Competent Authority Report

Programme for Inclusion of Active Substances in Annex I to Council Directive 98/8/EC

Permethrin (PT 8)

CAS-No. 52645-53-1

DOCUMENT IIIA (A7)

Evaluation Report

Tagros Chemicals India Ltd.

Rapporteur: Ireland

~~August 2009~~March 2011

Permethrin PT8

Document IIIA (A7)

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Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/1 Hydrolysis as a function of pH

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		1 REFERENCE
1.1	**Reference**	White, D.F., Mullee, D.M. (2003), Permethrin: Determination of Abiotic Degradation, Hydrolysis as a Function of pH and Adsorption Coefficient. Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K, unpublished report No.: 1667/004. Dates of experimental work: July 11, 2002 – October 02, 2002.
1.2	**Data protection**	Yes
1.2.1	Data owner	Copyr s.p.a
1.2.2	Companies with letter of access	Not applicable
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of its entry into Annex I/IA.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, test method was based on OECD guideline 111.
2.2	**GLP**	Yes
2.3	**Deviations**	Yes, with the following deviation: 1. The purity of the test substance was 94% rather than the recommended 95% This deviation is not considered to compromise the scientific validity of this study.
		3 MATERIALS AND METHODS
3.1	**Test material**	Please refer to section 2
3.1.1	Lot/Batch number	P-127
3.1.2	Specification	Please refer to section 2 (Permethrin 25:75)
3.1.3	Description	Pale yellow liquid
3.1.4	Purity	Not documented

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3.1.5	Vehicle/solvent	Buffer solutions at pH 4, 7 and 9 0.2 % methanol was used as a co-solvent
3.2	**Reference substance**	None
3.2.1	Initial concentration of reference substance	Not applicable
3.3	**Test solution**	Please refer to Tables A7.1.1.1.1/1 and A7.1.1.1.1/1-2.
3.4	**Testing procedure**	
3.4.1	Test system	Please refer to Table A7.1.1.1.1-3.
3.4.2	Temperature	pH 4, 7 and 9: 50.0 ± 0.5°C pH 9 : 60.0 ± 0.5°C and 70.0 ± 0.5°C
3.4.3	pH	pH 4, 7 and 9
3.4.4	Duration of the test	5 days
3.4.5	Number of replicates	Two
3.4.6	Analytical methods	An aliquot (500ml) of each sample was extracted with three portions (3 x 25 ml) of n-hexane, each extract being filtered through anhydrous sodium sulphate. The combined extracts were evaporated to dryness and the residue re-dissolved in n-hexane (1.0 ml). Duplicate standard solutions of the test material were prepared in n-hexane at a nominal concentration of 2.5 mg/l. Permethrin was identified and quantitatively determined using GC. The linearity of the detector response in respect to concentration was assessed over the nominal concentration range of 0 to 10 mg/l. This was satisfactory with a correlation coefficient of 1000 being obtained. Recovery of analysis of the sample procedure was assessed and proved adequate for the test. The standard and sample solutions were analysed by GC using the following conditions: GC System: Agilent Technologies 5890, incorporating autosampler and workstation Column: DB 5 (30 m x 0.25 mm id x 0.25 µm film) Oven temperature program: initial 175°C rate 15°C/min final 300°C for 5 mins Injection temperature: 275°C Electron capture detector temperature: 325°C Injection volume: 1 µl Retention time: ~ 8.5 mins
3.5	**Preliminary test**	Sample solutions at pH 4, 7 and 9 were maintained at 50.0 ± 0.5°C for a period of 5 days.

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Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/1 Hydrolysis as a function of pH

Preliminary testing indicated that further testing at pH 9 was required. pH 9 solutions were thus maintained at 60.0 ± 0.5°C and 70.0 ± 0.5°C.

4 RESULTS

4.1 Mean peak area and concentration of the test compound

Please refer to Tables A7.1.1.1.1/-4 to A7.1.1.1.1/1-8.

4.2 Hydrolysis rate constant (k_h)

Please refer to Table A7.1.1.1.1/1-9.

4.3 Dissipation time

Permethrin was found to be hydrolytically stable at pH 4 with less than 10 % hydrolysis after 5 days at 50°C and a half-life greater than 1 year at 25°C. Further testing at pH 1.2 at 37°C was therfore not required.

Permethrin was found to be hydrolytically stable at pH 7 with Approximately 10 % hydrolysis after 5 days at 50°C and a half-life approximately greater than 1 year at 25°C.

pH 9: The extent of hydrolysis after 120 hours indicated that a further test, conducted at 60°C and 70°C, was required to estimate the rate constant and half-life.

4.4 Concentration-time data

Please refer to Tables A7.1.1.1.1/1-4 to A7.1.1.1.1/1-8.

4.5 Specification of the transformation products

Based on the chemical structure of Permethrin, the following reaction scheme was predicted:

The test material was predicted to degrade into 3-(2,2-dichloroethenyl)-2,2-dimethyl cyclopropanecarboxylic acid and 3-phenoxybenzylalcohol. Further oxidative degradation of 3-phenoxybenzylalcohol could then occur.

3-phenoxybenzylalcohol was predicted to degrade into 3-phenoxybenzoic acid via the intermediate 3-phenoxybenzaldehyde.

Identification of the hydrolysis products was preformed using research papers provided by the Royal Society of Chemistry.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Sample solutions of Permethrin were prepared in stoppered glass flasks at a nominal concentration of 2.5 x 10^{-6} g/l in a pH 4, 7 and 9 buffer solutions. pH 4 and 7 bufferd samples were stored at 50°C while pH 9 samples were stored at 50°C 60°C and 70°C. Samples were then extracted and analysed by GC at various intervals over 5 days.

This study was conducted according OECD method 111 and is described under point 3 with the following deviation:

1. The purity of the test substance was 94% rather than the recommended 95%

This deviation is not considered to compromise the scientific validity of this study.

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5.2	**Results and discussion**	Permethrin was found to be hydrolytically stable at pH 4 with less than 10 % hydrolysis after 5 days at 50°C and a half-life greater than 1 year at 25°C. Further testing at pH 1.2 at 37°C was therfore not required. Permethrin was found to be hydrolytically stable at pH 7 with Approximately 10 % hydrolysis after 5 days at 50°C and a half-life approximately greater than 1 year at 25°C. pH 9: The extent of hydrolysis after 120 hours indicated that a further test, conducted at 60°C and 70°C, was required to estimate the rate constant and half-life. Straight line graphs of $\log_{10}$ concentration verses time are consistent with first order kinetics. Please be aware: Some variation was observed between samples results due to the sample concentrations approaching the limits of accurate analytical quantitation, differences in the recovery rates and adsorption to the surfaces of the glassware. However, the method was sufficiently sensitive and accurate enough to estimate the rate constant and half-life through the use of the Arrhenius relationship.
5.2.1	K_H	Rate constant (s^{-1}) at pH 9: 2.72×10^{-7}
5.2.2	DT_{50}	pH 4: > 1 year pH 7: approximately > 1 year pH 9: 29.5 days
5.2.3	R^2	Not documented
5.3	**Conclusion**	Permethrin is hydrolytically stable at pH 4 and 7, with estimated half-lives of > 1 year. At pH 9, Permethrin is found to undergo hydrolyisis with a half-live of 29.5 days.
5.3.1	Reliability	1
5.3.2	Deficiencies	One deficiency was noted and is outlined under points 2.3 and 5.1. However, it does not compromise the scientific validity of this 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	21 May 2009
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...

