Section A7.2.1/03 Annex Point IIIA-XII.1.1 Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

Table A7.2.1-3: Characterisation of the extractable radioactivity in soil LUFA 2.1 (mean values)

Sampling interval [days]	% of the applied radioactivity [% AR]	
	Permethrin	M1
0	97.0	n.d.
2	82.9	1.8
7	68.3	2.8
11	47.4	2.1
15	37.4	1.4
21	24.7	1.3
30	15.5	< 1
58	6.6	< 1
93	4.5	< 1

n.d. not detected

Table A7.2.1-4: Characterisation of the extractable radioactivity in soil LUFA 2.3 (mean values)

Sampling interval [days]	% of the applied radioactivity [% AR]	
	Permethrin	M1
0	102.0	n.d.
2	84.2	4.5
7	53.4	10.8
11	35.3	9.2
15	20.9	7.0
21	12.8	3.6
30	8.1	2.5
58	4.6	< 1
93	3.0	< 1

n.d. not detected

Section A7.2.1/03 Annex Point IIIA-XII.1.1 — Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

Table A7.2.1-5: Characterisation of the extractable radioactivity in soil LUFA 2.4 (mean values)

Sampling interval [days]	% of the applied radioactivity [% AR]	
	Permethrin	M1
0	101.1	n.d.
2	78.6	4.8
7	46.0	13.6
11	29.4	12.4
15	18.7	8.8
21	11.9	4.7
30	7.9	2.2
58	3.3	< 1
93	2.7	< 1

n.d. not detected

Table A7.2.1-6: DT_{50} and DT_{90} values (1st order) of [Phenyl-U-^{14}C]Permethrin and metabolite M1

Soil	LUFA 2.1	LUFA 2.3	LUFA 2.4
[Phenyl-U-^{14}C]Permethrin			
DT_{50} [days]	11 (11 – 12)	7 (6 – 8)	6 (6 – 7)
DT_{90} [days]	38 (34 – 41)	24 (22 – 26)	21 (20 – 23)
R^2	0.989	0.993	0.994
Metabolite M1			
DT_{50} [days]	n.d.	11 (9 – 13)	10 (8 – 12)
DT_{90} [days]	n.d.	35 (29 – 45)	32 (27 – 41)
R^2	n.d.	0.965	0.969

n.d. not detected

numbers in parentheses are the 95% confidence limits

Section A7.2.1/04 Annex Point IIIA-XII.1.1 — Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

		Official use only
	11 REFERENCE	
11.1 Reference	Stangelj, A. (2011): Calculations of environmental fate endpoints in soil for Permethrin and metabolites according to recommendations of the FOCUS working group on degradation kinetics. GAB Consulting GmbH, Lamstedt, Germany unpublished report number: 158250-A3-07020201-01	
11.2 Data protection	Yes	
11.2.1 Data owner	Tagros Chemicals India Ltd	
11.2.2 Companies with letter of access	Not applicable.	
11.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA of Directive 98/8/EC.	
	12 GUIDELINES AND QUALITY ASSURANCE	
12.1 Guideline study	Modelling and persistence endpoints for Permethrin and its main metabolites in soil investigated in different studies were re-calculated according to the FOCUS kinetics guidance (FOCUS, 2006)[3].	
12.2 GLP	No	
12.3 Deviations	None	
	13 MATERIALS AND METHODS	
13.1 Test material	Not relevant, the study is a model calculation.	
13.1.1 Lot/Batch number	Not relevant, the study is a model calculation.	
13.1.2 Specification	Not relevant, the study is a model calculation.	
13.1.3 Purity	Not relevant, the study is a model calculation.	
13.1.4 Further relevant properties	Not relevant, the study is a model calculation.	
13.1.5 Composition of Product	Not relevant, the study is a model calculation.	
13.1.6 TS inhibitory to microorganisms	Not relevant, the study is a model calculation.	
13.1.7 Specific chemical analysis	Not relevant, the study is a model calculation.	

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

Section A7.2.1/04 Annex Point IIIA-XII.1.1 — Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

13.2 Reference substance	Not relevant, the study is a model calculation.
13.2.1 Initial concentration of reference substance	Not relevant, the study is a model calculation.
13.3 Testing procedure	
13.3.1 Water/Sediment	Not relevant, the study is a model calculation.
13.3.2 Test system	Not relevant, the study is a model calculation.
13.3.3 Test conditions	Not relevant, the study is a model calculation.
13.3.4 Method of preparation of test solution	Not relevant, the study is a model calculation.
13.3.5 Application of test item	Not relevant, the study is a model calculation.
13.3.6 Duration of test	Not relevant, the study is a model calculation.
13.3.7 Sampling	Not relevant, the study is a model calculation.
13.3.8 Intermediates/ degradation products	Not relevant, the study is a model calculation.
13.3.9 Analytical methods	Not relevant, the study is a model calculation.
13.3.10 Statistics	The DT$_{50}$ values of Permethrin (Phenyl-U-^{14}C or Vinyl-2-^{14}C-labelled, respectively) and metabolites (if necessary) were determined for six soils originating from two soil laboratory degradation studies by Hellstern (2011a (study no. S10-00379), 2011b (study no. S10-00380)) and for two soils originating from a soil laboratory metabolism study by Traub (2011, study no. S10-00378). The data was evaluated according to the FOCUS Kinetics Guidance. Residue data (% of applied radioactivity) of Permethrin and unidentified metabolites M1 and M3, where applicable, were evaluated according to the stepwise approach as recommended by the FOCUS kinetics group in order to derive degradation rates for parent and metabolites. For these calculations the model software KinGUI version 1.1[4] was used. Modelling was done using all data (except for soil Lufa 2.2, sandy loam ([Vinyl-2-^{14}C]Permethrin): elimination of one outlier), no weighting and M0 (total amount at time 0) were not fixed for the parent. M0 of the metabolites were fixed to 0.

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[4] KinGUI vers. 1.1: User Interface for Kinetic Evaluations, Bayer CropScience (2006)

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Section A7.2.1/04 Annex Point IIIA-XII.1.1 — Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

As recommended by the FOCUS kinetics group both single first order (SFO) and biphasic kinetics (FOMC = first order multi compartment) are considered for the parent and SFO was preferred for metabolites.

In a first step the degradation rate of the parent substance was estimated with a two compartment model (parent and sink). Flows from parent to metabolites as well as from parent or metabolite, resp., to sink were considered for the simultaneous fittings. Furthermore for metabolite M3 occurring in significant amounts in one soil, formation from parent as well as from metabolite M1 was considered. The respective metabolism scheme used is shown in **Figure A7.2.1-1.**

X

14 RESULTS

14.1 Recovery	Not relevant, the study is a model calculation.	
14.2 Degradation of test substance		
14.2.1 Test item	Not relevant, the study is a model calculation.	
14.2.2 Metabolites	Not relevant, the study is a model calculation.	
14.2.3 Degradation rate	The obtained results indicate that SFO was the model that clearly fits best for soils Lufa 2.1, 2.3 and 2.4. In all cases the kinetic evaluation using SFO resulted in better curve fittings and lower Chi² values. For FOMC the probabilities of the t-test indicated that the parameters α and β are not significantly different from zero. FOMC did also not provide better Chi² (χ^2) values for these soils than the SFO model for these three soils. In one case (Lufa 2.4, phenyl-labelled Permethrin) FOMC showed a better fitting than the SFO model but the differences between these two models were not significant. For soil Lufa 2.2 (for both labelling positions) the FOMC resulted in better curve fittings and lower Chi2 values.	
	For several soil/substance combinations the simultaneous fittings led to acceptable results fulfilling all validation criteria. All resulting curve fittings and residual plots are visually acceptable.	X
	The results obtained for all soils indicate that the modelling (persistence) half-lives for Permethrin and M1 are in the range of 6.4 – 12.0 (5.7 – 11.3) days and 3.7 – 16.3 (3.7 – 16.3) days, respectively. For M3 the respective half-lives are 44.9 (44.9)	

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Section A7.2.1/04
Annex Point IIIA-XII.1.1

Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

days.

