Section A6.9/02 Neurotoxicity

Annex Point IIA6.9 Inhalation study with rats

3.6 Further remarks

Biological procedures:
Motor activity evaluations were performed prior to the initiation of exposures (ca. 1 week) and on the Saturday following 4, 7 and 9, 11 and 13 weeks of exposure. To assess reversibility, animals exposed over 9 weeks were further evaluated 2, 4 and 7 days following their final exposure. Animals exposed over 13 weeks were further evaluated 2, 4, 7, 14, 21, 28, 35 and 42 days following their final exposure. Approximately 18 and 20 hrs elapsed between the end of the exposure and the beginning of the 1 day post-exposure motor activity test sessions for the 13 and 9 week groups, respectively. Motor activity measurements were conducted in an isolated room modified to control sound levels, light levels and environmental odours. Animals were tested individually using an automated photocell-recording apparatus designed to measure activity in a novel environment. The length of the test session was 90 min and data for ambulatory activity, fine motor activity, rearing activity and the sum of these individual types of activity (sum of all counters or total activity) were collected automatically in nine consecutive 10 min intervals for subsequent analysis.

Statistical procedures:
The data for continuous, parametric variables were intercompared for the exposure and control groups by use of Levene's test for homogeneity of variances and by t-tests. If Levene's test indicated homogeneous variances, the groups were compared by pooled variance t-tests. If Levene's test indicated heterogeneous variances, the groups were compared by separate variance t-tests.
The shape of the motor activity versus test session time curves (hereafter referred to as the motor activity habituation curves) were analyzed for possible exposure-related changes using repeated-measures analyses with exposure concentration as the grouping factor and test session time as the within-subjects factor. These analyses used the epsilon-adjustment procedure (Greenhouse–Geisser correction). Repeated measures analyses were performed for ambulatory activity, fine movements, rearing activity and total activity. Numerical differences in motor activity between exposed and control groups at within-session intervals were not analyzed statistically.
Cumulative test session motor activity data were analyzed for possible exposure-related changes if the results of the repeated measures analyses indicated an effect of treatment. These analyses were performed using the methods described above for continuous parametric variables. All statistical tests were performed using BMDP Statistical Software. The probability value of $P < 0.05$ (two-tailed) was used as the critical level of significance for all tests.

4 RESULTS AND DISCUSSION

4.1	**Body Weight**	Body weight and body weight gain were decreased for the exposed animals after 1 week of exposure. Following 3 weeks of exposure, statistically significant increases in body weight and body weight gain were observed. Statistically significant increases in body weight were noted in exposed rats throughout the remainder of the study. In rats exposed over 9 week, the final mean body weight and body weight gain was increased by ca. 6 and 17 %, respectively. In rats exposed over 13 weeks, the final mean body weight and body weight gain was increased by ca. 5 and 13 %, respectively. During the recovery period, increases in body weight and body weight gain remained for exposed rats as compared to controls, although smaller increases in body weight variables were observed during the recovery period than during the exposure regimen. At week 19, the mean body weight and body weight gain was increased by 3 and 9 %, respectively.
4.2	**Clinical signs of toxicity**	No exposure-related mortality. During exposure an apparent decrease in movement within the animal enclosures and a diminished startle response to tapping on the wall of the inhalation chamber was noted. During the non-exposure periods swollen periocular tissue was observed.
4.3	**Clinical Chemistry**	Not done
4.4	**Pathology**	Not done
4.5	**Histopathology**	Not done

Section A6.9/02 **Neurotoxicity**

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4.6	**Other**	In exposed rats increases in mean cumulative motor activity (the sum of total activity across the 90 min test session) were observed at all of the evaluation time points during the exposure regimen. The increase in total activity reflected increases in ambulation, fine motor activity and rearing activity. There was no evidence for a preferential increase in any of these individual types of activity. In rats exposed over 9 weeks, increases in mean cumulative motor activity (the sum of total activity across the 90 min test session) were noted following the completion of 4, 7 and 9 weeks of exposure. Mean cumulative test session activity for these animals was increased by 41, 79 and 76 % at weeks 4, 7 and 9. During the recovery period, mean cumulative test session activity was not different from control values. In rats exposed over 13 weeks, mean cumulative test session activity was increased following the completion of 4, 7, 9, 11 and 13 weeks of exposure (35, 53, 144, 103 and 116 %, respectively). During the recovery period, increases in mean cumulative test session activity for these animals were also observed 2, 4, 7 and 28 days following their last exposure (79, 69, 38 and 50 %, respectively). Mean cumulative test session activity was not different from controls at days 14, 21, 35 and 42 days after exposure. Repeated measures analysis of motor activity habituation curves indicated statistically significant differences between exposed rats and controls at some study weeks. For rats exposed over 9 weeks, a change in the shape of the motor activity habituation curve was observed at week 6. For rats exposed over 13 weeks, changes in the shape of the motor activity habituation curve that were coincident with increased cumulative test session activity were observed at weeks 4, 9 and 11 as well as 4 days following the last exposure. At these time points, the mean activity was increased at most of the 10 min intra-session intervals. There were also statistically significant differences in the shape of the motor activity habituation curves for animals in both groups at time points where mean cumulative activity was not increased. These findings were attributed to an increase activity during the initial 10 – 30 min of the test session and were noted at day 7 or days 14, 21 and 35 following the last exposure over 9 or 13 weeks, respectively. No differences in the shape of the motor activity habituation curves were apparent between controls and the exposed group on day 42 following the last exposure.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	In this study two groups of 30 female Fischer 344 rats were exposed to concentrations of 0 or 5000 ppm (ca. 0 or 12500 mg/m^3) on 6 hrs day and 5 days per week. 15 rats in each group were exposed over 9 or 13 weeks, respectively. Motor activity was assessed for both subgroups prior to exposure and following 4, 7, 9, 11 and 13 weeks of exposure. These motor activity measurements were made 18 – 20 hrs following the end of the last exposure for that week. In addition, to evaluate the reversibility of motor activity effects, measurements were made on three occasions during the week following the final exposure for rats in both the 9 and 13 week subgroups and weekly thereafter for five additional weeks for rats in the 13 week subgroup.