Section IIIA 7.1.1.1 Abiotic

Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/1 Hydrolysis as a function of pH

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

Table A7.1.1.1.1/1-1: Type and composition of buffer solutions

pH	Composition
4	Potassium hydrogen phthalate (2.50 x 10^{-3} mol dm^{-3})
7	Disodium hydrogen orthophosphate (anhydrous) (1.5 x 10-3 mol dm-3)
9	Disodium tetraborate (5.0 x 10-4 mol dm-3) Sodium chloride (1.0 x 10-3 mol dm-3)

Table A7.1.1.1.1/1-2: Description of test solution

Criteria	Details
Purity of water	HPLC-grade water
Preparation of test solution	The buffer solutions were filtered through a 0.2 µm membrane filter to ensure they were sterile before commencement of the test. These solutions were also subjected to ultrasonication and degassing with nitrogen to minimise the dissolved oxygen content. Sample solutions were prepared in stoppered glass flasks at a nominal concentration of 2.5 x 10^{-6} g/l in the three buffer solutions. A 0.25% co-solvent of methanol was used to aid solubility. The solutions were shielded from the light whilst maintained at the test temperature.
Controls	None

Table A7.1.1.1.1/1-3: Description of test system

Glassware	500 mL Erlenmeyer flasks, 250 mL red coated Erlenmeyer flasks.
Other equipment	Low temperature incubator (model 30T, Fisher scientific), Colorphast strips (EM scientific) to measure the pH.
Method of sterilization	Autoclaving

Table A7.1.1.1.1/1-4: Mean Peak Area of Permethrin, at pH 9 at 60°C

Compound	Sampling Times (hours)							
	0		20		25		48	
	Sample A	Sample B	Sample A	Sample B	Sample A	Sample B	Sample A	Sample B
Determination A	2.360×10^5	$4.506 \times 10^{5*}$	1.375×10^5	1.266×10^5	1.252×10^5	1.095×10^5	6.013×10^4	6.145×10^4
Determination B	1.666×10^5	1.485×10^5	6.563×10^5	6.767×10^5	6.271×10^5	6.172×10^5	3.683×10^4	4.393×10^4
Mean Recovery (%)	126	126	126	126	126	126	126	126

* Not used – inconsistent with all other solutions

Table A7.1.1.1.1/1-5: Mean Peak Area of Permethrin, at pH 9 at 70°C

Compound	Sampling Times (hours)							
	0		08		24		27	
	Sample A	Sample B	Sample A	Sample B	Sample A	Sample B	Sample A	Sample B
Parent Compound	3.487×10^5	$2.762 \times 10^{5*}$	1.324×10^5	1.271×10^5	$9.790 \times 10^{4*}$	4.484×10^4	3.918×10^4	3.452×10^4
Mean Recovery (%)	126	126	126	126	126	126	126	126

* Not used – inconsistent with all other solutions

Table A7.1.1.1.1/1-6: Concentration (g/l) of Determination A at pH 9 at 60.0 ± 0.5°C

	Time (Hours)			
	0	**20**	**25**	**48**
Concentration (g/l)	2.62×10^{-6}	1.47×10^{-6}	1.31×10^{-6}	6.24×10^{-7}
Log_{10} [concentration (g/l)]	-5.58	-5.83	-5.88	-6.21

% of initial	-	56.1	49.9	23.8

Table A7.1.1.1.1/1-7: Concentration (g/l) of Determination B at pH 9 at 60.0 ± 0.5°C

	Time (Hours)			
	0	**20**	**25**	**48**
Concentration (g/l)	2.68×10^{-6}	9.05×10^{-7}	8.45×10^{-7}	5.09×10^{-7}
Log_{10} [concentration (g/l)]	-5.57	-6.04	-6.07	-6.29
% of initial	-	33.8	31.5	19.0

Table A7.1.1.1.1/1-8: Concentration (g/l) at pH 9 at 60.0 ± 0.5°C

	Time (Hours)			
	0	**20**	**25**	**48**
Concentration (g/l)	3.20×10^{-6}	1.33×10^{-6}	4.60×10^{-7}	3.78×10^{-7}
Log_{10} [concentration (g/l)]	-5.50	-5.88	-6.34	-6.42
% of initial	-	41.5	14.4	11.8

Table A7.1.1.1.1/1-9: Rate Constant and Estimated Half-Life, of the Permethrin, at 25°C

pH	Rate Constant (s^{-1})	Estimated Half-Life at 25°C
4	-	> 1 year
7	-	Approximately > 1 year
9	2.72×10^{-7}	29.5 days

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Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/2 Hydrolysis as a function of pH

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		1 REFERENCE
1.1	**Reference**	Joseph, R. (2004a), Studies on the Hydrolysis (Abiotic) of Permethrin Technical, International Institute of Biotechnology and Toxicology (IIBAT), Padappai – 601 301, Kancheepuram District, Tamil Nadu, India. Unpublished report No.: 14375. Dates of experimental work: February, 2004 – May, 2004.
1.2	**Data protection**	Yes
1.2.1	Data owner	Tagros Chemicals India Ltd.
1.2.2	Companies with letter of access	Not applicable
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of its entry into Annex I/IA.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, test method was based on OECD guideline 111
2.2	**GLP**	Yes
2.3	**Deviations**	Yes, with the following deviations: 1. No information is given on the products of hydrolysis which were observed during the experiment 2. No information is given about the incubation system used These deviations were not considered to compromise the scientific validity of this study.
		3 MATERIALS AND METHODS
3.1	**Test material**	Please refer to section 2
3.1.1	Lot/Batch number	P-203
3.1.2	Specification	Please refer to section 2 (Permethrin 25:75)
3.1.3	Description	Pale yellow liquid free from extraneous impurities
3.1.4	Purity	94%
3.1.5	Vehicle/solvent	Buffer solutions at pH 4, 7 and 9
3.2	**Reference substance**	None
3.3	**Test solution**	Please refer to Tables A7.1.1.1.1/2-1 and A7.1.1.1.1/2-2.
3.4	**Testing procedure**	
3.4.1	Test system	Please refer to Table A7.1.1.1.1/2-3.

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Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/2 Hydrolysis as a function of pH

3.4.2	Temperature	50.0 ± 0.1°C
3.4.3	pH	pH 4, 7 and 9
3.4.4	Duration of the test	5 days
3.4.5	Number of replicates	Not documented
3.4.6	Sampling	Please refer to Table A7.1.1.1.1/2-4.
3.4.7	Analytical methods	20ml of each test solution was collected and extracted with 75ml of hexane in a 250ml separatory. The phases were allowed to separate and the hexane layer was collected. The extraction was repeated with the aqueous phase with 50ml of hexane and the hexane layer was collected once again. The two hexane fractions were combined and the extract was then dried over anhydrous sodium sulphate. The solvent was evaporated under reduced pressure to near-dryness and the Permethrin was recovered in 3ml or hexane. A chromatographic column was prepared with 5g of florisil slurry using hexane. Florisil slurry was packed between two 1g layers of anhydrous sodium sulphate. The extract was transferred onto the top of the column and the sample was allowed to percolate onto the column. This was then washed with 30ml of hexane and the washings were discarded. The column was eluted with 25% of 60ml ether + hexane and the eluate was collected and evaporated to dryness and recovered in acetone for GC-ECD analysis. The linearity of the detector response in respect to concentration was assessed over the nominal concentration range of 0 to 5mg/l. A calibration curve was plotted and found to be linear up to the lowest concentration range 0.01mg/l. Please refer to Table A7.1.1.1.1/2-5 The standard and sample solutions were analysed by GC using the following conditions: 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 – 300°C Detector – 300°C Injection volume: 1 µl Solvent: Acetone Retention time: ~ 3.2mins
3.5	**Preliminary test**	Sample solutions at pH 4, 7 and 9 were maintained at 50.0 ± 0.1°C for a period of 5 days.

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Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/2 Hydrolysis as a function of pH

4 RESULTS

4.1	Mean peak area and concentration of the test compound	Please refer to Table A7.1.1.1.1/2-10 to Table A7.1.1.1.1/2-12.
4.2	Hydrolysis rate constant (k_h)	Not documented.
4.3	Dissipation time	Preliminary studies carried out on the three buffer solutions at 50± 0.1°C indicate that the compound is hydrolytically stable with 4.32%, 3.30% and 6.52% hydrolysis after 5 days at pH 4, 7 and 9, respectively. The half- life of Permethrin at 25°C was estimated to be > 1year.
4.4	Concentration – time data	Please refer to Tables A7.1.1.1.1/2-9 to A7.1.1.1.1/2-12
4.5	Specification of the transformation products	Not documented
4.6	Validation of the test method	Please refer to Tables A7.1.1.1.1/2-6 to A7.1.1.1.1/2-8 Please be aware: Some variation was observed between samples results due to the sample concentrations approaching the limits of accurate analytical quantitation, differences in the recovery rates and adsorption to the surfaces of the glassware. However, the method was sufficiently sensitive and accurate enough to estimate the rate constant and half-life through the use of the Arrhenius relationship.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	The hydrolysis of Permethrin was examined at half saturated concentrations of Permethrin in buffered solutions of pH 4, 7 and 9. Samples were stored at 50°C for a period of 5 days and analysed by GC-ECD. This study was conducted according to OECD guideline 111 and is described under point 3 with the following deviations: ~~6~~1. No information is given on the products of hydrolysis which were observed during the experiment ~~7~~2. No information is given about the incubation system used These deviations are not considered to affect the scientific validity of this study.
~~7.1~~5.2	Results and discussion	Preliminary studies carried out on the three buffer solutions at 50± 0.1°C indicate that the compound is hydrolytically stable with 4.32%, 3.30% and 6.52% hydrolysis after 5 days at pH 4, 7 and 9, respectively. The half- life of Permethrin at 25°C was estimated to be > 1year.
~~7.1.1~~5.2.1	K_H	Not documented
~~7.1.2~~5.2.2	DT_{50}	The rate of hydrolysis is less than 10% after 5 days, therefore the DT_{50} was estimated to be >1 year.

