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

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

Annex Point IIIA VII 5

			Official use only
		1 REFERENCE	
1.1	**Reference**	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**	[redacted]	
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 $\tau_{1/2} = \ln(2)/(k_{OH} \cdot [OH])$. 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**	$k(OH) = 5.1 \times 10^{-12}$ cm^3 $molecule^{-1}$ s^{-1} at 298 K with an estimated error of 20% . NO_3 radicals: $1.4 \cdot 10^{-15}$ cm^3 $molecule^{-1}$ s^{-1} at 298 K with an estimated error of 100% by Atkinson et al. (2006)	X
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.	

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**	Photodegradation via OH radicals was calculated according to generally accepted scientific principles: -k(OH) = 5.1 x 10^{-12} cm^3 $molecule^{-1}$ s^{-1} -$t_{1/2}$ = 3.1 days. The results indicate that propan-2-ol will be rapidly degraded in air by photochemically produced OH radicals. The estimation is considered to be valid	X
5.2.1	k^e_p		
5.2.2	K_{pE}		
5.2.3	ϕ^e_E		
5.2.4	$t_{1/2E}$	$t_{1/2}$ = 3.1 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	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.3.1/02 Phototransformation in air (measurement), including identification of breakdown products

Annex Point IIIA VII 5

Official use only

		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**	[redacted]
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_2O/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_2O 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)

Section A7.3.1/02 Phototransformation in air (measurement), including identification of breakdown products

Annex Point IIIA VII 5

3.3.4	Temperature	Ca. 23 °C (296 K)	
3.3.5	Pressure	150 torr (200 hPa)	
3.3.6	TS concentrations	$2 \cdot 10^{-9}$ to $20 \cdot 10^{-9}$ mol/cm³	X
3.3.7	OH concentration	$5 \cdot 10^{-11}$ to $10 \cdot 10^{-11}$ mol/cm³	
3.3.8	Duration of the test	No data	
3.3.9	Number of replicates	No data	
3.3.10	Sampling	-	
3.3.11	Analytical methods	No data.	
3.4	**Transformation products**	No data.	
3.4.1	Method of analysis for transformation products	No data.	
		4 RESULTS	
4.1	**Screening test**	Not performed	
4.2	**Controls**	-	
4.3	**Photolysis data**		
4.3.1	Concentration values	Propan-2-ol concentrations ranging from $2 \cdot 10^{9}$ to $20 \cdot 10^{9}$ mol/cm³ were tested.	
4.3.2	Mass balance	-	
4.3.3	k^{c}_{p}	-	
4.3.4	Kinetic order	Pseudo first order/second order	
4.3.5	k^{c}_{p} / k^{a}_{p}	-	
4.3.6	Reaction quantum yield (ϕ^{c}_{E})	-	
4.3.7	k_{pE}		
4.3.8	Half-life ($t_{1/2E}$)	$t_{1/2}$ = 2.9 days (based on second order rate constant k (OH)=$3.3 \cdot 10^{-12}$ cm³/mol · sec and a OH radical concentration of $5 \cdot 10^{5}$ radicals/cm³).	X
4.4	**Specification of the transformation products**	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The first and second order reaction rate constants of propan-2-ol at 296K in the gas phase were determined using flash-photolysis resonance-absorption technique. OH radicals were produced by two different methods (photolysis of water vapor or N_2O/H_2). The decay of OH concentration was monitored. At the time the study was conducted no guideline was available.	

Section A7.3.1/02 Phototransformation in air (measurement), including identification of breakdown products

Annex Point IIIA VII 5

5.2	**Results and discussion**	$t_{1/2}$ = 2.9 days (based on second order rate constant k (OH) = 3.3 · 10^{12} cm^3/mol · sec and a OH radical concentration of 5 · 10^5 radicals/cm^3). The study is well desribed and assignable and therefore regarded as valid.	
5.2.1	k^e_p	-	
5.2.2	K_{pE}	-	
5.2.3	ϕ^e_E	-	
5.2.4	$t_{1/2}$	$t_{1/2}$ = 2.9 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]
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 A7.3.1/03 Phototransformation in air (measurement), including identification of breakdown products

