Section A7.1.1.1.1/01(a+b) Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

In the dossier, one hydrolysis study (A7.1.1.1.1/01) and two publications (A7.1.1.1.1/02(a+b)) on hydrolysis are described as key studies. A further hydrolysis study (Anonymous, 1995, Doc No 711-007) is only described in IUCLID under 5.1.2.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Gamet, J. C. et al. (2000): Report about abiotic degradation of peracetic acid: Hydrolysis versus pH; Biocides Development Laboratory, Bioxal, Châlon sur Saône, France; Study No.: 04/00 MPP/DP, Doc. No. 711-005 (unpublished), Section A7.1.1.1.1/01a, in IUCLID under 5.1.2. Klein, C., Goossens, S (2007): Recalculation of DT_{50} and DT_{70} for the abiotic degradation of peracetic acid on the basis of results from Gamet, J.-C. et al. (2000); Doc. No. 781-003 (unpublished), Section A7.1.1.1.1/01b, in IUCLID under 5.1.2.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	PAR	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing active substance submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, Directive 92/69/EEC, C7, corresponding to OECD-Guideline 111	
2.2	**GLP**	No	X
2.3	**Deviations**	No	X
		3 MATERIAL AND METHODS	
3.1	**Test material**	Peracetic acid 40%	
3.1.1	Batch number	Peracetic acid 40%: [redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	Colourless and clear liquid	
3.1.5	Further relevant properties	Not indicated	
3.1.6	Composition of product	[redacted]	
3.2	**Reference substance**	No	

Section A7.1.1.1.1/01(a+b) Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

3.2.1	Initial concentration of reference substance	Not applicable
3.3	**Test solution**	The following concentrations of the test substance were tested: 0.01 mol peracetic acid/L and 0.001 mol PERACETIC ACID/L). The preparation is described in table A7.1.1.1.1/01-2. Details on the buffer solutions are given in table A7.1.1.1.1/01-1.
3.4	**Testing procedure**	
3.4.1	Test system	Details are given in table A7.1.1.1.1/01-3.
3.4.2	Temperature	25.0 ± 0.5°C
3.4.3	pH	Initial pH: 4.0, 7.0, 9.0; final pH values are given in table A7.1.1.1.1/01-4.
3.4.4	Duration of the test	13 days
3.4.5	Number of replicates	One
3.4.6	Sampling	Sampling intervals are given in table A7.1.1.1.1/01-4.
3.4.7	Analytical methods	Two methods were used: • Concentrations of peracetic acid higher than 500 ppm were determined by **cerimetric analysis** (BIOXAL method 06 AP 012): Arsenous anhydride was added in excess. Arsenous anhydride which has not reacted with peracetic acid was back titrated with ceric sulphate. • Concentrations of peracetic acid lower than 500 ppm were measured by **reflectometry** with an RQ Merck apparatus (reading of Reflectoquant 1.169750001 strips reacting with peracetic acid in the concentration range of 1 - 22.5 mg/L).
3.5	**Preliminary test**	No
		4 RESULTS
4.1	**Concentration and hydrolysis values**	Results are presented in Table A7.1.1.1.1/01-4.
4.2	**Hydrolysis rate constant (k_h)**	Hydrolysis rate constants are presented in table A7.1.1.1.1/01-5.
4.3	**Dissipation time**	Dissipation times of peracetic acid (DT_{50} and DT_{70}) are presented in Table A7.1.1.1.1/01-5.

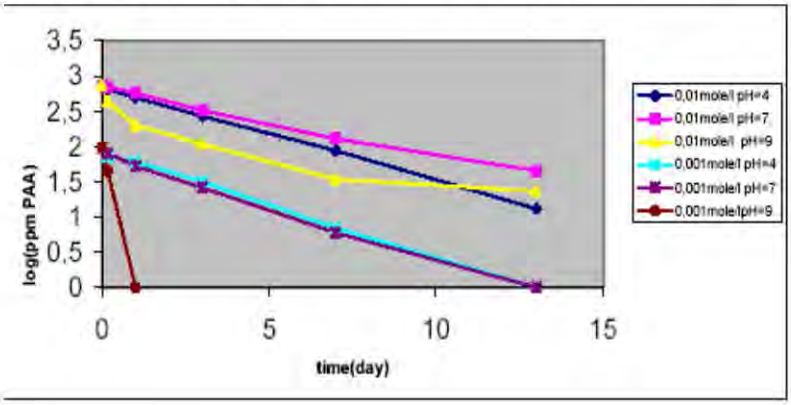
Section A7.1.1.1.1/01(a+b) Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

4.4 Concentration – time data

Results are presented in Table A7.1.1.1.1/01-4.

The graph log (conc. peracetic acid) versus time is given as follows:



4.5 Specification of the transformation products

Not indicated.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to test method C.7, Directive 92/69/EEC.

Peracetic acid was dissolved in buffer solutions of pH 4, 7 and 9 at 25°C.

5.2 Results and discussion

In the study report, the DT_{50} and DT_{70} values were calculated assuming a pseudo first-order kinetics: X

- For the high initial peracetic acid concentration of 748 ppm, the calculated DT_{70} values were very similar for the 3 pH values tested: 107 hours for pH 4, 109 hours for pH 7, and 112 hours for pH 9. The DT_{50}-values were determined to be 62 hours for pH 4, 63 hours for pH 7 and and 64 hours for pH 9.
- For the low initial peracetic acid concentration of 95 ppm, the calculated DT_{70} values for pH 4 and pH 7 were in both cases 84 hours, while for pH 9, a DT_{70} of only 6.3 hours was calculated. The DT_{50}-values for this concentration were determined to be 48 hours for pH 4 and 7 and 3.6 hours for pH 9.

The fact that the graphed logs (concentration of peracetic acid versus time) showed no linearity, indicates that the degradation of peracetic acid does not follow a pseudo first order kinetics. This can be explained by the fact that the abiotic degradation of peracetic acid is caused by hydrolysis (resulting in acetic acid and hydrogen peroxide) and by spontaneous decomposition (resulting in acetic acid and oxygen). As in this study only the decrease of peracetic acid-concentrations was measured, no distinction was made between the two pathways.

Nevertheless, the DT_{50} and DT_{70} values were recalculated for the present dossier using the First Order Multi-Compartment model of the ModelMaker Version 4.0. The results of the recalculation are included in table A7.1.1.1.1/01-5, in addition to the results presented in the study

Section A7.1.1.1.1/01(a+b)	**Hydrolysis as a function of pH and identification of breakdown products**	
Annex Point IIA, VII.7.6.2.1		
	report. • For the high initial peracetic acid concentration of 748 ppm, the DT_{70} values were recalculated to be: 84.6 hours for pH 4, 110.1 hours for pH 7, and 17.5 hours for pH 9. The DT_{50} values were recalculated to be 45.7 hours for pH 4, 60.3 hours for pH 7 and 6.3 hours for pH 9. • For the low initial peracetic acid concentration of 95 ppm, the DT_{70} values were recalculated to be: 82.8 hours for pH 4 and 61.0 for pH 7. The DT_{50}-values for this concentration were recalculated to be 46.7 hours for pH 4 and 31.7 hours for pH 7. Due to insufficient data points no recalculation was performed for pH 9. While for pH 4 a slightly worse fit of the curve (r^2) than in the report was found, the r^2 values for pH 7 and 9 were higher than those in the report. This is especially true for pH 9. At this pH, the recalculated DT_{50} and DT_{70} values were considerably lower than those calculated in the study report. They indicate that at this pH, hydrolysis is considerably faster than at pH 4 and 7. This could be shown by the recalculation for the high initial concentration of 748 ppm, whereas for the low initial concentration of 95 ppm, no recalculation was performed because of insufficient number of data points. Nevertheless, it seems to be justified to conclude that degradation is faster at high pH 9. This is in line with the findings of the second hydrolysis study (non-key study, described in IUCLID point 3.1.2: Anonymous, 1995, Doc No 711-007), which shows that the degradation rate increased with increasing pH.	
5.2.1 k_H	Please refer to table A7.1.1.1.1/01-5.	
5.2.2 DT_{50} and DT_{70}	Please refer to table A7.1.1.1.1/01-5.	
5.2.3 r^2	Please refer to table A7.1.1.1.1/01-5.	
5.3 Conclusion	The study indicates that decomposition is faster at low concentrations and high pH values.	X
5.3.1 Reliability	2	
5.3.2 Deficiencies	The formation of degradation products was not investigated. Nevertheless, the study can be regarded to be acceptable to predict the hydrolysis rate constant and dissipation times of peracetic acid.	

