

Section A6.9/02

Neurotoxicity

Annex Point IIA6.9

Inhalation study with rats

5.2 Results and discussion

Increases in cumulative test session motor activity counts were observed following 4, 7 and 9 weeks of exposure for rats in the 9 week subgroup. Increases in cumulative test session motor activity counts were also observed following 4, 7, 9, 11 and 13 weeks of exposure for rats in the 13 week subgroup. Reversibility of this effect was observed for rats in the 9 week subgroup within 2 days following the last exposure. Reversibility was also noted for rats in the 13 week subgroup but not until study week 15. Minor changes were observed in the shape of the motor activity habituation curves for exposed rats in the 9 and 13 week subgroups at ca. 50 % of the measurement intervals beginning at week 4. Most of these statistical changes were observed in conjunction with increases in cumulative test session motor activity and some were observed following time points where recovery of the cumulative test session motor activity counts had occurred. No change in the shape of the motor activity habituation curve was observed 6 weeks following the last exposure, i.e. there was a complete recovery of motor activity effects.

5.3 Conclusion

5.3.1 LOAEL

[REDACTED]

X

5.3.2 NOAEL

[REDACTED]

X

5.3.3 Reliability

[REDACTED]

5.3.4 Deficiencies

[REDACTED]

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

2008/02/28

Materials and Methods

[REDACTED]

Results and discussion

[REDACTED]

Conclusion

[REDACTED]

Reliability

[REDACTED]

Acceptability

[REDACTED]

Remarks

[REDACTED]

	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A6.12/01 Medical data

Annex Point IIA 6.12

Official
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1 REFERENCE

1.1 Reference

[REDACTED] (2003) 5th Periodic Safety Update Report for:
Alcohol solutions for disinfection of intact skin [REDACTED]
[REDACTED] 40 pp.

[REDACTED] (2006) Isopropyl alcohol (CAS 67-63-0). Master
file for a biocidal substance. [REDACTED] 37 pp.

[REDACTED] (2007) Addendum Report 4 to 5th Periodic
Safety Update Report for: Alcohol solutions for disinfection of intact skin
[REDACTED] 41
pp.

1.2 Data protection

[REDACTED]

1.2.1 Data owner

[REDACTED]

Detailed information:

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

x

Section A6.12/01 Medical data

Annex Point IIA 6.12

		X
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Section A6.12/01 Medical data

Annex Point IIA 6.12

	[REDACTED]	
	[REDACTED]	
	[REDACTED]	X
	[REDACTED]	
	[REDACTED]	x
	[REDACTED]	

Section A6.12/01 Medical data

Annex Point IIA 6.12

Undertaking of
intended data
submission

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2014/02/07

**Evaluation of
applicant's justification**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Section A6.12/01 Annex Point IIA 6.12	Medical data
	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i> Date <i>Give date of comments submitted</i> Evaluation of applicant's justification <i>Discuss if deviating from view of rapporteur member state</i> Conclusion <i>Discuss if deviating from view of rapporteur member state</i> Remarks

Section A6.12.2/01**Human Case Report****Annex Point IIA6.12**

Studies concerning allergic contact dermatitis after contact with isopropanol containing swabs

	1	REFERENCE	
1.1 Reference		Leow YH & Freeman S (1995) Acute allergic contact dermatitis from Medi-Swabs®, with negative patch tests to the individual ingredients, including isopropyl alcohol. Contact Dermatitis 33, 125 – 126	
1.2 Data protection		No	
1.2.1 Data owner		Not applicable	
1.2.2 Criteria for data protection		No data protection claimed	
	2	GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Not applicable	
2.2 GLP		■	
2.3 Deviations		Not applicable	
	3	MATERIALS AND METHODS	
3.1 Substance		Medi-Swab® (impregnated with 70 % isopropanol)	
3.2 Persons exposed		2	
3.2.1 Sex		1 female	1 male
3.2.2 Age/weight		41 years / no data	43 years / no data
3.2.3 Known Diseases		Morbus Hodgkin	Childhood asthma and hay fever
3.2.4 Number of persons		1	1
3.2.5 Other information		No data	No data
3.3 Exposure		Dermal	
3.3.1 Reason of exposure		in the course of medical treatment	No data
3.3.2 Frequency of exposure		Multiple	No data
3.3.3 Overall time period of exposure		No data	No data
3.3.4 Duration of single exposure		Contact during treatment of recurrent vesicular dermatitis in the cubital fossae	No data
3.3.5 Exposure concentration/dose		No data	No data
3.3.6 Other information		No data	No data
3.4 Examinations		Patch testing on the back with Finn chambers on Scanpor tape with complete Medi-Swabs® and single ingredients of Medi-Swabs®: isopropyl alcohol (10 – 95 %) and all other components. Readings after exposure over 2 and 4 days	
3.5 Treatment		Avoidance of Medi-Swabs®	
3.6 Remarks			

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Section A6.12.2/01

Human Case Report

Annex Point IIA6.12

Studies concerning allergic contact dermatitis after contact with isopropanol containing swabs

	4 RESULTS
4.1 Clinical Signs	No data
4.2 Results of examinations	Both subjects showed strongly, vesicular reactions to both types of Medi-Swabs®, while there was no positive reaction to isopropyl alcohol
4.3 Effectivity of medical treatment	Not applicable
4.4 Outcome	No more symptoms after avoidance of Medi-Swab®
4.5 Other	Not applicable
	5 APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods	Patch testing on the back with Finn chambers on Scanpor tape
5.2 Results and discussion	The dermal reaction is ascribed to a 'compound allergy' without further analysis of compound in question
5.3 Conclusion	[REDACTED]

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	2008/02/12
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]

COMMENTS FROM ... (specify)

Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A6.15 Food and feedingstuffs studies
Annex Point IIIA.VI.4

JUSTIFICATION FOR NON-SUBMISSION OF DATA

Official
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Other existing data Technically not feasible Scientifically unjustified
Limited exposure Other justification

Detailed justification:

[REDACTED]

Undertaking of intended
data submission

[REDACTED]

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2014/04/24

Evaluation of applicant's
justification

[REDACTED]

Conclusion

[REDACTED]

Remarks

[REDACTED]

