 × 2.0 mm, 4 µ (No. 00B-4434-B0) + 4 mm guard col.
	Temperature	40°C
	Injection volume	10 µL
	Flow rate	300 µL/min
	Detector	Sciex API4000
	Mobile phase	A: Water + 0.1% acetic acid B: Methanol + 0.1% acetic acid
	Gradient	T [min] % A % B Gradient 0.00 50 50 - 4.00 0 100 linear 7.00 0 100 - 7.01 50 50 - 9.00 50 50 -
	Retention time	Approx. 4.8 minutes

Section A7.2.3.1/02 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

Table A7.2.3.1-3: Freundlich adsorption and desorption coefficients of 3-Phenoxybenzoic acid in three soils

	Soil:	**LUFA 2.1**	**LUFA 2.2**	**LUFA 2.4**
Adsorption	1/n	0.8098	0.9467	0.6426
	log K^{ads}_{F}	0.2172	0.3396	0.5128
	K^{ads}_{F}	1.6489	1.7200	3.2569
	r^2	0.9928	0.9708	0.9700
	% OC	0.86	1.72	2.07
	K^{ads}_{Foc}	191.7	127.1	157.3
Desorption	1/n	0.5795	0.6330	n.d.
	log K^{ads}_{F}	0.1438	0.1553	n.d.
	K^{ads}_{F}	1.5795	1.4299	n.d.
	r^2	0.9966	0.9608	n.d.
	% OC	0.86	1.72	n.d.
	K^{ads}_{Foc}	161.9	83.1	n.d.

n.d. not detected

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

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		Offic use on
	26 REFERENCE	
26.1 Reference	Traub M. (2010), "Determination of the Adsorption/Desorption Behaviour of Cypermetric Acid in three Soils", Eurofins Agroscience Services GmbH, Niefern-Öschelbronn, Germany Unpublished report No. S10-00382 (23 December 2010)	
26.2 Data protection	Yes	
26.2.1 Data owner	Tagros Chemicals India Ltd.	
26.2.2 Companies with letter of access	Not applicable.	
26.2.3 Criteria for data protection	Data submitted to the MS after 13 May, 2000 on existing a.s. for the purpose of its entry Annex I/IA of Directive 98/8/EC.	
	27 GUIDELINES AND QUALITY ASSURANCE	
27.1 Guideline study	OECD 106 'Adsorption/Desorption'(2000)	
27.2 GLP	Yes	
27.3 Deviations	None	
	28 MATERIALS AND METHODS	
28.1 Test material	Cypermetric acid	X
28.1.1 Lot/Batch number	Batch No.: CMA/328/B/10	
28.1.2 Specification	As given below	X
28.1.3 Purity	99.23%	
28.1.4 Further relevant properties	Not radio-labelled	
28.2 Degradation products	None	
28.3 Reference substance	No	
28.4 Soil types	A set of 3 soils were used: I : LUFA 2.1, loamy sand II : LUFA 2.2, loamy sand III : LUFA 2.4, loam See **Table A7.2.3.1-1** for details. Soils were air dried at ambient temperature (between 20 - 25°C). Soils were already delivered sieved to a particle size ≤ 2 mm. The moisture content was determined at 105°C and for all calculations the mass of soils refers to the weight of soil corrected for moisture content.	X
28.5 Testing procedure		
28.5.1 Test system and	The test was conducted in three tiers, Tier I preliminary study, a Tier 2	

conditions

screening test and a Tier 3 test determining Freundlich isotherms.

All tests were conducted at a temperature between 20 and 25°C and all samples were protected from light to avoid any photochemical degradation. Air-dried soil samples were equilibrated by shaking with 0.01 M $CaCl_2$ (max. 90% of the final volume) overnight before application.

The application solutions were prepared just before application to soil samples and kept closed in the dark ambient conditions.

28.5.2 Test solution

A stock solution of the test item (1000 µg/mL) was prepared in acetonitrile:water (1:3, v/v) and 50 µg/mL and 5 µg/mL dilutions were prepared in water for application solutions. The application solutions had a concentration 10 times higher than the respective tested solution. The application solutions were prepared just before application to soil samples and were kept closed in the dark ambient conditions. The storage did not impair the stability of the test item and its concentration in the solution.

28.6 Test performance

28.6.1 Tier I Preliminary tests

Two soils LUFA 2.1 and 2.4 and three soil/solution ratios were used: 50 g (ratio 1/1), 10 g (ratio 1/5) and 2 g soil (ratio 1/25) in 50 cm^3 aqueous solution of the test substance. Each sample contained 50.8 µg test item for soil LUFA 2.1 and 50.6 µg test item for soil LUFA 2.4 and the sampling times were 2, 4, 6, 24 and 48 hours after applications. Two control samples (without soil) were examined in order to check the stability of the test item in 0.01 M $CaCl_2$ and its possible adsorption on the surfaces of the test vessels. Two blank runs (without test item) for each soil with the 1/1 soil/solution ratio and 0.01 M $CaCl_2$ solution were used to detect interfering compounds or contaminated soils.

All experiments were performed in duplicate and the agitation of the control, blank and test item samples was performed over a period of 48 hours. The mass balance was carried out at the soil/solution ratio 1/1.

The percentage adsorption was calculated at each time point and the distribution coefficient K_d at equilibrium, as well as the organic carbon normalized adsorption coefficient K_{oc}, was also calculated.

The pH of the aqueous phase was measured before and after contact with the soil.

28.6.2 Tier 2 Adsorption and desorption kinetics at one concentration of the test item

At Tier 2 level, one test soil was used (LUFA 2.2). The equilibrium time, the soil/solution ratio, the weight of the soil sample, the volume of the aqueous phase and the concentration of the test substance were chosen based on Tier 1 results. Each sample contained 49.2 µg test item and the sampling times were 2, 4, 6, 24 and 48 hours after applications. The pH values of the supernatants were determined during the test. Two control samples and two blank runs were prepared as in preliminary test. X

The percentage adsorption was calculated at each time point and the distribution coefficient K_d at equilibrium, as well as the organic carbon normalized adsorption coefficient K_{oc}, was also calculated.

After the adsorption kinetics experiment, the mixture was centrifuged and the aqueous phase was removed as much as possible. The volume of solution removed was replaced by equal volumes of 0.01 M $CaCl_2$. These mixtures were agitated until desorption equilibrium was reached.

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

The mixtures were centrifuged at defined time intervals, analysing 1 mL of the aqueous phase and continuing with the experiment with the original mixture. Fresh quantities of 0.01 M $CaCl_2$ were added to maintain the soil/solution ratio.

The mass balance was carried out at the soil/solution ratio 1/1. After the completion with Tier 1 and 2 experiments the aqueous phase was separated by centrifugation and recovered as completely as possible. The amount of the test item in the soil extracts was determined and the mass balance was calculated.

The sampling times were after 48 hours after application (Adsorption) and 2, 4, 6, 24 and 48 hours after replacing the 0.01 M $CaCl_2$ solution (Desorption).

The percentage desorption was calculated at each time point and the desorption coefficient K_{des} at equilibrium was also calculated.

28.6.3 Tier 3 Freundlich isotherms

The adsorption test was performed as described under 3.6.2, only that the aqueous phase was analysed only once after 48 hours of adsorption. Five test item concentrations were used, covering one order of magnitude and the same soli/solution ratio (1/1) per soil was kept along the study. The equilibrium concentrations in the solution were determined and the amount adsorbed calculated. The adsorbed mass per unit mass of soil was plotted as a function of the equilibrium concentration of the test item.

Freundlich desorption isotherms were then determined on the three soils used in the adsorption isotherms experiment and performed as desorption kinetics in 3.6.2. Again, only one analysis was made at desorption equilibrium. The amount of test substance desorbed was calculated and the content of test substance remaining adsorbed at desorption equilibrium was plotted as a function of the equilibrium concentration of the test substance in solution.

28.6.4 Analytics

A validated method was used for analysis of soil samples. The samples (0.5 mL) and soil extracts were mixed with acetonitrile and centrifuged and further diluted with acetonitrile:water prior to analysis by HPLC-MS/MS if necessary. The HPLC conditions are presented in **Table A7.2.3.1-2**.

The LOQ was defined at the lowest fortification level with mean recoveries ranging from 70 to 110% at the relative standard deviation of $\leq$ 20%and blanks not exceeding 30%. These criteria were fulfilled for the 0.001 mg/L fortification level. The LOD was defined as 30% of the LOQ (0.0003 mg/L).

Residues in the untreated test medium used for recovery experiments and blank samples were not detectable.