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	*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 A6.12/01 Medical data

Annex Point IIA 6.12

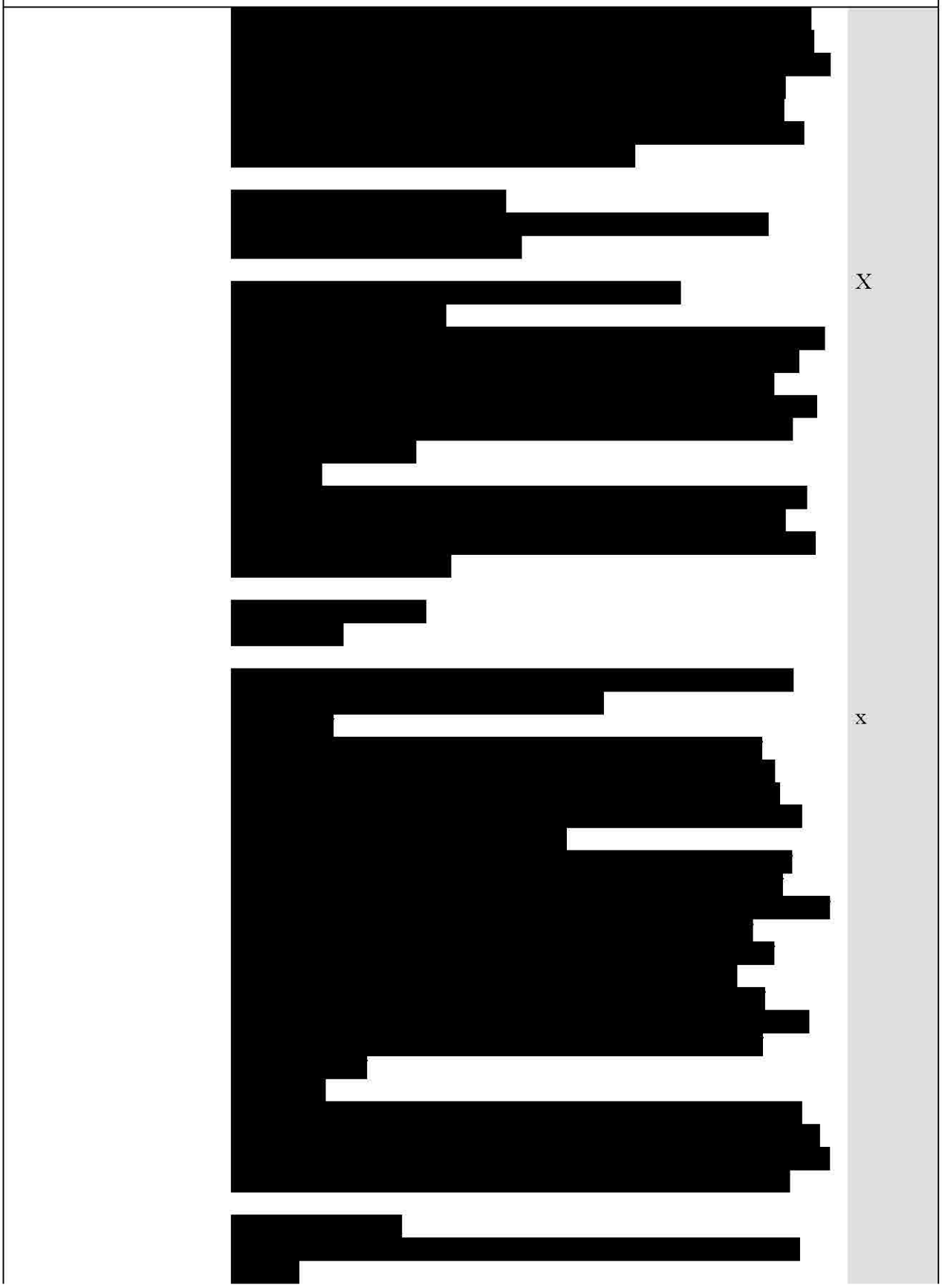
			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2003) 5th Periodic Safety Update Report for: Alcohol solutions for disinfection of intact skin [redacted] 40 pp. [redacted] (2006) Isopropyl alcohol (CAS 67-63-0). Master file for a biocidal substance. [redacted], 37 pp. [redacted] (2007) Addendum Report 4 to 5th Periodic Safety Update Report for: Alcohol solutions for disinfection of intact skin [redacted] 41 pp.	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
Detailed information:		[redacted]	x