Section A7.1.1.1.1/01(a+b) Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
	[redacted]
Results and discussion	[redacted]
	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Study is considered acceptable [redacted]
Remarks	[redacted]
	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.1.1.1.1/01(a+b) Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

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 A7.1.1.1.1/01-1: Type and composition of buffer solutions

pH	Type of buffer	Composition
4	citric acid	Titrisol Merck (composition not indicated)
7	phosphate	Titrisol Merck (composition not indicated)
9	boric acid	Titrisol Merck (composition not indicated)

Table A7.1.1.1.1/01-2: Description of test solution

Criteria	Details
Purity of water	Sterile distilled water; no further information is given.
Preparation of test medium	Dilution of 2.0150 g peracetic acid 40% in 100 mL water to obtain a solution with 0.76%. Then dilution in the buffers in order to obtain the test concentrations.
Test concentrations	748 ppm peracetic acid (approx. 0.01 mole peracetic acid/L) 95 ppm peracetic acid (approx. 0.001 mole peracetic acid/L)
Temperature (°C)	25.0 ± 0.5°C
Controls	Not indicated
Identity and concentration of co-solvent	Not applicable
Replicates	One replicate

Table A7.1.1.1.1/01-3: Description of test system

Glassware	Graduated flasks
Other equipment	Thermostated bath to maintain temperature at 25.0 ± 0.5°C Thermometer ± 0.1°C
Method of sterilization	Not indicated

Table A7.1.1.1.1/01-4: Hydrolysis of test compound at pH 4, 7 and 9

Test with 0.01 mol peracetic acid/L

	t_0		t=4h	t=24h	t=72h	t=7 days	t=13 days	
	ppm peracetic acid	pH	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	pH
Buffer pH 4.0	748	3.94	657	493	270	88	13	3.98
Buffer pH 7.0	748	6.93	706	567	326	129	45	6.03
Buffer pH 9.0	748	8.94	437	201	108	34	23	5.25

Test with 0.001 mol peracetic acid/L

	t_0		t=4h	t=24h	t=72h	t=7 days	t=13 days	
	ppm peracetic acid	pH	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	ppm peracetic acid	pH
Buffer pH 4.0	95	3.94	71	61	32	7	1	3.98
Buffer pH 7.0	95	6.93	80	53	26	6	<1	6.86
Buffer pH 9.0	95	8.94	45	<1	/	/	/	/

Table A7.1.1.1.1/01-5: Hydrolysis rate constants and dissipation times (DT_{50} and DT_{70}) of peracetic acid at pH 4, 7 and 9 (given in hours)

	pH 4				**pH 7**				**pH 9**			
	r^2	k_{obs}	DT_{50}	DT_{70}	r^2	k_{obs}	DT_{50}	DT_{70}	r^2	k_{obs}	DT_{50}	DT_{70}
Calculated assuming pseudo-first-order kinetics												
748 ppm (approx. 0.01 M)	0.9990	0.270	62	107	0.9986	0.265	63	109	0.8390	0.258	64	112
95 ppm (approx. 0.001 M)	0.9974	0.345	48	84	0.9944	0.345	48	84	0.9998	0.456	3.6	6.3
Calculated by non-linear regression (first order multi-compartment model from 'Model Maker')												
748 ppm (approx. 0.01 M)	0.9980	n.a.	45.7	84.6	0.9997	n.a.	60.3	110.1	0.9973	n.a.	6.3	17.5
95 ppm (approx. 0.001 M)	0.9730	n.a.	46.7	82.8	0.996	n.a.	31.7	61.0	Calculation was not appropriate because of insufficient data points.			

Section A7.1.1.1.1/02(a+b) Hydrolysis and spontaneous decomposition as a function of pH

Annex Point IIA, VII.7.6.2.1

Two studies, one on the alkaline hydrolysis of PAA and one on the spontaneous decomposition are summarised in the following.

Two other hydrolysis studies are available, one is described in Section A7.1.1.1.1/01(a+b) (key study) and one is described in IUCLID (Anonymous, 1995, Doc No 711-007) , in IUCLID under 5.1.2..

The standard structure of the template for this section point is not suitable to describe the publications. Therefore, and for reasons of better readability, the template was adapted.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Yuan, Z. et al. (1997): Kinetics of Peracetic decomposition Part I: Spontaneous decomposition at Typical Pulp Bleaching Conditions, The Canadian Journal of Chemical Engineering, Volume 75: 37-41, Doc. No. 792-012 (published), Section A7.1.1.1.1/02a, in IUCLID under 5.1.2. Yuan, Z. et al. (1997): Kinetics of the Peracetic decomposition Part II: pH Effect and Alkaline Hydrolysis, The Canadian Journal of Chemical Engineering, Volume 75: 42- 47, Doc. No. 792-013 (published), Section A7.1.1.1.1/02b, in IUCLID under 5.1.2.	
1.2	**Data protection**	No, studies are publications	
1.2.1	Data owner	Not applicable	
1.2.2	Companies with letter of access	Not applicable	
1.2.3	Criteria for data protection	Not applicable	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No.	
2.2	**GLP**	No	
2.3	**Deviations**	Not applicable	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Further relevant properties	[redacted]	

Section A7.1.1.1.1/02(a+b) Hydrolysis and spontaneous decomposition as a function of pH

Annex Point IIA, VII.7.6.2.1

3.1.6	Composition of product	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted]
3.3	**Test solution**	[redacted]
3.4	**Testing procedure**	[redacted]
3.4.1	Test system	[redacted]
3.4.2	Temperature	[redacted]
3.4.3	pH	[redacted]
3.4.4	Duration of the tests	[redacted]
3.4.5	Number of replicates	[redacted]
3.4.6	Sampling	[redacted]
3.4.7	Analytical methods	[redacted]

4 RESULTS

[redacted]

Section A7.1.1.1.1/02(a+b)

Hydrolysis and spontaneous decomposition as a function of pH

Annex Point IIA, VII.7.6.2.1

[redacted]

Section A7.1.1.1.1/02(a+b) **Hydrolysis and spontaneous decomposition as a function of pH**

Annex Point IIA, VII.7.6.2.1

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Conclusion

[redacted]

5.2.1 Reliability

[redacted]

5.2.2 Deficiencies

[redacted]

Section A7.1.1.1.1/02(a+b) Hydrolysis and spontaneous decomposition as a function of pH

Annex Point IIA, VII.7.6.2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable.
Remarks	[redacted]
	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 A7.1.1.1.1/02/03-1: [redacted]

[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	
[redacted]		[redacted]	

[redacted]

Table A7.1.1.1.1/02/03-2: [redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Section A7.1.1.1.2 **Annex Point IIA, VII.7.6.2.2**	**Phototransformation in water including identity of transformation products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Acceptable. [redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Three reports on ready biodegradation are available for peracetic acid. Two have been selected as key studies, one of which is described in the following, and one in section A7.1.1.2.1/02. The non-key report (publication) (Gerike, 1990, Doc. No. 792-006) is described in IUCLID, point 5.2.1.

In addition to these documents, which deal exclusively with biodegradation, an additional study is available (De Groot, 2001, Activated sludge, respiration inhibition with peracetic acid, Doc. No. 842-002, section A7.4.1.4./02) which also provides valid information on the degradation of peracetic acid in activated sludge medium. The information on degradation described in this study are used as the basis for the environmental risk assessment (endpoint for the degradation of peracetic acid in STP).

			Official use only
		1 REFERENCE	
1.1	**Reference**	Richterich, K.; Gode, P. (1986): Abbauprüfung toxischer Stoffe: Vermeidung störender toxischer Selbsthemmung durch gestufte Prüfmusterzugabe (AT-Test); TFB-Ökologie, Henkel, Düsseldorf, Germany; Study No.: 1986/2418, Doc. No. 713-002 (unpublished) This study deals with the biodegradation of several substances, of which one is peracetic acid. The results concerning peracetic acid were summarised in 2002 in: Steber, J.; Berger, (2002): Aerobic Biodegradation: Modified OECD Screening Test; Biological Research and Product Safety/Ecology, Henkel KGaA, Düsseldorf, Germany; Test Run No.: 458, 1986, Doc. No. 713-004 (unpublished). In the following, both publications (Richterich and Gode, 1986, as well as Steber and Berger, 2002) are considered.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	PAR	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing active substance submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 301 E (version adopted 1981)	
2.2	**GLP**	No, GLP was not compulsory at the time the study was performed.	
2.3	**Deviations**	Yes, in order to avoid inhibition effects towards the micro-organisms, the test substance was added stepwise until the required concentration (of 5 mg C/L) was reached after 2 weeks. The test was performed at a temperature of 25 ± 1°C, while in the guideline 22 ± 2C are requested. The test period was 35 days. Samples were taken on day 14, 21, 28 and 35.	X

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		3 MATERIAL AND METHODS	
3.1	**Test material**	Peracetic acid (40%)	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	No information provided	
3.1.5	Further relevant properties	No information given	
3.1.6	Composition of Product	[redacted]	
3.1.7	TS inhibitory to micro-organisms	The test conducted according to the standard procedure revealed strong inhibition of the degrading organisms: poor degradation of a well biodegradable reference substance (fatty alcohol ethoxylate) was observed in the presence of the test substance. However, a modification of the test procedure, i.e. stepwise addition of the test substance until the required test concentration was reached within two weeks, showed that the test substance is readily biodegradable.	X
3.1.8	Specific chemical analysis	No	
3.2	**Reference substance**	Yes, fatty alcohol ethoxylate (FA-8 EO)	
3.2.1	Initial concentration of reference substance	1:1 with test substance	
3.3	**Testing procedure**		
3.3.1	Inoculum / test species	Details on inoculum are summarised in table A7.1.1.2/01-1.	
3.3.2	Test system	Details on test system, laboratory equipment, etc. are given in table A7.1.1.2/01-2.	
3.3.3	Test conditions	Details on the relevant test conditions are given in table A7.1.1.2/01-3.	

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

3.3.4 Method of preparation of test solution

An aliquot of the test substance corresponding to 5 mg organic C was pipetted from a stock solution and filled up to 200 ml with deionised water. This sample contained the complete test amount to be added to the test preparation and was dosed into an incubation container (2 l Erlenmayer flask) filled with 800 ml inoculated mineral medium (acc. to the OECD guideline) as follows:

Day	Inoculated mineral medium [ml]	Test sample solution [ml]	Test sample solution [mg organic C]
0	800	5	0.125
3	---	10	0.250
5	---	15	0.375
7	---	25	0.625
10	---	40	1.000
12	---	50	1.250
14	---	55	1.375
Sum:	800	200	5.000

3.3.5 Initial TS concentration

15.8 mg peracetic acid/L, corresponding to 5 mg organic C/L (nominal concentration)

The total amount of 15.8 mg/L was applied over a two-week period by stepwise adding the test substance.

3.3.6 Duration of test

28 days: the routine-test and toxicity control according to the guideline

35 days: the modified test (adding the test substance stepwise until the required concentration)

3.3.7 Analytical parameter

Dissolved organic carbon (DOC) and total organic carbon (TOC)

3.3.8 Sampling

After 14, 21, 28 and 35 days

3.3.9 Intermediates/ degradation products

Not investigated

3.3.10 Nitrate/nitrite measurement

No

3.3.11 Controls

Yes, inoculum blank (containing inoculum, but no test substance) and toxicity control (containing inoculum and equal amounts of reference and test substance)

3.3.12 Statistics

The degree of biodegradation was calculated by expressing the concentration of the DOC removed (corrected for the DOC removed in the blank inoculum control) as a percentage of the nominal concentration of the test substance.