28.6.5 Other test

None

29 RESULTS

29.1 Tier 1 Preliminary test and Tier 2 Adsorption and desorption kinetics at one

Adsorption equilibrium was reached after 48 hours for all soil/solution ratios. The adsorption of the test item depended on the soil/solution ratio and reached a max. value at a soil/solution ratio of 1/1 of 10.9% for soil LUFA 2.1 and 39.0% for soil LUFA 2.4, respectively. X

The Tier 2 testing was only performed with the soil LUFA 2.2 at a

concentration of the test substance

soil/solution ration of 1/1, based on the results of Tier 1. The experimental procedure was identical to Tier 1. Each sample contained 49.2 µg test item. Adsorption equilibrium was reached after 48 hours and was 43.3%.

Desorption was performed with soils LUFA 2.1, 2.2 and 2.4 and a soil/solution ratio of 1/1. The samples contained 8.5 µg (soil LUFA 2.1), 21.3 µg (soil LUFA 2.2) and 18.5 µg (soil LUFA 2.4) test item at the end of the adsorption (48 hours). The desorption equilibrium was reached after 48 hours with maximum value of 27.9% and 28.5% for soil LUFA 2.1 and 2.2, respectively. For soil LUFA 2.4 no desorption equilibrium was reached during the 48 hours incubation.

The adsorption K_{OC} values ranged from 14.0 to 44.2 mL/g for soil/solution ratio 1/1 and the desorption K_{OC} values were 305.2 and 145.9 mL/g for soils LUFA 2.1 and 2.2, respectively.

29.2 Tier 3 Adsorption and desorption Freundlich isotherms

The adsorption isotherms were estimated at a soil/solution ratio of 1/1 and at five test item concentrations (0.01 to 1.08 mg/L) in 50 mL $CaCl_2$. The experimental procedure was identical to Tier 1&2.

X

For desorption a desorption time of 48 hours and soil/solution ratio of 1/1 was chosen and the experimental procedure was identical to Tier 1&2. After changing the $CaCl_2$.solution the concentration range for desorption was 0.01 to 0.69 mg/L in 50 mL $CaCl_2$. For soil LUFA 2.4 no desorption was detectable during Tier 3 desorption.

Adsorption behaviour of the test substance was described with the Freundlich equation. The correlation coefficients (r^2) for the individual isotherms are ≥ 0.9850. The constants K^{ads}_{Foc} ranged from 75.2 to 605.8 mL/g and the exponents 1/n were in range of 0.4216 to 0.0.8919.

For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value was 507.0 and 73.0 mL/g for soil LUFA 2.1 and 2.2, respectively.

Results are presented in **Table A7.2.3.1-3**.

29.3 Calculations

29.3.1 Ka, Kd — Refer to 4.1 and 4.2 and to **Table A7.2.3.1-3** for details.

29.3.2 Ka_{oc}, Kd_{oc} — Refer to 4.1 and 4.2 and to **Table A7.2.3.1-3** for details.

29.4 Degradation product(s)

No degradation products were monitored.

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

30 APPLICANT'S SUMMARY AND CONCLUSION

30.1 Materials and methods

OECD 106 'Adsorption/Desorption' and SETAC (1995).

The test was conducted to determine the adsorption-desorption behaviour of Cypermetric acid in three different soils (LUFA 2.1, 2.2 and 2.4). The test was conducted in three tiers, Tier I preliminary study, a Tier II screening test and a Tier III test determining Freundlich isotherms.

All tests were conducted at a temperature between 20 and 25°C. Two soils LUFA 2.1 and 2.4 and three soil/solution ratios were used: 50 g (ratio 1/1), 10 g (ratio 1/5) and 2 g soil (ratio 1/25) in 50 cm^3 aqueous solution of the test substance. Each sample contained 50.8 µg test item for soil LUFA 2.1 and 50.6 µg test item for soil LUFA 2.4 and the sampling times were 2, 4, 6, 24 and 48 hours after applications.

Desorption was performed with one test item concentration and a soil/solution ratio of 1/1 and the mixture was centrifuged after the adsorption kinetics experiment and the aqueous phase was removed as much as possible. The volume of solution removed was replaced by equal volumes of 0.01 M $CaCl_2$ without test item. These mixtures were agitated until the sampling time. After centrifugation 1 mL aliquot of the aqueous phase was analysed for the test item.

Freundlich adsorption/desorption isotherms test was performed as performed adsorption/desorption kinetics, only that the aqueous phase was analysed only once. Five test item concentrations and the same soli/solution ratio (1/1) were used. The equilibrium concentrations in the solution were determined and the amount adsorbed/desorbed calculated. The adsorbed mass per unit mass of soil was plotted as a function of the equilibrium concentration of the test item. For desorption the of test substance remaining adsorbed at desorption equilibrium was plotted as a function of the equilibrium concentration of the test substance in solution.

The analytical method used was HPLC/MS-MS.

30.2 Results and discussion

At Tier 1 each sample contained 50.8 µg test item for soil LUFA 2.1 and 50.6 µg test item for soil LUFA 2.4 and adsorption equilibrium was reached after 48 hours for all soil/solution ratios

At Tier 2 testing was only performed with the soil LUFA 2.2 at a soil/solution ratio 1/1. Each sample contained 49.2 µg test item. Adsorption equilibrium was reached after 48 hours and was 43.3%.

Desorption was performed with soils LUFA 2.1, 2.2 and 2.4 and a soil/solution ratio of 1/1. The samples contained 8.5 µg (soil LUFA 2.1), 21.3 µg (soil LUFA 2.2) and 18.5 µg (soil LUFA 2.4) test item at the end of the adsorption (48 hours). The desorption equilibrium was reached after 48 hours with maximum value of 27.9% and 28.5% for soil LUFA 2.1 and 2.2, respectively. For soil LUFA 2.4 no desorption equilibrium was reached during the 48 hours incubation.

The adsorption K_{OC} values ranged from 14.0 to 44.2 mL/g for soil/solution ratio 1/1 and the desorption K_{OC} values were 305.2 and 145.9 mL/g for soils LUFA 2.1 and 2.2, respectively.

The adsorption and desorption isotherms (Tier 3) were estimated at a

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

soil/solution ratio of 1/1 and at five test item concentrations from 0.01 to 1.08 mg/L (adsorption) and 0.01 to 0.69 mg/L (desorption) for soil LUFA 2.1 and 2.2, respectively. For soil LUFA 2.4 no desorption was detectable during Tier 3 desorption.

Adsorption behaviour of the test substance was described with the Freundlich equation. The correlation coefficients (r^2) for the individual isotherms are ≥ 0.9850. The constants K^{ads}_{Foc} ranged from 75.2 to 605.8 mL/g and the exponents 1/n were in range of 0.4216 to 0.0.8919.

For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value was 507.0 and 73.0 mL/g for soil LUFA 2.1 and 2.2, respectively.

30.3 Conclusion Validity criteria can be considered as fulfilled for the determination of adsorption-desorption of Cypermetric acid.

The K_{OC} values indicate that Cypermetric acid is moderately mobile in soil and the adsorption is considered to be non-reversible.

30.3.1 Reliability 1

30.3.2 Deficiencies No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 24-11-11

Materials and Methods Applicant’s version is acceptable

Results and discussion Adopt applicant’s version with the addition of the following comments:

Sub-heading 3.1

In the ‘Materials and Methods’ section of the study the chemical structure of 3-Phenoxybenzoic acid is shown instead of Cypermetric acid. This is an error but does not affect the results presented.

Like its parent compound Permethrin, Cypermetric acid has two chiral centres and therefore can exist in both *cis*- and *trans*- configurations. The isomeric ratio used here was not specified in the study. However the applicant informed the RMS in a subsequent correspondence that the ratio used was 25% *cis*, 75% *trans*.

Sub-heading 3.4

The three soils used in the study are classified using the USDA soil classification system. However based on the clay and sand percentages given in Table A7.2.3.1-

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

1, soil Lufa 2.1 has been classified incorrectly. It should be described as 'sand'.

Sub-heading 3.6.2

Tier 2 adsorption and desorption studies were performed using one soil type (Lufa 2.2). When the Tier 1 studies are included the data covers three soil types. However OECD 106 states that five different soils should be used at this stage of the study. The competent authority evaluator notes that adsorption studies on a further three soils are available for cypermetric acid (53.7% cis, 46.3% trans) in the dossier supplied by the applicant Bayer-Sumitomo.

Sub-heading 4.1

Though not reported in the applicant's study summary, the Tier 1 and 2 adsorption K_d values for soils Lufa 2.1, Lufa 2.2 and Lufa 2.4 are 0.12, 0.76 and 0.64 cm^3g^{-1} respectively. All these have been included by the evaluator in the table at the bottom of this section. OECD 106 states that K_d values below 0.3 cannot be estimated accurately from the indirect method – rather the solid phase should be analysed separately. Also Freundlich values should only be evaluated in those cases where the product of the K_d value and the soil/solution ratio is greater than 0.3. As that is not the case for soil Lufa 2.1 only the results for soils Lufa 2.2 and Lufa 2.4 are considered accurate enough.