Section A6.12/01 **Medical data**

Annex Point IIA 6.12

Section A6.12/01 **Medical data**

Annex Point IIA 6.12



Section A6.12/01 Annex Point IIA 6.12	Medical data
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]

Section A6.12/01 Annex Point IIA 6.12	Medical data
	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	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 A6.12.2/01 Human Case Report

Annex Point IIA6.12

Studies concerning allergic contact dermatitis after contact with isopropanol containing swabs

Official use only

		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**	[redacted]	
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	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**		

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	*Give date of comments submitted*
Materials and Methods	*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*
Remarks	

Section A6.15 Annex Point IIIAVI.4	Food and feedingstuffs studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [x] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [x] Other justification [x]	
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 *(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 A7.1.1.1.1 **Annex Point IIA7.6.2.1**	**Hydrolysis as a function of pH and identification of breakdown products**	
	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] **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)	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/03	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.1.1.1.2 Annex Point IIA7.6.2.2	Phototransformation in water including identity of transformation products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification: References:	[redacted] X	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/01	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

	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 Ready biodegradability

Annex Point IIA7.6.1.1

Official use only

		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	-

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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	**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.
3.3.3	Test conditions	**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 citeria	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	

	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

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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]
Remarks	[redacted]

Section A7.1.1.2.1/01 Ready biodegradability

Annex Point IIA7.6.1.1

	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 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**	[redacted]	
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		

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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		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
3.3.2	Test system	**Criteria**	**Details**
		Culturing apparatus	BOD bottles (no further information stated)
		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. Closed bottle test.
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	No data
		Suspended solids concentration	No data
		Other relevant citeria	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	

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_0 >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	*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 A7.1.1.2.1/03 Ready biodegradability

Annex Point IIA7.6.1.1

			Official use only
		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		

Criteria	Details
Nature	Settled domestic waste water, non adapted
Species	-
Strain	-

Section A7.1.1.2.1/03 Ready biodegradability

Annex Point IIA7.6.1.1

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.

3.3.2 Test system

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 reaerated 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 citeria	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=$100(O'_s - O_b)/C_x$ x 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. x

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

[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

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]

	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 A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

Official use only

		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]
3.3.2	Test system	[redacted]

Section A7.1.1.2.1/05 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.3	Test conditions	[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 $HgCl_2$. Abiotic control: test item 20 mg DOC/L sterilized mineral test medium. Assay sterilized by adding $HgCl_2$. 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	[redacted] 	
4.1.2	Degradation	[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

[redacted]

5.2	**Results and discussion**	[redacted]	x
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	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]
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	*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 A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (1993) Propyl alcohol [by using isopropyl alcohol, the number of the tested substanc: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**	

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] x
		[redacted]
		[redacted]
		[redacted]
		[redacted]

Section A7.1.1.2.1/06 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.2	Test system	[redacted]	
3.3.3	Test conditions	[redacted]	x
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	

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

[redacted]

4.1.2 Degradation

[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	[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]

5.2 Results and discussion

[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	*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 A7.1.1.2.2 Annex Point IIA7.6.2.1	Inherent biodegradability	
	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] **Reference:** None	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/04	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 **Biodegradation in seawater**

Annex Point IIA7.6.1.1

			Official use only
		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**	[redacted]	
2.3	**Deviations**	-	x
		3 MATERIALS AND METHODS	x
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		

Criteria	Details
Nature	Seed developed from sea water (not further specified).
Species	-
Strain	-
Source	Sea water taken from Lavaca Bay,

	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.

3.3.2 Test system

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 Magneium 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

Section A7.1.1.2.3 **Biodegradation in seawater**

Annex Point IIA7.6.1.1

Test temperature	No data
pH	No data
Aeration of dilution water	Yes, no further information available
Suspended solids concentration	No data
Other relevant citeria	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=$100(O'_s - O_b)/C_x$ x 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. x

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

Section A7.1.1.2.3 **Biodegradation in seawater**

Annex Point IIA7.6.1.1

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	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

	[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 A7.1.3 Annex Point IIA7.7	Adsorption / Desorption screening test	
	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] [redacted] X [redacted] X [redacted] [redacted] [redacted] [redacted]	
References:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	