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

<p>Section A7.1.1.1.1 Annex Point II A7.6.2.1</p>	<p>Hydrolysis as a function of pH and identification of breakdown products</p>	
<p>JUSTIFICATION FOR NON-SUBMISSION OF DATA</p>		<p>Official use only</p>
<p>Other existing data <input type="checkbox"/></p> <p>Limited exposure <input type="checkbox"/></p>	<p>Technically not feasible <input type="checkbox"/></p> <p>Scientifically unjustified <input checked="" type="checkbox"/></p> <p>Other justification <input type="checkbox"/></p>	
<p>Detailed justification:</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Reference: Harris (1990) Rate of hydrolysis. In: Handbook of chemical property estimation methods (eds.: Lyman WJ, Reehl WF and Rosenblatt DH), American Chemical Society, Washington DC, 1990, pp. 7-1 – 7-48 (published)</p>	
<p>Undertaking of intended data submission <input type="checkbox"/></p>	<p>Not applicable, no study is planned.</p>	
<p>Evaluation by Competent Authorities</p>		
<p>EVALUATION BY RAPPORTEUR MEMBER STATE</p>		
<p>Date</p>	<p>2008/07/03</p>	
<p>Evaluation of applicant's justification</p>	<p>[REDACTED]</p>	
<p>Conclusion</p>	<p>[REDACTED]</p>	
<p>Remarks</p>	<p>[REDACTED]</p>	
<p>COMMENTS FROM OTHER MEMBER STATE (specify)</p>		
<p>Date</p>	<p><i>Give date of comments submitted</i></p>	
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<p>Conclusion</p>	<p><i>Discuss if deviating from view of rapporteur member state</i></p>	
<p>Remarks</p>	<p></p>	

<p>Section A7.1.1.2 Annex Point IIA7.6.2.2</p>	<p>Phototransformation in water including identity of transformation products</p>	
<p>JUSTIFICATION FOR NON-SUBMISSION OF DATA</p>		<p>Official use only</p>
<p>Other existing data <input type="checkbox"/></p> <p>Limited exposure <input type="checkbox"/></p>	<p>Technically not feasible <input type="checkbox"/></p> <p>Other justification <input type="checkbox"/></p>	<p>Scientifically unjustified <input checked="" type="checkbox"/></p>
<p>Detailed justification:</p> <p>References:</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	<p>X</p>
<p>Undertaking of intended data submission <input type="checkbox"/></p>	<p>Not applicable, no study is planned.</p>	
<p>Evaluation by Competent Authorities</p>		
<p>EVALUATION BY RAPPORTEUR MEMBER STATE</p>		
<p>Date</p>	<p>2008/07/01</p>	
<p>Evaluation of applicant's justification</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	
<p>Conclusion</p>	<p>[REDACTED]</p>	
<p>Remarks</p>	<p>[REDACTED]</p>	

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

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

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1 REFERENCE

- 1.1 Reference** Bridie AL, Wolff CJM, Winter M (1979) BOD and COD of some petrochemicals. Water Res 13, 627-630 (published)
- 1.2 Data protection** No
- 1.2.1 Data owner -
- 1.2.2 Criteria for data protection No data protection claimed

2 GUIDELINES AND QUALITY ASSURANCE

- 2.1 Guideline study** No. No international guidelines available at the time the study was conducted. However, the study was conducted in accordance with US APHA (1971) 'Standard methods for examination of water and waste water' No. 219
- 2.2 GLP** [REDACTED]
- 2.3 Deviations** Yes. In all tests 0.5 mg/L allylthiourea was added to prevent nitrification.

3 MATERIALS AND METHODS

- 3.1 Test material** Propan-2-ol
- 3.1.1 Lot/Batch number -
- 3.1.2 Specification i-propyl alcohol
- 3.1.3 Purity Not stated
- 3.1.4 Further relevant properties -
- 3.1.5 Composition of Product Not applicable.
- 3.1.6 TS inhibitory to microorganisms No data. Based on the results inhibition of respiration is not to be expected.
- 3.1.7 Specific chemical analysis No data
- 3.2 Reference substance** Yes. In each series of determinations a mixture of glucose and glutamic acid was used to check the activity of the inoculum. These tests were run in duplicate.
- 3.2.1 Initial concentration of reference substance No data

3.3 Testing procedure

3.3.1 Inoculum / test species

Criteria	Details
Nature	Microbial inoculum
Species	-
Strain	-

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

	Source	Effluent from a biological sanitary waste treatment plant, non-adapted																
	Sampling site	No data																
	Laboratory culture	No																
	Method of cultivation	No data																
	Preparation of inoculum for exposure	10 mL of the effluent from a biological sanitary waste treatment plant was filtered and used as seed, the inoculum was non-adapted																
	Pretreatment	No adaptation																
	Initial cell concentration	No data																
3.3.2	Test system	<table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Culturing apparatus</td> <td>BOD bottles (respirometer; not further specified)</td> </tr> <tr> <td>Number of culture flasks/concentration</td> <td>No data</td> </tr> <tr> <td>Aeration device</td> <td>No data</td> </tr> <tr> <td>Measuring equipment</td> <td>No data</td> </tr> <tr> <td>Test performed in closed vessels due to significant volatility of TS</td> <td>Yes. The test was conducted in BOD bottles.</td> </tr> </tbody> </table>	Criteria	Details	Culturing apparatus	BOD bottles (respirometer; not further specified)	Number of culture flasks/concentration	No data	Aeration device	No data	Measuring equipment	No data	Test performed in closed vessels due to significant volatility of TS	Yes. The test was conducted in BOD bottles.				
Criteria	Details																	
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Number of culture flasks/concentration	No data																	
Aeration device	No data																	
Measuring equipment	No data																	
Test performed in closed vessels due to significant volatility of TS	Yes. The test was conducted in BOD bottles.																	
3.3.3	Test conditions	<table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Composition of medium</td> <td>No data</td> </tr> <tr> <td>Additional substrate</td> <td>No data</td> </tr> <tr> <td>Test temperature</td> <td>20 ± 1 °C</td> </tr> <tr> <td>pH</td> <td>No data</td> </tr> <tr> <td>Aeration of dilution water</td> <td>No data</td> </tr> <tr> <td>Suspended solids concentration</td> <td>No data</td> </tr> <tr> <td>Other relevant criteria</td> <td>No stirring of test solution</td> </tr> </tbody> </table>	Criteria	Details	Composition of medium	No data	Additional substrate	No data	Test temperature	20 ± 1 °C	pH	No data	Aeration of dilution water	No data	Suspended solids concentration	No data	Other relevant criteria	No stirring of test solution
Criteria	Details																	
Composition of medium	No data																	
Additional substrate	No data																	
Test temperature	20 ± 1 °C																	
pH	No data																	
Aeration of dilution water	No data																	
Suspended solids concentration	No data																	
Other relevant criteria	No stirring of test solution																	
3.3.4	Method of preparation of test solution	Propan-2-ol is indefinitely miscible with water (cf. Doc III A3.5).																
3.3.5	Initial TS concentration	No data																
3.3.6	Duration of test	5 days																
3.3.7	Analytical parameter	Measurement of dissolved oxygen																
3.3.8	Sampling	No data																
3.3.9	Intermediates/	Not identified																