Sub-heading 4.2

The parameters K^{ads}_{Foc} and K^{des}_{Foc} presented here have been evaluated in the study from the intercept of the Freundlich isotherm with the y-axis. All these intercept values are negative numbers but have been reported as positive numbers in error. Therefore the subsequently evaluated equilibrium constants are incorrect. The corrected values are included in the table at the bottom of this section.

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

	Soil:	LUFA 2.1 *	LUFA 2.2	LUFA 2.4
Adsorption	$K_{d(ads)}$**	0.12	0.76	0.64
	1/n	0.8919	0.8682	0.4216
	log K^{ads}_F	-0.7168	-0.1116	-0.3909
	K^{ads}_F	0.1920	0.7734	0.4065
	r^2	0.9978	0.9965	0.985
	% OC	0.86	1.72	2.07
	K^{ads}_{Foc}	22.32	44.96	19.64
Desorption	$K_{d(des)}$**	2.63	2.51	n.d.
	1/n	0.7763	0.8383	n.d.
	log K^{des}_F	-0.6395	-0.0986	n.d.
	K^{des}_F	0.2294	0.7969	n.d.
	r^2	0.9857	0.9972	n.d.
	% OC	0.86	1.72	n.d.
	K^{des}_{Foc}	26.67	46.33	n.d.

* The results for soil Lufa 2.1 are unreliable as described above

** from Tier 1/2 studies.

Conclusion	The results presented in the study are of good quality however some issues detailed above limit the usefulness of the data.
Reliability	2
Acceptability	Acceptable
Remarks	The results are comparable to two of the three values reported for cypermetric acid (53.7% cis, 46.3% trans) in the Bayer-Sumitomo dossier (K^{ads}_{Foc} = 31.05 for Speyer 2.1 soil and K^{ads}_{Foc} = 13.95 for Cranfield 115 soil).

COMMENTS FROM ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

Remarks

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA XII2.1

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

Soil description	LUFA 2.1	LUFA 2.2	LUFA 2.4
Batch No.	F2.10209	F2.23708	F2.44209
pH ($CaCl_2$)	5.67	5.74	7.04
Organic carbon [%]	0.86	1.72	2.07
Maximum water holding capacitiy [g/100g]]	32.2	42.6	43.7
Cation exchange capacity [meq/100 g]	3.4	9.4	24.9
Soil density [g/L]	1524	1271	1310
Soil type [a]	loamy sand	loamy sand	loam
Particle size [%] [a]			
<0.002 mm	2.4	4.7	26.9
0.002-0.05 mm	8.0	11.1	39.0
0.05-2.00 mm	89.6	84.2	34.1

a USDA. classification system

Table A7.2.3.1-2: Analytical methods used for soil samples

HPLC/MS-MS	Instrument	HPLC with MS/MS detector – Shimazu / API 4000
	Column	Phenomenex Synergi Fusion-RP 80A, 50 × 2.0 mm, 4 µ (No. 00B-4434-B0) + 4 mm guard col.
	Temperature	40 °C
	Injection volume	10 µL
	Flow rate	350 µL/min
	Detector	Sciex API4000
	Mobile phase	A: Water + 0.1% acetic acid B: Methanol + 0.1% acetic acid
	Gradient	T [min] % A % B Gradient 0 60 40 - 4.00 0 100 linear 7.00 0 100 - 7.01 60 40 - 9.00 60 40 -
	Retention time	Approx. 4.5 minutes

Section A7.2.3.1/03 Adsorption / Desorption in at least three soil types

Annex Point IIIA-XII.1.2

Table A7.2.3.1-3: **Freundlich adsorption and desorption coefficients of Cypermetric acid in three soils**

	Soil:	LUFA 2.1	LUFA 2.2	LUFA 2.4
Adsorption	1/n	0.8919	0.8682	0.4216
	log K^{ads}_{F}	0.7168	0.1116	0.3909
	K^{ads}_{F}	5.2095	1.2930	2.4598
	r^2	0.9978	0.9965	0.9850
	% OC	0.86	1.72	2.07
	K^{ads}_{Foc}	605.8	75.2	118.8
Desorption	1/n	0.7763	0.8383	n.d.
	log K^{ads}_{F}	0.6395	0.0986	n.d.
	K^{ads}_{F}	4.36	1.25	n.d.
	r^2	0.9857	0.9972	n.d.
	% OC	0.86	1.72	n.d.
	K^{ads}_{Foc}	507.0	73.0	n.d.

n.d. not detected

Section IIIA7.2.3	**Adsorption and Mobility In Soil**
Annex Point XII.1.2	**IIIA 7.2.3.1 Adsorption and desorption studies**

	~~31~~1 REFERENCE	**Offici use or**
~~31.1~~1.1 Reference	Joseph, R. (2004b), Studies on the Adsorption-Desorption of Permethrin Technical. International Institute of Biotechnology and Toxicology (IIBAT), Padappai – 601 301, Kancheepuram District, Tamil Nadu, India, unpublished report No.: 14291. Dates of experimental work: 12 March, 2004	
~~31.2~~1.2 Data protection	Yes	
~~31.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.	
~~31.2.2~~1.2.2 Companies with letter of access	Not applicable	
~~31.2.3~~1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of its entry into Annex I/IA.	
	~~32~~2 GUIDELINES AND QUALITY ASSURANCE	
~~32.1~~2.1 Guideline study	Yes, test method was based on OECD guideline 106	
~~32.2~~2.2 GLP	Yes	
~~32.3~~2.3 Deviations	Yes, with the following deviation: 1. The desorption coefficient is not reported This deviation is not considered to compromise the scientific validity of this study.	
	~~33~~3 MATERIALS AND METHODS	
~~33.1~~3.1 Test material	Please refer to section 2	
~~33.1.1~~3.1.1 Lot/Batch number	P-203	
~~33.1.2~~3.1.2 Specification	Please refer to section 2 (Permethrin 25:75)	

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Section IIIA7.2.3 **Adsorption and Mobility In Soil**

Annex Point XII.1.2 **IIIA 7.2.3.1 Adsorption and desorption studies**

~~33.1.3~~3.1.3 Purity	94%	**Formatted:** Bullets and Numbering
~~33.1.4~~3.1.4 Further relevant properties	None	**Formatted:** Bullets and Numbering
~~33.1.5~~3.1.5 Method of analysis	25ml of CaCal$_2$ was added to 5g of soil and shaken for 1 hr. Samples were then centrifuged and the supernatant removed. 10 ml of the supernatant was then extracted with 25ml of hexane and the hexane layer collected. The extraction was repeated with the aqueous phase and the hexane layer collected again. The combined hexane extracts were dried over anhydrous sodium sulphate. The solvent was evaporated under reduced pressure to near dryness and recovered in 3ml of hexane. The extract was eluted through a chromatographic column prepared with 5g florisil slurried using hexane. The eluate was collected and evaporated to dryness and recovered in acetone for GC-ECD analysis (for the determination of Permethrin content): GC System: Shimadzu GC-14B Gas Chromatograph with ECD Column: DB-5 Megabore column 30m length, 0.53mm i.d., 1.5µm film thickness Gas flow rate: Nitrogen(N$_2$) 35 ml/min Make up(N$_2$) 15 ml/min Temperature conditions: Oven – 280°C Injector – 230°C Detector – 270°C Injection volume: 1 µl Solvent: Acetone Retention time: ~ 3.2mins	**Formatted:** Bullets and Numbering
~~33.2~~3.2 Degradation Products	No	**Formatted:** Bullets and Numbering
~~33.2.1~~3.2.1 Method of analysis for degradation products	Not appliacble	**Formatted:** Bullets and Numbering
~~33.3~~3.3 Reference substance	No	**Formatted:** Bullets and Numbering
~~33.3.1~~3.3.1 Method of analysis for reference substance	Not applicable	**Formatted:** Bullets and Numbering
~~33.4~~3.4 Soil types	Please refer to Table A7.2.3.1-1	**Formatted:** Bullets and Numbering
~~33.5~~3.5 Testing procedure		**Formatted:** Bullets and Numbering
~~33.5.1~~3.5.1 Test system	Soil samples selected for the study hada pH of 5 – 8, an organic carbon content of 0.2 – 1.0%. Soil was stored damp after collection and sieved to ≤ 2mm. The dry weight content (100°C for approximately 12 hours) fo the soil was determined.	**Formatted:** Bullets and Numbering
~~33.5.2~~3.5.2 Test solution and test conditions	The test solution was prepared by saturating Permethrin in 0.01M CaCl$_2$ solution.	**Formatted:** Bullets and Numbering

Section IIIA7.2.3	**Adsorption and Mobility In Soil**
Annex Point XII.1.2	**IIIA 7.2.3.1 Adsorption and desorption studies**

Half the saturation concentration of Permethrin was prepared by taking a known quantity of saturated test solution prepared in 0.01M $CaCl_2$ and adding an equal volume of 0.01M $CaCl_2$.