A summary of results is given in **Table A7.2.1-1** and **Table A7.2.1-2**.

15 APPLICANT'S SUMMARY AND CONCLUSION

15.1 Materials and methods	Modelling and persistence endpoints for Permethrin and main metabolites in soil were re-calculated according to the FOCUS kinetics guidance (FOCUS, 2006).
15.2 Results and discussion	The results obtained for all soils indicate that the modelling (persistence) half-lives for Permethrin and M1 are in the range of 6.4 – 12.0 (5.7 – 11.3) days and 3.7 – 16.3 (3.7 – 16.3) days, respectively. For M3 the respective half-lives are 44.9 (44.9) days.
15.3 Conclusion	Modelling and persistence endpoints for Permethrin and the main metabolites in soil were satisfactorily re-calculated according to the FOCUS kinetics guidance (FOCUS, 2006). The study is well conducted and reported and can be considered valid.
15.3.1 Reliability	1
15.3.2 Deficiencies	none

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	27-10-11
Materials and Methods	Applicant's version is acceptable
Results and discussion	Adopt applicant's version with the addition of the following comments:

Sub-heading 3.3.10

The applicant states that two soils were analysed in the two Hellstern studies and two more in the Traub study. This is incorrect. Three soils were analysed in the Hellstern studies and one in the Traub study.

A total of six metabolites were detected in the four soils analysed in these studied but none were identified. The expected permethrin degradation products (Cypermethric acid, 3-phenoxybenzoic acid and 3-

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Section A7.2.1/04 Annex Point IIIA-XII.1.1 — Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

phenoxybenzyl alcohol) were not detected. Therefore this study can only be used in the determination of the rate of degradation of permethrin and not its route of degradation.

Sub-heading 4.2.3

For the studies involving soils Lufa 2.1 and 2.2, there is a problem with the microbial viability after day 30. Please refer to sections 7.2.1 (01-03) for further details. Therefore the evaluator has repeated the kinetic analysis using only the data for the first 30 days for these two soils. The calculated DT50 values are given in the table at the end of this section.

The applicant presented the DT50 value for metabolite M3 forming in soil Lufa 2.1 from vinyl-labelled permethrin. As the figures up to day 30 do not show a discernible degradation trend in levels of M3 the evaluator does not believe that a reliable DT50 value can be determined and so the presented figure is not included in the table at the end of this section.

Sub-heading 5.2

DT50 values for Permethrin and its metabolites are presented from the three cited studies. However the labwork in these studies was carried out at 20°C. The EC Technical Guidance Document (section 2.3.6.1) requires DT50 values to be reported at 12°C. The following formula is provided to convert values from 20 °C to 12 °C:

$$DT_{50}(12\ ^{\circ}C) = DT_{50}(20) \cdot e^{(0.08\,(20-12))}$$

This allows for the figures in Tables A7.2.1-1 and A7.2.1-2 to be re-evaluated at the correct temperature. The table below shows the figures to be used as endpoints for all the soils studied:

Soil	**Kinetic model**	**degDT$_{50}$ @ 20°C**	**degDT$_{50}$ @ 12°C**	**degDT$_{90}$ @ 20°C**
[Phenyl-U-^{14}C]Permethrin				
Lufa 2.1				
Permethrin	SFO	11.2	21.2	37.1
Lufa 2.2				
Permethrin	FOMC	10.4	19.7	55.0
Lufa 2.3				
Permethrin	SFO	7.1	13.5	23.7
M1	SFO	3.7	7.0	12.3

Section A7.2.1/04
Annex Point IIIA-XII.1.1

Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

Lufa 2.4				
Permethrin	FOMC	5.8	11.0	24.4
M1	SFO	5.1	9.7	16.8
[Vinyl-2-^{14}C]Permethrin				
Lufa 2.1				
Permethrin	SFO	10.2	19.3	33.8
M1	SFO	11.2	21.2	37.3
M3	SFO	10.4	19.7	34.7
Lufa 2.2				
Permethrin	FOMC	9.6	18.2	46.8
M1	SFO	7.8	14.8	26.0
Lufa 2.3				
Permethrin	SFO	6.6	12.5	21.8
M1	SFO	16.3	30.9	54.2
Lufa 2.4				
Permethrin	SFO	6.7	12.7	22.4
M1	SFO	19.2	36.4	63.8

Conclusion Adopt applicant’s version subject to the corrections made above

Reliability 2

Acceptability Acceptable but this study only provides information on the rate of degradation and not the route.

Remarks In the case of soils Lufa 2.1 and Lufa 2.2 only the data from the first 30 days is considered reliable due to concerns about the microbial viability of the soil thereafter.

COMMENTS FROM ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Section A7.2.1/04 Annex Point IIIA-XII.1.1 Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

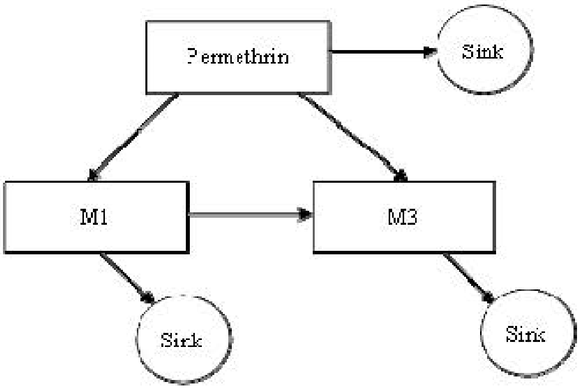

Figure A7.2.1-1. Metabolism scheme of Permethrin ([Vinyl-2-^{14}C]Permethrin) and metabolites M1 and M3 resulting in best fitting

Section A7.2.1/04 Aerobic degradation in soil (rate and route of degradation, including identification of metabolites and degradation products)

Annex Point IIIA-XII.1.1

Table A7.2.1-1: Results of the kinetic evaluation for the active substance Permethrin (parent to sink)

Soil	Kinetic model	degDT$_{50}$ [d]	degDT$_{90}$ [d]	Plots visually acceptable	Chi^2 (trigger: 15)[a]	t-test (trigger: 0.05)[b]	EF [c]
[Phenyl-U-^{14}C]Permethrin							
LUFA 2.1	SFO[e,f]	11.3	37.6	yes	5.5	< 0.05	0.9892
	FOMC	11.1	39.4	yes	5.6	> 0.05 (α,β)	0.9897
LUFA 2.2	SFO[e]	12.0	40.0	yes	9.9	< 0.05	0.9725
	FOMC[f]	10.2	60.1	yes	6.1	< 0.05 (α,β)	0.9894
LUFA 2.3	SFO[e,f]	7.1	23.7	yes	5.0	< 0.05	0.9929
	FOMC	7.0	24.2	yes	5.2	> 0.05 (α,β)	0.9930
LUFA 2.4	SFO[e]	6.4	21.2	yes	5.2	< 0.05	0.9938
	FOMC[f]	5.7	24.2	yes	3.5	< 0.05 (α,β)	0.9964
[Vinyl-2-^{14}C]Permethrin							
LUFA 2.1	SFO[e,f]	10.3	34.1	yes	6.5	< 0.05	0.9830
	FOMC	9.8	38.4	yes	6.5	> 0.05 (α,β)	0.9835
LUFA 2.2 [d]	SFO[e]	10.9	36.1	yes	10.5	< 0.05	0.9668
	FOMC[f]	9.3	62.0	yes	5.8	< 0.05 (α,β)	0.9897
LUFA 2.3	SFO[e,f]	6.6	21.8	yes	7.3	< 0.05	0.9894
	FOMC	6.1	24.4	yes	6.8	$\alpha = < 0.05$, $\beta = > 0.05$	0.9913
LUFA 2.4	SFO[e,f]	6.7	22.4	yes	5.1	< 0.05	0.9936
	FOMC	6.6	23.2	yes	5.4	> 0.05 (α,β)	0.9936

a Error value at which the Chi²-test is passed should be below 15%. The Chi²-test considers the deviations between observed and calculated values relative to the uncertainty of the measurements.