Annex Point IIIA VII 5

Official use only

1 REFERENCE

1.1	**Reference**	Wallington TJ, Atkinson R, Winer AM, Pitts JN jr (1987) A study of the reaction $NO_3 + NO_2 + M \rightarrow N_2O_5 + M$ (M=N_2, O_2). Int J Chem Kinet 19, 243-249 (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 the time the study was conducted no guidelines were available.
2.2	**GLP**	[redacted]
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	≥99%
3.1.4	Radiolabelling	No
3.1.5	UV/VIS absorption spectra and absorbance value	Not available
3.1.6	Further relevant properties	-
3.2	**Reference substances**	No
3.3	**Test**	The gas-phase reaction of NO_3 radical with 2-propanol was carried out and the reaction rate constant determined.
3.4	**Testing procedure**	
3.4.1	Test system	Nitric acid and propan-2-ol were introduced into the reaction vessel by saturating a known fraction of the total flow with the reactant propan-2-ol maintained at 298K. The reaction of the generated NO_3 radicals were studied at a total pressure of 100 Torr (=133.3 hPA) of nitrogen diluent.
3.4.2	Properties of light source	The flash lamp was operated at energies of 100-500 J per flash.
3.4.3	Determination of reaction rate constant	Decay of NO_3 was measured. Reaction rate constant was determined graphically by plotting (R-k_o) against NO_2 concentration (R = NO_3 radical decay rates; k_o = first order rate for NO_3 removal in the absence of reactant; k = reaction rate constant of test substance).
3.4.4	Temperature	The temperature was maintained at 298 ± 2 K by circulating distilled water around the reaction vessel.

3.4.5	pH	Not applicable (gas-phase reaction)
3.4.6	Duration of the test	No data
3.4.7	Number of replicates	No data
3.4.8	Sampling	Continuous sampling: reactants were flowing through the reaction vessels (typical residence times: 5 - 15 sec). Pressures were monitored with MKS Baratron capacitance manometer. All flows were measured by calibrated flowmeters.
3.4.9	Analytical methods	Pressures were monitored by manometer, and all flows were measured by calibrated flowmeter. NO_3 was measured by long pathlength absorption at 662 nm.
3.5	**Transformation products**	Not determined.
3.5.1	Method of analysis for transformation products	-
		4 RESULTS
4.1	**Screening test**	No data
4.2	**Actinometer data**	-
4.3	**Controls**	-
4.4	**Photolysis data**	
4.4.1	Concentration values	Initial propan-2-ol concentration: $3.9 \cdot 10^{15}$ molecules/cm³
4.4.2	Mass balance	-
4.4.3	k(NO_3)	$\leq 2.3 \cdot 10^{-15}$ cm³/(molecule · sec)
4.4.4	Kinetic order	pseudo first order
4.4.5	k^e_p / k^a_p	-
4.4.6	Reaction quantum yield (ϕ^e_E)	-
4.4.7	k_{pE}	-
4.4.8	Half-life ($t_{1/2E}$)	$t_{½}$ ca. 1.45-14.5 days based on NO_3 radical concentrations of 10-100 ppt ($2.4\text{-}24 \cdot 10^8$ radicals/cm³).
4.5	**Specification of the transformation products**	-
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	At the time the investigation was conducted no guideline was available. The gas-phase reaction of NO_3 with propan-2-ol at 298K and a total pressure of 100 Torr (=133.3 hPa) of nitrogen diluent was studied using Flash-Photolysis-Visible Absorption Technique. The upper limit of the reaction rate constant (pseudo first order kinetic) was determined.
5.2	**Results and**	Half-lives $t_{½}$ ranging from ca. 1.45 to ca.14.5 days based on NO_3 radical

Section A7.3.1/03 Phototransformation in air (measurement), including identification of breakdown products

Annex Point IIIA VII 5

	discussion	concentrations of 10-100 ppt (2.4 - 24 · 10^8 radicals/cm³) were determined. Based on the information provided the study can be regarded as valid.
5.2.1	k (NO_3)	≤2.3 · 10^{-15} cm³/(molecule · sec)
5.2.2	K_{pE}	-
5.2.3	ϕ^e_E	-
5.2.4	$t_{1/2}$	$t_{½}$ ca. 1.45-14.5 days based on NO_3 radical concentrations of 10 - 100 ppt (2.4 - 24 · 10^8 radicals/cm³)
5.3	**Conclusion**	[redacted]
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]
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	