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

	degradation products	
3.3.10	Nitrate/nitrite measurement	Not applicable
3.3.11	Controls	In each series of determinations a mixture of glucose and glutamic acid was used for checking the activity of the inoculum. These tests were run in duplicate. No further details stated.
3.3.12	Statistics	No data

4 RESULTS

4.1 Degradation of test substance

4.1.1	Graph	Not available
4.1.2	Degradation	49% BOD of ThOD after 5 days
4.1.3	Other observations	No data
4.1.4	Degradation of TS in abiotic control	No data
4.1.5	Degradation of reference substance	Activity of inoculum was checked using a mixture of glucose and glutamic acid, no further details stated.
4.1.6	Intermediates/ degradation products	No data

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The study was conducted in accordance with US APHA (1971) 'Standard methods for examination of water and waste water' No. 219. However, only a few details of the testing procedure were reported. Deviation from test procedure: in all tests 0.5 mg/L allylthiourea was added to prevent nitrification. The 5 day BOD was determined.

5.2 Results and discussion

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or ThCO ₂	Not applicable due to test duration	
Pass values reached within 10-d window (within 28-d test period)	Not applicable due to test duration	
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%	-	
Percentage of removal of reference substance reaches pass level by day 14	No data	

The study (Closed Bottle Test) was conducted in accordance with APHA (1971) 'Standard Methods for examination of water and waste

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

water' No. 219. Only a few details of the procedure were reported in the study, but due to the statement of the authors and the hint on the only deviation (addition of allylthiourea for prevention of nitrification) from the national standard method it can be assumed that all validity criteria of the national standard method were fulfilled. Based on the duration (5 days) and the results obtained it can be assumed that propan-2-ol is readily biodegradable and the criterion of the 10 day window will be fulfilled.

Propan-2-ol is indefinitely miscible in water and adsorption is not to be expected based on a log P_{ow} of 0.05 (cf. Doc III A3.9). The Henry's law constant (cf. Doc III A3.2.1) indicates a moderate volatilisation of propan-2-ol from aqueous solution. However, as the test was conducted in closed bottles volatility of propan-2-ol is not relevant.

5.3 Conclusion

[Redacted]

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

2008/07/03

Materials and Methods

[Redacted]

Results and discussion

[Redacted]

Conclusion

[Redacted]

Reliability


[Redacted]

Acceptability

[Redacted]

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

Remarks	
Date	COMMENTS FROM ... <i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.1/02 Ready biodegradability**Annex Point IIA7.6.1.1**

		Official use only												
1 REFERENCE														
1.1 Reference	Gerike P, Gode P (1990) The biodegradability and inhibitory threshold concentration of some disinfectants. Chemosphere 21(6), 799-812 (published)													
1.2 Data protection	No													
1.2.1 Data owner	-													
1.2.2 Criteria for data protection	No data protection claimed													
2 GUIDELINES AND QUALITY ASSURANCE														
2.1 Guideline study	Yes, OECD guideline 301D 'Ready biodegradability: Closed Bottle Test' 1990													
2.2 GLP	██████████													
2.3 Deviations	No data	x												
3 MATERIALS AND METHODS														
3.1 Test material	Propan-2-ol	x												
3.1.1 Lot/Batch number	-													
3.1.2 Specification	2-Propanol													
3.1.3 Purity	Purity not stated													
3.1.4 Further relevant properties	-													
3.1.5 Composition of Product	Not applicable													
3.1.6 TS inhibitory to microorganisms	An oxygen consumption inhibition test was performed according to ISO 8192 (cf. Doc III A7.4.1.4 ; $IC_0 > 1000$ mg/L).	x												
3.1.7 Specific chemical analysis	Not performed and not required by guideline.													
3.2 Reference substance	No data													
3.2.1 Initial concentration of reference substance	-													
3.3 Testing procedure														
3.3.1 Inoculum / test species	<table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Nature</td> <td>Microbial inoculum (not further specified)</td> </tr> <tr> <td>Species</td> <td>No data</td> </tr> <tr> <td>Strain</td> <td>No data</td> </tr> <tr> <td>Source</td> <td>No data</td> </tr> <tr> <td>Sampling site</td> <td>No data</td> </tr> </tbody> </table>	Criteria	Details	Nature	Microbial inoculum (not further specified)	Species	No data	Strain	No data	Source	No data	Sampling site	No data	
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Strain	No data													
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Section A7.1.1.2.1/02 Ready biodegradability

Annex Point IIA7.6.1.1

	Laboratory culture	No data																
	Method of cultivation	No data																
	Preparation of inoculum for exposure	No data																
	Pretreatment	Non-adapted culture used for testing																
	Initial cell concentration	No data																
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Suspended solids concentration	No data																	
Other relevant criteria	No data																	
3.3.4	Method of preparation of test solution	No data																
3.3.5	Initial TS concentration	2 - 5 mg propan-2-ol/L																
3.3.6	Duration of test	28 days																
3.3.7	Analytical parameter	% BOD of ThOD																
3.3.8	Sampling	No data																
3.3.9	Intermediates/ degradation products	No data																
3.3.10	Nitrate/nitrite measurement	-																
3.3.11	Controls	No data																

Section A7.1.1.2.1/02 Ready biodegradability**Annex Point IIA7.6.1.1**

3.3.12 Statistics No data

4 RESULTS**4.1 Degradation of test substance**

4.1.1 Graph Not available

4.1.2 Degradation 84% BOD of ThOD after 28 days

4.1.3 Other observations No data

4.1.4 Degradation of TS in abiotic control No data

4.1.5 Degradation of reference substance No data

4.1.6 Intermediates/ degradation products No data

5 APPLICANT'S SUMMARY AND CONCLUSION**5.1 Materials and methods**

This test on ready biodegradability of propan-2-ol was performed according to OECD guideline 301D (Closed Bottle Test). Test concentration of propan-2-ol was within the range given in the guideline. Further details were not stated in the reference. Deviations from guideline were not reported. Therefore, the test results were regarded as reliable although the testing procedure and detailed results were not presented in the reference.