b A model parameter (e.g. k, α, β) is considered significantly different from zero if the probability corresponding to the calculated t-value is smaller than 0.05, i.e. considering a 5 percent significance level.

c corresponding to model efficiency ("EF", see FOCUS kinetics guidance, EC Document Reference Sanco/10058/2005 version 2.0)

d outlier not considered

e proposed modelling endpoints

f proposed persistence endpoints (used as triggers for additional work)

SFO Single First Order model

FOMC First Order Multi Compartment model (shape parameter: α, location parameter: β)

Table A7.2.1-2 Results of the kinetic evaluation for Permethrin, M1 and M3 simultaneously fitted (after final optimization with unfixed parameters)

Substance	**Kinetic model**	**degDT$_{50}$ [d]**	**degDT$_{90}$ [d]**	**Formation fraction ^{a}**	**Plots visually acceptable**	**Chi² ^{b}**	**t-test ^{c}**	**EF ^{d}**
[Phenyl-U-^{14}C]Permethrin								
Lufa 2.3								
Permethrin^{f,g}	SFO	**7.1**	**23.7**	n.a.	yes	5.0	< 0.05	0.9946
M1^{f,g}	SFO	**3.7**	**12.3**	0.376	yes	13.2	< 0.05	
Lufa 2.4								
Permethrin^{f}	SFO	**6.4**	**21.2**	n.a.	yes	5.2	< 0.05	0.9948
M1^{f}	SFO	**4.2**	**14.1**	0.421	yes	15.9	< 0.05	
Permethrin^{g}	FOMC	**5.8**	**24.0**	n.a.	yes	3.5	α: < 0.05 β: < 0.05	0.9965
M1^{g}	SFO	**5.1**	**16.8**	0.36	yes	17.8	< 0.05	
[Vinyl-2-^{14}C]Permethrin								
Lufa 2.1								
Permethrin^{f,g}	SFO	**10.3**	**34.1**	n.a.	yes	6.5	< 0.05	0.9868
M1^{f,g}	SFO	**12.6**	**41.9**	0.473	yes	11.8	< 0.05	
M3^{f,g}	SFO	**44.9**	**149.1**	from parent: 0.031 from M1: 0.279	yes	21.2	0.05	
Lufa 2.2^{e}								
Permethrin^{f}	SFO	**10.9**	**36.1**	n.a.	yes	10.5	< 0.05	0.9792
M1^{f}	SFO	**5.9**	**19.5**	0.379	yes	14.7	< 0.05	
Permethrin^{g}	FOMC	**9.3**	**62.0**	n.a.	yes	5.8	α: < 0.05 β: < 0.05	0.9928
M1^{g}	SFO	**9.4**	**31.1**	0.27	yes	14.7	< 0.05	
Lufa 2.3								
Permethrin^{f,g}	SFO	**6.6**	**22.0**	n.a.	yes	7.3	< 0.05	0.9858
M1^{f,g}	SFO	**16.3**	**54.2**	0.596	yes	13.3	< 0.05	
Lufa 2.4								
Permethrin^{f,g}	SFO	**6.7**	**22.3**	n.a.	yes	5.1	< 0.05	0.9914
M1^{f,g}	SFO	**5.2**	**17.2**	0.60	yes	22.3	< 0.05	

n.a. not applicable

a Formation fraction from parent unless otherwise stated

b Error value at which the Chi²-test is passed should be below 15%. The Chi²-test considers the deviations between observed and calculated values relative to the uncertainty of the measurements.

c A model parameter (e.g. k, α, β) is considered significantly different from zero if the probability corresponding to the calculated t-value is smaller than 0.05, i.e. considering a 5 percent significance level.

d corresponding to model efficiency ("EF", see FOCUS kinetics guidance, EC Document Reference Sanco/10058/2005 version 2.0)

e outlier not considered

f	proposed modelling endpoints
g	proposed persistence endpoints (used as triggers for additional work)
SFO	Single First Order model
FOMC	First Order Multi Compartment model

~~**Section IIIA 7.2.1**~~ ~~**Annex Point VII.4, XII.1.1**~~	~~**Aerobic Degradation in Soil - Initial Study**~~	
	~~**JUSTIFICATION FOR NON SUBMISSION OF DATA**~~	~~Official use only~~
~~**Other existing data []**~~	~~**Technically not feasible [ ]**~~ ~~**Scientifically unjustified [X]**~~	
~~**Limited exposure [X]**~~	~~**Other justification [ ]**~~	
~~**Detailed justification:**~~	~~According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), soil simulation tests are required if the biocide is directly emitted to soil or the solids water equilibrium partition coefficient (K_p) of the substance being investigated is > 5000.~~ ~~The use pattern of the product is localised, low volume and does not involve direct application to soil. The K_p of Permethrin, derived from the equation $K_p = F_{oc} x K_{oc}$, was calculated to be 198.6 and is thus below the threshold value set in the guidance. It is therefore proposed that a study is not required to address this point.~~	
~~**Undertaking of intended data submission [ ]**~~		

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~~**Section IIIA 7.2.1**~~ ~~**Annex Point VII.4, XII.1.1**~~	~~**Aerobic Degradation in Soil - Initial 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**~~	~~03 June 2009~~
~~**Evaluation of applicant's justification**~~	~~Applicant's justification is not acceptable. According to the Technical Notes for Guidance on data requirements, a soil simulation test is required if a biocide is directly applied/emitted to soil. The uses assessed for the representative product involve releases to soil. For example, soil is the primary receiving environmental compartment for emissions from treated wood in service coming under Use Class 3 (fence, noise barrier, house).~~ ~~The Technical Notes for Guidance on data requirements also state that tests on fate and behaviour in soil shall be required if the active substance has an overall low or absent abiotic degradation. The information presented by the applicant on hydrolysis (*IIIA 7.1.1.1.1*) and aqueous photolysis (*IIIA 7.1.1.1.2*) indicates that these abiotic processes would not be a significant cause of degradation under environmentally relevant conditions.~~ ~~Information on degradation behaviour in soil would identify if there are metabolites formed in soil that need to be considered and would also be useful to refine exposure assessments for the soil compartment. In addition, such information would provide input data for a groundwater exposure assessment and would facilitate assessment against PBT/vPvB and POPs screening criteria.~~
~~**Conclusion**~~	~~Applicant's justification is not acceptable.~~ ~~However, the applicant is not required to provide information on this data point for the purpose of the EU review programme, since information on the fate and behaviour of permethrin in soil is available in a dossier supplied by another applicant for this active substance/Product Type combination.~~
~~**Remarks**~~	~~This interpretation is based on the guidance given in the note on evaluation of multiple dossiers that was presented at the 33rd Competent Authorities meeting in May 2009 (CA-May09-Doc.8.3).~~
	~~COMMENTS FROM OTHER MEMBER STATE~~ ~~*(specify)*~~
~~**Date**~~	~~*Give date of comments submitted*~~
~~**Evaluation of applicant's justification**~~	~~*Discuss if deviating from view of rapporteur member state*~~
~~**Conclusion**~~	~~*Discuss if deviating from view of rapporteur member state*~~
~~**Remarks**~~	

Section IIIA 7.2.2 **Annex Point VII.4, XII.1.1. XII.1.4**	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.1 Route and Rate of Degradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), soil simulation tests are required if the biocide is directly emitted to soil or the solids water equilibrium partition coefficient (K_p) of the substance being investigated is > 5000. The use pattern of the product is localised, low volume and does not involve direct application to soil. The K_p of Permethrin, derived from the equation $K_p = F_{oc} \times K_{oc}$, was calculated to be 198.6 and is thus below the threshold value set in the guidance. It is therefore proposed that a study is not required to address this point.	