Table A7_1_1_2-1: Description of the test

Criteria	Details
Preparation of NO_3 radicals	Photolysis at ≥180 nm of mixtures of fluorine and HNO_3
Initial NO_3 concentration (molecule/cm³)	1-4 x 10^{12}
Test concentrations (molecule/cm³)	3.9 x 10^{15}
Temperature (°C)	298K
Pressure of diluent N_2 (torr)	100
Controls	-
Analytical methods	Pressures were monitored by manometer, and all flows were measured by calibrated flowmeter. NO_3 was measured by long pathlength absorption at 662 nm.
Determination of reaction rate constant	NO_3 radical decay rates ($R=(t-t_0)^{-1}$ x $\ln([NO_3]_{t0}/[NO_3]_t)$ were determined. Based on pseudo-first order decay the rate constant can be determined graphically via $R=k_o + k$ [reactant]

Table A7_1_1_2-2: Description of test system

Criteria	Details
Laboratory equipment	No deatails on the type and geometry of the reaction vessels are given.
Test apparatus	Test vessels not further described. All experiments were performed with the reactants flowing through the reaction vessel, with typical residence times of 5-15 sec. The temperature was maintained at 298K
Properties of artificial light source:	
Nature of light source	Flash lamp
Emission wavelenght spectrum	-
Light intensity	100-500 J
Filters	-
Properties of natural sunlight:	-
Latitude	
Hours of daylight	
Time of year	
Light intensity	
Solar irradiance (L_λ)	

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1984) Acute toxicities of organic chemicals to fathead minnows (*Pimephales promelas*), [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**	No. [redacted]
2.2	**GLP**	[redacted].
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	2-Propanol
3.1.3	Purity	Reagent grade (one test) and 99.8 % (two tests)
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	The test was conducted under flow-through conditions.
3.1.6	Method of analysis	GLC (Gas Liquid Chromatography)
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc IIIA3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc IIIA3.2.1**). Continuously the test compound was added undiluted to the exposure tanks. The test was conducted under flow-through conditions.
3.3	**Reference substance**	No data.
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details
Source	Lake Superior
Alkalinity	39.5 - 45.9 mg/L ($CaCO_3$)
Hardness	44 - 52.5 mg/L ($CaCO_3$)

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

pH	7.09 - 7.87
Oxygen content	6.6 - 6.7 mg/L
Conductance	No data
Holding water different from dilution water	No data.

3.4.2 Test organisms

Criteria	**Details**
Species/strain	*Pimephales promelas* (fathead minnow)
Source	US EPA Environmental Research Laboratory-Duluth
Wild caught	No
Age/size	29 - 31 days/ mean length: 17.4 - 20.6 mm; mean weight:0.08 - 0.11 g
Kind of food	Before testing: *Artemia* sp.; during the test fish were not fed
Amount of food	No data.
Feeding frequency	No data.
Pretreatment	Fish were held at 25 °C in flowing water with 16 h light/8 h dark (no further information).
Feeding of animals during test	No.

3.4.3 Test system

Criteria	**Details**
Test type	Flow-through
Renewal of test solution	flow-rates: 23.6, 36.0, and 72.05 L/d
Volume of test vessels	1, 5.5, and 6.3 L
Volume/animal	0.252, 0.22, and 0.05 L/animal
Number of animals/vessel	20 - 25
Number of vessels/ concentration	5 - 10 (some concentrations were tested in duplicate)
Test performed in closed vessels due to significant volatility of TS	No

3.4.4 Test conditions

Criteria	**Details**
Test temperature	24.4- 24.6 °C
Dissolved oxygen	6.6 - 6.7 mg/L
pH	7.09 - 7.87
Adjustment of pH	No

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

Aeration of dilution water	No data
Intensity of irradiation	No data
Photoperiod	16 h light daily

3.4.5 Duration of the test: 96 h

3.4.6 Test parameter: Mortality and behavior

3.4.7 Sampling: Test exposure chambers were sampled at 0 and 96 h and one of the duplicate exposure chambers at 24, 48, and 72 h. All samples were analysed immediately or adequately preserved for later analysis (no further data given).

3.4.8 Monitoring of TS concentration: Yes. Test exposure chambers were sampled at 0 and 96 h and one of the duplicate exposure chambers at 24, 48, and 72 h. All samples were analysed immediately or adequately preserved for later analysis.

3.4.9 Statistics: Estimation of LC_{50} and EC_{50} was made by using the "trimmed Spearman-Karber" method (Hamilton et al. (1977) Environ Sci Technol 11, 714-719 and Correction 12, 417 (1978).