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Section IIIA 7.1.1.1 Abiotic

Annex Point IIA7.6.2.1 IIIA 7.1.1.1.1/2 Hydrolysis as a function of pH

~~7.1.3~~5.2.3	R^2	pH 4: 0.9997 pH 7:0.9997 pH 9: 0.9996
~~7.2~~5.3	**Conclusion**	The results clearly show that the dissipation of Permethrin is very slow in all three buffer solutions. The loss of permethrin exhibited is less than 10%, which leads to the conclusion that the compound is highly stable with a half-life of > 1 year, under hydrolytic conditions.
~~7.2.1~~5.3.1	Reliability	2
~~7.2.2~~5.3.2	Deficiencies	No deficiencies were noted and are outlined under points 2.3 and 5.1. However, they do not compromise the scientific validity of this study.

Table A7.1.1.1.1/2-1: Type and composition of buffer solutions

pH	Composition
4.0	8ml 0.1 N NaOH + 100ml 0.1 M Potassium biphthalate mixed together and made up to 2000ml with sterile distilled water
7.0	592ml 0.1 N NaOH + 1000ml 0.1 M Monopotassium phosphate mixed together and made up to 2000ml with sterile distilled water
9.0	426ml 0.1 N NaOH + 1000ml 0.1 M Boric acid mixed together and made up to 2000ml with sterile distilled water

Table A7.1.1.1.1/2-2: Description of test solution

Criteria	Details
Purity of water	HPLC-grade water
Preparation of test solution	Oxygen was excluded from the system by bubbling nitrogen for 5 minutes before preparation of the test solution. The test solution was prepared by saturating the test substance in buffer medium. The purest available form of Permethrin was employed in preparing the test solution. Half the saturation concentration was prepared by mixing equal volumes of saturated test solution and buffer medium.
Controls	None.

Table A7.1.1.1.1/2-3: Description of test system

Glassware	Amber coloured bottles 500ml capacity (to avoid photolytic effects) Volumetric standard flask 100ml (Class A, calibrated) Conical flasks 500ml (Class A, calibrated) Pipette 1ml (Class A, calibrated) Pipette 5ml (Class A, calibrated) Separatory funnel 250ml
Other equipment	Shimadzu Gas Chromatograph 14B with ECD, CBM-101 integrator and Class GC-10 software DB-5, Mega bore column Mettler Toledo Analytical balance Model AG-245 Microlitre syringe (10µl) MilliQ ultra pure water purification systemConstant temperature bath pH meter
Method of sterilisation	Glassware is described as having been inert in the pH range and sterilised, however the method of sterilisation is not documented.

Table A7.1.1.1.1/2-4: Sampling details

No.	Parameters	Details		
1	Compound	Permethrin		
2	**Preliminary test @ 50°±0.1°C**	**pH 4.0**	**pH 7.0**	**pH 9.0**
	Initial	02/04/2004	02/04/2004	02/04/2004
	5 days after storage	07/04/2004	07/04/2004	07/04/2004

Table A7.1.1.1.1/2-5: Calibration Details

Injected concentration (mg/l)	Observed Area (µV-sec)
0.01	852
0.2	16174
0.5	41329
1.0	81316
2.0	159220
5.0	394457

Minimum detectable concentration: 0.01mg/l
Correlation coefficient: 0.9999

Table A7.1.1.1.1/2-6: Validation of the method – Buffer pH 4.0

Fortified Concentration (mg/l)	Concentration Found (mg/l)	% of Recovery	Standard Deviation
0.02	0.019	95	0.000
0.02	0.019	95	
0.02	0.019	95	
0.2	0.190	95	0.003
0.2	0.185	93	
0.2	0.191	96	
1.0	0.931	93	0.019
1.0	0.922	92	
1.0	0.958	96	

Average recovery percentage: 94%
Correlation Coefficient : 0.9997

Table A7.1.1.1.1/2-7: Validation of the method – Buffer pH 7.0

Fortified Concentration (mg/l)	Concentration Found (mg/l)	% of Recovery	Standard Deviation
0.02	0.019	95	0.001
0.02	0.018	90	
0.02	0.019	95	
0.2	0.194	97	0.002
0.2	0.190	95	
0.2	0.193	96	
1.0	0.938	94	0.021
1.0	0.974	97	
1.0	0.973	97	

Average recovery percentage: 95%
Correlation Coefficient: 0.9997

Table A7.1.1.1.1/2-8: Validation of the method – Buffer pH 4.0

Fortified Concentration (mg/l)	Concentration Found (mg/l)	% of Recovery	Standard Deviation
0.02	0.018	90	0.001
0.02	0.019	95	
0.02	0.019	95	
0.2	0.185	92	0.005
0.2	0.193	97	
0.2	0.195	98	
1.0	0.925	93	0.019
1.0	0.888	89	
1.0	0.900	90	

Average recovery percentage: 93%
Correlation Coefficient: 0.9996

Table A7.1.1.1.1/2-9: Preliminary hydrolysis results

pH	4.0	7.0	9.0
C_o – Initial Concentration (mg/l)	1.39	0.91	2.30
C_t – Concentration at time t (mg/l) t_{max} = after 5 days	1.33	0.88	2.15
C_o - C_t x 100/ C_o At 50°± 0.1°C	4.32	3.30	6.52

Table A7.1.1.1.1/2-10: Hydrolysis of Permethrin at pH 4 and 50°± 0.1°C

CODE	PEAK AREA (µV-sec)	STD AREA (µV-sec)	STD CONC (mg/l)	SAMPLE VOLUME (ml)	FINAL VOLUME (ml)	DILUTION FACTOR	RESIDUE mg/l	AVE mg/l
Initial								
CR1	ND	80994	1.0	20.0	5.0	10.0	ND	ND
CR2	ND	80994	1.0	20.0	5.0	10.0	ND	
SR1	43637	80994	1.0	20.0	5.0	10.0	1.347	1.39
SR2	46235	80994	1.0	20.0	5.0	10.0	1.427	
5 days after storage								
CR1	ND	80665	1.0	20.0	5.0	10.0	ND	ND
CR2	ND	80665	1.0	20.0	5.0	10.0	ND	
SR1	42509	80665	1.0	20.0	5.0	10.0	1.317	1.33
SR2	43270	80665	1.0	20.0	5.0	10.0	1.341	

ND = Not Detectable

Table A7.1.1.1.1/2-11: Hydrolysis of Permethrin at pH 7 and 50°± 0.1°C

CODE	PEAK AREA (µV-sec)	STD AREA (µV-sec)	STD CONC (mg/l)	SAMPLE VOLUME (ml)	FINAL VOLUME (ml)	DILUTION FACTOR	RESIDUE mg/l	AVE mg/l
Initial								
CR1	ND	80994	1.0	20.0	5.0	1.0	ND	ND
CR2	ND	80994	1.0	20.0	5.0	1.0	ND	
SR1	278516	80994	1.0	20.0	5.0	1.0	0.860	0.91
SR2	312037	80994	1.0	20.0	5.0	1.0	0.963	
5 days after storage								
CR1	ND	80665	1.0	20.0	5.0	1.2	ND	ND
CR2	ND	80665	1.0	20.0	5.0	1.2	ND	
SR1	238598	80665	1.0	20.0	5.0	1.2	0.887	0.88
SR2	236770	80665	1.0	20.0	5.0	1.2	0.881	