5.2 Results and discussion

After 28 days 84% biodegradation was observed by measurement of BOD.

	fulfilled	not fulfilled
Pass levels		
60% removal of ThOD	X	
Pass values reached within 10-d/14-d window	No data	No data
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%	No data	No data
Percentage of removal of reference substance reaches pass level by day 14	No data	No data

In the publication no information is given whether the criteria of the 10 day-window is fulfilled.

An oxygen consumption inhibition test was performed according to ISO 8192. Based on the concentrations applied in the biodegradation test inhibition of oxygen consumption is not to be expected ($IC_{50} > 1000$ mg/L; cf. Doc III A7.4.1.4).

Propan-2-ol is indefinitely miscible in water and adsorption is not to be expected based on a $\log P_{ow}$ of 0.05 (cf. Doc III A3.9). The Henry's law constant (cf. Doc III A3.2.1) indicates a moderate volatilisation of propan-2-ol from aqueous solution. However, as the test was conducted

Section A7.1.1.2.1/02 Ready biodegradability

Annex Point IIA7.6.1.1

in closed bottles volatility of propan-2-ol is not relevant.
As the study was conducted according to guideline the study is regarded as valid although some data are not reported (e.g. 10 day-window, controls without test substance).

5.3 Conclusion

[Redacted]

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

Evaluation by Competent Authorities

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

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

2008/07/03

Materials and Methods

[Redacted]

Results and discussion

[Redacted]

Conclusion

[Redacted]

Reliability

[Redacted]

Acceptability

[Redacted]

Remarks

[Redacted]

COMMENTS FROM ...

Date

Give date of comments submitted

Section A7.1.1.2.1/02 Ready biodegradability

Annex Point IIA7.6.1.1

Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.1/03 Ready biodegradability

Annex Point IIA7.6.1.1

		1 REFERENCE									
1.1	Reference	Price KS, Waggy GT, Conway RA (1974) Brine shrimp bioassay and seawater BOD of petrochemicals. J Water Pollut Control Fed 46, 63-77 (published)									
1.2	Data protection	No									
1.2.1	Data owner	-									
1.2.2	Criteria for data protection	No data protection claimed									
		2 GUIDELINES AND QUALITY ASSURANCE									
2.1	Guideline study	No. No guidelines available at the time the study was conducted. The study was conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water.									
2.2	GLP	[REDACTED]									
2.3	Deviations	-	x								
		3 MATERIALS AND METHODS	x								
3.1	Test material	Propan-2-ol	x								
3.1.1	Lot/Batch number	-									
3.1.2	Specification	Isopropanol									
3.1.3	Purity	No data									
3.1.4	Further relevant properties	-									
3.1.5	Composition of Product	Not applicable.									
3.1.6	TS inhibitory to microorganisms	No data.									
3.1.7	Specific chemical analysis	No.									
3.2	Reference substance	No data.									
3.2.1	Initial concentration of reference substance	No data									
3.3	Testing procedure										
3.3.1	Inoculum / test species	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Criteria</th> <th style="width: 50%;">Details</th> </tr> </thead> <tbody> <tr> <td>Nature</td> <td>Settled domestic waste water, non adapted</td> </tr> <tr> <td>Species</td> <td style="text-align: center;">-</td> </tr> <tr> <td>Strain</td> <td style="text-align: center;">-</td> </tr> </tbody> </table>	Criteria	Details	Nature	Settled domestic waste water, non adapted	Species	-	Strain	-	
Criteria	Details										
Nature	Settled domestic waste water, non adapted										
Species	-										
Strain	-										

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x
x
x

Section A7.1.1.2.1/03 Ready biodegradability

Annex Point IIA7.6.1.1

3.3.2 Test system

Source	Settled domestic waste water, non adapted. No further details specified.
Sampling site	No data.
Laboratory culture	No.
Method of cultivation	No data
Preparation of inoculum for exposure	Settled domestic waste water was filtered, added to BOD bottles (3 mL/bottle). The bottles were half filled with aerated dilution water containing specified minerals and buffer.
Pretreatment	No adaptation
Initial cell concentration	No data.
Criteria	Details
Culturing apparatus	BOD bottles (respirometer; BOD bottles: 300 mL volume)
Number of culture flasks/concentration	At least two of the test concentrations were tested in duplicate.
Aeration device	When the dissolved oxygen in the bottles dropped below 4 mg/L, the contents were re-aerated through an adapter
Measuring equipment	Dissolved oxygen was measured, no further details stated
Test performed in closed vessels due to significant volatility of TS	Yes. BOD bottles

3.3.3 Test conditions

Criteria	Details
Composition of medium	No data
Additional substrate	No data
Test temperature	No data
pH	No data
Aeration of dilution water	Yes, no further information available
Suspended solids concentration	No data
Other relevant criteria	From 0.1 percent stock solutions small aliquots were added to the test bottles yielding test concentrations of 3, 7, and 10 mg/L; these concentrations resulted in an oxygen demand of 3-30 mg/L over the 20-day test duration. No further details provided.