4 RESULTS

4.1 Limit Test: No data

4.1.1 Concentration: -

4.1.2 Number/ percentage of animals showing adverse effects: -

4.1.3 Nature of adverse effects: -

4.2 Results test substance

4.2.1 Initial concentrations of test substance:

Test 1: 3800, 6300, 10500, 17600, 29300 mg/L

Test 2: 2210, 3670, 6120, 10200, and 1700 mg/L

Test 3: 3080, 3760, 5500, 8280, and 13000 mg/L

(all values cited here refer to nominal concentrations)

4.2.2 Actual concentrations of test substance:

Actual concentration determined analytically (in mg/L)

Test 1

nominal	3800	6300	10500	17600	29300
effectiv	2620/ 2810	4790/ 4790	7570/ 7720	13400/ 13700	21700/ 22500/

Test 2

nominal	2210	3670	6120	10200	17000
effectiv	1260/ 1300	2500/ 2590	4320/ 4580	7720/ 7760	14200/ 14400

Test 3

nominal	3080	3760	5500	8280	13000
effectiv	3090	3760	5500	8280	1300

4.2.3 Effect data (Mortality)

Test 1

Test substance Concentration (measured) [mg/L]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
<250 (control)	0	0	0	0	0	0	0	0
2620-2810	0	0	0	0	0	0	0	0
4790	0	0	0	0	0	0	0	0
7570-7720	0	1	4	5	0	2	8	10
13400-13700	50	50	50	50	100	100	100	100
21700-22500	50	50	50	50	100	100	100	100
Temp. [°C]				24.4				
pH				7.79				
Oxygen [mg/l]				6.6				

Test 2

Test substance Concentration (measured) [mg/L]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
0 (control)	0	0	0	0	0	0	0	0
1260-1300	0	0	0	0	0	0	0	0
2500-2590	0	0	0	0	0	0	0	0
4320-4580	0	0	0	0	0	0	0	0
7720-7760	0	1	1	1	0	2	2	2
14200-14400	50	50	50	50	100	100	100	100
Temp. [°C]				24.6				
pH				7.09				
Oxygen [mg/l]				6.7				

Test 3

Test substance Concentration (measured) [mg/L]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
<250 (control)	0	0	0	0	0	0	0	0
3090	2	2	2	2	10	10	10	10
3760	1	1	1	1	5	5	5	5
5500	5	5	5	5	25	25	25	25
8280	16	16	16	16	80	80	80	80
13000	20	20	20	20	100	100	100	100
Temp. [°C]				24.6				
pH				7.87				
Oxygen [mg/l]				6.7				

96 h LC_{50} values obtained in the three tests

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

	48 h [mg/L][1]	95 % c.l.	96 h [mg/L][1]	95 % c.l.
LC_0	-	-	-	-
LC_{50}			6550 (m) 9640 (m) 10400 (m)	5770-7450 9230-10000 10200-10600
LC_{100}	-	-	-	-

[1] measured (m) concentrations

4.2.4 Concentration / response curve — See effect data for information regarding concentration/ response relationship.

4.2.5 Other effects — In the test 96 h EC_{50} values were determined also (96 h EC_{50} = 6120 - 9540 mg/L). Affected fish lost equilibrium prior to death.

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects — No mortalities occurred in the controls (test substance omitted) in test 1 and 2. In test 3 investigating the behavior one affected fish was observed (corresponding to 5% of control fish) 3 hours after initiating the test. No adverse effects or mortalities occurred in test 3 examinating lethality.

4.3.2 Nature of adverse effects — In test 3 one affected fish was observed in the controls (test substance omitted). The affected fish lost equilibrium prior to death. No other adverse effects were seen.

4.4 Test with reference substance — No data.

4.4.1 Concentrations -

4.4.2 Results -

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted under flow-through conditions and was similar to OECD Guideline 203 'Fish, Acute toxicity test'.

At total 3 different tests were conducted and using 5 concentrations each and one control. 20 - 25 fish were used per concentration. Partly, the tests were performed in duplicate (before 1 December 1981). Lake Superior water was used as dilution water. The actual concentration of test substance was determined analytically.