ND = Not Detectable

Table A7.1.1.1.1/2-12: Hydrolysis of Permethrin at pH 9 and 50°± 0.1°C

CODE	PEAK AREA (µV-sec)	STD AREA (µV-sec)	STD CONC (mg/l)	SAMPLE VOLUME (ml)	FINAL VOLUME (ml)	DILUTION FACTOR	RESIDUE mg/l	AVE mg/l
Initial								
CR1	ND	80994	1.0	20.0	5.0	5.0	ND	ND
CR2	ND	80994	1.0	20.0	5.0	5.0	ND	
SR1	154332	80994	1.0	20.0	5.0	5.0	2.382	2.30
SR2	144122	80994	1.0	20.0	5.0	5.0	2.224	
5 days after storage								
CR1	ND	80665	1.0	20.0	5.0	5.0	ND	ND
CR2	ND	80665	1.0	20.0	5.0	5.0	ND	
SR1	140593	80665	1.0	20.0	5.0	5.0	2.179	2.15
SR2	136747	80665	1.0	20.0	5.0	5.0	2.119	

ND = Not Detectable

Section IIIA 7.1.1.1. Abiotic

Annex Point IIA7.6.2.2 IIIA 7.1.1.1.2 Phototransformation in water

		Official use only
	~~6~~1 REFERENCE	
~~6.1~~1.1 Reference	Klöppel, H. (2006), Aquatic photodegradation and quantum yield of Permethrin, Fraunhofer Institute for Molecular Biology and Applied Ecology, Division Applied Ecology, 57392 Schmallenberg, Germany, unpublished report No.: GAB-012/7-05 (July 10, 2006) Dates of experimental work: May 04, 2006 – July 10, 2006	
~~6.2~~1.2 Data protection	Yes	
~~6.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.	
~~6.2.2~~1.2.2 Companies with letter of access	Not applicable	
~~6.2.3~~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.	
	~~7~~2 GUIDELINES AND QUALITY ASSURANCE	
~~7.1~~2.1 Guideline study	Yes, test method was based on OECD draft guideline 'Phototransformation of Chemicals in Water - Direct and Indirect Photolysis'.	
~~7.2~~2.2 GLP	Yes	
~~7.3~~2.3 Deviations	No	
	~~8~~3 MATERIALS AND METHODS	
~~8.1~~3.1 Test material	Permethrin Technical (25:75)	
~~8.1.1~~3.1.1 Lot/Batch number	P-38	
~~8.1.2~~3.1.2 Specification	Please refer to points 3.1.3 to 3.1.5	
~~8.1.3~~3.1.3 Purity	93.61% (23.51 % cis – isomer content)	
~~8.1.4~~3.1.4 Radiolabelling	Not applicable	

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Section IIIA 7.1.1.1. Abiotic

Annex Point IIA7.6.2.2 **IIIA 7.1.1.1.2 Phototransformation in water**

~~8.1.5~~3.1.5 UV/VIS absorption spectra and absorbance value	λ_{max} 300 nm; ε 0.0019 at pH 7, λ_{max} 290 nm; ε 0.0118 at pH 7, λ_{max} 290 nm; ε 0.00456 at pH 9	X	Formatted: Bullets and Numbering
~~8.1.6~~3.1.6 Further relevant properties	Permethrin has a water solubility of 0.006 mg/l at 20 °C, pH 7		Formatted: Bullets and Numbering
~~8.2~~3.2 Reference substances	None		Formatted: Bullets and Numbering
~~8.3~~3.3 Test solution	Please refer to Table A 7.1.1.1.2-1		Formatted: Bullets and Numbering
~~8.4~~3.4 Testing procedure			Formatted: Bullets and Numbering
~~8.4.1~~3.4.1 Test system	Please refer to Table A7.1.1.1.2-2		Formatted: Bullets and Numbering
~~8.4.2~~3.4.2 Properties of light source	Polychromatic irradiation with filtered xenon arc light		Formatted: Bullets and Numbering
~~8.4.3~~3.4.3 Determination of irradiance	Not applicable		Formatted: Bullets and Numbering
~~8.4.4~~3.4.4 Temperature	Room temperature		Formatted: Bullets and Numbering
~~8.4.5~~3.4.5 pH	UV/VIS spectra were recorded at pH 5.0, 7.0 and 9.0		Formatted: Bullets and Numbering
~~8.4.6~~3.4.6 Duration of the test	Not applicable		Formatted: Bullets and Numbering
~~8.4.7~~3.4.7 Number of replicates	Not given		Formatted: Bullets and Numbering
~~8.4.8~~3.4.8 Sampling	Not applicable		Formatted: Bullets and Numbering
~~8.4.9~~3.4.9 Analytical methods	Not applicable		Formatted: Bullets and Numbering
~~8.5~~3.5 Transformation products	Transformation products tested: No		Formatted: Bullets and Numbering
~~8.5.1~~3.5.1 Method of analysis for transformation products	Not applicable		Formatted: Bullets and Numbering
	~~9~~4 RESULTS		Formatted: Bullets and Numbering
~~9.1~~4.1 Screening test	All the obtained results indicate that Permethrin is photolytically stable. Therefore no further experiments were carried out. Since the maximum possible losses due to the phototransformation are < 50% no further direct photolysis work is required to be performed according to the Draft OECD Guideline.		Formatted: Bullets and Numbering

Section IIIA 7.1.1.1. Abiotic

Annex Point IIA7.6.2.2 **IIIA 7.1.1.1.2 Phototransformation in water**

~~9.2~~4.2 **Actinometer data**	Not applicable
~~9.3~~4.3 **Controls**	Self tests were performed on the photometer
~~9.4~~4.4 **Photolysis data**	
~~9.4.1~~4.4.1 Concentration values	Please refer to Table A7.1.1.1.2-3
~~9.4.2~~4.4.2 Mass balance	Not applicable
~~9.4.3~~4.4.3 k^c_p	Not determined
~~9.4.4~~4.4.4 Kinetic order	Not determined
~~9.4.5~~4.4.5 k^c_p / k^a_p	Not applicable
~~9.4.6~~4.4.6 Reaction quantum yield (ϕ^c_E)	Not determined
~~9.4.7~~4.4.7 k_{pE}	Not determined
~~9.4.8~~4.4.8 Half-life ($t_{1/2E}$)	The results for the shortest half-lives in Central Europe (55°) from January through December are shown in Table A7.1.1.1.2-3. The shortest half-lives were between 6.42 x 10^5 and 3.35 x 10^{14} days.
~~9.5~~4.5 **Specification of the transformation products**	Not applicable

~~10~~5 APPLICANT'S SUMMARY AND CONCLUSION

~~10.1~~5.1 **Materials and methods**

To determine the extent and rate of aqueous photolysis of Permethrin, the dependence of the UV/VIS spectrum on pH (5, 7 and 9) and Permethrin concentration (1mg/l, 5mg/l and 10mg/l) was measured.

The minimum theoretical half-life considering only photolytic degradation was determined using the ABIWAS computer programme. As input, a quantum yield of 1.0 and an initial concentration of 1.37 x 10^{-5} mol/L were used and tabular irradiation values were taken from January through December for Central Europe (55°) to estimate the maximum degradation rate.

This study was conducted according to OECD draft guideline

Section IIIA 7.1.1.1. Abiotic

Annex Point IIA7.6.2.2 **IIIA 7.1.1.1.2 Phototransformation in water**

'Phototransformation of Chemicals in Water - Direct and Indirect Photolysis'.