The test solutions were added to the respective test containers and equilibrated. Containers were closed during agitation and centrifugation to avoid volatility losses.

Actual determination was carried out in triplicate using 1:5 w/w soil: solution ratio (5g soil and 25 ml of test solution).

The experiment was run at room temperature (approx. 22°C)

~~33.6~~3.6 Test performance

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~~33.6.1~~3.6.1 Preliminary test

According to (a)"OECD 106": Yes

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The soil was equilibrated with 0.1M $CaCl_2$ as per the screening test described in section 3.6.2. The aqueous phase was separated by centrifugation, and sufficient test chemical was added to form a solution of approximately one-half saturation. The solution was then subjected to chemical analysis.

~~33.6.2~~3.6.2 Screening test: Adsorption

According to (a)"OECD 106": Yes

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The test solution was prepared in 0.1M $CaCl_2$ at a level of one-half saturation.

5 g soil samples were added to each test solution and agitation was initiated immediately for a period of 1 hr. Following agitation, the suspension was centrifuged to obtain a clear solution, which was measured and analysed for parent compound concentration. The volume of equilibrium test solution retained in the solid phase following centrifugation and the volume V of the supernatant were recorded for subsequent correction of the desorption data.

Three blanks were run consisiting of each of the 3 soil types with only 0.1M $CaCl_2$ solution. A single control vessel consisting of the test chemical solution with no soil was also run. The same procedure was applied to the 3 blanks and control with appropriate corrections made where necessary.

~~33.6.3~~3.6.3 Screening test: Desorption

According to (a)"OECD 106": Yes

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The supernatant (0.1M $CaCl_2$) retained from the adsorption screening test was added to each solid phase and the mixture was gently agitated for 1 hour.

The mixture was then centrifuged and the supernatant collected for analysis. This procedure was repeated on the solid phase with a further quantity of fresh 0.1M $CaCl_2$ solution.

The solute and desorbed material retained in the entrained equilibrium test solution from the adsorption screening test were assumed to be completely removed follwing two washings.

An appropriate correction was applied to decrease the measured concentration by the calculated amount of retained solute.

~~33.6.4~~3.6.4 HPLC-method	Not applicable	**Formatted:** Bullets and Numbering
~~33.6.5~~3.6.5 Other test	Not applicable	**Formatted:** Bullets and Numbering
	~~34~~4 RESULTS	**Formatted:** Bullets and Numbering
~~34.1~~4.1 Preliminary test	Please refer to Table A7.2.3.1-2	**Formatted:** Bullets and Numbering
~~34.2~~4.2 Screening test: Adsorption:	Please refer to Tables A7.2.3.1-3 to A7.2.3.1-5	**Formatted:** Bullets and Numbering
~~34.3~~4.3 Screening test: Desorption	Please refer to Tables A7.2.3.1-6 to A7.2.3.1-8	**Formatted:** Bullets and Numbering
~~34.4~~4.4 Calculations		**Formatted:** Bullets and Numbering
~~34.4.1~~4.4.1 Ka , Kd	Ka values for Permethrin in soil ranged from 25.03 to 64.39 with an average value of 48.75.	**Formatted:** Bullets and Numbering
~~34.4.2~~4.4.2 Ka_{oc} , Kd_{oc}	Ka_{oc} values for Permetrhin technical in soil ranged from 5962.10 to 14204.71 with an average value of 9930.6.	**Formatted:** Bullets and Numbering
~~34.5~~4.5 Degradation Products	Not evaluated	**Formatted:** Bullets and Numbering
	~~35~~5 APPLICANT'S SUMMARY AND CONCLUSION	**Formatted:** Bullets and Numbering
~~35.1~~5.1 Materials and methods	The adsorption and desorption of Permethrin was studied in three soil types. The test substance, in 0.01M $CaCl_2$ was added to 5g soil samples, which had been pre-equilibrated in 0.01M $CaCl_2$. The mixture was agitated for an hour and the soil suspensions then separated by centrifugation. The amount of test substance adsorbed on the soil sample was calculated as the difference between the amount of test substance initially present in solution and the amount remaining at the end of the experiment. This study was conducted according OECD method 106 and is described under point 3 with the following deviation: 1. The desorption coefficient is not reported This deviation is not considered to compromise the scientific validity of this study.	**Formatted:** Bullets and Numbering **Formatted:** Numbered + Level: 1 + Numbering Style: 1, 2, 3, … + Start at: 1 + Alignment: Left + Aligned at: 0.63 cm + Tab after: 1.27 cm + Indent at: 1.27 cm
~~35.2~~5.2 Results and discussion	Please refer to Tables A7.2.3.1-2 to A7.2.3.1-8.	**Formatted:** Bullets and Numbering
~~35.2.1~~5.2.1 Adsorbed a.s. [%]	The amount of Permethrin adsorbed to the soil ranged from 83.27% to 92.78% with an average adsorption value of 89.3%	**Formatted:** Bullets and Numbering
~~35.2.2~~5.2.2 Ka	Ka values for Permethrin in soil ranged from 25.03 to 64.39 with an average value of 48.7.	**Formatted:** Bullets and Numbering
~~35.2.3~~5.2.3 K_d	Not documented	**Formatted:** Bullets and Numbering

Section IIIA7.2.3	**Adsorption and Mobility In Soil**
Annex Point XII.1.2	**IIIA 7.2.3.1 Adsorption and desorption studies**

~~35.2.4~~5.2.4 Ka$_{oc}$	Ka$_{oc}$ values for Permetrhin technical in soil ranged from 5962.10 to 14204.71 with an average value of 9930.6.	**Formatted:** Bullets and Numbering
~~35.2.5~~5.2.5 Ka/Kd	Not documented	**Formatted:** Bullets and Numbering
~~35.3~~5.3 Conclusion	Permethrin is strongly adsorbed to soil. According to the McCall classification system and the SSLRC mobility classification scheme, Permethrin is immobile in soil.	**Formatted:** Bullets and Numbering
~~35.3.1~~5.3.1 Reliability	1	**Formatted:** Bullets and Numbering
~~35.3.2~~5.3.2 Deficiencies	One deficiency was noted and is outlined under points 2.3 and 5.1. However, this does not compromise the scientific validity of this study.	**Formatted:** Bullets and Numbering

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	15 June 2009
Materials and Methods	Applicant's version is acceptable but the following points should be noted. Sub-heading 2.3 Test Guideline OECD 106 states that five soils should be used for a Tier 2 study (adsorption kinetics at one concentration of the test substance). In this case, three Indian soils were used, two of which had low organic carbon contents. It is not clear if these soils are representative of EU soils that could be exposed to permethrin when used as a wood preservative. It is noted that some confusion on the number of soils required could arise, since, in relation to additional sorption data, Directive 98/8/EC (Annex IIIA, XII.1.2) and the TNsG on data requirements (dossier section IIIA 7.2.3.1) state that at least three soil types are required, whereas in relation to core sorption data, the TNsG on data requirements (dossier section IIIA 7.1.3) state that a screening test is always required (conducted according to EC method C.18 or OECD 106) in which adsorption at a single concentration is determined in five different soil types. The study presented here is in effect a screening test in which adsorption at a single concentration has been determined in three soils. Sub-headings 2.3 and 3.4 (Table A7.2.3.1-1) One of the soils had an organic carbon content of 0.26%. OECD 106 recommends that the minimum organic carbon content of soil used should be 0.3%, since in soil with a lower organic carbon content than this the correlation between organic content and adsorption may be disturbed. Sub-headings 2.3, 4.4.1, 4.4.2, 5.1, 5.2.3, 5.2.5 and 5.3.2 The applicant details as a deviation that the desrption coefficent is not reported. The RMS evaluator has calculated desorption coefficients based on the reported desorption percentages. Refer to the evaluator's comments under 'Results and discussion' for further details. Sub-heading 3.1.2 Cis/trans ratio of permethrin used is not specified in the study report.

Section IIIA7.2.3 Adsorption and Mobility In Soil

Annex Point XII.1.2 IIIA 7.2.3.1 Adsorption and desorption studies

Sub-heading 3.4 (Table A7.2.3.1-1)
The soil classified as a USDA loamy sand should actually be classified as a USDA sandy loam (based on 73% sand, 17% silt, 10% clay). Table A7.2.3.1-1 states that soil pH was measured in water. OECD 106 recommends that soil pH should be measured in a solution of 0.01M $CaCl_2$.

Sub-heading 3.6.2
Test substance concentration used was nominally 0.15 mg/L.