Section A7.1.1.2.1/03 Ready biodegradability**Annex Point IIA7.6.1.1**

3.3.4	Method of preparation of test solution	Propan-2-ol is indefinitely miscible with water (cf. Doc III A3.5). A 0.1% stock solution was prepared.
3.3.5	Initial TS concentration	3 - 10 mg propan-2-ol/L (corresponding to an oxygen demand of 3 - 30 mg/L over the 20 day test duration).
3.3.6	Duration of test	20 days
3.3.7	Analytical parameter	% BOD of ThOD
3.3.8	Sampling	The bottles were opened for sampling and dissolved oxygen measurements about five times during the course of the 20-day test
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	Not applicable
3.3.11	Controls	Controls were performed, but no details were provided.
3.3.12	Statistics	Results of biodegradation tests were expressed in terms of percent bio-oxidation, defined as follows: Percent bio-oxidized= $100(O'_s - O_b)/C_x \times \text{ThOD}$ O'_s =cumulative oxygen uptake for the oxidation of the carbonaceous material in the test sample bottle from day zero to the day of interest (mg/L) O_b = cumulative oxygen uptake in a blank, containing the same amount and type of microbial seed as the test sample bottle, from day zero to the day of interest (mg/L) C_x =initial concentration of compound being tested (mg/L) ThOD=theoretical oxygen demand

4 RESULTS**4.1 Degradation of test substance**

4.1.1	Graph	Not available
4.1.2	Degradation	Biodegradation after 5 days: 28 % 10 days: 77% 15 days: 80% 20 days: 78%
4.1.3	Other observations	No data
4.1.4	Degradation of TS in abiotic control	No data, but the results of controls were taken into account by calculating biodegradation.
4.1.5	Degradation of reference substance	No data
4.1.6	Intermediates/ degradation products	No data

Section A7.1.1.2.1/03 Ready biodegradability**Annex Point IIA7.6.1.1****5 APPLICANT'S SUMMARY AND CONCLUSION****5.1 Materials and methods**

Test (Closed Bottle Test) conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water. Deviations from the national standard method are not reported. In comparison to OECD guideline 301D the two concentrations tested (7 and 10 mg/L) were higher than that recommended by guideline.

5.2 Results and discussion

	fulfilled	not fulfilled
Pass levels		
60% removal of ThOD	X	
Pass values reached within 10-d window	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%	No data	
Percentage of removal of reference substance reaches pass level by day 14	No data	

The biodegradation test was conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water. Within 20 days 78% of propan-2-ol was degraded. The criterion of the 10-day-window is fulfilled. Therefore, propan-2-ol can be considered as readily biodegradable. Based on the information provided the study can be regarded as valid although composition of medium (e.g. nutrient solution), additional substrate, pH, test temperature, and concentration of inoculum were not given.

Propan-2-ol is indefinitely miscible in water and adsorption is not to be expected based on a log P_{ow} of 0.05 (cf. Doc III A3.9). The Henry's law constant (cf. Doc III A3.2.1) indicates a moderate volatilisation of propan-2-ol from aqueous solution. However, as the test was conducted in closed bottles volatility of propan-2-ol is not relevant.

5.3 Conclusion

5.3.1 Reliability

5.3.2 Deficiencies

Evaluation by Competent Authorities

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

EVALUATION BY RAPporteur MEMBER STATE**Date**

2008/07/03

Section A7.1.1.2.1/03 Ready biodegradability

Annex Point IIA7.6.1.1

Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
Date	COMMENTS FROM ... <i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

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1 REFERENCE

- 1.1 Reference** [REDACTED] (2012) DOC Die-Away Test. Ready Biodegradability of Propanol-2 by Activated Sludge. [REDACTED]
- 1.2 Data protection** Yes
- 1.2.1 Data owner Task Force Alkohole equal to Task Force “2-Propanol”
- 1.2.2 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

2 GUIDELINES AND QUALITY ASSURANCE

- 2.1 Guideline study** Yes
[REDACTED]
- 2.2 GLP** [REDACTED]
- 2.3 Deviations** [REDACTED]

3 MATERIALS AND METHODS

- 3.1 Test material** Propan-2-ol
- 3.1.1 Lot/Batch number [REDACTED]
- 3.1.2 Specification [REDACTED]
- 3.1.3 Purity [REDACTED]
- 3.1.4 Further relevant properties [REDACTED]
- 3.1.5 Composition of Product Not applicable
- 3.1.6 TS inhibitory to microorganisms No data given in the test report
- 3.1.7 Specific chemical analysis Not performed
- 3.2 Reference substance** Yes: Sodium benzoate, purity 99 %
- 3.2.1 Initial concentration of reference substance 20 mg DOC/L
- 3.3 Testing procedure**

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.1 Inoculum /
test species

[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]

3.3.2 Test system

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.3 Test conditions

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

3.3.4 Method of preparation of test solution

[REDACTED]

3.3.5 Initial TS concentration

20 mg DOC/L

3.3.6 Duration of test

28 days

3.3.7 Analytical parameter

DOC removal, duplicate measurements

3.3.8 Sampling

DOC determined at day 4, 7, 11, 14, 21, and 28

3.3.9 Intermediates/ degradation products

Not identified

3.3.10 Nitrate/nitrite measurement

No

3.3.11 Controls

Blank control: inoculated mineral medium only
 Adsorption control: test item 20 mg DOC/L sterilized inoculated mineral test medium. Assay sterilized by adding HgCl₂.
 Abiotic control: test item 20 mg DOC/L sterilized mineral test medium. Assay sterilized by adding HgCl₂.
 Procedural control: reference item and inoculum.
 Toxicity control: test item 20 mg DOC/L and reference at 10 mg DOC/L mineral test medium.

x

3.3.12 Statistics

Mean values of at least duplicate measurements were used

4 RESULTS

4.1 Degradation of test substance

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

4.1.1 Graph



4.1.2 Degradation

[Redacted]					
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]					

x

4.1.3 Other observations

[Redacted]

4.1.4 Degradation of TS in abiotic control

[Redacted]

4.1.5 Degradation of reference substance

[Redacted]

4.1.6 Intermediates/ degradation products

[Redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[Redacted]

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

5.2 Results and discussion	[Redacted]			x
	[Redacted]			
		[Redacted]	[Redacted]	
	[Redacted]			
	[Redacted]	[Redacted]		
	[Redacted]	[Redacted]		
	[Redacted]	[Redacted]		
	[Redacted]	[Redacted]		
	[Redacted]	[Redacted]		
5.3 Conclusion	[Redacted]			
5.3.1 Reliability	[Redacted]			
5.3.2 Deficiencies	[Redacted]			

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	EVALUATION BY RAPPORTEUR MEMBER STATE 2014/01/13
Materials and Methods	[Redacted]

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

Results and discussion

[REDACTED]

Conclusion

[REDACTED]