~~10.2~~5.2 **Results and discussion**	No specific spectra of the test items were obtained. Generally, the light absorption was very low and was not significantly above the measured inaccuracy. For the dependence of the UV/VIS spectrum on pH the results were as follows: at pH 7 the light absorbance at 300 nm was 0.0019 and at 290 nm was 0.0118. At pH 9 at 290 nm the light absorbance was 0.00456 and at pH 5 no significant absorbance was measured. For the dependence of the UV/VIS spectrum on Permethrin concentration, molar absorption coefficients were calculated as follows: for 5 mg/l at 290 nm the molar absorbance coefficient was 18.9 l/ml x cm and for 10 mg/l it was 52.32 l/ml x cm. The results could be caused by scattered light at lower wavelengths and the experiment confirmed that Permethrin solution does not absorb light significantly above 290 nm. The results for the shortest half-lives in Central Europe (55°) from January through December are shown in Table A7.1.1.1.2-3. The shortest half-lives were between 6.42 x 10^5 and 3.35 x 10^{14} days. No further direct photolysis work is required according to the Draft OECD Guideline.	X	Formatted: Bullets and Numbering
~~10.2.1~~5.2.1 k^c_p	Not determined		Formatted: Bullets and Numbering
~~10.2.2~~5.2.2 K_{pE}	Not determined		Formatted: Bullets and Numbering
~~10.2.3~~5.2.3 ϕ^c_E	Not determined		Formatted: Bullets and Numbering
~~10.2.4~~5.2.4 $t_{1/2E}$	Not applicable		Formatted: Bullets and Numbering
~~10.3~~5.3 **Conclusion**	The very low light absorption of Permethrin above 290 nm and the very low molar absorption coefficients indicate that the test substance is photolytically inactive. This was confirmed by a calculation using the ABIWAS computer programme which simulated the maximum possible direct photolysis by assuming a quantum yield of one. The shortest half lives calculated were between 6.42 x10^5 and 3.35 x 10^{14}. No further direct photolysis work is required according to the Draft OECD Guideline. The validity criteria can be considered as fulfilled.		Formatted: Bullets and Numbering
~~10.3.1~~5.3.1 Reliability	1		Formatted: Bullets and Numbering

Section IIIA 7.1.1.1. Abiotic

Annex Point IIA7.6.2.2 **IIIA 7.1.1.1.2 Phototransformation in water**

~~10.3.2~~5.3.2 Deficiencies	None	

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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	22 May 2009
Materials and Methods	Applicant's version is acceptable with the addition of the following correction. Sub-heading 3.1.5 ε represents the molar absorption coefficient. The values reported for ε are actually light absorbance values, not molar absorption coefficients. This has no bearing on the quality of the study.
Results and discussion	Adopt applicant's version with the addition of the following correction. Sub-heading 5.2 Correct units for molar absorption coefficient are L mol^{-1} cm^{-1} (not l/ml x cm).
Conclusion	Adopt applicant's version.
Reliability	1
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 A7.1.1.1.2-1: Description of test solution and controls

Criteria	Details
Purity of water	Due the very low solubility of Permethrin in water, the UV/VIS spectrum was recorded in a mixture of aqueous buffer/acetonitrile 50:50 (v/v).
Preparation of test chemical solution	For recording the dependence of the UV/VIS spectrum on the pH value, buffer solutions (0.01M) with pH values 5.0 (citrate buffer), 7.0 (phosphate buffer) and 9.0 (borate buffer) were prepared. 25 ml of each buffer solution was mixed with 25 ml acetonitrile and 71 µl of unlabelled Permethrin stock solution to obtain a solution of 10 mg/l Permethrin in a mixture of buffer/acetonitrile. For recording the dependence of light absorption on the Permethrin concentration, 7.1µl, 35.5µl and 71.0µl of unlabelled Permethrin stock solution were each brought to 50 ml with acetonitrile to obtain Permethrin solutions of 1.0 mg/l, 5.0 mg/l and 10.0 mg/l.
Test concentrations (mg a.s./l)	1.0 mg/l, 5.0 mg/l and 10.0 mg/l.
Preparation of a.s. solution	Not applicable
Identity and concentration of co-solvent	Due the very low solubility of Permethrin in water, the UV/VIS spectrum was recorded in a mixture of aqueous buffer/acetonitrile 50:50 (v/v).
Controls	Self tests were performed on the photometer to assess the quality of the data generated.

Table A7.1.1.1.2-2: Description of test system

~~10.3.2.1~~5.3.2.1 Criteria	**Details**
Laboratory equipment	5cm thick vessels were used along with a Cary 1 UV/VIS spectrophotometer from Varian.
Test apparatus	The UV/VIS absorption was measured in the range 290–800 nm.
Properties of artificial light source:	Not applicable
Properties of natural sunlight:	Not applicable

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Table A7.1.1.1.2-3: Shortest calculated half-lives of Permethrin in the environment of Central Europe

Month	Half-Life (days)	Month	Half-Life (days)
January	5.12×10^{13}	July	6.42×10^{5}
February	1.12×10^{11}	August	8.95×10^{5}
March	5.86×10^{8}	September	5.86×10^{6}
April	1.69×10^{7}	October	1.26×10^{8}
May	2.83×10^{6}	November	2.03×10^{11}
June	9.71×10^{5}	December	3.35×10^{14}

Section A7.1.1.2 Annex Point IIA7.6.1.1 Biotic

IIIA 7.1.1.2.1 Ready Biodegradability

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~~11~~1 REFERENCE

~~11~~.1.1 Reference

Clarke, N. (2003), Permethrin: Assessment of Ready Biodegradability; CO_2 Evolution Test, Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K, unpublished report No.: 1667/003.

Dates of experimental work: July 23, 2002 – August 21, 2002.

~~11~~.2 Data protection: Yes

~~11.2.1~~1.2.1 Data owner: Copyr s.p.a

~~11.2.2~~1.2.2 Companies with letter of access: Not applicable

~~11.2.3~~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.

~~12~~2 GUIDELINES AND QUALITY ASSURANCE

~~12.1~~2.1 Guideline study: Yes, test method was based on OECD guideline 301B and US EPA OPPTS 835.3110.

~~12.2~~2.2 GLP: Yes

~~12.3~~2.3 Deviations: Yes, with the following deviation:

1. Information on the purity of the test substance has not been presented in the study report.

This deviation is not considered to compromise the scientific validity of this study.

~~13~~3 MATERIALS AND METHODS

~~13.1~~3.1 Test material: Please refer to section 2

~~13.1.1~~3.1.1 Lot/Batch number: P-127

~~13.1.2~~3.1.2 Specification: Please refer to section 2 (Permethrin 25:75)

~~13.1.3~~3.1.3 Purity: Not documented

~~13.2~~3.2 Reference substance: Yes, Sodium Benzoate

~~13.2.1~~3.2.1 Initial concentration of reference substance: 17.1 mg/l

~~13.3~~3.3 Testing procedure

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Section A7.1.1.2 Biotic
Annex Point IIA7.6.1.1 IIIA 7.1.1.2.1 Ready Biodegradability

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~~13.3.1~~3.3.1 Inoculum / test species	Please refer to Table A7.1.1.2-1		Formatted: Bullets and Numbering
~~13.3.2~~3.3.2 Test system	Please refer to Table A7.1.1.2.1-2		Formatted: Bullets and Numbering
~~13.3.3~~3.3.3 Test conditions	Please refer to Table A7.1.1.2.1-3		Formatted: Bullets and Numbering
~~13.3.4~~3.3.4 Method of preparation of test solution	Approximately 24 hours prior to addition of the test and reference substances, the vessels were filled with 2400 ml of culture medium and 29 ml of inoculum and then aerated over night. Each test vessel was inoculated with the prepared inoculum at a final concentration of 30 mg suspended solids (ss)/l. On day 0, test and reference substances were added and the volume in all the vessels was adjusted to 3 litres by the addition of culture medium. Silica gel was added to the control and reference vessels in order to maintain consistency between these vessels and the test material vessels. The culture vessels were sealed, CO_2-free air was bubbled through the solution and the solution was stirred continuously with the aid of a magnetic stirrer. The study was carried out in a temperature-controlled room at 21°C, in darkness. CO_2 produced by degradation was collected in two 500 ml Dreschel bottles containing 350 ml of 0.05 M NaOH. The CO_2 adsorbing solutions were prepared using purified de-gassed water.	X	Formatted: Bullets and Numbering
~~13.3.5~~3.3.5 Initial TS concentration	Please refer to Table A7.1.1.2.1-2		Formatted: Bullets and Numbering
~~13.3.6~~3.3.6 Duration of test	29 days		Formatted: Bullets and Numbering
~~13.3.7~~3.3.7 Analytical parameter	CO_2 evolution test. Samples (300 or 40 µl) were analysed for their CO_2 content by injection into the IC (Inorganic Carbon) channel of the TOC analyser. Inorganic carbon analysis occurs by means of the conversion of an aqueous sample by orthophosphoric acid using zero grade air or nitrogen (oxygen free) as the carrier gas. Calibration was by standard solutions of sodium carbonate (Na_2CO_3). Each analysis was carried out in triplicate.		Formatted: Bullets and Numbering
~~13.3.8~~3.3.8 Sampling	Samples were taken from the first CO_2 absorber vessel on Days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 28 and 29. The second absorber vessel was sampled on Days 0 and 29.		Formatted: Bullets and Numbering
~~13.3.9~~3.3.9 Intermediates/ degradation products	Not identified		Formatted: Bullets and Numbering
~~13.3.10~~3.3.10 Nitrate/nitrite measurement	No		Formatted: Bullets and Numbering
~~13.3.11~~3.3.11 Controls	There were two replicate controls consisting of inoculated culture		Formatted: Bullets and Numbering

Section A7.1.1.2 Annex Point IIA7.6.1.1 **Biotic**

IIIA 7.1.1.2.1 Ready Biodegradability

medium and 100 mg silica gel.