Sub-heading 3.6.5
Further investigations were not undertaken to study sorption behaviour at different concentrations, e.g. by determining Freundlich adsorption isotherms. This would have been feasible, since accurate adsorption coefficients (K_a) at one concentration were obtained for all three soils tested [K_a*(m_{soil}/V_0) > 0.3 in all cases].

Results and discussion

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

Sub-headings 4.3 and 5.2 (Table A7.2.3.1-8)
The value of D (%) for Rep - III should be 19.87 (not 82.94). The value of R (%) for Rep - III should be 80.13 (not 19.87).

Sub-headings 2.3, 4.4.1, 4.4.2, 5.1, 5.2.3 and 5.3.2
The RMS evaluator calculated desorption coefficient values (K_{des}), based on average percentage desorption values of 10.33%, 11.96% and 20.60% for the three soils. Desorption coeffiecents were calculated using the following equation:

$$K_{des} = \left(\frac{100}{D_{eq}} - 1\right) \cdot \frac{V_T}{m_{soil}}$$

where K_{des} = distribution (partition) coefficient for desorption ($cm^3\ g^{-1}$), D_{eq} = percentage of desorption at desorption equilibrium (%), V_T = total volume of the aqueous phase in contact with the soil during the desorption test (cm^3) and m_{soil} = quantity of the soil phase, expressed in dry mass of soil (g). [m_{soil} was 5 g and V_T was assumed to be 25 cm^3] Results obtained are shown in the table below.

Soil texture (USDA)	Sandy clay	Clay	Sandy loam
Organic carbon (%)	1.08	0.40	0.26
Desorption (%)*	10.33	11.96	20.60
K_{des} ($cm^3\ g^{-1}$)#	43	37	19
$K_{des,\ oc}$ ($cm^3\ g^{-1}$) #	4000	9200	7400

* Mean value (arithmetic mean of three replicates)
\# K_{des} and $K_{des,\ oc}$ rounded off to 2 significant figures.

Sub-heading 5.2.5
The ratio of the adsorption partition coefficient to the desorption partition coefficient (Ka/Kd) was calculated by the RMS evaluator and determined at 1.5 for the sandy clay, 1.5 for the clay and 1.3 for the sandy loam.

Conclusion Adopt applicant's version.

Reliability 2

Acceptability Acceptable

Overall the study is acceptable but it is of limited use for risk assessment purposes since it only provides adsorption partition values at a single test concentration for 3 soil types (2 of which had very low organic carbon contents).

Remarks

COMMENTS FROM ...

Section IIIA7.2.3 Adsorption and Mobility In Soil

Annex Point XII.1.2 IIIA 7.2.3.1 Adsorption and desorption studies

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: Soil characterisation results

Soil type	**Sandy clay**	**Clay**	**Loamy sand**
Soil series	Clayey Typic Rhodustalf	Typic Ustropept	Typic/Fluventic Haplustalf
Classification	USDA	USDA	USDA
Location	Padappai, Tamil Nadu, India	Padappai, Tamil Nadu, India	Padappai, Tamil Nadu, India
Horizon	Ap	Ap	Ap
% Sand	55	10	73
% Silt	10	30	17
% Clay	35	60	10
% Organic carbon	1.08	0.40	0.26
pH (1:1 H_2O)	8.02	6.22	5.78
Cation exchange capacity (MEQ/100g)	9.50	15.5	10.71
Ca	10.5%	7.0%	0.1%
Mg	0.036%	0.05%	0.06%
Na	0.18%	0.0126%	0.1146%
K	0.05%	0.09%	0.06%
Test substance	Permethrin	Permethrin	Permethrin
Room temperature T, °C	25	25	25

Table A7.2.3.1-2: Results of Preliminary Test

Soil Type	**Sandy Clay**			**Clay**			**Loamy Sand**		
	REP-I	REP-II	REP-III	REP-I	REP-II	REP-III	REP-I	REP-II	REP-III
Adsorption after 0.5hrs	80.77	81.07	80.98	78.47	78.28	79.44	75.26	75.37	76.32
Adsorption after 1.0hrs	92.08	92.35	91.76	91.92	91.96	91.92	84.29	84.11	84.64
Adsorption after 1.5hrs	91.87	92.12	92.09	92.13	91.76	92.61	84.36	83.42	84.29

Table A7.2.3.1-3: Screening Test; Adsorption – Sandy Clay

Soil Type	**Sandy Clay**		
	Rep – I	Rep – II	Rep – III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
C_e (mg/l)	0.0105	0.0107	0.0115
X	3.5148	3.5085	3.4889
m (g)	5	5	5
X/m	0.7030	0.7017	0.6978
G (mg)	3.7766	3.7766	3.7766
V (ml)	24	24	24

Table A7.2.3.1-4: Screening Test; Adsorption – Clay

Soil Type	**Clay**		
	Rep – I	Rep – II	Rep – III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
C_e (mg/l)	0.0115	0.0130	0.0122
X	3.4879	3.4525	3.4710
m (g)	5	5	5
X/m	0.6976	0.6905	0.6942
G (mg)	3.7766	3.7766	3.7766
V (ml)	24	24	24

Table A7.2.3.1-5: Screening Test; Adsorption – Loamy Sand

Soil Type	**Loamy Sand**		
	Rep – I	Rep – II	Rep – III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
C_e (mg/l)	0.0230	0.0271	0.0258
X	3.2024	3.0993	3.1324
m (g)	5	5	5
X/m	0.6405	0.6199	0.6265
G (mg)	3.7766	3.7766	3.7766
V (ml)	24	24	24

Table A7.2.3.1-6: **Screening Test; Desorption – Sandy Clay**

Soil Type	**Sandy Clay**		
	Rep - I	Rep – II	Rep - III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
D (%)	11.72	9.91	9.36
R (%)	88.28	90.09	90.64

Table A7.2.3.1-7: **Screening Test; Desorption – Clay**

Soil Type	**Clay**		
	Rep - I	Rep - II	Rep - III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
D (%)	12.07	11.63	12.18
R (%)	87.93	88.37	87.82

Table A7.2.3.1-8: **Screening Test; Desorption – Loamy Sand**

Soil Type	**Loamy Sand**		
	Rep - I	Rep - II	Rep - III
Room Temperature (°C)	25	25	25
C_i (mg/l)	0.1503	0.1451	0.1578
D (%)	21.52	20.41	82.94
R (%)	78.48	79.59	19.87

Section IIIA 7.2.3 **Annex Point XII.1.3**	**Adsorption and Mobility in Soil - Further Studies** **IIIA 7.2.3.2 Mobility**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2 (October 2000)', such studies are only required if it is indicated in adsorption/desorption and soil degradation studies that relevant amounts of the substance may reach ground water. A batch equilibrium test was carried out on three soil types to determine the adsorption coefficient of Permethrin ("Studies on the Adsorption-Desorption of Permethrin", Joseph, R. (2004) (IIIA, 7.2.3.1)). This study demonstrated that Permethrin is highly immobile in soil with an average K_{oc} of 9930.63. Thus, any risk of leaching and subsequent ground water contamination can be excluded. It is therefore proposed that no further testing on mobility in soil is required.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	01 July 2009	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Further studies on mobility in soil are not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section IIIA 7.3 Fate and behaviour in air

Annex Point IIIA VII.5

IIIA 7.3.1 Phototransformation in air (Atkinson calculation)

		Officia **use onl**
	~~36~~1 REFERENCE	
~~36.1~~1.1 **Reference**	McManus, K (2006a), Atmospheric oxidation of Permethrin – Atkinson calculation, Rivendell Consulting Limited, Rivendell House, Stamullen, Co. Meath, unpublished report no.: RI/2006/04/07. Date of experimental work: April 04, 2006.	
~~36.2~~1.2 **Data protection**	Yes	X
~~36.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.	
~~36.2.2~~1.2.2 Companies with letter of access	Not applicable	
~~36.2.3~~1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	~~37~~2 GUIDELINES AND QUALITY ASSURANCE	
~~37.1~~2.1 **Guideline study**	Not applicable	
~~37.2~~2.2 **GLP**	Not applicable	
~~37.3~~2.3 **Deviations**	Not applicable	
	~~38~~3 MATERIALS AND METHODS	
~~38.1~~3.1 **Test material**	Not applicable	
~~38.2~~3.2 **Testing procedure**		
3.2.1 Test system	A computer modelling program AOP (Atmospheric Oxidation Program) was used to estimate the atmospheric half-life of Permtehrin technical. The program estimated the rate constant for the gas phase reaction between photochemically produced hydroxyl radicals and organic chemicals. The reaction between ozone and olefinic/acetylenic compounds was also estimated. This was done by estimating the rate constant (k) of the active substance based on the chemical structure of Permethrin. The degradation of the active substance followed pseudo-first order kinetics. The rate constants were used by the program to calculate the	X