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	Not provided in the report
4.1.2	Degradation	In a routine-test performed over a period of 28 days without modification of the guideline procedure (i.e. by adding the whole amount of test substance at once at the beginning of the test), the toxic effect of peracetic acid towards the micro-organisms affected the results. For this reason, only 48% DOC removal (27% TOC removal) after 28 days was obtained. In a second test, the toxicity of peracetic acid towards micro-organisms was taken into account. The second test was performed with stepwise addition of peracetic acid. The following results were obtained: After 14 days: 78% DOC removal / 58% TOC removal After 21 days: 66% DOC removal / 44% TOC removal After 28 days: 98% DOC removal / 75% TOC removal After 35 days: 96% DOC removal / 81% TOC removal
4.1.3	Other observations	In toxicity controls (administration of the reference substance fatty alcohol ethoxylate, which is known to be readily biodegradable, and peracetic acid at a 1:1 ratio), it was found that the degradation of the reference substance was retarded. This retardation effect declined continuously during the test and disappeared completely towards the end of the test (on day 28).
4.1.4	Degradation of TS in abiotic control	Not performed
4.1.5	Degradation of reference substance	No details are given.
4.1.6	Intermediates/ degradation products	Not investigated.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Modified OECD Screening Test according to OECD Guideline 301 E with • Administration of the test substance peracetic acid at day 0 (duration 28 days) • Administration of the test substance peracetic acid in a stepwise manner (duration of test 35 days)
5.2	**Results and discussion**	When the whole amount of the test substance peracetic acid was applied at day 0, inhibition of the micro-organisms occurred, resulting in a low degradation rates of the test and reference substance. X Therefore, the test procedure was modified: the test substance was applied gradually over a two-week period until the whole amount of 15.8 mg peracetic acid/L, corresponding to 5 mg organic C/L (nominal

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		concentration) had been applied. Under these conditions, 98% of DOC removal was obtained after 28 days and peracetic acid was shown to be ready biodegradable.	
5.3	**Conclusion**	As summarised in table A7.1.1.2./01-4, the pass levels were reached. No information, however, is provided on the other two validity criteria. Peracetic acid can be regarded to be readily biodegradable when applied at concentrations which are not inhibitory to micro-organisms.	X
5.3.1	Reliability	2	
5.3.2	Deficiencies	No abiotic control was included.	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Results and discussion [redacted]

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]
Remarks	[redacted]

	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*

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.1.1.2/01/02-1: Inoculum / Test organism

Criteria	Details
Nature	Effluent of a municipal sewage treatment plant
Species	Not specified
Strain	Not applicable
Source	Not reported
Sampling site	Not reported
Laboratory culture	No
Method of cultivation	Not reported
Preparation of inoculum for exposure	Not described
Pre-treatment	Not mentioned
Initial cell concentration	Not given

Table A7.1.1.2/01/02-2: Test system

Criteria	Details
Culturing apparatus	Shaking machine
Number of culture flasks/concentration	Not described
Aeration device	Not mentioned
Measuring equipment	Not described
Test performed in closed vessels due to significant volatility of TS	Not applicable

Table A7.1.1.2/01/02-3: Test conditions

Criteria	Details
Composition of medium [g/L]	According to the guideline
Additional substrate	Not mentioned

Test temperature	25 ± 1°C
PH	Not given
Aeration of dilution water	Not mentioned
Suspended solids concentration	Not given
Other relevant criteria	Not given

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Table A7.1.1.2/01/02-4: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC	x	
Pass values reached within 10-d window (within 28-d test period)	x	
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%	Not reported	
Percentage of removal of reference substance reaches pass level by day 14.	Not reported	

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Three studies on ready biodegradation are available for peracetic acid. Two have been selected as key studies, one of which is described in the following, and one in section A7.1.1.2.1/01. The non-key report (publication) (Gerike, 1990, Doc. No. 792-006) is described in IUCLID, point 5.2.1..

In addition to these documents, which deal exclusively with biodegradation, an additional study is available (De Groot, 2001, Activated sludge, respiration inhibition with peracetic acid, Doc. No. 842-002, section A7.4.1.4./02) which also provides valid information on the degradation of peracetic acid in activated sludge medium. The information on degradation described in this study are used as the basis for the environmental risk assessment (endpoint for the degradation of peracetic acid in STP).

Official use only

1 REFERENCE

1.1	**Reference**	L´Haridon, J. (2003): Determination of Ready Biodegradability - Closed Bottle Test; CIT, Evreux, France , Study No.: 23246 ECS, Date of report: 01 September 2003, Doc. No. 713-005 (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	PAR
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing active substance submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, Commission Directive 92/69/EEC(C.4-E), Directive 93/21/EEC and OECD guideline 301 D
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	Acide peracetique 5% [redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	Colourless liquid
3.1.5	Further relevant properties	No further information is provided in the study.
3.1.6	Composition of Product	[redacted]

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		[redacted]
3.1.7	TS inhibitory to micro-organisms	Yes: the biodegradation in the toxicity control was 32% after 14 days and 49% after 28 days. These results show a slight toxic effect of peracetic acid towards the used micro-organisms.
3.1.8	Specific chemical analysis	No
3.2	**Reference substance**	Sodium acetate
3.2.1	Initial concentration of reference substance	3 mg/L
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Details on inoculum are summarised in table A7.1.1.2/01-1.
3.3.2	Test system	Details on test system, laboratory equipment, etc. are given in table A7.1.1.2/01-2.
3.3.3	Test conditions	Details on the relevant test conditions are given in table A7.1.1.2/01-3.
3.3.4	Method of preparation of test solution	Direct administration of test substance to culture medium.
3.3.5	Initial TS concentration	15 mg [redacted]L corresponding to 0.78 mg peracetic acid/L
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	Biological oxygen demand (BOD)
3.3.8	Sampling	The dissolved oxygen was measured on days 0, 3, 7, 10, 14, 17, 21, 24 and 28.
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Inoculum control: inoculum, but no test substance Procedure control: inoculum with reference substance Toxicity control: inoculum with test substance and reference substance
3.3.12	Statistics	Calculations were made according to the OECD-guideline: the % biodegradation values were calculated by dividing the specific BOD values by the specific ThOD values x 100. It was assumed that: - the BOD of a given test item replicate can only increase or remain constant between two consecutive measurement days.

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

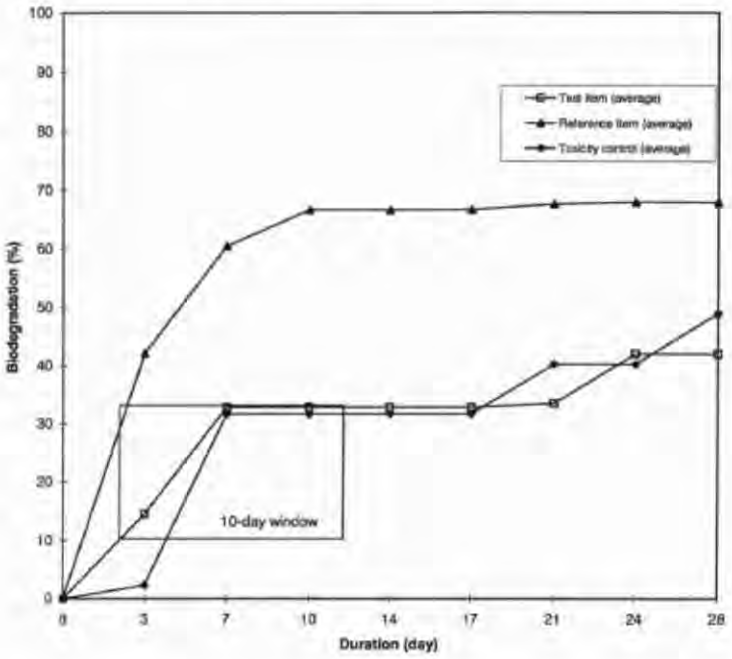
- to determine the percentage of biodegradation, the total BOD of a test or reference item replicate (or that of a control replicate) cannot be lower than the total BOD of the inoculum blank (average of the two replicates) at any time of the test.

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

Graph of percent biodegradation reached on each measurement day:



4.1.2 Degradation

The 10-day window started on the 1st day. The biodegradation of the test item [redacted] was determined to be 33% (mean of two replicates) at the end of the 10-day window (11th day) and 42% at the end of the test (day 28).

4.1.3 Other observations

The biodegradation in the toxicity control was 32% after 14 days and 49% after 28 days. These results show a slight toxic effect towards the used micro-organisms.

4.1.4 Degradation of TS in abiotic control

Not performed

4.1.5 Degradation of reference substance

The biodegradation of the reference substance reached 67% of the ThOD within 14 days.