Reliability

[REDACTED]

Acceptability

[REDACTED]

[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*

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

		1 REFERENCE	
1.1 Reference		[REDACTED] (1993) Propyl alcohol [by using isopropyl alcohol, the number of the tested substance:K-1085]'s biodegradability by microorganisms. [REDACTED]	
1.2 Data protection		No	
1.2.1 Data owner		-	
1.2.2 Criteria for data protection		No data protection claimed	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Yes	
		[REDACTED]	
2.2 GLP		[REDACTED]	
2.3 Deviations		No	
		3 MATERIALS AND METHODS	
3.1 Test material		Propan-2-ol	
3.1.1 Lot/Batch number		[REDACTED]	
3.1.2 Specification		[REDACTED]	
3.1.3 Purity		[REDACTED]	
3.1.4 Further relevant properties		[REDACTED]	
3.1.5 Composition of Product		Not applicable	
3.1.6 TS inhibitory to microorganisms		No data	
3.1.7 Specific chemical analysis		[REDACTED]	
3.2 Reference substance		Yes: Aniline	
3.2.1 Initial concentration of reference substance		100 mg/L	
3.3 Test ing procedure			

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Section A7.1.1.2.1/06 **Biodegradability (ready)**

Annex Point IIA7.6.1.1

3.3.1 Inoculum /
test species

[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]

x

Section A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.2	Test system	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
3.3.3	Test conditions	[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
		[REDACTED]	[REDACTED]
3.3.4	Method of preparation of test solution	[REDACTED]	
3.3.5	Initial TS concentration	100 mL/L	
3.3.6	Duration of test	14 days	
3.3.7	Analytical parameter	BOD, TOC, analysis of the test substance by gas chromatography (GC)	
3.3.8	Sampling	Measured at end of test	
3.3.9	Intermediates/ degradation products	Not identified	
3.3.10	Nitrate/nitrite measurement	No	

x

Section A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

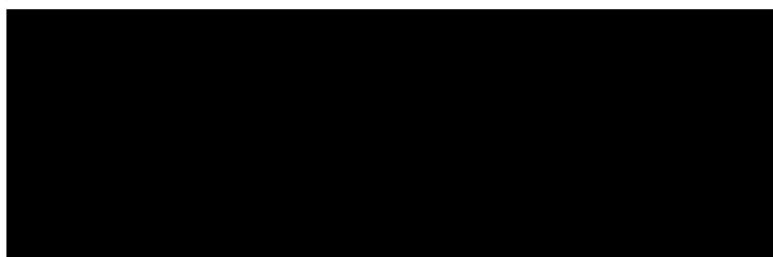
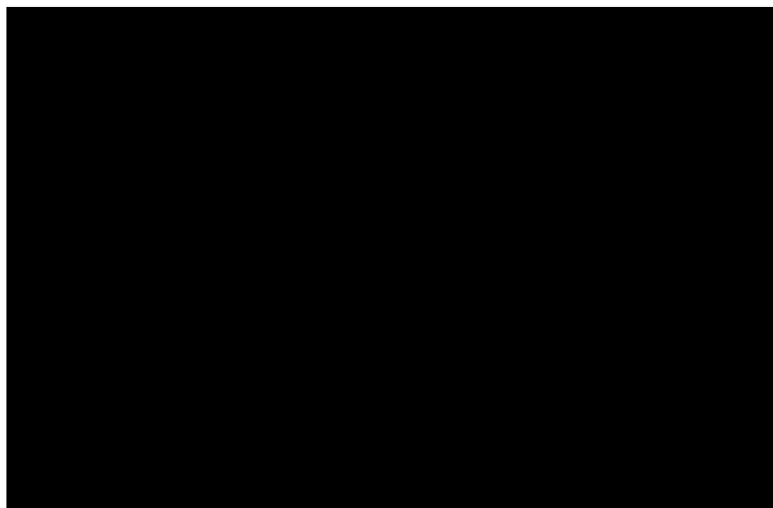
3.3.11 Controls Abiotic control (water + test substance)

3.3.12 Statistics None

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph



4.1.2 Degradation

[Redacted]

[Redacted]	[Redacted]		
[Redacted]	■	■	■
[Redacted]	■	■	■

[Redacted]

[Redacted]	[Redacted]		
[Redacted]	■	■	■
[Redacted]	■	■	■
[Redacted]	■	■	■
[Redacted]	■	■	■

Section A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

- 4.1.3 Other observations
- 4.1.4 Degradation of TS in abiotic control
- 4.1.5 Degradation of reference substance
- 4.1.6 Intermediates/ degradation products

[Redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[Redacted]

5.2 Results and discussion

[Redacted]

[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

5.3 Conclusion

[Redacted]

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

x

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.	
EVALUATION BY RAPporteur MEMBER STATE	
Date	2014/01/13
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.2 Inherent biodegradability		
Annex Point IIA7.6.2.1		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	<div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 100%; height: 15px; margin-bottom: 5px;"></div>	
	Reference: None	
Undertaking of intended data submission <input type="checkbox"/>	Not applicable, no study is planned.	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	2008/07/04	
Evaluation of applicant's justification	<div style="background-color: black; width: 100%; height: 15px;"></div>	
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>	
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Section A7.1.1.2.3 Biodegradation in seawater

Annex Point IIA7.6.1.1

		1 REFERENCE											
1.1	Reference	Price KS, Waggy GT, Conway RA (1974) Brine shrimp bioassay and seawater BOD of petrochemicals. J Water Pollut Control Fed 46, 63-77 (published)											
1.2	Data protection	No											
1.2.1	Data owner	-											
1.2.2	Criteria for data protection	No data protection claimed											
		2 GUIDELINES AND QUALITY ASSURANCE											
2.1	Guideline study	No. No international guidelines available at the time the study was conducted. However, the study was conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water.											
2.2	GLP												
2.3	Deviations	-	x										
		3 MATERIALS AND METHODS											
3.1	Test material	Propan-2-ol											
3.1.1	Lot/Batch number	-											
3.1.2	Specification	Isopropanol											
3.1.3	Purity	No data											
3.1.4	Further relevant properties	-											
3.1.5	Composition of Product	Not applicable.											
3.1.6	TS inhibitory to microorganisms	No data.											
3.1.7	Specific chemical analysis	No.											
3.2	Reference substance	No data.											
3.2.1	Initial concentration of reference substance	No data											
3.3	Test ing procedure												
3.3.1	Inoculum / test species	<table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Nature</td> <td>Seed developed from sea water (not further specified).</td> </tr> <tr> <td>Species</td> <td>-</td> </tr> <tr> <td>Strain</td> <td>-</td> </tr> <tr> <td>Source</td> <td>Sea water taken from Lavaca Bay,</td> </tr> </tbody> </table>	Criteria	Details	Nature	Seed developed from sea water (not further specified).	Species	-	Strain	-	Source	Sea water taken from Lavaca Bay,	
Criteria	Details												
Nature	Seed developed from sea water (not further specified).												
Species	-												
Strain	-												
Source	Sea water taken from Lavaca Bay,												