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Section IIIA 7.3 **Annex Point IIIA VII.5**	**Fate and behaviour in air** **IIIA 7.3.1 Phototransformation in air (Atkinson calculation)**	
	atmospheric half-life for Permethrin based upon average concentrations of hydroxyl radicals and ozone.	
	~~39~~4 RESULTS	
~~39.1~~4.1 **Rate constant (k)**	AOP estimated the overall rate constant for the gas phase reaction of Permethrin between hydroxyl radicals (OH) and ozone to be 22.88 x 10^{-12} and 0.02 x 10^{-17} cm^3/molecule-sec, respectively. Permethrin does not react with olefinic/acetylenic compounds.	X
~~39.2~~4.2 **DT50**	The atmospheric half-life (DT_{50}) of Permethrin, as a result of gas-phase reactions with photochemically produced atmospheric hydroxyl radicals and ozone, was estimated to be 5.6 hrs and 49.27 days (based on 12-hour days), respectively.	X
	~~40~~5 APPLICANT'S SUMMARY AND CONCLUSION	
~~40.1~~5.1 **Materials and methods**	The rate constants and half-lives for reactions of Permethrin with OH radicals and ozone in the atmosphere were estimated using the Atmospheric oxidation program (AOP). Using the weighted global average OH radical and ozone concentration in the troposphere, the half-life of these processes were calculated.	
~~40.2~~5.2 **Results and discussion**		
5.2.1 Rate constant (k)	AOP estimated the overall rate constant for the gas phase reaction of Permethrin between hydroxyl radicals (OH) and ozone to be 22.88 x 10^{-12} and 0.02 x 10^{-17} cm^3/molecule-sec, respectively.	
5.2.2 DT_{50}	The atmospheric half-life (DT_{50}) of Permethrin, as a result of gas-phase reactions with photochemically produced atmospheric hydroxyl radicals and ozone, was estimated to be 5.6 hrs and 49.27 days (based on 12-hour days), respectively.	X
~~40.3~~5.3 **Conclusion**	According to the Atkinson method of calculation, the main route of degradation of Permethrin in air is *via* the reaction with hydroxyl radicals. This degradation in air is rapid with a DT_{50} of 5.6 hrs (based on 12-hour days).	X
~~40.3.1~~5.3.1 Reliability	1	
5.3.2 Deficiencies	No	

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Section IIIA 7.3 Fate and behaviour in air

Annex Point IIIA VII.5

IIIA 7.3.1 Phototransformation in air (Atkinson calculation)

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	02 July 2009
Materials and Methods	Applicant's version is acceptable with the addition of the following information. Sub-heading 3.2.1 The software used for the calculation was AOPWIN v1.91, which is freely available from the U.S. Environmental Protection Agency.
Results and discussion	Applicant's version is acceptable with the addition of the following information. Sub-heading 4.1 The applicant states that permethrin does not react with olefinic/acetylenic compounds. This is a misunderstanding of how the software works. The software does not perform a calculation for the reaction of the test substance with olefinic/acetylenic compounds. It performs a calculation for the gas phase reaction between ozone and the test substance if the substance is an olefinic/acetylenic compound. If the test substance is not an olefinic/acetylenic compound, no ozone reaction estimation is performed. Sub-headings 4.2 and 5.2.2 The atmospheric half-life of 5.6 hours for the gas-phase reaction with hydroxyl radicals is based on a hydroxyl radical concentration of 1.5 x 10^6 radicals/cm^3 and a 12-hour day (5.6 hours = 0.47 days). The atmospheric half-life of 49.27 days for the gas-phase reaction with ozone is based on an ozone concentration of 7 x 10^{11} molecules/cm^3 and a 24-hour day. The RMS evaluator has calculated an alternative atmospheric half-life for the gas-phase reaction of permethrin with hydroxyl radicals using the Technical Guidance Document assumptions of a 24-hour day and a hydroxyl radical concentration of 5 x 10^5 radicals/cm^3. This resulted in a value of 0.701 days (16.83 hours).
Conclusion	Applicant's version is acceptable with the addition of the following information. The atmospheric half-life of 5.6 hours for the gas-phase reaction with hydroxyl radicals is based on a hydroxyl radical concentration of 1.5 x 10^6 radicals/cm^3 and a 12-hour day (5.6 hours = 0.47 days). Using Technical Guidance Document assumptions of a 24-hour day and a hydroxyl radical concentration of 5 x 10^5 radicals/cm^3, an alternative value of 0.701 days (16.83 hours) is obtained.
Reliability	1
Acceptability	Acceptable
Remarks	Sub-heading 1.2 The applicant states that the results are data protected but the study is only a calculation using publicly available software.
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section IIIA 7.3 Annex Point IIIA VII.5	**Fate and behaviour in air** **IIIA 7.3.1 Phototransformation in air (Atkinson calculation)**

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

Section IIIA 7.3 — Fate and behaviour in air, further studies

Annex Point IIIA VII.5

IIIA 7.3.2 Distribution in the environment

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	~~41~~1 REFERENCE
~~41.1~~1.1 Reference	McManus, K. (2006b), Environmental distribution of Permethrin (Mackay Level I fugacity model), Rivendell Consulting Limited, Rivendell House, Stamullen, Co. Meath, unpublished report no.: RI/2006/03/30. Date of experimental work: March 30, 2006
~~41.2~~1.2 Data protection	Yes
~~41.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.
~~41.2.2~~1.2.2 Companies with letter of access	Not applicable
~~41.2.3~~1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.
	~~42~~2 GUIDELINES AND QUALITY ASSURANCE
~~42.1~~2.1 Guideline study	Not applicable
~~42.2~~2.2 GLP	Not applicable
~~42.3~~2.3 Deviations	Not applicable
	~~43~~3 MATERIALS AND METHODS
~~43.1~~3.1 Test material	Not applicable
~~43.2~~3.2 Testing procedure	
~~43.2.1~~3.2.1 Test system	The Mackay Level I fugacity model was used to simulate the equilibrium distribution of a fixed quantity of conserved (i.e. non-reacting) Permethrin in a closed environment at equilibrium. No degrading reactions, advective processes or intermedia transport processes (e.g. wet deposition or sedimentation) were considered. Three types of chemicals are considered in this model – Type 1:

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Section IIIA 7.3 — Fate and behaviour in air, further studies

Annex Point IIIA VII.5

IIIA 7.3.2 Distribution in the environment

chemicals that partition into all media, Type 2: involatile chemicals and Type 3: chemicals with zero or near-zero solubility. Permethrin was assessed under Type 2 (involatile chemical).

Physical-chemical properties and partition coefficient data were input values used by the model to derive environmental properties such as volume, density and organic matter. These parameters were then used to quantify Permethrin behaviour in an evaluative environment. Please refer to Table A7.3.2-1 and A7.3.2-2 for input parameters and environmental properties generated by the model.

Distribution was simulated for the following homogenous environmental media (or compartments): air, water, soil, sediment, suspended sediment, fish and aerosols.

~~44~~4 RESULTS

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~~44.1~~4.1 Aquivalence — 1.03×10^{-5} mol/m^3

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Please note: The term aquivalence rather than fugacity is used with reference to Permethrin as, due to its involatility, water concentration is used as the equilibrium criterion rather than air-water partition coefficients as for fugacity measurements.

~~44.2~~4.2 Distribution

Permethrin was predicted to partition predominantly to soil (98.5%) and to a much lesser extent to sediment (0.9%) and to water (0.4%). Insignificant amounts are anticipated to be distributed to the air (0.2%) and to the suspended sediment (0.003%).

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~~45~~5 APPLICANT'S SUMMARY AND CONCLUSION

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~~45.1~~5.1 Materials and Methods

The Mackay Level I fugacity model was used to simulate the equilibrium distribution of Permethrin in a closed environment at equilibrium. The physical-chemical properties, partition coefficient data and user-defined volumes and densities were used to quantify the behaviour of Permethrin for the following homogenous environmental compartments: air, water, soil, sediment, suspended sediment, fish and aerosols.

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~~45.2~~5.2 Results and discussion

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5.2.1 Aquivalence — 1.03×10^{-5} mol/m^3

5.2.2 Distribution

Permethrin was predicted to partition predominantly to soil (98.5%) and to a much lesser extent to sediment (0.9%) and to water (0.4%). Insignificant amounts are anticipated to be distributed to the air (0.2%) and to the suspended sediment (0.003%).

Section IIIA 7.3 Fate and behaviour in air, further studies

Annex Point IIIA VII.5

IIIA 7.3.2 Distribution in the environment

Please refer to Table A7.3.2-3 and Figure A7.3.2-1.

~~45.3~~5.3 **Conclusion** Permethrin has an aquivalence value of 1.03 x 10^{-5} mol/m^3 and is found to partition predominantly to soil.