4.1.6 Intermediates/ degradation products

Not investigated

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	A Closed Bottle Test was conducted over a period of 28 days according to OECD Guideline 301 D and Commission Directive 92/69/EEC (C.4 E).	
5.2	**Results and discussion**	The biodegradation of the test item [redacted] was determined to be 33% (mean of two replicates) at the end of the 10-day window (11th day) and 42% at the end of the test (day 28). Consequently, the test item cannot be regarded as ready biodegradable under the conditions of the test. This result is in conflict with the result of the other key study on ready biodegradation (Doc. IIIA-7.1.1.2.1/01), in which ready biodegradability could be shown at concentrations which are not toxic to the degrading micro-organisms. In the present test, a slight toxic effect towards the used micro-organisms was found. This explains the result (non ready biodegradable) of the test.	
5.3	**Conclusion**	According to table A7.1.1.2/02-4, the only validity criteria which was not fulfilled was the deviation of the biodegradation values of the test item replicates. The deviation was above 20%. at the end of the 10-day window and at the end of the test. It is reasoned by the study director that this does not question the validity of this study. The result of the study (not ready biodegradable) can be explained by the slight toxic effects of the test item towards the degrading bacteria.	X
5.3.1	Reliability	2	X
5.3.2	Deficiencies	The abiotic degradation of the test substance was not determined.	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Acceptability	Non acceptable. [redacted]
Remarks	

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

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Table A7.1.1.2/02-1: Inoculum / Test organism

Criteria	Details
Nature	Secondary effluent
Species	Not specified
Strain	Not applicable
Source	Water treatment plant, receiving sewage from a predominantly domestic origin
Sampling site	Evreux, France
Laboratory culture	No
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Initially removing the biggest particles and sieving across a filter paper (porosity 4-7 µm)
Pre-treatment	No preconditioning was made.
Initial cell concentration	Approx. 80 x 10^4 bacteria/mL

Table A7.1.1.2/02-2: Test system

Criteria	Details
Culturing apparatus	BOD flasks (dark glass bottles, filled to the brim and fitted with bungs)
Number of culture flasks/concentration	2 containing the inoculum (inoculum blank) 2 containing the test item (15 mg/L) and inoculum 2 containing the reference substance (3 mg/L) and inoculum (procedure control) 2 containing the test item (15 mg/L), the reference substance (3 mg/L) and inoculum (toxicity control)
Aeration device	Not given
Measuring equipment	Not given
Test performed in closed vessels due to significant volatility of TS	The test was performed in closed flasks.

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Table A7.1.1.2/02-3: Test conditions

Criteria	Details
Composition of medium [g/L]	According to the OECD-guideline
Additional substrate	No
Test temperature	20 - 24°C
PH	7.57 measured in the mineral medium before the start of the test
Aeration of dilution water	The mineral medium was aerated for at least 20 minutes, 20 to 24 hours prior to the start of the test.
Suspended solids concentration	A concentration of approx. 10^4 bacteria/L was prepared in each test flask.
Other relevant citeria	Not indicated

Table A7.1.1.2/02-4: 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 $ThCO_2$		x
Pass values reached within 10-d window (within 28-d test period) - 14-d window acceptable for Closed-Bottle-Test		x
Criteria for validity		
Dissolved oxygen depletion in the inoculum blank not to exceed 1.5 mg/L after 28 days	x	
Dissolved oxygen ≥ 0.5 mg/L in all test suspension replicates during the test	x	
the biodegradation in the toxicity control > 25% within 14 days.	x	
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%		x
Percentage of removal of reference substance reaches pass level by day 14	x	

Section A7.1.1.2.2 Annex Point IIA, VII.7.6.1.2	Biodegradability (inherent)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [...]	
Detailed justification:	[redacted]	X
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	May 6, 2008	
Evaluation of applicant's justification	[redacted]	
Conclusion	Justification is acceptable [redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	*Give date of Comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

The study described in the following investigates the decomposition of peracetic acid in synthetic seawater. The degradation found can be attributed to the salinity of the test water, and not to the presence of micro-organisms (most likely not present in the test water). Consequently, the test in not a **bio**-degradation test.

Official use only

1 REFERENCE

1.1	**Reference**	Kuhn, F. (2000): Decomposition of peracetic acid in synthetic seawater, Degussa-Hüls AG, Hanau, Germany, Study No.: 69/00; Doc. No. 711-006 (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	PAR
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing active substance submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	No
2.3	**Deviations**	Not applicable

3 MATERIAL AND METHODS

3.1	**Test material**	Product named [redacted], containing 15% peracetic acid
3.1.1	Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	No details provided in the report
3.1.5	Further relevant properties	Not indicated
3.1.6	Composition of product	[redacted]
3.2	**Reference substance**	No
3.2.1	Initial concentration of reference substance	Not applicable

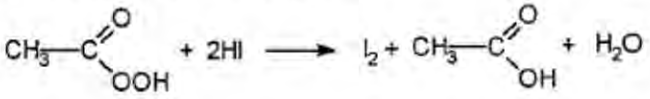
Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

3.3	**Test solution**	The following concentrations of the test substance were tested: 350 ppm product corresponding to 52.5 mg peracetic acid/L 700 ppm product corresponding to 105 mg peracetic acid/L The test was performed in synthetic sea water at 2.0 and 3.3% (w/w) salinity. More details are given in tables A7.1.1.2.3/01-1 and A7.1.1.2.3/01-2.
3.4	**Testing procedure**	
3.4.1	Test system	Details are given in table A7.1.1.2.3/01-3.
3.4.2	Temperature	Room temperature
3.4.3	pH	Initial and final pH values are given in table A7.1.1.2.3/01-4.
3.4.4	Duration of the test	85 minutes
3.4.5	Number of replicates	One
3.4.6	Sampling	Sampling intervals are given in table A7.1.1.2.3/01-5.
3.4.7	Analytical methods	**Determination of hydrogen peroxide** The hydrogen peroxide content was determined by an oxidation reduction titration with ceric sulphate according to equation 1. **Determination of peracetic acid** After the endpoint of this titration has been reached, an excess of potassium iodide was added to the solution. The hydroiodic acid formed in acidic media reacts with peracetic acid to liberate iodine, according to equations 2. A standard solution of sodium thiosulfate was used to titrate the liberated Iodine, as shown in equation 3. The endpoint of this titration was used to calculate the peracetic acid content.

1. $H_2O_2 + 2\ Ce(SO_4)_2 \rightarrow Ce_2(SO_4)_3 + H_2SO_4 + O_2$

2. $2\ KI + H_2SO_4 \rightarrow 2\ HI + K_2SO_4$



3. $I_2 + 2\ S_2O_3^{2-} \rightarrow S_4O_6^{2-} + 2\ I^-$

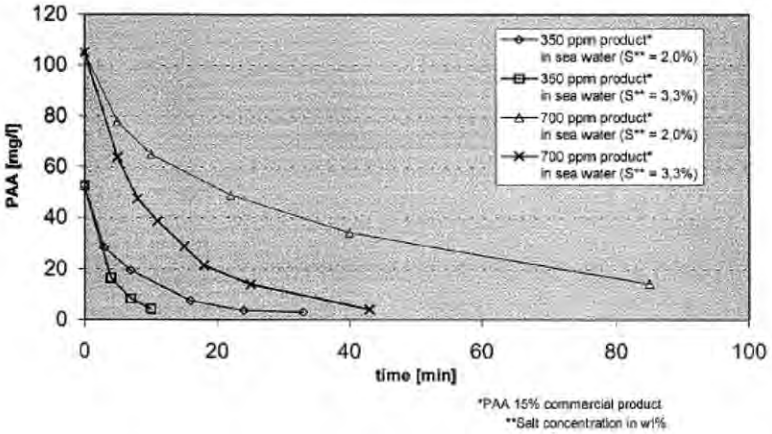
3.5	**Preliminary test**	No

4 RESULTS

4.1	**Concentration values**	Results are presented in table A7.1.1.2.3/01-5.
4.2	**Half life**	The half lives of peracetic acid are presented in table A7.1.1.2.3/01-5.

Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

4.3	**Concentration – time data**	Results are presented in Table A7.1.1.2.3 /01-5. The graph "concentration of peracetic acid versus time" is given as follows:  	
4.5	**Specification of the transformation products**	Not indicated	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The half life of peracetic acid at two different concentrations was analytically determined in synthetic seawater with 2 and 3.3% (w/w) salinity.	
5.2	**Results and discussion**	When applied at an initial concentration of 52.5 mg peracetic acid/L, the half-life was 2 minutes, irrespective of the salinity. At 105 mg peracetic acid/L, the half-lives were 7 and 20 minutes at 3.3 and 2% (w/w) salinity, respectively.	
5.3	**Conclusion**	The results of the test indicate fast decomposition of peracetic acid in seawater. This may be explained by the high pH of the seawater. Increased salinity of the water resulted in enhanced decomposition. Higher initial peracetic acid concentrations resulted in reduced degradation. These observations can be explained as pH effects.	X
5.3.1	Reliability	2	
5.3.2	Deficiencies	Not applicable because no guideline study	

Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

Table A7.1.1.2.3/01-1: Type and composition of synthetic sea water

Salinity of 2.0%	50.0 g of sea salt (Fa. Sera, D-Heinsberg) were dissolved in 2.5 litre of water, stirred for 20 hours and filtrated.	
Salinity of 3.3%	82.5 g of sea salt (Fa. Sera, D-Heinsberg) were dissolved in 2.5 litre of water, stirred for 20 hours and filtrated.	