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x
x

Section A7.1.1.2.3

Biodegradation in seawater

Annex Point IIA7.6.1.1

3.3.2 Test system

	Texas
Sampling site	Lavaca Bay, Texas
Laboratory culture	No.
Method of cultivation	-
Preparation of inoculum for exposure	Sea water taken from Lavaca Bay, Texas was maintained by adding small amounts of settled raw wastewater about every 3 to 4 days. Nutrient salts and buffer were added to the artificial seawater (according to US APHA (1971)).
Pretreatment	No adaptation
Initial cell concentration	No data.
Criteria	Details
Culturing apparatus	BOD bottles (respirometer; BOD bottles: 300 mL volume)
Number of culture flasks/concentration	At least two of the test concentrations were tested in duplicate.
Aeration device	When the dissolved oxygen in the bottles dropped below 4 mg/L, the contents were re-aerated through an adapter
Measuring equipment	Dissolved oxygen was measured, no further details stated
Test performed in closed vessels due to significant volatility of TS	Yes. BOD bottles

3.3.3 Test conditions

Criteria	Details
Composition of medium	Synthetic seawater (dissolved in 20 L of distilled water) Sodium chloride: 557.37 mg Calcium sulfate: 27.20 mg Magnesium sulfate, heptahydrate: 63.36 mg Magnesium chloride: 168.30 mg Potassium chloride: 15.84 mg Magnesium bromide, hexahydrate: 3.14 mg Nutrient salts and buffer according to US APHA (1971; not further specified)
Additional substrate	No data

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Biodegradation in seawater

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Test temperature	No data
pH	No data
Aeration of dilution water	Yes, no further information available
Suspended solids concentration	No data
Other relevant criteria	From 0.1 percent stock solutions small aliquots were added to the test bottles yielding test concentrations of 3, 7, and 10 mg/L; these concentrations resulted in an oxygen demand of 3-30 mg/L over the 20-day test duration. No further details provided.

- 3.3.4 Method of preparation of test solution Propan-2-ol is indefinitely miscible with water (cf. Doc III A3.5). A 0.1% stock solution was prepared.
- 3.3.5 Initial TS concentration 3 - 10 mg propan-2-ol/L (corresponding to an oxygen demand of 3 - 30 mg/L over the 20 day test duration).
- 3.3.6 Duration of test 20 days
- 3.3.7 Analytical parameter % BOD of ThOD
- 3.3.8 Sampling The bottles were opened for sampling and dissolved oxygen measurements about five times during the course of the 20-day test
- 3.3.9 Intermediates/ degradation products Not identified
- 3.3.10 Nitrate/nitrite measurement Not applicable
- 3.3.11 Controls Controls were performed, but no details were provided.
- 3.3.12 Statistics Results of biodegradation tests were expressed in terms of percent bio-oxidation, defined as follows:
Percent bio-oxidized= $100(O'_s - O_b)/C_x \times \text{ThOD}$
 O'_s =cumulative oxygen uptake for the oxidation of the carbonaceous material in the test sample bottle from day zero to the day of interest (mg/L)
 O_b = cumulative oxygen uptake in a blank, containing the same amount and type of microbial seed as the test sample bottle, from day zero to the day of interest (mg/L)
 C_x =initial concentration of compound being tested (mg/L)
ThOD = theoretical oxygen demand

4 RESULTS

4.1 Degradation of test substance

4.2 Degradation of

Not available

Section A7.1.1.2.3

Biodegradation in seawater

Annex Point IIA7.6.1.1

test substance	
4.2.1	Graph
	Biodegradation after
	5 days: 13 %
	10 days: 42%
	15 days: 60%
	20 days: 72%
4.2.2	Degradation
	No data
4.2.3	Other observations
	No data, but the results of controls were taken into account by calculating biodegradation.
4.2.4	Degradation of TS in abiotic control
	No data
4.2.5	Degradation of reference substance
	No data

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	Biodegradation test (Closed Bottle Test) conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water. In deviation from the national standard method the biodegradation test was performed in artificial seawater using an inoculum obtained from natural seawater and maintained by adding settled raw wastewater. In comparison to OECD guideline 301D the two concentrations tested (7 and 10 mg/L) were higher than that recommended by guideline.
5.2	Results and discussion	

	fulfilled	not fulfilled
Pass levels		
60% removal of ThOD	X	
Pass values reached within 10-d window		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%	No data	
Percentage of removal of reference substance reaches pass level by day 14	No data	

The biodegradation test was conducted according to national standard method: US APHA (1971) Standard methods for the examination of water and waste water. The biodegradation test was performed in artificial seawater. Within 20 days 72% of propan-2-ol were degraded. In this instance the criteria of the 10-day-window is not fulfilled. Under the conditions employed propan-2-ol can be considered as biodegradable. Based on the information provided the study can be regarded as valid although composition of medium (e.g. nutrient solution), additional substrate, pH, test temperature, and concentration of inoculum were not given.

Propan-2-ol is indefinitely miscible in water and adsorption is not to be

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Biodegradation in seawater

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expected based on a log P_{ow} of 0.05 (cf. Doc III A3.9). The Henry's law constant (cf. Doc III A3.2.1) indicates a moderate volatilisation of propan-2-ol from aqueous solution. However, as the test was conducted in closed bottles volatility of propan-2-ol is not relevant.