5.2 Results and discussion

The substance shows a very low acute toxicity towards *Pimephales promelas* (96 h LC_{50} = 6550-10400 mg/L; 96 h EC_{50} = 6120-9540 mg/L).

	fulfilled	Not fullfilled
Mortality of control animals <10%	**yes**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**yes**	
Concentration of test substance ≥80% of initial concentration during test	**yes**	

The acute toxicity towards *Pimephales promelas* was determined in a study conducted similar to OECD Guideline 203. The test was performed under flow-through conditions and the actual substance

x

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

		concentration was measured periodically. The study is very well documented and meets the validity criteria. The test was performed under flow-through conditions and the actual substance concentration was measured periodically. Therefore, the volatility (**cf. Doc IIIA3.2.1**) of the test substance does not play an important role in the present study.	
5.2.1	LC_0	-	
5.2.2	LC_{50}	96 h LC_{50}: 6550 mg/L; 9640 mg/L;10400 mg/L (effective)	x
5.2.3	LC_{100}	-	
5.3	**Conclusion**	[redacted]	
5.3.1	Other Conclusions	[redacted]	
5.3.2	Reliability	[redacted]	
5.3.3	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	2008/06/30
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 A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1983) Estimating the acute toxicity of narcotic industrial chemicals to fathead minnows. [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**	No. [redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	No information

3 MATERIALS AND METHODS

3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	2-Propanol
3.1.3	Purity	Purity not stated
3.1.4	Composition of Product	Not applicable.
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	UV-spectroscopy or GC/FID
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**). The test was conducted under flow-through conditions.
3.3	**Reference substance**	No information
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details
Source	Lake Superior
Alkalinity	42.2 mg/L as CaCO3
Hardness	56.3 mg/L as CaCO3

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

pH	7.5
Oxygen content	> 60% of saturation
Conductance	No data
Holding water different from dilution water	No

3.4.2 Test organisms

Criteria	**Details**
Species/strain	*Pimephales promelas*
Source	Environmental Research Laboratory-Duluth
Wild caught	No
Age/size	30 days old/ weight 0.12 g
Kind of food	No data
Amount of food	No data
Feeding frequency	No data
Pretreatment	No data
Feeding of animals during test	No

3.4.3 Test system

Criteria	**Details**
Test type	Flow-through
Renewal of test solution	No information
Volume of test vessels	No information
Volume/animal	No information
Number of animals/vessel	25
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	No. However, the test was conducted under flow-through conditions.

3.4.4 Test conditions

Criteria	**Details**
Test temperature	25 ± 1 °C
Dissolved oxygen	> 60% of saturation
pH	7.5 (pH of dilution water; pH during the test not stated)
Adjustment of pH	No data
Aeration of dilution water	No information
Intensity of irradiation	No information
Photoperiod	No information

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

3.4.5	Duration of the test	96 h
3.4.6	Test parameter	Mortality
3.4.7	Sampling	Dead fish were recorded after 1, 3, 6, 12, 24, 48, 72, and 96 h
3.4.8	Monitoring of TS concentration	Yes. Concentrations were measured throughout the test.
3.4.9	Statistics	The LC_{50} was calculated using the trimmed Spearman-Karber method
		4 RESULTS
4.1	**Limit Test**	No information
4.1.1	Concentration	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Five concentrations and one control were tested in duplicate (no further information). Test was performed twice.
4.2.2	Actual concentrations of test substance	Concentrations measured throughout the test (no further information provided).
4.2.3	Effect data (Mortality)	96 h LC_{50} values based on measured concentrations

	48 h [mg/L]	95 % c.l.	96 h [mg/L]	95 % c.l.
LC_0				
LC_{50}			9640 and 10000 (measured)	
LC_{100}				

4.2.4	Concentration / response curve	No information.
4.2.5	Other effects	No information.
4.3	**Results of controls**	No information.
4.3.1	Number/ percentage of animals showing adverse effects	-
4.3.2	Nature of adverse effects	-
4.4	**Test with reference**	No information

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

	substance		
4.4.1	Concentrations	-	
4.4.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The study was conducted according to US EPA (1975) Toxicity tests with aquatic organisms. Twenty-five fish (*Pimephales promelas*) per concentration were exposed to 2-propanol. Six concentrations (incl. control) were tested under flow-through conditions; the tests were conducted in duplicate. Lake Superior water was used as dilution water in all tests. The concentration of the test substance was monitored continuously during the test.