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Section IIIA 7.2.2 **Annex Point VII.4, XII.1.1. XII.1.4**	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.1 Route and Rate of Degradation**
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	10 June 2009
Evaluation of applicant's justification	Applicant's justification is not acceptable. The applicant did not provide any information on degradation of permethrin in soil, even though the uses assessed involve direct releases to soil and the initial risk assessment showed a significant risk for the soil compartment. The Technical Notes for Guidance on data requirements indicate that further studies on the aerobic rate and route of degradation in soil are warranted if the DT_{50lab} determined in an initial study on aerobic degradation in soil (for point *IIIA 7.2.1*) exceeds 21 days and PEC/PNEC > 1 for soil or there is danger for groundwater or other refinement of the preliminary risk assessment for soil is necessary. Given that the applicant did not submit an initial study on aerobic degradation in soil, the need for further studies is difficult to assess. The RMS evaluator considers that information on aerobic degradation in a range of soil types would be useful to refine exposure assessments for the soil compartment and to identify if there are metabolites formed in soil that need to be considered.
Conclusion	Applicant's justification is not acceptable. However, the applicant is not required to provide information on this data point for the purpose of the EU review programme, since sufficient information on the aerobic rate and route of degradation of permethrin in a number of soil types, and on the fate and behaviour of metabolites formed in soil, is available in a dossier supplied by another applicant for this active substance/Product Type combination.
Remarks	This interpretation is based on the guidance given in the note on evaluation of multiple dossiers that was presented at the 33rd Competent Authorities meeting in May 2009 (CA-May09-Doc.8.3).
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section IIIA 7.2.2 **Annex Point XII.1.1, Annex VI**	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.2 Field Soil Dissipation and Accumulation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), soil simulation tests are required if the biocide is directly emitted to soil or the solids water equilibrium partition coefficient (K_p) of the substance being investigated is > 5000. The use pattern of the product is localised, low volume and does not involve direct application to soil. The K_p of Permethrin, derived from the equation $K_p = F_{oc} \times K_{oc}$, was calculated to be 198.6 and is thus below the threshold value set in the guidance. It is therefore proposed that a study is not required to address this point.	

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Section IIIA 7.2.2 **Annex Point XII.1.1, Annex VI**	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.2 Field Soil Dissipation and Accumulation**
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	11 June 2009
Evaluation of applicant's justification	Applicant's justification is not acceptable. The applicant did not provide any information on degradation of permethrin in soil, even though the uses assessed involve direct releases to soil and the initial risk assessment showed a significant risk for the soil compartment. Given that the applicant did not submit an initial study on aerobic degradation in soil (for point *IIIA 7.2.1*) nor further studies on the aerobic rate and route of degradation in a number of soils (for point *IIIA 7.2.2.1*), the need for field soil dissipation and accumulation studies cannot be assessed on the basis of the dossier submitted by this applicant.
Conclusion	Applicant's justification is not acceptable. However, an acceptable justification for non-submission of data for this point was provided in a dossier supplied by another applicant for this active substance/Product Type combination. Field soil dissipation and accumulation studies are not required since the dossier referred to contains sufficient laboratory aerobic soil degradation data to characterise the degradation behaviour in soil of permethrin and metabolites formed.
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 7.2.2 Annex Point XII.1.4	**Aerobic Degradation in Soil - Further Studies** **IIIA7.2.2.3 Extent and Nature of Bound Residues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), soil simulation tests are required if the biocide is directly emitted to soil or the solids water equilibrium partition coefficient (K_p) of the substance being investigated is > 5000. The use pattern of the product is localised, low volume and does not involve direct application to soil. The K_p of Permethrin, derived from the equation $K_p = F_{oc} \times K_{oc}$, was calculated to be 198.6 and is thus below the threshold value set in the guidance. It is therefore proposed that a study is not required to address this point.	

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Section IIIA 7.2.2 Annex Point XII.1.4	**Aerobic Degradation in Soil - Further Studies** **IIIA7.2.2.3 Extent and Nature of Bound Residues**
Undertaking of intended data submission [ ]	

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Evaluation by Competent Authorities

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

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12 June 2009
Evaluation of applicant's justification	Applicant's justification is not acceptable. The applicant did not provide any information on degradation of permethrin in soil, even though the uses assessed involve direct releases to soil and the initial risk assessment showed a significant risk for the soil compartment. Given that the applicant did not submit an initial study on aerobic degradation in soil (for point *IIIA 7.2.1*) nor further studies on the aerobic rate and route of degradation in a number of soils (for point *IIIA 7.2.2.1*), the need for data on the extent and nature of bound residues cannot be assessed on the basis of the dossier submitted by this applicant.
Conclusion	Applicant's justification is not acceptable. However, the applicant is not required to provide information on this data point for the purpose of the EU review programme, since data on the extent and nature of bound residues formation in soil treated with permethrin are available in a dossier supplied by another applicant for this active substance/Product Type combination.
Remarks	This interpretation is based on the guidance given in the note on evaluation of multiple dossiers that was presented at the 33rd Competent Authorities meeting in May 2009 (CA-May09-Doc.8.3).
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section IIIA 7.2.2 Annex Point XII.1.1	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.4 Other Soil Degradation Studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), soil simulation tests are required if the biocide is directly emitted to soil or the solids water equilibrium partition coefficient (K_p) of the substance being investigated is > 5000. The use pattern of the product is localised, low volume and does not involve direct application to soil. The K_p of Permethrin, derived from the equation $K_p = F_{oc} \times K_{oc}$, was calculated to be 198.6 and is thus below the threshold value set in the guidance. It is therefore proposed that a study is not required to address this point.	