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~~45.3.1~~5.3.1 Reliability 1

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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	02 July 2009
Materials and Methods	Applicant's version is acceptable but the following points should be noted. Sub-headings 3.2.1 and 5.1 The model version used was 2.1. Sub-headings 3.2.1 and 5.1 (Table A7.3.2-1) The report does not give details of how the partition coefficients used as inputs were obtained.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.
Reliability	2
Acceptability	Acceptable The study is acceptable but of limited relevance for this data point. Section IIIA 7.3.2 refers to further studies on degradation behaviour in air if the active substance is to be used in preparations for fumigants or causes risk to the atmospheric environment. Such studies are not required for permethrin.
Remarks	The reliability rating was lowered because neither the study report nor the detailed summary explain how the partition coefficients used as inputs were obtained. Level I fugacity modelling does not deal with degradation and as such is not really relevant to this data point. It gives a general impression of the environmental media into which a fixed quantity of a substance will tend to partition, assuming equilibrium distribution and closed conditions (showing in this case 0.2% of permethrin in the air compartment, based on the partition coefficients used as inputs). Sub-heading 1.2 The applicant states that the results are data protected but the study is only a calculation using publicly available software.

Section IIIA 7.3 Fate and behaviour in air, further studies
Annex Point IIIA VII.5

IIIA 7.3.2 Distribution in the environment

	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 A7.3.2-1: Physical and partition coefficient input data for Level I Fugacity Model

Input Parameter	**Value**
Molecular mass (g/mol)	391.3
Data temperature (°C)	25
Air-water partition coefficient	9.05×10^{-4}
Soil-water partition coefficient	5448
Soil-water partition coefficient (l/kg)	2270
Sediment-water partition coefficient	4488
Sediment-water partition coefficient (l/kg)	1870
Suspended sediment-water partition coefficient	1403
Suspended sediment-water partition coefficient (l/kg)	935
Aerosol-water partition coefficient	0
Aerosol-air partition coefficient	0
Amount of chemical (kg)	200

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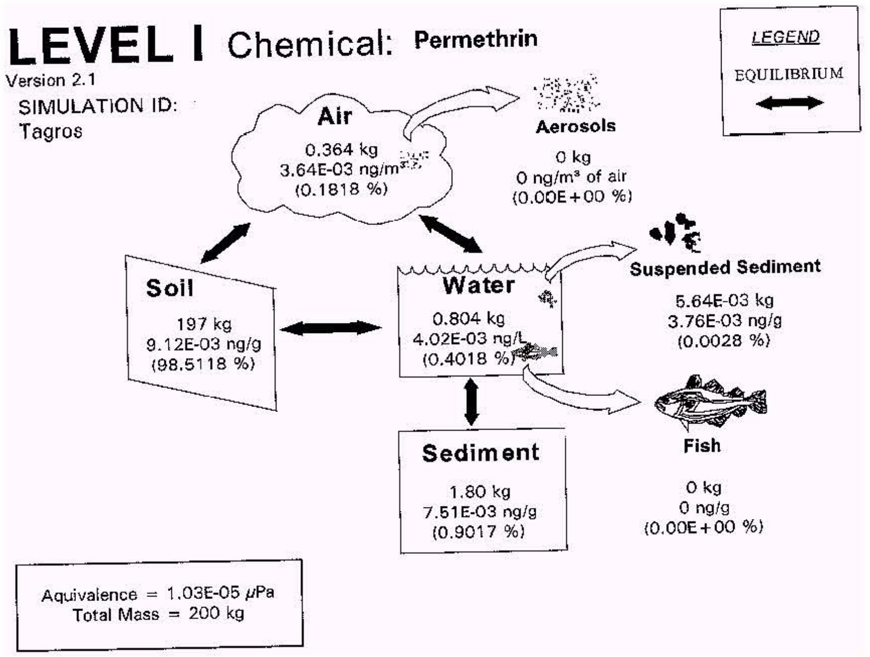
Table A7.3.2-2: Environmental properties for Permethrin as generated by the Level I Fugacity model

Environmental properties	**Air**	**Water**	**Soil**	**Sediment**	**Suspended sediment**	**Fish**	**Aerosol**
Volume, V (m^3)	1.00×10^{14}	2.00×10^{11}	9.00×10^{9}	1.00×10^{8}	1.00×10^{6}	2.00×10^{5}	2000
Density (kg/m^3)	1.185	1000	2400	2400	1500	1000	2000
Organic carbon (g/g)	-	-	0.02	0.04	0.2	-	-

Table A7.3.2-3: Phase properties and composition of Permethrin in the relevant environmmental compartments

Model output	Air	Water	Soil	Sediment	Suspended sediment	Fish	Aerosol
Z (dimessionless)	9.05×10^{-4}	1.00	5.45×10^{3}	4.49×10^{3}	1.40×10^{3}	0.00	0.00
VZ (m^3)	9.05×10^{10}	2.00×10^{11}	4.90×10^{13}	4.49×10^{11}	1.40×10^{9}	0.00	0.00
Concentration (mol/m^3)	9.29×10^{-15}	1.03×10^{-11}	5.59×10^{-8}	4.61×10^{-8}	1.44×10^{-8}	0.00	0.00
Amount (%)	0.1818	0.4018	98.5118	0.9017	0.0028	0.00	0.00

Figure A7.3.2-1: Distribution of Permethrin in the environment as predicted by the Mackay Level 1 Fugacity Model



Section A7.4.1.1/1 Acute toxicity to fish

Annex Point IIA7.1

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~~46~~1 REFERENCE

~~46.1~~1.1 **Reference**	[redacted] (2004), Acute Toxicity Study of Permethrin technical in Freshwater Fish, *Poecilia reticulata*, [redacted] unpublished report no.: 13870 Dates of experimental work: March 11, 2004 – March 15, 2004
~~46.2~~1.2 **Data protection**	Yes
~~46.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.
~~46.2.2~~1.2.2 Companies with letters of access	Not applicable
~~46.2.3~~1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.

~~47~~2 GUIDELINES AND QUALITY ASSURANCE

~~47.1~~2.1 **Guideline study**	Yes OECD test guideline 203: "Fish, Acute Toxicity Test".
~~47.2~~2.2 **GLP**	Yes
~~47.3~~2.3 **Deviations**	Yes, this study deviates from OECD Guideline 203 in the following respects: 1. The concentration of the test material was not measured, before or during the course of the experiment. 2. The OECD guideline recommends a temperature range of 21 – 25°C for *Poecilia reticulata*. The temperature used in this experiment ranged from 27 - 28°C. However, these deviations are not considered to compromise the scientific validity of the study.

~~48~~3 MATERIALS AND METHODS

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Section A7.4.1.1/1 Acute toxicity to fish

Annex Point IIA7.1

~~48.1~~3.1 Test material	As given in section 2 (Permethrin 25:75)	**Formatted:** Bullets and Numbering
~~48.1.1~~3.1.1 Lot/Batch number	P-203	**Formatted:** Bullets and Numbering
~~48.1.2~~3.1.2 Specification	As given in section 2 (Permethrin 25:75)	**Formatted:** Bullets and Numbering
~~48.1.3~~3.1.3 Purity	94.10%	**Formatted:** Bullets and Numbering
~~48.1.4~~3.1.4 Composition of Product	Not applicable	**Formatted:** Bullets and Numbering
~~48.1.5~~3.1.5 Further relevant properties	None	**Formatted:** Bullets and Numbering
~~48.1.6~~3.1.6 Method of analysis	Not applicable	**Formatted:** Bullets and Numbering
~~48.2~~3.2 Preparation of TS solution for poorly soluble or volatile test substances	Details are given in Table A7.4.1.1/1-1.	**Formatted:** Bullets and Numbering
~~48.3~~3.3 Reference substance	No	**Formatted:** Bullets and Numbering
~~48.4~~3.4 Testing procedure		**Formatted:** Bullets and Numbering
~~48.4.1~~3.4.1 Dilution water	Details are given in Table A7.4.1.1/1-2.	**Formatted:** Bullets and Numbering
~~48.4.2~~3.4.2 Test organisms	*Poecilia reticulata,* details are given in Table A7.4.1.1/1-3.	**Formatted:** Bullets and Numbering
~~48.4.3~~3.4.3 Test system	Details are given in Table A7.4.1.1/1-4.	**Formatted:** Bullets and Numbering
~~48.4.4~~3.4.4 Test conditions	Details are given in Table A7.4.1.1/1-5.	**Formatted:** Bullets and Numbering
~~48.4.5~~3.4.5 Duration of the test	96 hours	**Formatted:** Bullets and Numbering
~~48.4.6~~3.4.6 Test parameter	Mortality and abnormal behavioural responses.	**Formatted:** Bullets and Numbering
~~48.4.7~~3.4.7 Sampling	Twice at test initiation and once at each subsequent 24-hour interval until test termination.	**Formatted:** Bullets and Numbering
~~48.4.8~~3.4.8 Monitoring of TS concentration	No Test solutions were renewed daily	**Formatted:** Bullets and Numbering