Table A7.1.1.2.3/01-2: Description of test solution

Criteria	Details
Purity of water	The test substance was added directly to the synthetic sea water.
Preparation of test medium	350 µl / 700 µl of the test substance were added to 1 litre of synthetic seawater.
Test concentrations (mg peracetic acid/L)	350 ppm TS corresponding to 52.5 mg peracetic acid/L 700 ppm TS corresponding to 105 mg peracetic acid/L
Temperature (°C)	Room temperature
Controls	Not indicated
Identity and concentration of co-solvent	Not applicable
Replicates	One replicate

Table A7.1.1.2.3/01-3: Description of test system

Glassware	2-litre beakers
Other equipment	Not indicated; permanent stirring during the test
Method of sterilization	Not applicable

Table A7.1.1.2.3/01-4: pH-values of seawater samples

	350 ppm product salinity 2.0%	350 ppm product salinity 3.3%	700 ppm product salinity 2.0%	700 ppm product salinity 3.3%
pH after addition of peracetic acid	7.32	7.33	6.47	6.80
pH at the end of the test	6.97	7.24	5.82	6.11

Section A7.1.1.2.3/01 Biodegradation in seawater

Annex Point IIIA, XII.2.1

Table A7.1.1.2.3/01-5: Decomposition of peracetic acid in synthetic seawater

Reaction time [min]	350 ppm product in sea water (salinity=2.0%)		350 ppm product in sea water (salinity=3.3%)		700 ppm product in sea water (salinity=2.0%)		700 ppm product in sea water (salinity=3.3%)	
	peracetic acid [mg/L]	H_2O_2 [mg/L]	peracetic acid [mg/L]	H_2O_2 [mg/L]	peracetic acid [mg/L]	H_2O_2 [mg/L]	peracetic acid [mg/L]	H_2O_2 [mg/L]
0	52.5	77.9	52.5	77.9	105	156	105	156
3	28.2	70.1	-	-	-	-	-	-
4	-	-	16.5	67.5	-	-	-	-
5	-	-	-	-	77.8	143	63.8	140
7	19.2	66.1	8.3	63.8	-	-	-	-
8	-	-	-	-	-	-	47.5	135
10	-	-	4.4	62.5	65.3	139	-	-
11	-	-	-	-	-	-	38.8	131
15	-	-	-	-	-	-	28.8	128
16	7.3	62.7	-	-	-	-	-	-
18	-	-	-	-	-	-	21.3	125
22	-	-	-	-	49.4	132	-	-
24	3.5	61.0	-	-	-	-	-	-
25	-	-	-	-	-	-	13.8	122
33	2.8	60.2	-	-	-	-	-	-
40	-	-	-	-	33.7	125	-	-
43	-	-	-	-	-	-	4	118
85	-	-	-	-	14.5	116	-	-
$t_{1/2}$ [min]	2	n.d.*	2	n.d.*	20	n.d.*	7	n.d.*

n.d. = not determined

Section A7.1.2.1.1/01 Aerobic biodegradation: Degradation in the effluent from an STP

Annex Point IIIA, XI.-2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Van Egdom, T. R. (2007): Evaluation of the Degradation of Peracetic acid and Hydrogen peroxide in Effluent from a Waste Water Treatment Plant; Solvay Pharmaceuticals, Weesp, The Netherlands, Study No.: E.SOL.S.025, Date of report: June 2007, Doc. No. 714-001 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	PAR	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing active substance submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	The study was not performed according to a standard guideline. It was designed to investigate a specific, non-standard question, i.e. the degradation of peracetic acid in effluent water, for which no guideline exists.	
2.2	**GLP**	Yes	
2.3	**Deviations**	Not applicable	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	Clear colourless liquid	
3.1.5	Further relevant properties	No further information is provided in the study.	
3.1.6	Composition of Product	[redacted]	
3.1.7	TS inhibitory to microorganisms	Yes, the EC_{50} in two respiration inhibition tests (section A7.4.1.4/01 and 02) was determined to be 38.6 mg peracetic acid/L and 5.1 mg peracetic acid/L, respectively.	
3.1.8	Specific chemical analysis	Not given in the study	
3.2	**Reference**	No	

Section A7.1.2.1.1/01 Aerobic biodegradation: Degradation in the effluent from an STP

Annex Point IIIA, XI.-2.1

	substance	
3.2.1	Initial concentration of reference substance	Not applicable
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Details on inoculum are summarised in table A7.1.2.1.1/01-1.
3.3.2	Test system	Details on test system, laboratory equipment, etc. are given in table A7.1.2.1.1/01-2.
3.3.3	Test conditions	Details on the relevant test conditions are given in table A7.1.2.1.1/01-3.
3.3.4	Method of preparation of test solution	Test solutions were prepared by dilution according to the scheme presented in table A7.1.2.1.1/01-2.
3.3.5	Initial TS concentration	[redacted] was applied at a concentration which corresponded to 2 mg peracetic acid/L and 3.2 mg H_2O_2/L.
3.3.6	Duration of test	240 minutes (4 hours)
3.3.7	Analytical parameter	Degradation of peracetic acid and hydrogen peroxide
3.3.8	Sampling	Concentration of peracetic acid was measured at 0, 5, 15, 30, 60, 120 and 240 minutes. Concentration of H_2O_2 was measured at 0, 15, 30, 60, 120, 180 and 240 minutes.
3.3.9	Analytical methods	**Peracetic acid**: The concentration of peracetic acid in the test solutions was determined by reversed phase HPLC using UV detection. The method is based on the oxidation of methyl-p-tolylsulfide (MTS), resulting in the formation of methyl-p-tolylsulfoxide (MTSO), which is known to be stable in solution for several days. The samples were stored in a refrigerator on the day of preparation and analysed within two days of sampling. The correlation coefficient (r^2) of the linearity curve was > 0.99. It can be concluded that the method is linear between 0.2-20 mg/L MTSO, corresponding to 0.1-10 mg/L peracetic acid. The LOQ was indicated as 0.1 mg peracetic acid/L. **H_2O_2**: H_2O_2 was determined spectrophotometrically after enzymatic reduction of H_2O_2 with peroxidase in the presence of 4-amino-antipyrine and phenol. The formed red 4-(benzoquinone mono-imino)-phenoxon was quanitified by measurement of the light absorption at 505 nm within 10 to 60 minutes after preparation of the samples. The correlation coefficient (r^2) of the linearity curve was > 0.99. It can be concluded that the method is linear between 0.1-2.4 mg H_2O_2/L. The LOQ was indicated as 0.1 mg H_2O_2/L.

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3.3.10	Intermediates/ degradation products	Not investigated
3.3.11	Controls	Inoculum control: effluent, but no test substance Abiotic control: sterilized water and test substance
3.3.12	Calculations	**Calculation of half-life of H_2O_2:** The rate constant ($K_{observed}$) was calculated as follows: $K_{observed} = 2.303 *$ slope In which: Slope = concentration of H_2O_2 at 0 minutes/concentration of H_2O_2 at time t (x minutes) $t_{1/2}$ (20°C) = $0.693/K_{observed}$ **Determination of half-life of peracetic acid:** The half-life of peracetic acid was not calculated because already after 5 minutes the level of peracetic acid was below the LOQ in the effluent water. For the sterilized and purified water no reliable half life could be determined because of analytical inconsistencies.

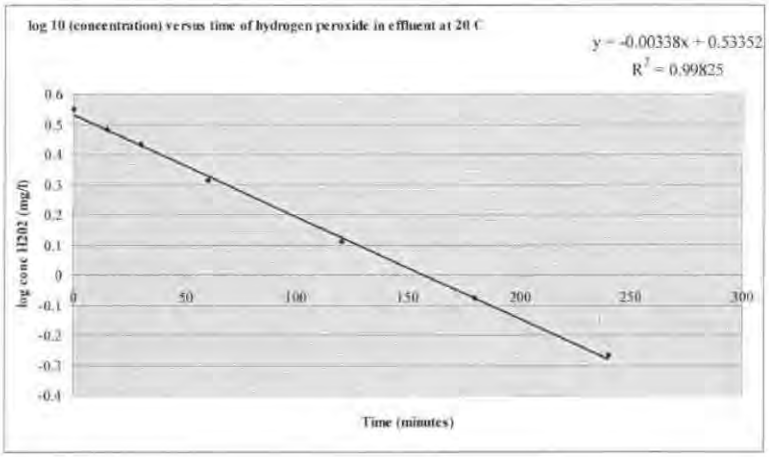
4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

No graph for the degradation of peracetic acid is provided in the study report.

The following graph is provided for H_2O_2:



4.1.2 Degradation

The results of the peracetic acid-analysis are presented in table A7.1.2.1.1/01-4 and the measured concentrations of H_2O_2 are presented in table A7.1.2.1.1/01-5.

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4.1.3	Other observations	None
4.1.4	Degradation of TS in abiotic control	**Peracetic acid:** In the first trial, the half-life of peracetic acid in sterilized, purified water was found to be as fast as in the effluent (less than 5 minutes). As this result could not be explained (no organic matter present to be oxidised and no micro- organisms present which could have contributed to degradation of peracetic acid), the experiment was repeated. In the second test, the half life of peracetic acid in sterilized and purified water was between 30 and 60 minutes. However, this result must be treated with caution because at t_0, the recovery rate was 227% of applied peracetic acid. **H_2O_2:** No degradation of H_2O_2 in sterilized purified water was observed during the test period of 4 hours at 20°C.
4.1.5	Degradation of reference substance	Not applicable
4.1.6	Intermediates/ degradation products	Not investigated

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The degradation of peracetic acid and hydrogen peroxide in the effluent of a waste water treatment plant treating predominantly domestic waste water was tested.
5.2	**Results and discussion**	**Peracetic acid:** 1st test: In the effluent control, 0.26 mg MTSO/L, corresponding to 0.13 mg peracetic acid/L, were found, suggesting that the effluent contained compounds which caused an oxidation of MTS to MTSO. The concentrations of peracetic acid measured after addition of the test substance to the effluent or to the sterilized and purified water showed recoveries at t_0 ranging from 73 to 86%. After 5 minutes, no peracetic acid > LOQ was found, indicating that peracetic acid had fully degraded. The half-life of peracetic acid in both effluent and sterilized, purified water was less than 5 minutes. Since the rapid degradation of peracetic acid in the purified and sterilised water could not be explained (see above, point 4.1.4), the experiment was repeated (2nd test). 2nd test: Even at t_0, no peracetic acid could be found in the peracetic acid treated effluent water. The study director concluded that the time between the addition of peracetic acid to the effluent water and sample preparation (ca. 40 – 60 seconds) was sufficient for peracetic acid to degrade completely. In the purified and sterilised water, at t_0, 4.53 mg peracetic acid/L were determined, corresponding to a recovery of 227%. This value could not be explained. The peracetic acid concentrations fell rapidly below the LOQ within 60 minutes. As at 30 minutes 2.95 mg peracetic acid/L (ca. 65% of the t_0 value) were still present, the half-life can be estimated to be somewhere between 30 and 60 minutes.