5.3 Conclusion

[Redacted]

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

Evaluation by Competent Authorities

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

Date

EVALUATION BY RAPPORTEUR MEMBER STATE

2009/02/26

Materials and Methods

[Redacted]

Results and discussion

[Redacted]

Conclusion

[Redacted]

Reliability

[Redacted]

Acceptability


[Redacted]




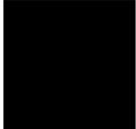





Remarks

[Redacted]

Section A7.1.1.2.3 Biodegradation in seawater

Annex Point IIA7.6.1.1

	
	COMMENTS FROM ...
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.3		Adsorption / Desorption screening test
Annex Point IIA7.7		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data []	Technically not feasible []	Scientifically unjustified [X]
Limited exposure []	Other justification []	
Detailed justification:		
		X
		X
		
		
		
		
References:		
Undertaking of intended data submission []		

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/04
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

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

Annex Point IIIA VII 5

		1 REFERENCE	
1.1 Reference		Atkinson R, Baulch DL, Cox RA, Crowley, JN, Hampson RF, Hynes RG, Jenkin ME, Rossi MJ, Troe J (2006) Evaluated kinetic and photochemical data for atmospheric chemistry: Volume II – Reactions of organic species, IUPAC Subcommittee on Gas Kinetic Data Evaluation for Atmospheric Chemistry. In: Atmos Chem Phy 6, pp. 3723-3729 & 3816-3820 of 3625-4055 (published)	
1.2 Data protection		No.	
1.2.1 Data owner		-	
1.2.2 Criteria for data protection		No data protection claimed.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		Not applicable. Preferred value from critical review	
2.2 GLP		██████████	
2.3 Deviations		Not applicable.	
		3 MATERIALS AND METHODS	
3.1 Test material		Propan-2-ol	
3.1.1 Lot/Batch number		Not applicable.	
3.1.2 Specification		Isopropanol	
3.1.3 Purity		For estimation, 100% purity was assumed	
3.2 Estimation method			
3.2.1 Considered reaction		Reaction in the atmosphere of photochemically produced OH radicals with propan-2-ol. Hydrogen abstraction was observed.	
3.2.2 Assumptions		The degradation half-life for OH radicals was calculated by the applicant using the formula $\tau_{1/2} = \ln(2)/(k_{OH} [OH])$. The calculation is based on $0.5 \cdot 10^6$ OH radicals per cm^3 for a 24-hours-day according to the TGD (EC 2003, part II chapter 3, 2.3.6.3, p. 51).	
3.2.3 Calculation		The rate constant of propan-2-ol for the photochemical oxidative reaction with OH radicals is the preferred value by Atkinson et al. (2006) using reviewed data from several authors.	
		4 RESULTS	
4.1 Rate constant		$k(OH) = 5.1 \times 10^{-12} \text{ cm}^3 \text{ molecule}^{-1} \text{ s}^{-1}$ at 298 K with an estimated error of 20% . NO_3 radicals: $1.4 \cdot 10^{-15} \text{ cm}^3 \text{ molecule}^{-1} \text{ s}^{-1}$ at 298 K with an estimated error of 100% by Atkinson et al. (2006)	
4.2 Half-life		$t_{1/2} = 3.1$ days. For the large error bars no significant contribution can be estimated by NO_3 reactivity.	

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

Annex Point IIIA VII 5

4.3	Specification of breakdown products	The specification of breakdown products was not examined.	
5 APPLICANT'S SUMMARY AND CONCLUSION			
5.1	Materials and methods	The atmospheric photo-oxidative degradation of 2-propanol by OH radicals was estimated based on various experimental data. No guidelines for this purpose are available. But the calculation method takes into account generally accepted scientific principles.	
5.2	Results and discussion	<p>Photodegradation via OH radicals was calculated according to generally accepted scientific principles:</p> <p>$-k(\text{OH}) = 5.1 \times 10^{-12} \text{ cm}^3 \text{ molecule}^{-1} \text{ s}^{-1}$</p> <p>$-t_{1/2} = 3.1 \text{ days}$.</p> <p>The results indicate that propan-2-ol will be rapidly degraded in air by photochemically produced OH radicals.</p> <p>The estimation is considered to be valid</p>	X
5.2.1	k_p^c		
5.2.2	K_{pE}		
5.2.3	ϕ_E^c		
5.2.4	$t_{1/2E}$	$t_{1/2} = 3.1 \text{ days}$	
5.3	Conclusion	[REDACTED]	X
5.3.1	Reliability	[REDACTED]	
5.3.2	Deficiencies	[REDACTED]	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/01
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]

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

Annex Point IIIA VII 5

Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.3.1/02
Annex Point IIIA VII 5Phototransformation in air (measurement), including
identification of breakdown products

		1 REFERENCE
1.1	Reference	Overend R, Parasekevopoulos G (1978) Rates of OH radical reactions. 4. Reactions with methanol, ethanol, 1-propanol, and 2-propanol at 296 K. J Phys Colloid Chem 82, 1329-1333 (published)
1.2	Data protection	No.
1.2.1	Data owner	-
1.2.2	Criteria for data protection	No data protection claimed
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	Guideline study	No. At that time no guideline was available.
2.2	GLP	
2.3	Deviations	-
		3 MATERIALS AND METHODS
3.1	Test material	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	Propan-2-ol
3.1.3	Purity	Purity not stated
3.1.4	Radiolabelling	No.
3.1.5	UV/VIS absorption spectra and absorbance value	No data.
3.1.6	Further relevant properties	-
3.2	Reference substances	No data.
3.3	Testing procedure	
3.3.1	Test system	Rate constants for the reaction of OH with propan-2-ol were measured using flash-photolysis resonance absorption technique. The apparatus consists of a fast flash-photolysis system coupled to a spectrophotometric detection system. The flash lamp was coaxial with the reaction vessel and was operated at ca. 160 J. OH radicals were produced either by photolysis of water vapor or photolysis of N ₂ O/H ₂ . OH concentrations were monitored by following the time resolved attenuation of the OH resonance radiation produced by a microwave discharge in a low pressure Ar/H ₂ O mixture. The radiation was detected with a photomultiplier (EMI 9783B) mounted at the exit slit of a 1-m Czerny-Turner monochromator (Jarell-Ash).
3.3.2	Properties of light source	The flash lamp operated at ca. 160 J
3.3.3	Determination of irradiance	Photomultiplier (EMI 9783B)

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