Section A7.4.1.1/1 Acute toxicity to fish

Annex Point IIA7.1

~~48.4.9~~3.4.9 Statistics	From the mortality data an estimate of the acute median lethal concentration (LC_{50}) of Permethrin at 96 hr exposure period, was calculated by using Finney's probit analysis method (Finney, 1971)	**Formatted:** Bullets and Numbering
	~~49~~4 **RESULTS**	**Formatted:** Bullets and Numbering
~~49.1~~4.1 Limit test	Not performed	**Formatted:** Bullets and Numbering
~~49.1.1~~4.1.1 Concentration	Not applicable	**Formatted:** Bullets and Numbering
~~49.1.2~~4.1.2 Number/ percentage of animals showing adverse effects	Not applicable	**Formatted:** Bullets and Numbering
~~49.1.3~~4.1.3 Nature of adverse effects	Not applicable	**Formatted:** Bullets and Numbering
~~49.2~~4.2 Results test substance		**Formatted:** Bullets and Numbering
~~49.2.1~~4.2.1 Initial concentrations of test substance	2.2, 4, 7.1, 12.8, 23.1 µg/L	**Formatted:** Bullets and Numbering
~~49.2.2~~4.2.2 Actual concentrations of test substance	Not documented, however a sample from the exposure media was checked for stability and found to be within the permissible limits.	**Formatted:** Bullets and Numbering
~~49.2.3~~4.2.3 Effect data (Mortality)	Please refer to Tables A7.4.1.1/1-6 and A7.4.1.1/1-7.	**Formatted:** Bullets and Numbering
~~49.2.4~~4.2.4 Concentration / response curve	Not documented	**Formatted:** Bullets and Numbering
~~49.2.5~~4.2.5 Other effects	Loss of equilibrium and surfacing movements.	**Formatted:** Bullets and Numbering
4.3 Results of controls		
4.3.1 Number/ percentage of animals showing adverse effects	Please refer to Table A7.4.1.1/1-6.	
4.3.2 Nature of adverse effects	No adverse effects were observed.	
4.4 Test with reference substance	Not performed	

Section A7.4.1.1/1 Acute toxicity to fish

Annex Point IIA7.1

4.4.1	Concentrations	Not applicable
4.4.2	Results	Not applicable

~~50~~5 APPLICANT'S SUMMARY AND CONCLUSION

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~~50.1~~5.1	**Materials and methods**	The test system used was a semi-static and *Poecilia reticulata* was chosen as the test organism. The test was conducted according to OECD test guideline 203: "Fish, Acute Toxicity Test" and is described under point 3.	**Formatted:** Bullets and Numbering
~~50.2~~5.2	**Results and discussion**	No signs were exhibited in fish exposed to 2.2, 4 and 7.1 µg/l throughout the exposure period. Fish exposed to 12.8 µg/l demonstrated loss of equilibrium at the end of 48, 72 and 96 h. Fish exposed to 23.1 µg/l exhibited loss of equilibrium and surfacing movements at the end of 24 h and only loss of equilibrium was observed at the end of 48 h. No mortality was observed in the control group and the 2.2µg/l treatment group, and only one mortality was observed in the 4µg/l concentration at the end of 96h. Fish exposed to 7.1µg/l of Permethrin showed 2/10 and 1/10 mortalities at the end of 48 and 96 h, respectively and those exposed to the 12.8µg/l concentration showed similar results. Fish exposed to 23.1µg/l displayed one instance of a 60% mortality rate, with only 20% at different time intervals. Please refer to Tables A7.4.1.1/1-6 and A7.4.1.1/1-7. The acute median lethal toxicity (LC_{50}) of Permethrin for freshwater fish, *Poecilia reticulata* at 96 h exposure period is 8.9µg/l with fiducial limits of 7.59 and 10.32 µg/l water.	**Formatted:** Bullets and Numbering
~~50.2.1~~5.2.1	LC_0	Not documented	**Formatted:** Bullets and Numbering
~~50.2.2~~5.2.2	LC_{50}	8.9µg/l	**Formatted:** Bullets and Numbering
~~50.2.3~~5.2.3	LC_{100}	Not documented	**Formatted:** Bullets and Numbering
~~50.3~~5.3	**Conclusion**	In accordance with Council Directive 67/548/EEC, Permethrin is very toxic to freshwater fish *Poecilia reticulata* and should be assigned the symbol N and the R phrase R50.	**Formatted:** Bullets and Numbering
~~50.3.1~~5.3.1	Reliability	2	**Formatted:** Bullets and Numbering
~~50.3.2~~5.3.2	Deficiencies	Three deviations were noted and are outlined under point 2.3. However, they are not considered to compromise the scientific validity of this study.	**Formatted:** Bullets and Numbering

Section A7.4.1.1/1 Acute toxicity to fish

Annex Point IIA7.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	1 April 2009
Materials and Methods	The concentration of the test material was not measured, before or during the course of the experiment. The OECD guideline recommends a temperature range of 21 – 25°C for Poecilia reticulata. The temperature used in this experiment ranged from 27 - 28°C.
Results and discussion	Adopt ~~Applicants~~ applicant's version
Conclusion	Adopt applicant's version
Reliability	~~2~~3
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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

Criteria	**Details**
Dispersion	Not documented
Vehicle	Acetone
Concentration of vehicle	Not documented
Vehicle control performed	Yes
Other procedures	No

Table A7.4.1.1/1-2: Dilution water

Criteria	**Details**
Source	Drinking well-water
Alkalinity	Not documented
Hardness	242 to 244 mg/l (total hardness as $CaCO_3$)
pH	7.31 - 7.40
Oxygen content	7.8 - 8.2 mg/l
Conductance	Not documented
Holding water different from dilution	No

Table A7.4.1.1/1-3: Test organisms

Criteria	**Details**
Species/strain	Guppy (*Poecilia reticulata)*
Source	Commercial fish farm
Wild caught	No; Farmed
Age/size	2 ± 1cm
Kind of food	Commercially available fish food
Amount of food	Not documented
Feeding frequency	Daily
Pretreatment	Loading not in excess of 1g fish/ 1 water. Acclimation period = 7 days. Fish were fed up to 24 hrs prior to the experiment
Feeding of animals during test	No

Table A7.4.1.1/1-4: Test system

Criteria	**Details**
Test type	Semi-static
Renewal of test solution	Daily
Volume of test vessels	10 L aquaria
Loading	Not in excess of 1g fish/ l water
Volume/animal	1 l / fish
Number of animals/vessel	10 fish per vessel
Number of vessels/ concentration	1 vessel/concentration
Test performed in closed vessels due to significant volatility of TS	Not documented

Table A7.4.1.1/1-5: Test conditions

Criteria	**Details**
Test temperature	Ranged between 27 – 28°C
Dissolved oxygen	Ranged between 7.8 – 8.2 mg/l
pH	Ranged between 7.31 – 7.40
Adjustment of pH	Not documented
Aeration of dilution water	Not documented
Intensity of irradiation	Not documented
Photoperiod	Not documented

Table A7.4.1.1/1-6: Mortality data

Test-Substance Concentration (nominal/measured)^1 [µg/l]	~~50.3.2.1.1.1.1.1~~5.3.2.1.1.1.1.1 **Mortality**							
	Number				**Percentage (cumulative)**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
0	0	0	0	0	0	0	0	0
2.2	0	0	0	0	0	0	0	0
4	0	0	0	1	0	0	0	10
7.1	0	2	0	1	0	2	20	30
12.8	0	3	2	2	0	30	50	70
23.1	6	2	2	0	60	80	100	100

N = 10

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Table A7.4.1.1/1-7: Relationship between per cent mortality and concentration of Permethrin

Exposure time (h)	~~50.3.2.1.1.1.1.2~~5.3.2.1.1.1.1.2 Regression equation $Y = a + b\chi$	LC50 value (µg/l)	Fiducial Limits to LC50 (µg/l)
24	-	<23.1	-
48	$Y = 1.9371 + 2.6189\chi$	14.8	11.55 – 17.99
72	$Y = 1.4456 + 3.4098\chi$	11.0	9.29 – 12.76
96	$Y = 1.7454 + 3.4178\chi$	8.9	7.59 – 10.32

Y = Probit value of mortality, χ = log concentration of Permethrin technical in µg/l,

a = intercept, b = slope, h = hour.

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Table A7.4.1.1/1-8: Validity criteria for acute fish test according to OECD Guideline 203

	Fulfilled
Mortality of control animals <10%	**Yes**
Concentration of dissolved oxygen in all test vessels > 60% saturation	**Yes**
Concentration of test substance ≥80% of initial concentration during test	**No***

* Concentration of test material not measured during the course of the experiment