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		H_2O_2: In the effluent control, no H_2O_2 was found. At t_0, the recovery rates were 106% of nominal for the purified water sample and 108% and 114% for the two treated effluent samples. In the purified water, no degradation of H_2O_2 was observed during the test duration of 4 hours. In effluent water, the half-life of H_2O_2 was calculated to be 89 minutes (at 20°C). .
5.3	**Conclusion**	The half-life of peracetic acid in effluent water (at 20°C) was determined to be << 5 minutes. The half-life of H_2O_2 in the effluent water was calculated as 89 minutes at 20°C.
5.3.1	Reliability	1
5.3.2	Deficiencies	Different results in trial 1 and 2 concerning degradation of peracetic acid in purified water could not be explained. The high recovery of peracetic acid (227% of nominal) at t_0 in the purified water in test 2 could not be explained.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

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

Section A7.1.2.1.1/01 Aerobic biodegradation: Degradation in the effluent from an STP

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Table A7.1.2.1.1/01-1: Inoculum / Test organism

Criteria	Details	
Nature	Effluent	
Species	Not specified	
Strain	Not applicable	
Source	Activated sludge plant, treating predominantly domestic waste water	
Sampling site	RWZI Horstenmeer in Nederhorst den Berg, NL	
Laboratory culture	No	
Method of cultivation	Not applicable	
Preparation of inoculum for exposure	No preparation was made.	
Pretreatment	No preconditioning was made.	
Initial cell concentration	1.74×10^5 cfu/mL	
Further characterization of the effluent	pH	7.03
	Oxygen concentration	6.2 mg/L
	Conductivity	843.2 µS/cm
	TOC	19.6 mg/L
	Total phosphorus	4.63 mg/L (PO_4)
	Total nitrogen	9.29 mg/L

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Annex Point IIIA, XI.-2.1

Table A7.1.2.1.1/01-2: Test system

Criteria	Details
Culturing apparatus	Glass beakers with a volume of 250 ml; Thermostated room
Number of culture flasks/concentration	1 flask containing a sample of effluent (inoculum control) 2 flasks (200 ml effluent water each) containing the test item at a concentration corresponding to 2 mg peracetic acid/L and 3.2 mg H_2O_2/L 1 sterilized (by heating at 170°C for one hour) beaker (200 ml) containing the test item at a concentration corresponding to 2 mg peracetic acid/L and 3.2 mg H_2O_2/L (abiotic control). The water had been sterilized by filtration through a Nalgene filter of 0.2 µm in a biosafety cabinet.
Aeration device	No information provided
Measuring equipment	Temperature recording system, hand held thermometer, pH meter, conductivity meter, oxygen meter, spectrophotometer, HPLC
Test performed in closed vessels due to significant volatility of TS	No

Table A7.1.1.2/01-3: Test conditions

Criteria	Details
Composition of medium [g/L]	The effluent as collected was used as medium. For the characterisation of the effluent, please refer to table A7.1.2.1.1/03-1.
Additional substrate	No
Test temperature	20 ± 2°C
pH	7.03, measured in the effluent before the addition of the test substance
Aeration	Permanent agitation during the test
Suspended solids concentration	Not indicated
Other relevant criteria	Not indicated

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Table A7.1.1.2/01-4: Measured concentrations of peracetic acid

1st test:

Test solution	Nominal concentration peracetic acid (mg/L)	Recovery [%] (at t_0)	Measured concentration of peracetic acid (mg/L)						
			0 min	5 min	15 min	30 min	60 min	120 min	240 min
Effluent	0.0		0.13*	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Effluent	2.0	75	1.49	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Effluent	2.0	86	1.71	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Purified water	2.0	73	1.45	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1

*this value is likely to be caused by components of the effluent which are able to oxidise MTS to MTSO.

2nd test:

Test solution	Nominal conc. of peracetic acid (mg/L)	Recovery [%] (at t_0)	Measured concentration of peracetic acid (mg/L)						
			0 min	5 min	15 min	30 min	60 min	120 min	240 min
Effluent	0.0		<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Effluent	2.0	0	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Effluent	2.0	0	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Purified water	2.0	227	4.53	4.02	4.07	2.95	<0.1	<0.1	<0.1

Table A7.1.1.2/03-5: Measured concentrations of H_2O_2

Test solution	Nominal conc. of peracetic acid (mg/L)	Recovery [%] (at t_0)	Measured concentration of H_2O_2 (mg/L)						
			0 min	15 min	30 min	60 min	120 min	180 min	240 min
Effluent	0.0		<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Effluent	3.2	108	3.46	3.00	2.68	2.05	1.30	0.84	0.53
Effluent	3.2	114	3.66	3.09	2.74	2.08	1.28	0.84	0.55
Purified water	3.2	106	3.40	3.46	3.43	3.50	3.51	3.38	3.40

Section A7.1.2.1.1 **Annex Point IIIA, XI.-2.1**	**Aerobic biodegradation in an STP**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [...]	
Detailed justification:	[redacted]	
[redacted]		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section A7.1.2.1.1 Annex Point IIIA, XI.-2.1	Aerobic biodegradation in an STP
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justifications [redacted] are acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.2 Anaerobic biodegradation Annex Point IIIA, XII.2.1		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [X]**	X
Detailed justification:	[redacted]	X
[redacted]		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section A7.1.2.1.2 Annex Point IIIA, XII.2.1	Anaerobic biodegradation
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification can be considered acceptable [redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.2.1/01 Aerobic aquatic degradation

Annex Point IIIA, XII.-2.1

Official use only

1.1 Introduction

No guideline compliant study has been performed. The general waiving argument for A7.1.2 (Rate and route of degradation in aquatic systems including identification of metabolites and degradation products) does apply

Nevertheless, information on the degradation of peracetic acid in water can be derived from analytical data from aquatic ecotoxicity studies on peracetic acid (summarised in Table 7.1.2.2.1-1) and from several non-guideline studies on the degradation of peracetic acid in water of different origin and quality (Table 7.1.2.2.1-2 – Table 7.1.2.2.1-4).

1.2 References

[redacted] (1996): Static Acute Toxicity of 5% Peracetic Acid ([redacted]) to Rainbow Trout (*Oncorhynchus mykiss)*; [redacted]; Study No. [redacted]; Date of report: 10 July 1996; Doc. No. 821-007; (unpublished)
Study summarised in IUCLID.

[redacted] (1996): Static Renewal Acute Toxicity of 5% Peracetic Acid [redacted] to Bluegill (*Lepomis macrochirus;* [redacted]; Study No. [redacted]; Date of Report: 10 July 1996; Doc. No. 821-008; (unpublished)
Study summarised in Doc. IIIA7.4.1.1/02

[redacted] (1995): Test to Evaluate Acute Toxicity (96 hours) in Freshwater Fish *(Brachydanio rerio)*; [redacted]; Study No. [redacted]; Date of Report: 18 December 1995; Doc. No. 821-006; (unpublished)
Study summarised in Iuclid

Lammy, M-H. (1997): Toxicite Aigue Vis-à-Vis des Daphnies, INERIS, Laboratoire d'Ecotoxicologie, Verneuil-en-Halatte, France; Study No. Ba567b; Date of Report 01 April 1997; Doc. No. 822-007; (unpublished)
Study summarised in IUCLID.

Hicks, S. L. (1996): Acute Toxicity of 5% Peracetic Acid ([redacted]) to *Selenastrum capricornutum,* ABC Laboratories Inc. Environmental Toxicology, Columbia, Missouri, USA; Study No. 195-2027; Date of Report 18 June 1996; Doc. No. 823-003; (unpublished)
Study summarised in Doc. IIIA7.4.1.3/01

Petit-Poulsen, V. (1997): Esssai D'Inhibition de la Croissance de L'Algue d'eau Douce *Pseudokirchneriella subcapitata;* Laboratoire d'Ecotoxicologie, Verneuil-en-Halatte, France; Study No. Ba567c; Date of Report: 22 July 1997; Doc. No. 823-004; (unpublished)
Study summarised in IUCLID.

Hanstveit, A.O., Schoonmade, J.A. (1999): The Determination of the Effect of [redacted] on the Growth of the Alga *Selenastrum capricornutum*; TNO Nutrition and Food Research Institute, Delft, The Netherlands; Study No. IMW-98-0044-01; Date of Report: 08 January 1999; Doc. No. 823-005; (unpublished)
Study summarised in IUCLID.

Section A7.1.2.2.1/01 Aerobic aquatic degradation

Annex Point IIIA, XII.-2.1

Wetton, P.M., Mullee, D.M. (2000): *Daphnia magna* Reproduction Test, Safepharm Laboratories Ltd. Derby, U.K.; Study No. 663/007; Date of Report: 12 May 2000; Doc. No. 827-001; (unpublished)
Study summarised in Doc. IIIA7.4.3.4/01

Chalkley, N.J. (1991): Memorandum: Degradation of Peracetic Acid; interox Research & Development Widnes Laboratory; Study No. not applicable; Date of Memo:15 May 1991; Doc. No. 711-001; (unpublished)
Study summarised in IUCLID.

Brougham, P; Simms, R.A.; (1991):Memorandum – Degradation of Peracetic Acid; interox, Research & Development Widnes Laboratory; Study No. not applicable; Date of Memo: 20 March 1991; Doc. No. 721-002
Study summarised in IUCLID.

Chalkley, N.J. (1992): Degradation of peracetic acid in contact with coir and various samples of water; interox Reseach & Development Widnes Laboratory; Study No. not applicable; Date of Memo: 19 March 1992; Doc. No. 711-002; unpublished)
Study summarised in IUCLID.

Teral, G.; Harmon, G.; (1995): Détermination de Faibles Teneurs en Acide Peracetique ; Air Liquide, Les Loges, France ; Study No. AT.CHEM 95.05 373.95/STA/CH CLB GT225 ; Doc. No. 435-001
Study summarised in IUCLID.