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Section IIIA 7.2.2 Annex Point XII.1.1	**Aerobic Degradation in Soil - Further Studies** **IIIA 7.2.2.4 Other Soil Degradation Studies**
Undertaking of intended data submission [ ]	
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	12 June 2009
Evaluation of applicant's justification	Applicant's justification is not acceptable. The applicant did not provide any information on degradation of permethrin in soil, even though the uses assessed involve direct releases to soil and the initial risk assessment showed a significant risk for the soil compartment. The need for further studies to identify rates of degradation in different release conditions and main routes of degradation in soil in detail (such as soil photolysis or anaerobic soil degradation studies) cannot be assessed on the basis of the dossier submitted by this applicant.
Conclusion	Applicant's justification is not acceptable. However, the applicant is not required to provide information on this data point for the purpose of the EU review programme. A study on photolysis of permethrin on a soil surface is available in a dossier provided by another applicant for this active substance/Product Type combination. The RMS evaluator considers that a study on anaerobic soil degradation is not required for the EU review, since prolonged exposure to anaerobic soil conditions would not be widely expected for the uses assessed.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Annex Point IIIA–XII.1.2

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	16 REFERENCE
16.1 Reference	Traub, M. (2011), "Determination of the Adsorption/Desorption Behaviour of Permethrin in five Soils"
	Eurofins Agroscience Services GmbH, Niefern-Öschelbronn, Germany
	Unpublished report No. S10-00377 (27 May 2011)
16.2 Data protection	Yes
16.2.1 Data owner	Tagros Chemicals India Ltd.
16.2.2 Companies with letter of access	Not applicable.
16.2.3 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.
	17 GUIDELINES AND QUALITY ASSURANCE
17.1 Guideline study	OECD 106 'Adsorption/Desorption'(2000)
17.2 GLP	Yes
17.3 Deviations	None
	18 MATERIALS AND METHODS
18.1 Test material	[Phenyl-U-14C]Permethrin (CFQ40816)
	Permethrin technical
18.1.1 Lot/Batch number	Batch number: labelled substance – not given,
	Unlabelled substance – P-283
18.1.2 Specification	Permethrin radiolabelled at Phenyl-U-carbon position
	Specific activity: 2.07 GBq/mmol, 56 mCi/mmol
18.1.3 Purity	Labelled substance: Radiochemical purity: 99.9%
	Unlabelled substance: 93.34%
18.1.4 Further relevant properties	Trans/Cis Isomer of radiolabeled substance: 73.1/26.9
18.1.5 Method of analysis	The quantity of radioactivity in solutions was determined by liquid scintillation counting (LSC). From every sample an aliquot was diluted and mixed with scintillation cocktail.
18.2 Degradation products	None
18.2.1 Method of analysis for degradation products	Not relevant
18.3 Reference substance	None

Section A7.2.3.1/01 Adsorption / Desorption in at least three soil types

Annex Point IIIA–XII.1.2

18.3.1 Method of analysis for reference substance: Not relevant

18.4 Soil types

A set of 5 soils were used: X

I : LUFA 2.1, loamy sand

II : LUFA 2.2, loamy sand

III : LUFA 2.3, sandy loam

IV: LUFA 2.4, loam

V: LUFA 6S, clay 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.

18.5 Testing procedure

18.5.1 Test system and conditions

The test was conducted in three tiers, Tier 1/Tier 2 preliminary study and 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 $CaCl_2$ (nearly 100% of the final volume) overnight before application.

All experiments including controls (without soil) and blanks (without test item) were performed with the parallel method in duplicate.

18.5.2 Test solution

A stock solution of the test item (0.5 µCi/mL) was prepared in acetonitrile (Tier 1 adsorption) or acetonitrile:water (1:1, v/v) (Tier 3 and desorption) and the respective application solutions were prepared in acetonitrile:water (1:1, v/v). The application solutions had a concentration 500 (Tier 3 and desorption) to 1000 (Tier 1 adsorption) times higher than the respective tested solution.

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

18.6 Test performance

18.6.1 Tier 1 Preliminary test and Tier 2 Adsorption and desorption kinetics at one concentration of the test substance

Tier 1 was conducted in order to determine the soil-to-solution ratio, the equilibration time for adsorption, the adsorption of the test item on the surfaces of the test vessels and the stability of the test item during the test period and the complete Tier 2 was part of Tier 1. Furthermore, the percentage adsorption was calculated at each time point and the distribution coefficients K_d and K_{OC} were also calculated.

Five soils LUFA 2.1, 2.2, 2.3, 2.4 and 6S and three soil/solution ratios were used: 10 g (ratio 1/5), 2 g (ratio 1/25) and 1 g soil (ratio 1/50) in 50 cm^3 aqueous solution of the test substance. The concentration of the application solution was 3.54 mg/L (Tier 1) and the sampling times were 0.5, 2, 4, 24 and 48 hours after applications. Two control samples (without soil) were examined in order to check the stability of the test

Section A7.2.3.1/01 Adsorption / Desorption in at least three soil types

Annex Point IIIA–XII.1.2

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 1/5 soil/solution ratio and 0.01 M $CaCl_2$ solution were used to detect any interfering compounds or contaminated soils.

At Tier 1, the mass adsorbed from the soil samplings apart from the final sampling was determined by the indirect method. Each sample contained 0.162 µg Permethrin which is equivalent to initial amount of 3.24 µg/L.

The mass balance was carried out at all soil/solution ratios of the Tier 1&2 experiments and aqueous phase was separated by centrifugation and recovered as completely as possible. The test item was extracted and the amount and the mass balance was calculated.

Desorption was performed with soils LUFA 2.1, 2.2, 2.3, 2.4 and 6S and a soil/solution ratio of 1/50. The mass adsorbed from the soil at all samplings apart from the final sampling was determined by the parallel and indirect method. The samples contained 0.150 µg (soil LUFA 2.1), 0.156 µg (soil LUFA 2.2), 0.151 µg (soil LUFA 2.3), 0.147 µg (soil LUFA 2.4) and 0.148 µg (soil LUFA 6S) test item at the end of the adsorption (24 hours). 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, 2 mL aliquot of the aqueous phase was analysed for the test item.

The sampling times were after 24 hours after application (Adsorption) 0and 2, 4, 6, 24 and 48 hours after replacing the 0.01 M $CaCl_2$ solution (Desorption).

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

18.6.2 Tier 3 Freundlich isotherms

The adsorption test was performed as described under 3.6.1, only that the aqueous phase was analysed only once after 24 hours of adsorption. Five test item concentrations and the soil/solution ratio (1/50) were used. 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 five soils used in the adsorption isotherms experiment and performed as desorption kinetics in 3.6.1. 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.

18.6.3 Analytics

The quantity of radioactivity in solutions was determined by liquid scintillation counting (LSC). Aliquot from every sample was diluted and mixed with scintillation cocktail. The efficiency of photochemical excitation and observation of the emitted photons by photo multiplier was corrected for external standard radiation in the LSC and analysed on their energy spectrum and quantified. The analytical limits were obtained from blank samples. Typical blanks contained 15 dpm/sample.

The thin layer chromatography (TLC) was used to characterize the

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extractable radioactivity. The radioactivity on the TLC plates was determined optically by a digital autoradiography.

The amount of radioactivity which could still be detected (LOD) was below 25 dpm and the lowest amount quantified by TLC (LOQ) was set to 50 dpm.

For details of quantification of radioactivity by liquid scintillation counting (LSC) and thin layer chromatography (TLC) and of characterisation of radioactivity by reversed and normal phase TLC, please see **Table A7.2.3.1-2**.

18.6.4 Other test

The solubility and stability of the test item in water and 0.1 M $CaCl_2$ was checked during the pretest and the mass adsorbed from the test vessel was determined by the indirect method. All samples were spiked with the respective amount of Permethrin and incubated on a flask shaker at 180 rpm.

19 RESULTS

19.1 Pretest

The results suggest that the initial amount of Permethrin was not stable in glass flasks with water or 0.01 M $CaCl_2$ solution. There was no difference between the glass and Teflon flasks. Due to these results the further experiments were done in glass flasks with the indirect parallel method, whereas the respective initial amount was analysed by application in control flasks containing 50 mL acetonitrile/water (80/20, v/v).