A single toxicity control consisting of Permethrin and Sodium benzoate were inoculated culture medium plus 100 mg silica gel to give a final concentration of 20 mg carbon/l

~~13.3.12~~3.3.12 Statistics

Theoretical carbon dioxide production was calculated by dividing the molecular weight of carbon dioxide by the atomic weight of carbon and multiplying this answer by the volume and the concentration of the test substance.

~~14~~4 RESULTS

~~14.1~~4.1 Degradation of test substance

~~14.1.1~~4.1.1 Degradation

Permethrin attained 5% degradation after 28 days.

Inorganic carbon analysis of samples from the first absorber vessels on Day 29 showed an increase in all replicate vessels. These increases were considered to be due to the CO_2 present in solution being driven off by the addition of hydrochloric acid on Day 28, which resulted in an increase in the percentage degradation value for the test material from 5% on Day 28 to 9% on Day 29. Please refer to A7.1.1.2.1-5.

~~14.1.2~~4.1.2 Other observations

The toxicity control attained 51% degradation after 28 days.

~~14.1.3~~4.1.3 Degradation of TS in abiotic control

No abiotic control

~~14.1.4~~4.1.4 Degradation of reference substance

Sodium benzoate attained 79% degradation after 28 days.

Analysis of the test media taken from the reference substance culture vessels on Day 0 and Day 28 for Dissolved Organic Carbon (DOC), gave percentage degradation values of 108% and 105% respectively for Replicates R_1 and R_2. Degradation values in excess of 100% were considered to be due to sampling/analytical variation.

Please refer to A7.1.1.2.1-5

~~14.1.5~~4.1.5 Intermediates/ degradation products

Not identified

~~15~~5 APPLICANT'S SUMMARY AND CONCLUSION

~~15.1~~5.1 Materials and methods

The ready biodegradability of Permethrin extract was assessed in a CO_2 evolution test.

This study was conducted according to OECD guideline 301B and US EPA OPPTS 835.3110 and is described underpoint 3 with the following deviation:

1. Information on the purity of the test substance has not

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Section A7.1.1.2 Annex Point IIA7.6.1.1 **Biotic**

IIIA 7.1.1.2.1 Ready Biodegradability

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been presented in the study report.

This deviation is not considered to compromise the scientific validity of this study.

~~15.2~~5.2 Results and discussion

Permethrin attained 5% degradation after 28 days.

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Inorganic carbon analysis of samples from the first absorber vessels on Day 29 showed an increase in all replicate vessels. These increases were considered to be due to the CO_2 present in solution being driven off by the addition of hydrochloric acid on Day 28.

The toxicity control attained 51% degradation after 28 days, confirming that the test material is not toxic to the sewage treatment microorganisms used in this study.

Sodium benzoate attained 79% degradation after 28 days, thereby confirming the suitability of the inoculum and test conditions.

Analysis of the test media taken from the reference substance culture vessels on Day 0 and Day 28 for Dissolved Organic Carbon (DOC), gave percentage degradation values of 108% and 105% respectively for Replicates R_1 and R_2. The degradation rates calculated from the results of DOC analyses were higher than those calculated from inorganic carbon analysis. This was considered to be due to incorporation of sodium benzoate into the microbial biomass prior to degradation, and hence CO_2 evolution occurring. Degradation values in excess of 100% were considered to be due to sampling/analytical variation.

~~15.3~~5.3 Conclusion

Permethrin is not considered to be readily biodegradable.

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~~15.3.1~~5.3.1 Reliability

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~~15.3.2~~5.3.2 Deficiencies

One deviation was noted and is outlined under points 2.3 and 5.1. However, it does not compromise the scientific validity of this study.

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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	25 May 2009
Materials and Methods	Applicant's version is acceptable with the addition of the following information. Sub-heading 3.3.4 Prior to dispersion in the culture medium, the test substance was prepared by adsorption onto silica gel in order to aid its dispersion and to increase the surface area exposed to test organisms.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.

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Section A7.1.1.2 Biotic
Annex Point IIA7.6.1.1 IIIA 7.1.1.2.1 Ready Biodegradability

Reliability	2
Acceptability	Acceptable
Remarks	Reliability rating of 2 assigned because the purity of the test substance was not reported. Guidance followed states that, preferably, the purity of the test substance should be known. However, the result of the study is reliable for risk assessment purposes and the study is acceptable.
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.1.1.2.1-1: Inoculum / Test Organism

Criteria	Details
Nature	Activated sewage sludge
Species	Not relevant
Strain	Not relevant
Source	Sewage treatment plant treating predominantly domestic sewage
Sampling site	Severn Trent Plc sewage treatment plant at Loughborough, Leicestershire, UK
Laboratory culture	Yes
Preparation of inoculum for exposure	The inoculum was continuously aerated upon receipt and then washed three times by settlement and resuspension in culture medium. The sewage sample was then filtered so as to determine the suspended solids content.
Initial cell concentration	Suspended solids were equal to 3.1g/l prior to use.

Table A7.1.1.2.1-2: Test System

Criteria	Details
Culturing apparatus	Respirometer, magnetic stirrer, a glass column containing self-indicating soda lime granules.
Number of culture flasks/concentration	Number of culture flasks: ~~1.~~a) A control, in duplicate, consisting of inoculated culture medium plus 100 mg silica gel. ~~2.~~b) A standard material (sodium benzoate), in duplicate, in inoculated culture medium plus 100 mg silica gel to give a final concentration of 10 mg carbon/l. ~~3.~~c) The test material, in duplicate, in inoculated culture medium plus 100 mg silica gel to give a final concentration of 10 mg carbon/l. ~~4.~~d) The test material plus the standard material in inoculated culture medium plus 100 mg silica gel to give a final concentration of 20 mg carbon/l to act as a toxicity control (one vessel only).
Aeration device	Not documented
Measuring equipment	Samples were analysed for CO_2 using a Tekmar-Dohrmann Apollo 9000 TOC analyser and an Ionics 1555B TOC analyser. Samples were analysed for DOC using a Shimadzu TOC-5050A TOC analyser. The pH of the test preparations were determined using a WTW pH 320 pH meter.
Test performed in closed vessels due to significant volatility of TS	Yes The culture vessels were sealed, so as to exclude oxygen, and CO_2-free air was bubbled through the solution.

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Table A7.1.1.2.1-3: Test Conditions

Criteria	Details
Composition of medium	Solution a: KH_2PO_4 8.50 g/l K_2HPO_4 21.75 g/l $Na_2HPO_4.2H_2O$ 33.4 g/l NH_4Cl 0.50 g/l pH = 7.4 Solution b: $CaCl_2$ 27.5 g/l Solution c: $MgSO_4.7H_2O$ 22.5 g/l Solution d: $FeCl_3.6H_20$ 0.25 g/l The following volumes of solutions a-d were added to 1 litre (final volume) of purified water: 10 ml of Solution a 1 ml of Solution b 1 ml of Solution c 1 ml of Solution d
Additional substrate	No
Test temperature	The study was carried out in a temperature-controlled room at 21°C
pH	pH values of the test preparation on Day 28: Test Vessel- pH- a) Control R_1 7.5 b) Control R_2 7.4 c) Sodium Benzoate 10 mg C/l R_1 7.6 d) Sodium Benzoate 10 mg C/l R_2 7.6 e) Test Material 10 mg C/l R_1 7.5 f) Test Material 10 mg C/l R_2 7.5 g) Test Material plus Sodium Benzoate Toxicity 10 mg C/l R_1 7.5
Aeration of dilution water	Not documented
Suspended solids concentration	Suspended solids were equal to 3.1g/l prior to use.