2. Summary of degradation data derived from above studies

2.1. Overview on test results of ecotox studies

Table A7.1.2.2.1-1 Overview on the degradation of peracetic acid as observed in aquatic ecotoxicity studies

Reference	Study type	Composition of test item in % (peracetic acid/H_2O_2/ HAc*)	pH of test medium	Tempe-rature in test medium in °C	Recovery of peracetic acid in test medium at t_0 [% of nominal]	Degradation rate of peracetic acid during indicated time period	Comments and conclusions
[redacted] 1996, Doc. No.: 821-007, IUCLID (non-key study)	Acute toxicity to rainbow trout, static test	[redacted]	7.7 – 8.1	11 - 12	93 – 108; average: 100.08%	14 – 30% within 96 hours; average: 19.2%	No dose-dependency of the degradation rate was found.
[redacted] 1996, Doc.-No. 821-008, Document IIIA, section 7, 7.4.1.1/02	Acute toxicity to bluegill, static renewal test	[redacted]	7.7 – 8.1	22 - 23	79 – 97; average: 86.6%	0 – 36 % within 24 hours; average: 12.5%	No dose-dependency of the degradation rate was found.

Reference	**Study type**	**Composition of test item in % (peracetic acid/H_2O_2/ HAc*)**	**pH of test medium**	**Tempe-rature in test medium in °C**	**Recovery of peracetic acid in test medium at t_0 [% of nominal]**	**Degradation rate of peracetic acid during indicated time period**	**Comments and conclusions**
Gardner and Bucksath, 1996, Doc.-No. 821-006, Document IIIA, section 7, 7.4.1.2/01	Acute toxicity to Daphnia magna, static test	[redacted]	8.0 – 8.3	19 - 21	111-116; average: 113.2%	19 – 35 % within 48 hours; average: 24.4%	A clear dose dependency was found with 35% degradation at the highest nominal concentration (1.5 mg peracetic acid/L) and 19% degradation at the lowest nominal concentra-tions (0.19 and 0.32 mg peracetic acid/L).
Lamy, 1996, Doc-No. 822-007; IUCLID (non-key study)	Acute toxicity to Daphnia, semi-static test	[redacted]	7.5 – 8.1	19 - 21	100 - 113	21 – 31% within 4 hours; average: 24.9% (3 out of 12 measurements are considered to	No dose-dependency of the degradation

						be outliers)	rate was found.
Reference	**Study type**	**Composition of test item in % (peracetic acid/H_2O_2/ HAc*)**	**pH of test medium**	**Tempe-rature in test medium in °C**	**Recovery of peracetic acid in test medium at t_0 [% of nominal]**	**Degradation of peracetic acid during indicated time period**	**Comments and conclusions**
Hicks, 1996, Doc.-No. 823-003; Document IIIA, section 7, 7.4.1.3/01	Acute toxicity to Selenastrum, static test	[redacted]	7.3 - 9.0	22 - 24	92 - 110	9.1% - 87% within 120 hours, depending on nominal concentrations; average 47.1%	The degradation rate was lower at the high nominal concentra-tions. However, no clear dose dependency of degradation was found.
Petit-Poulsen, 1997, Doc.-No. 823-004; IUCLID (non-key study)	Acute toxicity to Pseudokirch-neriella, static test	[redacted]	7.37 – 9.09	21 - 25	95 - 156	0 – 29% within 4 hours; average for nominal conc. of 1 mg peracetic acid/L: 14.3% (18 measurements); average for	The degradation rate was lower at the high nominal concentration.

						nominal conc. of 10 mg peracetic acid/L: 6.4% (18 measurements)	
Reference	**Study type**	**Composition of test item in % (peracetic acid/H_2O_2/ HAc*)**	**pH of test medium**	**Tempe-rature in test medium in °C**	**Recovery of peracetic acid in test medium at t_0 [% of nominal]**	**Degradation of peracetic acid during indicated time period**	**Comments and conclusions**
Hanstveit, 1999, Doc.-No. 823-005; IUCLID (non-key study)	Acute toxicity to Selenastrum, static test	[redacted]	8.0 – 8.7	22 - 24	70 - 77	Due to analytical problems, no conclusion on the degradation can be drawn from this test.	No information on degradation can be derived from this study.
Wetton, 2000, Doc.-No. 827-001; Document IIIA, section 7, 7.4.3.4/01	Repro-toxicity test with Daphnia, semi-static test	[redacted]	7.3 – 8.0	20 – 22	Pre-test: 107 – 194 Main test: measured concentrations of peracetic	Pre-test: 67 – 92% under light conditions and 67 – 90% under dark conditions within 48 hours. Average: 77% (light conditions) and 70% (dark conditions) Due to analytical problems, no conclusion on degradation can	In the pre-test, rapid degradation of peracetic acid was found. From the main test, however, no

					acid ranged between 4% and 785% of nominal values.	be drawn from the main test.	information on degradation can be derived.

*HAc = acetic acid
**ns = not stated

The recovery of peracetic acid in above tests is generally high. For this reason, it can be assumed that the degradation determined in the tests are not due to analytical errors. The degradation values found show a great variation, the interpretation of which is difficult. In the tests with a duration of 4h, degradation between 0 and 29% of the added peracetic acid was found. In the tests with longer duration, degradation between 19 and 92% after 48 hours and of 9.1 and 87% after 120 hours was found. Any interpretation seems to be speculative on the basis of the data.

2.2 Summary of non-guideline degradation tests performed in water

Table A7.1.2.2.1-2 Degradation test 1, conducted with water of different sources (Teral, G., Harmon, G. (1995), Doc. No.: 435-001):

Type of Water	pH	Nominal concentration [mg/L]	Measured concentration on day 0 [mg/L]	Degradation after 1 day	Degradation after 2 days	Degradation after 4 days
Demineralised	5	20	19.1	12.6 %	16.2 %	28.3 %
Drinking water	6	20	18.8	94.7 %	100 %	--
Seawater	7	20	18.5	97.3 %	100 %	--

Demineralised	5	10	12	30.8 %	34.2 %	46.7 %
Drinking water	6	10	10.3	95.1 %	100 %	--
Seawater	7	10	12.1	95.9 %	100 %	--

Peracetic acid was rapidly degraded in drinking- and seawater at both concentrations tested, while in demineralised water, degradation was low. Though the pH of the demineralised water was lower than the pH of drinking- and seawater, the pH seems not to be the mediating factor for degradation: Please refer to the study on abiotic degradation, (Doc. IIIA 7.1.1.1.1/01/02) which does not reveal great differences in degradation between pH 4 and pH 7. It is more likely, that traces of metals ions or organic load (absent in demineralised water) could explain the differences.

Table A7.1.2.2.1-3 Degradation test 2, conducted with tap water (Chalkley, N.J. (1992), Doc. No.: 711-002):

Origin of tap water	**Test Duration [min]**	**% Degradation of peracetic acid**		**Hardness [in mg $CaCO_3$/L]**	
		200 mg/L peracetic acid PX0510	20 mg/L peracetic acid PX0510	Permanent	Temporary
Hensby	120	28 %	87.5 %	98	182
Tinsley	120	22 %	91 %	192	202
PAO	120	17 %	91 %	134	180
R+D Widnes	120	20 %	38.5 %	58	2

Higher initial peracetic acid concentration in the test resulted in lower degradation rates. After 120 min, 17-28 % degradation was measured at the high test concentration and 35.5 – 91 % at the low test concentration.
To assume an influence of the water hardness on the degradation at the low test concentration would be speculative because other water

parameters which might have an influence, such as organic or microbial load, have not been determined.

Table A7.1.2.2.1-4 Degradation test3, conducted in different water types (Chalkley, N.J. (1991), Doc. No.: 711-001/ Brougham, P, Simms, R.A. (1991), Doc. No.: 721-002):

Type of Water	Nominal concentration [mg/L]	Measured concentration on day 0 [mg/L]	Degradation after 5 days [%]	Degradation after 13 days [%]	Degradation after 28 days [%]
Test 1: Measurement period 2 h to 5 days					
Demineralised	2000		24	n.d.	n.d.
Stream	2000		30.1	n.d.	n.d.
Pond	2000		43.5	n.d.	n.d.
Tap	2000		39.8	n.d.	n.d.
Lake	2000		25.6	n.d.	n.d.
Test 2: Measurement period 13 d to 28 days					
Demineralised	100	86	n.d.	58.1	86
Stream	100	72	n.d.	88	> 98
Pond	100	75	n.d.	91.7	> 98

n.d. = not determined

At the high peracetic acid concentration (2000 ppm – test duration 5 days), the differences in the degradation of peracetic acid in the different water sources cannot be explained because parameters such as the organic or microbial load or the content of metal ions have not been investigated.
At the low test concentration (100 ppm – test duration 28 days), only demineralised water, stream and pond water were tested. As

expected, the lowest degradation of peracetic acid was found in demineralised water. It may be speculated, that differences in metal ion contents or organic load explain the differences.

3 Overall Conclusion

The degradation of peracetic acid in water of different sources showed a great variation, which is difficult to interpret because the test conditions and characteristics of the water sources are not described.

The following mechanisms may have contributed at different shares (depending on the water sources) to the degradation of peracetic acid:

- hydrolysis
- spontaneous decomposition
- metal catalysed decomposition (Fe, Cr, Mn)
- decomposition due to reaction with organic substance
- biodegradation through micro-organisms

Section A7.1.2.2.1/01-14 Aerobic aquatic degradation

Annex Point IIIA, XII.-2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 15, 2008
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2.2.2 Annex Point IIIA, XII.2.1	Water/sediment degradation study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	[redacted]	

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable [redacted]
Remarks	

	COMMENTS FROM ... *(specify)*
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*

Section 7.1.2.2.2 Annex Point IIIA, XII.2.1	Water/sediment degradation study
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2 Annex Point IIIA, XI.-2.1	Rate and route of degradation in aquatic systems including identification of metabolites and degradation products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [...]**	
Detailed justification:	[redacted]	

Section A7.1.2 **Annex Point IIIA, XI.-2.1**	**Rate and route of degradation in aquatic systems including identification of metabolites and degradation products**
	[redacted]
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.3 **Annex Point IIA, VII.7.7**	**Adsorption / Desorption screening test**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [X]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.1.3 **Annex Point IIA, VII.7.7**	**Adsorption / Desorption screening test**
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable.
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.4.1 Field study on accumulation in the sediment

Annex Point IIIA, XII.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable.
Remarks	

COMMENTS FROM OTHER MEMBER STATE (specify)

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

Section A7.1.4.1 Field study on accumulation in the sediment

Annex Point IIIA, XII.2.1

Remarks

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

There are three studies concerning the degradation of peracetic acid in soil. The study described below has been retrieved from the internet and though PAR has no full access to this study, it is described in the dossier in order not to leave out any significant information. The other studies are summarised in IUCLID, chapter 5.3.2 (Chalkley, N.J., Doc. No. 721-001; Chalkley, N.J., Doc. No. 721-002).