19.2 Tier 1 Preliminary test and Tier 2 Adsorption and desorption kinetics at one concentration of the test substance

Adsorption equilibrium was reached after 2 hours for all soil/solution ratios. The adsorption reached a max. value at a soil/solution ratio of 1/50 between 94.6 and 96.8% for all five soils. X

Desorption equilibrium was reached after 48 hours for soil LUFA 2.1 2.3, 2.4 and 6S and desorption of the test item reached a maximum value of 30.4, 24.5, 30.1 and 37.9%, respectively. For soil LUFA 2.2 desorption equilibrium was reached during the 24 hours and desorption of the test item reached a maximum value of 5.3%.

Due to the high adsorption of Permethrin on the surface of the glass flasks in the samples containing $CaCl_2$-solution without soil the adsorption and desorption was analysed. The adsorption was corrected by subtracting this adsorption from the adsorption of samples with the respective soil. The desorption from the surface of the glass flasks was between 26.4 and 31.0%.

The K_{OC} values ranged from 14,600.0 to 32,576.7 mL/g for soil/solution ratio 1/50 and the desorption K_{OC} values ranged from 2,827.4 to 51,843.3 mL/g and the corrected (for the adsorption of Permethrin on the surface of the glass flasks in the samples containing $CaCl_2$-solution) adsorption K_{OC} values ranged from 2,691.3 to 6,555.8 mL/g for soil/solution ratio 1/50.

19.3 Adsorption and desorption Freundlich isotherms

For adsorption, due to low water solubility of Permethrin and the LOQ of the analytical method (LSC) the concentration rang was 0.33 to 3.25 µg/L in 50 mL $CaCl_2$.

For desorption a desorption time of 48 hours and soil/solution ratio of 1/50 was chosen and the experimental procedure was identical to

Section A7.2.3.1/01 Adsorption / Desorption in at least three soil types

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Tier 1&2. The concentration range was 0.33 to 3.25 µg/L in 50 mL $CaCl_2$ for the adsorption. After changing the $CaCl_2$ solution the concentration range for desorption was 0.30 to 3.25 µg/L in 50 mL $CaCl_2$.

Adsorption behaviour of the test substance was described with the Freundlich equation. The correlation coefficients (r^2) for the individual isotherms are ≥ 0.9816. The constants K^{ads}_{Foc} ranged from 24,696 to 155,552 mL/g and the exponents 1/n were in range of 1.0028 to 1.1363, see **Table A7.2.3.1-3**. The corrected (for the adsorption of Permethrin on the surface of the glass flasks in the samples containing $CaCl_2$-solution) K^{ads}_{Foc} ranged from 13,165 to 139,092 mL/g. The respective results are presented in **Table A7.2.3.1-4**.

For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value between 20,242.8 and 197,504.2 mL/g, the results are presented in **Table A7.2.3.1-3**.

19.4 Calculations

19.4.1 Ka, Kd	Refer to 4.2, 4.3, and to **Tables A7.2.3.1-3** and **A7.2.3.1-4** for details.
19.4.2 Ka_{oc}, Kd_{oc}	Refer to 4.2, 4.3, and to **Tables A7.2.3.1-3** and **A7.2.3.1-4** for details.
19.5 Degradation product(s)	No degradation products were monitored.

Section A7.2.3.1/01 Adsorption / Desorption in at least three soil types

Annex Point IIIA–XII.1.2

20 APPLICANT'S SUMMARY AND CONCLUSION

20.1 Materials and methods

OECD 106 ‘Adsorption/Desorption’

The solubility and stability of the test item in water and 0.1 M $CaCl_2$ was checked during the pretest and the mass adsorbed from the test vessel was determined by the indirect method. All samples were spiked with the respective amount of Permethrin and incubated on a flask shaker at 180 rpm.

The test was conducted in three tiers, Tier/Tier 2 preliminary study and a Tier 3 test determining Freundlich isotherms. Tier 1 was conducted in order to determine the soil-to-solution ratio, the equilibration time for adsorption, the adsorption of the test item on the surfaces of the test vessels and the stability of the test item during the test period and the complete Tier 2 was part of Tier 1. Furthermore the percentage adsorption was calculated at each time point and the distribution coefficients K_d and K_{OC} were also calculated.

Five soils LUFA 2.1, 2.2, 2.3, 2.4 and 6S and three soil/solution ratios were used: 1/5, 1/25 and 1/50, respectively. The concentration of the application solution was 3.54 mg/L (Tier 1) and the sampling times were 0.5, 2, 4, 24 and 48 hours after applications. For adsorption and desorption kinetics, each test soil and solution was performed in duplicate and a blank consisting of the soil and the $CaCl_2$ solution was run with every experiment. The mass balance was performed after the end of the Tier 1 and 2 for all soil/solution ratios.

Desorption was performed with five test item concentrations and a soil/solution ratio of 1/50 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 2 mL aliquot of the aqueous phase was analysed for the test item.

The Freundlich adsorption/desorption isotherms test was performed as the adsorption/desorption kinetics test, only that the aqueous phase was analysed only once. Five test item concentrations and the soil/solution ratio (1/50) were used. The equilibrium concentrations in the solution were determined and the amount adsorbed/desorbed calculated. For adsorption the adsorbed mass per unit mass of soil was plotted as a function of the equilibrium concentration of the test item. For desorption 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.

20.2 Results and discussion

The results of the pretest suggest that the initial amount of Permethrin was not stable in glass flasks with water or 0.01 M $CaCl_2$ solution. X

At Tier 1, each sample contained 0.162 µg Permethrin which is equivalent to initial amount of 3.24 µg/L. Adsorption equilibrium was reached after 2 hours for all soil/solution ratios. The adsorption of the test item depended on the soil/solution ratio and reached the max. value at a soil/solution ratio of 1/50 between 94.6 and 96.8% for all five soils.

The Tier 2 testing was part of Tier 1.

Desorption was performed with soils LUFA 2.1, 2.2, 2.3, 2.4 and 6S and

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a soil/solution ratio of 1/50. The samples contained 0.150 µg (soil LUFA 2.1), 0.156 µg (soil LUFA 2.2), 0.151 µg (soil LUFA 2.3), 0.147 µg (soil LUFA 2.4) and 0.148 µg (soil LUFA 6S) test item at the end of the adsorption (24 hours).

Due to the high adsorption of Permethrin on the surface of the glass flasks in the samples containing $CaCl_2$-solution without soil the adsorption and desorption from these flasks was analysed. The adsorption was corrected by subtracting this adsorption from the adsorption of samples with the respective soil. The desorption form the surface of the glass flasks was between 26.4 and 31.0%.

The K_{OC} values ranged from 14,600.0 to 32,576.7 mL/g for soil/solution ratio 1/50 and the desorption K_{OC} values ranged from 2,827.4 to 51,843.3 mL/g and the corrected adsorption K_{OC} values ranged from 2,691.3 to 6,555.8 mL/g for soil/solution ratio 1/50.

The mass balance was performed after the end of the Tier 1 and 2 for all soil/solution ratios. For soils LUFA 2.1, 2.2, 2.3, 2.4 and 6S a 97.6%, 99.9%, 105.8%, 94.7% and 92.5%, respectively, were recovered for a soil solution ratio of 1/50.

Adsorption and desorption isotherms (Tier 3) were estimated at a soil/solution ratio of 1/50 and at five test item concentrations (0.33 to 3.25 µg/L).

Adsorption behaviour of the test substance was described with the Freundlich equation. The correlation coefficients (r^2) for the individual isotherms are ≥ 0.9816. The constants K^{ads}_{Foc} ranged from 24,696 to 155,552 mL/g and the exponents 1/n were in range of 1.0028 to 1.1363. And the corrected (for the adsorption of Permethrin on the surface of the glass flasks in the samples containing $CaCl_2$-solution) K^{ads}_{Foc} ranged from 13,165 to 139,092 mL/g. For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value between 20,242.8 and 197,504.2 mL/g.