Table A7.1.1.2.1-4: Total, Inorganic and Dissolved Organic Carbon (DOC) Values in Culture Vessels on Day 0

Test vessel	Total Carbon* (mg/l)	Inorganic Carbon* (mg/l)	IC/TC Ratio (%)	DOC Concentration	
				mg C/l	% of Nominal Carbon Content
Sodium Benzoate 10 mg C/l R_1	9.16	0.40	4	8.75	88
Sodium Benzoate 10 mg C/l R_2	9.08	0.31	3	8.77	88
Test Material 10 mg C/l R_1	10.78**	0.30	3	-	-
Test Material 10 mg C/l R_2	10.36**	0.35	3	-	-
Test Material plus Sodium Benzoate Toxicity Control 20 mg C/l	20.40**	0.46	2	-	-

R1 – R2 = Replicates 1 and 2

*Corrected for control values.

**Total carbon value given is the sum of the TC value obtained from analysis and the nominal TC contribution of the test material and sodium benzoate where applicable.

Table A7.1.1.2.1-5: Percentage Biodegradtion Values

Day	% Degradation Sodium Benzoate	% Degradation Test Material	% Degradation Test Material plus Sodium Benzoate Toxicity Control
0	0	0	0
1	21	2	9
2	46	4	18
3	48	7	27
6	68	6	31
8	68	1	34
10	73	0	46
14	75	5	43
16	76	0	44
20	80	0	44
22	82	0	44
24	82	0	43
27	82	2	49
28	79	5	51
29	86	9	56

Table A7.1.1.2.1-6: Pass levels and validity criteria for tests on ready biodegradability

	Fulfilled
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$	No
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test	No
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	Yes
Percentage of removal of reference substance reaches pass level by day 14	Yes

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Biotic

IIIA 7.1.1.2.2 Inherent Biodegradability

		Official use only
	~~16~~1 REFERENCE	
~~16.1~~1.1 **Reference**	Sathiyanarayanan S. (2006), Assessment of Inherent Biodegradability of Permethrin Technical by modified MITI Test (II), International Institute of Biotechnology and Toxicology (IIBAT) Padappai - 601 301, Kancheepuram District, Tamil Nadu, India, unpublished report No.: 06012. Dates of experimental work: July 03, 2006 – July 31, 2006	
~~16.2~~1.2 **Data protection**	Yes	
~~16.2.1~~1.2.1 Data owner	Tagros Chemicals India Ltd.	
~~16.2.2~~1.2.2 Companies with letter of access	Not applicable	
~~16.2.3~~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	
	~~17~~2 GUIDELINES AND QUALITY ASSURANCE	
~~17.1~~2.1 **Guideline study**	Yes, test method was based on OECD guideline 302C	
~~17.2~~2.2 **GLP**	Yes	
~~17.3~~2.3 **Deviations**	No	
	~~18~~3 MATERIALS AND METHODS	
~~18.1~~3.1 **Test material**	Permethrin Technical	
~~18.1.1~~3.1.1 Lot/Batch number	P-203	
~~18.1.2~~3.1.2 Specification	As given in section 2	
~~18.1.3~~3.1.3 Purity	94.10 % (cis: trans ratio 25:75)	
~~18.1.4~~3.1.4 Further relevant properties	Not given	
~~18.1.5~~3.1.5 Composition of Product	Not applicable	
~~18.1.6~~3.1.6 TS inhibitory to microorganisms	No	
~~18.1.7~~3.1.7 Specific chemical analysis	Residual Permethrin in test samples was determined by GC with ECD detection.	
~~18.2~~3.2 **Reference substance**	Yes Aniline	
~~18.2.1~~3.2.1 Initial concentration of	100 ppm	

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reference substance	
~~18.3~~3.3 **Testing procedure**	
~~18.3.1~~3.3.1 Inoculum / test species	See table A7.1.1.2-2
~~18.3.2~~3.3.2 Test system	See table A7.1.1.2-3
~~18.3.3~~3.3.3 Test conditions	See table A7.1.1.2-4
~~18.3.4~~3.3.4 Method of preparation of test solution	Permethrin (9 mg) was added to three test vessels containing the basal culture medium (300 ml) and activated sludge (30 mg). There were two control vessels, one contained only the basal culture medium (300 ml) and activated sludge (30 mg) and the other contained Permethrin (9 mg) and water (300 ml). The reference compound, aniline, (30 mg) was added to a vessel containing basal culture medium (300 ml) and activated sludge (30 mg).
~~18.3.5~~3.3.5 Initial TS concentration	30 ppm
~~18.3.6~~3.3.6 Duration of test	28 days
~~18.3.7~~3.3.7 Analytical parameter	BOD
~~18.3.8~~3.3.8 Sampling	A reading was taken from the BOD meter once a day and chemical analysis was carried out after 28 days.
~~18.3.9~~3.3.9 Intermediates/ degradation products	Not identified
~~18.3.10~~3.3.10 Nitrate/nitrite measurement	No
~~18.3.11~~3.3.11 Controls	One control contained basal culture medium (300 ml) and activated sludge (30 mg) and the other contained Permethrin technical (9 mg) in deionised water (300 ml).
~~18.3.12~~3.3.12 Statistics	$\text{Biodegradation (\%)} = \frac{\text{BOD - B}}{\text{TOD}} \times 100$ Where BOD is the biological oxygen demand of the test substance, B is the oxygen consumption of the activated sludge and TOD is the theoretical oxygen demand of the test substance.
~~19~~4 **RESULTS**	
~~19.1~~4.1 **Degradation of test substance**	

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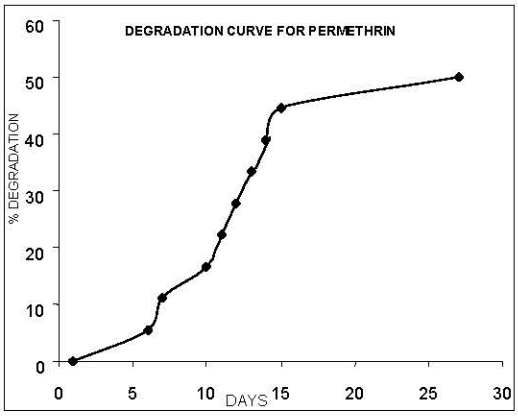
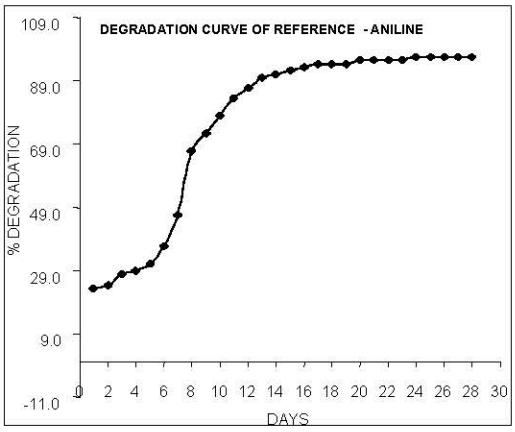
~~19.1.1~~4.1.1	Graph	
~~19.1.2~~4.1.2	Degradation	The percentage degradation was 38.9 % on the 14th day and 55.6 % on the 28th day.
~~19.1.3~~4.1.3	Other observations	Not given
~~19.1.4~~4.1.4	Degradation of TS in abiotic control	0%
~~19.1.5~~4.1.5	Degradation of reference substance	
~~19.1.6~~4.1.6	Intermediates/ degradation products	Not applicable; none identified.