Official use only

1 REFERENCE

1.1	**Reference**	Howarth, J. (2003): The Environmental Fate and Impact of [redacted] (Equilibrium Mixtures of Peroxyacetic Acid and Hydrogene Peroxyde) in Soil; Doc. No. 721-003
1.2	**Data protection**	No
1.2.1	Data owner	Enviro Tech Chemical Services, Inc.
1.2.2	Companies with letter of access	Not applicable
1.2.3	Criteria for data protection	Not applicable

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	No
2.3	**Deviations**	Not applicable

3 MATERIAL AND METHODS

3.1	**Test material**	1) [redacted] 2) [redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	See point 3.1.6
3.1.5	Further relevant properties	Not relevant
3.1.6	Composition of Product	[redacted]
3.1.7	TS inhibitory to microorganisms	Not indicated
3.1.8	Specific chemical analysis	Not indicated
3.2	**Reference**	Not indicated

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

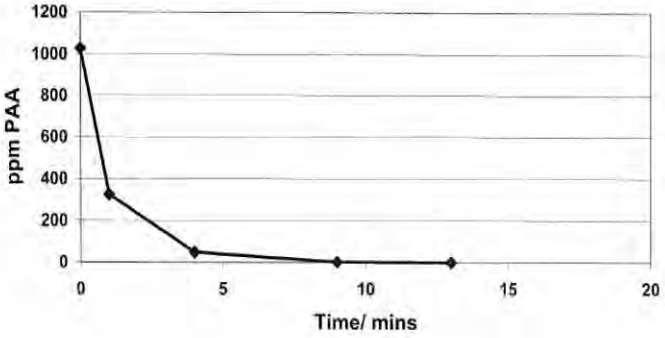
	substance		
3.2.1	Initial concentration of reference substance	Not indicated	
3.4	**Testing procedure**		
3.4.1	Test soil	Sandy loam from a fallow unimproved pasture in Modesto, California	X
3.4.2	Test system	Part 1: The soil saturation index (SSI) was determined by measuring and mixing the amount of water needed to flood the soil pores and produce a thin standing film of water on the surface. Using the calculated SSI the 1027 ppm peracetic acid stock solution ([redacted]) was mixed into the soil and a stop watch was started. Within 1 minute a small portion of the saturated soil was vacuum filtered and diluted for analysis of peracetic acid and hydrogen peroxide. This process was repeated several times until no peracetic acid or hydrogen peroxide was detectable. Part 2: A soil sample was treated to the SSI with a 1.5% v/v solution of [redacted] An aliquot of the soil sample was vacuum filtered for measurement of pH and conductivity. The saturated soil was covered and pH and conductivity monitored for the next 9 days.	
3.4.3	Temperature	Not indicated	
3.4.4	Initial TS concentration	1027 ppm peracetic acid	
3.4.5	Duration of test	Part 1: 30 minutes Part 2: 9 days	
3.4.6	Analytical parameter	Peracetic acid, hydrogen peroxide	
3.4.7	Sampling	See 3.4.2	
3.4.8	Analytical methods	Modified DPD methods	X
3.4.9	Calculations	No	
		4 RESULTS	
4.1	**Material balance**	Not indicated	
4.2	**Distribution of radioactivity**	Not relevant	

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

4.3 Concentration – time data

Figure 1: Degradation of PAA in Soil (1027 ppm PAA from Perasan 15)



4.4 Specification of the transformation products

The decomposition reactions of peracetic acid and hydrogen peroxide were accompanied by the generation of oxygen bubbles, indicating complete degradation.

4.5 Dissipation time

Less than half of the peracetic acid applied to the soil is recovered analytically after 1 minute contact. After 9 minutes, less than 0.2 % of the initial peracetic acid charge was detected and after 13 minutes the soil became devoid of peracetic acid.

From the initial hydrogen peroxide charge of 1468 ppm, less than 1 ppm was detected after 19 minutes.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The decomposition of peracetic acid and hydrogen peroxide was measured in a sandy loam soil by specific analytic. In addition changes in pH and electrical conductivity of the test soil were monitored

5.2 Results and discussion

Peracetic acid and hydrogen peroxide are very unstable when in contact with the test soil, 2/3 of the added peracetic acid has disappeared after 1 minute contact time. Both peracetic acid and hydrogen peroxide were essentially depleted from soil 20 minutes after contact (only a trace amount of 0.33 ppm peracetic acid was detected after 13 minutes contact time). Transition metal components like iron and manganese minerals in the soil catalyse the decomposition reactions.

The pH of the soil decreases to a pH of 4.7 (formerly 6.2) and the conductivity increases to a value of 1900µScm-1 (formerly 750 µScm-1), after addition of [redacted] Both pH and electrical conductivity rebound to values close to those obtained for untreated soil within 9 days due to biodegradation of acetate ion mediated by soil micro-organisms.

5.3 Conclusion

Peracetic acid decomposes rapidly in soil when in contact with transition metal components like iron and manganese minerals with a DT_{50} of < 1 minute.

5.3.1 Reliability

2

Section 7.2.1/01 **Annex Point IIIA, VII.4, XII.1.1**	**Aerobic degradation in soil, initial study**	
5.3.2 Deficiencies	None	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Non acceptable
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.1 Annex Point IIIA, 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** [ ]	
Limited exposure [x]	**Other justification [...]**	
Detailed justification:	[redacted]	

[redacted]

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]

Section 7.2.1 **Annex Point IIIA, VII.4, XII.1.1**	**Aerobic degradation in soil, initial study**
Conclusion	Applicant's justification is acceptable [redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.2.2	Aerobic degradation in soil, further studies:	
Annex Point IIIA, VII.4, XII.1.1, XII.1.4	The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	[redacted]	X

Section A7.2.2	Aerobic degradation in soil, further studies:
Annex Point IIIA, VII.4, XII.1.1, XII.1.4	The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable [redacted]
Remarks	

COMMENTS FROM OTHER MEMBER STATE *(specify)*

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

Section A7.2.3 **Annex Point IIIA, XII.1.2**	**Adsorption and mobility in soil, further studies:** Adsorption and desorption in at least three soil types and, where relevant, the adsorption and desorption of metabolites and degradation products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [X]	
Detailed justification:	[redacted]	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's justification is acceptable.	

Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

			Official use only
		1 REFERENCE	
1.1	**Reference**	Görg, J, Glöckner, T (2007): Estimation of the atmospheric residence time of peracetic acid using the Atkinson method, SCC GmbH, Wendelsheim, Germany, Doc. No. 743-001 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	PAR	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Not applicable; model calculation according to the Atkinson calculation method.	
2.2	**GLP**	No; study is a model calculation.	
2.3	**Deviations**	Not applicable.	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Not applicable.	
3.2	**Reference substance**	Not applicable.	
3.3	**Test solution**	Not applicable.	
3.4	**Testing procedure**	The photochemical and oxidative decomposition of peracetic acid in air was calculated according to Atkinson. The calculation was performed with the help of the programme AOPWIN, Atmospheric Oxidation Programme v1.92 for (© 2000 US Environmental Protection Agency).	
		4 RESULTS	
4.1	**OH radical reaction rate constant k_{OH}**	The overall OH rate constant is estimated to be: $k_{OH} = 4.0422 \times 10^{-12}$ cm^3 molecule^{-1} sec^{-1}.	
4.2	**Ozone reaction rate constant k_{Ozone}**	No ozone reaction is estimated (peracetic acid contains no olefinic carbon-carbon double and acetylic triple bonds).	
4.3	**Atmospheric half-life using k_{OH}**	The tropospherical half life can be calculated using the following relation: $t_{1/2} = \ln 2/k_{OH} \times [OH]$. with OH being the OH radicals concentration in the troposphere of 0.5 x	

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

		10^6 molecule cm³ considering 24 hours irradiation per day. The DT_{50} for peracetic acid is estimated to be 3.969 days (24-hr day), corresponding to 95.260 hours
4.4	**Atmospheric half-life using k_{Ozone}**	No ozone reaction is estimated (peracetic acid contains no olefinic carbon-carbon double and acetylic triple bonds).
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The photochemical and oxidative decomposition of peracetic acid in air was calculated according to Atkinson.
5.2	**Results and discussion**	
5.2.1	Reaction rate constant	$k_{OH} = 4.0422 \times 10^{-12}$ cm^3 molecule^{-1} sec^{-1}.
5.2.2	Tropospherical half life	The DT_{50} for peracetic acid was estimated to be 3.969 days (24-hr day), corresponding to 95.260 hours, using the reaction rate constant k_{OH}.
5.3	**Conclusion**	Peracetic acid degrades in the atmosphere with a DT_{50} of 3.969 days (24-hr day), corresponding to 95.260 hours. As peracetic acid contains no olefinic carbon-carbon double and acetylic triple bonds, it is not supposed to react with ozone.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.3.2 **Annex Point IIIA, XII.3**	**Fate and behaviour in air, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [...]**	
Detailed justification:	[redacted]	X
	[redacted]	
	[redacted]	
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section A7.3.2 Fate and behaviour in air, further studies

Annex Point IIIA, XII.3

Evaluation of applicant's justification	[redacted]
Conclusion	Applicant's justification is acceptable [redacted]
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	