20.3 Conclusion	Validity criteria can be considered as fulfilled for the determination of adsorption-desorption of Permethrin. The high K_{OC} values indicate that Permethrin is immobile in soil and the adsorption is considered to be non-reversible.
20.3.1 Reliability	1
20.3.2 Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	27-10-11
Materials and Methods	Applicant’s version is acceptable
Results and discussion	Adopt applicant’s version with the addition of the following comments:

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Sub-heading 3.4

The five soils used in the study are classified using the USDA soil classification system. However based on the clay and sand percentages given in Table A7.2.3.1-1, soils Lufa 2.1 and Lufa 6S have been classified incorrectly. They should be described as 'sand' and 'clay' respectively.

Sub-headings 4.2 and 5.2

For Tier 1 and 2 studies adsorption equilibrium was reached after 2 hours. However it should be noted that the K_{oc} values presented in the study are derived from adsorption percentages (A%) measured after 48 hours. On the other hand the adjusted K_{oc} values (which take into account adsorption by the glass vessel) were derived from A% figures measured after 24 hours. This, according to the study director, is because of the high adsorption of Permethrin to the glass flasks in the control samples at 48 hours.

Although not reported in the applicant's study summary the study also evaluates the K_{oc} for soil/solution ratios of 1/5 and 1/25. The figure reported for soil Lufa 6S in a 1/25 ratio (1093.1, see p40) is incorrect – it should read 10281.

K_d values evaluated in the Tier 1/2 study are merely quoted as a range in the study summary. The full list of K_d values have been added by the evaluator to the table below for completeness – for adsorption, desorption and corrected adsorption. It should be noted that the $K_{d(des)}$ values for soils 2.1, 2.3 and 6S were calculated incorrectly. The evaluator has repeated the calculations and the corrected values are included below.

The applicant demonstrates clearly that Permethrin adsorbs strongly to the glass walls of the vessels used in the study. Therefore two sets of results are presented:

- The first are evaluated by measuring the decrease in concentration permethrin in the liquid phase and using it to calculate how much h been adsorbed.
- The second involves measuring how much permethrin is adsorbed to the glass vessel in a solution with no soil present. This is then used as a baseline to subtract from the adsorbed concentration evaluated in the first method.

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Undoubtedly the first method yields K_d values which are higher than the true value for Permethrin as it fails to take account of adsorption to glass. On the other hand the results obtained using the second method underestimate the K_d as the presence of soil in the samples would decrease the adsorption to glass. Therefore this correction gives values which represent a good worst case scenario for permethrin.

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Annex Point IIIA–XII.1.2

	Soil:	LUFA 2.1	LUFA 2.2	LUFA 2.3	LUFA 2.4	LUFA 6S
Adsorption	$K_{d(ads)}^{*}$	125.6	560.3	242.6	217.6	249.7
	$1/n$	1.1363	1.0789	1.1099	1.0061	1.0028
	$\log K^{ads}_{F}$	3.304	3.383	3.2253	2.7086	2.765
	K^{ads}_{F}	2013.7	2415.5	1680	511.2	582.1
	r^2	0.9816	0.985	0.9956	0.9986	0.9984
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{ads}_{Foc}	234154	140434	155552	24696	33263
Desorption	$K_{d(des)}^{*}$	118.5	891.7	161.5	116.9	97.7
	$1/n$	1.1083	0.8749	1.0913	1.0362	1.059
	$\log K^{des}_{F}$	3.1962	2.5418	3.329	2.8175	2.987
	K^{des}_{F}	1571.1	348.2	2133	656.9	970.5
	r^2	0.8985	0.9701	0.996	0.9963	0.9992
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{des}_{Foc}	182684	20243	197504	31735	55458
Adsorption (corrected)	$K_{d(ads)}^{*}$	56.4	75.9	64.7	55.7	59.7
	$1/n$	1.156	1.0978	1.1284	1.0155	1.0139
	$\log K^{ads}_{F}$	3.0778	3.1772	2.9973	2.4354	2.5057
	K^{ads}_{F}	1196.2	1503.8	993.8	272.5	320.4
	r^2	0.9612	0.9926	0.9853	0.9914	0.9966
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{ads}_{Foc}	139092	87432	92019	13165	18309

* from Tier 1/2 studies.

Conclusion	Adopt applicant's version
Reliability	2
Acceptability	Acceptable
Remarks	The average (arithmetic mean) corrected K^{ads}_{Foc} is 70,003 ml/g. This is comparable to the arithmetic mean K^{ads}_{Foc} value of 76,900 ml/g reported in the Bayer-Sumitomo dossier for permethrin (unspecified cis/trans ratio).

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Annex Point IIIA–XII.1.2

	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.2.3.1/01 Adsorption / Desorption in at least three soil types

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

Soil description	LUFA 2.1	LUFA 2.2	LUFA 2.3	LUFA 2.4	6S
Batch No.	2.10209	2.23708	2.2.32508	2.44209	6S380
pH ($CaCl_2$)	5.67	5.74	6.96	7.04	7.23
Organic carbon [%]	0.86	1.72	1.08	2.07	1.75
Maximum water holding capacitiy [g/100g]]	32.2	42.6	35.8	43.7	40.8
Cation exchange capacity [mval/100 g]	3.4	9.4	12.1	24.9	25.5
Soil density [g/L]	1524	1271	1268	1310	1372
Soil type [a]	loamy sand	loamy sand	sandy loam	loam	clay loam
Particle size [%] [a]					
<0.002 mm	2.4	4.7	10.3	26.9	41.1
0.002-0.05 mm	8.0	11.1	33.8	39.0	37.2
0.05-2.00 mm	89.6	84.2	55.9	34.1	21.7

[a] USDA. classification system

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

LSC – Quantification of radioactivity	Instrument	1409, Wallac, Finland
	Cocktails	Scintillator Aquasafe Plus, Zinsser 1.008500
TLC – Quantification of radioactivity	Digital autoradiography to determine radioactivity on the TLC plates	Fuji Film Imaging plate (IP) – a complex matrix of BaFX:Eu^{2+} (X: halogen) crystals excited by ionizing radiation
	Optical reading	Fuji FLA 3000-2R Radioluminographic Scanner, Raytest, Germany
	Exposure time	Dependant on amount of radioactivity
	Quantification	Integration: $\text{Peak Area [\%]} = \frac{\text{Counts in Peak Area} \times 100}{\text{Sum of all Peak Areas}}$
Reversed phase TLC – Characterisation of radioactivity)	Stationary phase	Macherey-Nagel C_{18} F254 (length: 10 cm)
	Solvent system	Acetonitrile/water (60/40; v/v)
Normal phase TLC – Characterisation of radioactivity (Confirmatory method)	Stationary phase	Merck Silicagel 60 F254 (length: 10 cm)
	Solvent system	Acetonitrile/water (90/10; v/v)

Table A7.2.3.1-3: Freundlich adsorption and desorption coefficients of Permethrin