~~20~~5 APPLICANT'S SUMMARY AND CONCLUSION

~~20.1~~5.1	**Materials and methods**	Permethrin (9 mg) was added to three test vessels containing the basal culture medium (300 ml) and activated sludge (30 mg). There were two control vessels, one contained only the basal culture medium (300 ml) and activated sludge (30 mg) and the other contained Permethrin (9 mg)

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and water (300 ml). The reference compound, aniline, (30 mg) was added to a vessel containing basal culture medium (300 ml) and activated sludge (30 mg). Substances in these test vessels were cultivated by stirring at 25±2°C for 28 days in a BOD meter. The BOD meter reading was noted every day. After 28 days of exposure the remaining Permethrin Technical was analysed and determined by GC.

This study was conducted according to OECD guideline 302C "Inherent Biodegradability: Modified MITI Test II"

~~20.2~~5.2 **Results and discussion**

The mean percentage biodegradability determined for the vessels containing the basal culture medium, Permethrin Technical and activated sludge was 38.9 % after 14 days and 55.6 % after 28 days (confirmed as 57.2 % *via* chemical analysis). The percentage biodegradation for the reference substance, aniline, was 46.7 % after 7 days and 91.1 % after 14 days.

~~20.3~~5.3 **Conclusion**

The Inherent biodegradability of Permethrin Technical was determined from the BOD measurement over 28 days according to OECD guideline 302C. The percentage of degradation of Permethrin Technical was calculated using the BOD method, and supplemental chemical analysis was also carried out using GC. From the BOD method the biodegradability was calculated to be 55.6% and by chemical analysis the degradation was found to be 57.2%.

The validity criteria as presented in tables A7.1.1.2-5 and A7.1.1.2-6 can be considered fulfilled and therefore the test result is indicative of inherent biodegradability.

~~20.3.1~~5.3.1 Reliability 1

~~20.3.2~~5.3.2 Deficiencies No

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Evaluation by Competent Authorities	
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	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	26 May 2009
Materials and Methods	Applicant's version is acceptable.
Results and discussion	Adopt applicant's version.
Conclusion	Adopt applicant's version.
Reliability	1
Acceptability	Acceptable
Remarks	
	COMMENTS FROM ...

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Annex Point VII.7.6.1.2

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IIIA 7.1.1.2.2 Inherent Biodegradability

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

Table A7.1.1.2-1: Guidline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
DOC Die-Away-Test	C.4-A	301A	ready
CO_2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready
Modified OECD-Screening-Test	C.4-B	301E	ready
Manometric Respirometry	C.4-D	301F	ready
MITI-I-Test	C.4-F	301C	ready
Closed-Bottle-Test	C.4-E	301D	ready
Zahn-Wellens-test	C.9	302B	Inherent
Modified MITI-Test (II)	-	302C	Inherent
Modified SCAS-Test	C.12	302A	Inherent
Simulation Test with activated Sewage (Coupled Units-Test)	C.10	302A	Simulation Test[1)]

[1)] Test for the determination of the ultimate degradation of test material under conditions which simulate the treatment in an activated sludge plant

Table A7.1.1.2-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	Hydracarina were observed along with filamentous fungi.
Strain	Not given
Source	Fresh sludge samples were collected from sewage plants, rivers and the lake and sea
Sampling sites	In and around Chennai, Tamil Nadu, India.
Laboratory culture	No
Method of cultivation	One litre of activated sludge was aerated in an activated sludge cultivating tank for 23.5 hours. Thirty minutes after aeration, one third of supernatant was discarded and an equal volume of 0.1% synthetic-sewage with a pH value of 7.0 was added and aeration continued. This procedure was repeated once a day at a temperature of 25±2°C.
Preparation of inoculum for exposure	Basal culture medium was prepared and the pH of the solutions adjusted to 7.0 ± 0.1 before inoculation.
Pretreatment	Not given
Initial cell concentration	Inoculum was added to test vessels so that the concentration of suspended matter (100 ppm v/v) was achieved.

Table A7.1.1.2-3: Test system

Criteria	Details
Culturing apparatus	BOD test bottles
Number of culture flasks/concentration	3
Aeration device	Not given
Measuring equipment	BOD meter
Test performed in closed vessels due to significant volatility of TS	No

Table A7.1.1.2-4: Test conditions

Criteria	Details
Composition of medium	Permethrin (9 mg) was added to three test vessels containing the basal culture medium (300 ml) and activated sludge (30 mg). There were two control vessels, one contained only the basal culture medium (300 ml) and activated sludge (30 mg) and the other contained Permethrin (9 mg) and water (300 ml). The reference compound, aniline, (30 mg) was added to a vessel containing basal culture medium (300 ml) and activated sludge (30 mg).
Additional substrate	No
Test temperature	25± 2°C
pH	See nested table below
Aeration of dilution water	Not given

Bottle Contents	pH value	
	Before	After
Permethrin Technical + Deionised water	7.42	7.33
Permethrin Technical + Sludge + Basal medium	7.13	6.81
Permethrin Technical + Sludge + Basal medium	7.12	6.83
Permethrin Technical + Sludge + Basal medium	7.14	6.91
Aniline + Sludge + Basal medium	7.42	8.62
Sludge + Basal medium	7.51	7.75

Suspended solids concentration	100 ppm V/V
Other relevant criteria	Test solution was stirred

Table A7.1.1.2-5: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$		No
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test		No
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	Yes	
Percentage of removal of reference substance reaches pass level by day 14	Yes	

~~20.3.2.1~~5.3.2.1 **Criteria for poorly soluble test substances**	~~20.3.2.2~~5.3.2.2	~~20.3.2.3~~5.3.2.3
~~20.3.2.4~~5.3.2.4	~~20.3.2.5~~5.3.2.5	~~20.3.2.6~~5.3.2.6
~~20.3.2.7~~5.3.2.7	~~20.3.2.8~~5.3.2.8	~~20.3.2.9~~5.3.2.9

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Table A7.1.1.2-6: Pass levels and validity criteria for inherent biodegradability tests

	fulfilled	not fulfilled
Pass levels		
20% removal (DOC or COD);	fulfilled	
Pass values reached within 10-d window (within 28-d test period)		not fulfilled
Removal of reference substance (DOC or COD) > 70 % within 14 d	fulfilled	
Criteria for validity		
Percentage of DOC/COD-removal of reference compound ≥ 70 % within 14 days (OECD 302 B)	N/A	N/A
Percentage of DOC-removal of reference compound ≥ 40 % within 7 days and ≥ 65 % within 14 days Average residual amount of test compound in blank tests ≥ 40 % (OECD 302 C)	fulfilled	
Removal curve of DOC or COD in the test suspension indicative for biodegradation (gradual elimination over days/weeks)	fulfilled	

Criteria for poorly soluble test substances	~~20.3.2.10~~5.3.2.1	~~20.3.2.11~~5.3.2.1
	~~20.3.2.12~~5.3.2.1	~~20.3.2.13~~5.3.2.1
	~~20.3.2.14~~5.3.2.1	~~20.3.2.15~~5.3.2.1

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Section IIIA 7.1.1.2 **Annex Point XII 2.1**	**Biotic** **IIIA 7.1.1.2.3 Biodegradation in Seawater**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	It is proposed that this point is not relevant to Permethrin as according to its recommended use as a wood preservative, Permethrin will neither be used directly on nor released into marine environments. The use pattern of the product is localised and of low volume. Therefore, further study commissioning is not required to address this point.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	26 May 2009	
Evaluation of applicant's justification	The RMS considers that a study is not required based on the following justification. Uses for wood in Hazard Class 5 (salt water) are not being supported. Therefore a study on biodegradation in seawater is not required.	
Conclusion	Study is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section IIIA 7.1.2.1 Annex Point XII.2.1	**Biological sewage treatment** **IIIA 7.1.2.1.2 Anaerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	According to the 'Data requirements for biocidal product types, Version 4.3.2' (October, 2000), an anaerobic degradation study is required if exposure to anaerobic conditions is likely. Permethrin, according to its recommended use as a wood preservative, is to be applied by brushing, spraying and high-pressure injection indoors and outdoors, directly to the wood surface. The use pattern of the product is localised and of low volume. Permethrin is not to be used in veterinary hygiene products or in animal housing situations, thus release into manure storage facilities where anaerobic conditions might occur is not possible. A study therefore is not presented to address this point.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	26 May 2009	
Evaluation of applicant's justification	Applicant's justification is acceptable. Exposure to anaerobic conditions is unlikely.	
Conclusion	Anaerobic biodegradation study is not required.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

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