	Soil:	**LUFA 2.1**	**LUFA 2.2**	**LUFA 2.3**	**LUFA 2.4**	**LUFA 6S**
Adsorption	1/n	1.1363	1.0789	1.1099	1.0061	1.0028
	log K^{ads}_{F}	3.3040	3.3830	3.2253	2.7086	2.7650
	K^{ads}_{F}	2013.7	2415.5	1680.0	511.2	582.1
	r^2	0.9816	0.9850	0.9956	0.9986	0.9984
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{ads}_{Foc}	234,154	140,434	155,552	24,696	33,263
Desorption	1/n	1.1083	0.8749	1.0913	1.0362	1.0590
	log K^{ads}_{F}	3.1962	2.5418	3.3290	2.8175	2.9870
	K^{ads}_{F}	1571.1	348.2	2133.0	656.9	970.5
	r^2	0.8985	0.9701	0.9960	0.9963	0.9992
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{ads}_{Foc}	182,684.4	20,242.8	197,504.2	31,734.5	55,457.7

Table A7.2.3.1-4: Freundlich adsorption coefficients of Permethrin (corrected)

	Soil:	**LUFA 2.1**	**LUFA 2.2**	**LUFA 2.3**	**LUFA 2.4**	**LUFA 6S**
Adsorption	1/n	1.1560	1.0978	1.1284	1.0155	1.0139
	log K^{ads}_{F}	3.0778	3.1772	2.9973	2.4354	2.5057
	K^{ads}_{F}	1196.2	1503.8	993.8	272.5	320.4
	r^2	0.9612	0.9926	0.9853	0.9914	0.9966
	% OC	0.86	1.72	1.08	2.07	1.75
	K^{ads}_{Foc}	139,092	87,432	92,019	13,165	18,309

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Annex Point IIIA-XII.1.2

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		Offic use on
	21 REFERENCE	
21.1 Reference	Traub M. (2010), "Determination of the Adsorption/Desorption Behaviour of 3-Phenoxybenzoic Acid in three Soils", Eurofins Agroscience Services GmbH, Niefern-Öschelbronn, Germany Unpublished report No. S10-00381 (23 December 2010)	
21.2 Data protection	Yes	
21.2.1 Data owner	Tagros Chemicals India Ltd.	
21.2.2 Companies with letter of access	Not applicable.	
21.2.3 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.	
	22 GUIDELINES AND QUALITY ASSURANCE	
22.1 Guideline study	OECD 106 'Adsorption/Desorption'(2000)	
22.2 GLP	Yes	
22.3 Deviations	None	
	23 MATERIALS AND METHODS	
23.1 Test material	3-Phenoxybenzoic acid	X
23.1.1 Lot/Batch number	Batch No.: 6116X	
23.1.2 Specification	As given below	
23.1.3 Purity	99.90%	
23.1.4 Further relevant properties	Not radio-labelled	
23.2 Degradation products	None	
23.3 Reference substance	No	
23.4 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
23.5 Testing procedure		
23.5.1 Test system and	The test was conducted in three tiers, Tier 1 preliminary study, a Tier 2	

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

Annex Point IIIA-XII.1.2

	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.	
23.5.2	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.	
23.6	**Test performance**		
23.6.1	Tier 1 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 48.4 µg test item for soil LUFA 2.1 and 44.3 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.	
23.6.2	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. The concentration of the application solution was 50 mg/L 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. 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 $CaCl_2$.	X

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Annex Point IIIA-XII.1.2

These mixtures were agitated until desorption equilibrium was reached. 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.

23.6.3 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.

23.6.4 Analytics

A HPLC-MS/MS 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 ≤ 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.

23.6.5 Other test

None

24 RESULTS

24.1 Tier 1 Preliminary test and Tier 2 Adsorption and desorption kinetics

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 43.3% for soil LUFA 2.1 and 85.8% for soil LUFA 2.4, respectively.

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	at one concentration of the test substance	The Tier 2 testing was only performed with the soil LUFA 2.2 at a soil/solution ration of 1/1, based on the results of Tier 1. The experimental procedure was identical to Tier 1. Each sample contained 37.8 µg test item. Adsorption equilibrium was reached after 48 hours and was 76.6%. Desorption was performed with soils LUFA 2.1, 2.2 and 2.4 and a soil/solution ratio of 1/1. The samples contained 24.5 µg (soil LUFA 2.1), 35.3 µg (soil LUFA 2.2) and 42.9 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 18.5% and 19.8% 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 K_{OC} values ranged from 83.7 to 291.8 mL/g for soil/solution ratio 1/1 and the desorption K_{OC} values were 808.7 and 258.14 mL/g for soils LUFA 2.1 and 2.2, respectively.	
24.2	**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 0.92 mg/L) in 50 mL $CaCl_2$. The experimental procedure was identical to Tier 1&2. 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 0.68 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 ≥ 0.9700. The constants K^{ads}_{Foc} ranged from 127.1 to 191.7 mL/g and the exponents 1/n were in range of 0.6426 to 0.9467. For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value was 161.9 and 83.1 mL/g for soil LUFA 2.1 and 2.2, respectively. Results are presented in **Table A7.2.3.1-3**.	X
24.3	**Calculations**		
24.3.1	Ka, Kd	Refer to 4.1 and 4.2 and to **Table A7.2.3.1-3** for details.	
24.3.2	Ka_{oc}, Kd_{oc}	Refer to 4.1 and 4.2 and to **Table A7.2.3.1-3** for details.	
24.4	**Degradation product(s)**	No degradation products were monitored.	

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Annex Point IIIA-XII.1.2

25 APPLICANT'S SUMMARY AND CONCLUSION

25.1 Materials and methods

OECD 106 'Adsorption/Desorption' X

The test was conducted to determine the adsorption-desorption behaviour of 3-Phenoxybenzoic acid in three different soils (LUFA 2.1, 2.2 and 2.4). The test was conducted in three tiers, Tier 1 preliminary study, a Tier 2 screening test and a Tier 3 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 48.4 µg test item for soil LUFA 2.1 and 44.3 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.

25.2 Results and discussion

At Tier 1, each sample contained 37.8 µg test item. 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 43.3% for soil LUFA 2.1 and 85.8% for soil LUFA 2.4, respectively. X

The Tier 2 testing was only performed with the soil LUFA 2.2 at a soil/solution ration 1/1. Each sample contained 37.8 µg test item. Adsorption equilibrium was reached after 48 hours and was 76.6%.

Desorption was performed with soils LUFA 2.1, 2.2 and 2.4 and a soil/solution ratio of 1/1. The samples contained 24.5 µg (soil LUFA 2.1), 35.3 µg (soil LUFA 2.2) and 42.9 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 18.5% and 19.8% 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 K$_{OC}$ values ranged from 83.7 to 291.8 mL/g for soil/solution ratio 1/1 and the desorption K$_{OC}$ values were 808.7 and 258.14 mL/g for soils LUFA 2.1 and 2.2, respectively.

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

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soil/solution ratio of 1/1 and at five test item concentrations from 0.01 to 0.92 mg/L (adsorption) and 0.01 to 0.68 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 ≥ 0.9700. The constants K^{ads}_{Foc} ranged from 127.1 to 191.7 mL/g and the exponents 1/n were in range of 0.6426 to 0.9467.

For the desorption step, Freundlich isotherms were calculated. K^{des}_{Foc} value was 161.9 and 83.1 mL/g for soil LUFA 2.1 and 2.2, respectively.

25.3 Conclusion

Validity criteria can be considered as fulfilled for the determination of adsorption-desorption of 3-Phenoxybenzoic acid.

The K_{OC} values indicate that 3-Phenoxybenzoic is moderately mobile in soil and the adsorption is considered to be non-reversible.

25.3.1 Reliability	1
25.3.2 Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	27-10-11
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 Cypermetric acid is shown instead of 3-Phenoxybenzoic acid. This is an error but does not affect the results presented.

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 A7.2.3.1-1, soil Lufa 2.1 has been classified incorrectly. It should be described as 'sand'.

Sub-headings 3.6.2 and 5.1

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