5.2 Results and discussion

	fulfilled	**Not fullfilled**
Mortality of control animals <10%	**No data**	
Concentration of dissolved oxygen in all test vessels > 60% saturation	**Yes**	
Concentration of test substance ≥80% of initial concentration during test	-*	

**concentration of test substance was monitored analytically throughout the test*

The study was conducted according to national standard method under flow-through conditions. Some details (e.g. mortality of control animals, concentrations tested) are not reported. However, deviations from the standard procedure and/or special observations during the test are not reported. The concentration of the test substance was measured throughout the test and so the test results refer to effective concentrations. Based on the informations provided it can be assumed that all validity criteria were fulfilled. x

Propan-2-ol showed a very low acute toxicity towards *Pimephales promelas* (96 h LC_{50}=9640 and 10000 mg/L effective).

No information on dose-response relationship is available.

The test was performed under flow-through conditions and the actual substance concentration was measured periodically. Therefore the volatility (**cf. Doc III A3.2.1**) of the test substance does not play an important role in the present study.

5.2.1	LC_0		
5.2.2	LC_{50}	96 h LC_{50} = 9640 and 10000 mg/L (effective)	x
5.2.3	LC_{100}		

5.3 Conclusion [redacted]

5.3.1	Other Conclusions		
5.3.2	Reliability	[redacted]	x
5.3.3	Deficiencies	[redacted]	

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/06/30
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	

[redacted]A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA7.1 *Oryzias latipes*

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (1998) Final Report, Acute Toxicity Test on *Orzias latipes* to 2-Propanol. [redacted] [redacted] 2007 Chemical Risk Information Platform (CHRIP) Total Search System for Chemical Substances: 2-Propanol; [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**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	2-Propanol
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	Yes: copper sulfate pentahydrate
3.3.1	Method of analysis for reference	No data

[redacted]A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA7.1 *Oryzias latipes*

substance

3.4 Testing procedure

3.4.1 Dilution water

[redacted]

3.4.2 Test organisms

[redacted]

3.4.3 Test system

[redacted]

[redacted]A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA7.1 *Oryzias latipes*

		[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]
	4 RESULTS	
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	Not applicable
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Not applicable
4.2.2	Actual	Not applicable

[redacted]A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA7.1 *Oryzias latipes*

	concentrations of test substance	
4.2.3	Effect data (Mortality)	Not applicable
4.2.4	Concentration / response curve	Not applicable
4.2.5	Other effects	Not applicable
4.3	**Results of controls**	[redacted]
4.3.1	Number/ percentage of animals showing adverse effects	Not applicable
4.3.2	Nature of adverse effects	Not applicable
4.4	**Test with reference substance**	Copper sulfate pentahydrate
4.4.1	Concentrations	No data
4.4.2	Results	96 h LC_{50} = 0.930 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.2.1	LC_0	[redacted]
5.2.2	LC_{50}	[redacted]
5.2.3	LC_{100}	[redacted]
5.3	**Conclusion**	[redacted]

[redacted]A7.4.1.1/03 **Acute toxicity to fish**

Annex Point IIA7.1 *Oryzias latipes*

5.3.1 Other Conclusions

5.3.2 Reliability [redacted]

5.3.3 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	2014/02/12
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 A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1998) Final Report, Acute Immobilisation Test of 2-Propanol on Daphnia Magna. [redacted] [redacted] 2007 Chemical Risk Information Platform (CHRIP) Total Search System for Chemical Substances: 2-Propanol; [redacted]
1.2	**Data protection**	
1.2.1	Data owner	No
1.2.2	Criteria for data protection	Not applicable

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes. [redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	None

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	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	Potassium dichromate

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

3.3.1	Method of analysis for reference substance	No data
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

4.1.3	Nature of adverse effects	Not applicable
4.2	**Results test substance**	Not applicable
4.2.1	Initial concentrations of test substance (mg/L)	Not applicable
4.2.2	Actual concentrations of test substance	Not applicable
4.2.3	Effect data (Immobilisation)	Not applicable
4.2.4	Concentration / response curve	Not applicable
4.2.5	Other effects	No data
4.3	**Results of controls**	No immobilisation during the exposure period was observed.
4.4	**Test with reference substance**	Potassium dichromate
4.4.1	Concentrations	No data
4.4.2	Results	48 h EC_{50} = 0.141 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

5.2.1	EC_0	[redacted]
5.2.2	EC_{50}	[redacted]
5.2.3	EC_{100}	[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
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2014/02/12
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 A7.4.1.2/02 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

Official use only

1 REFERENCE

1.1	**Reference**	Bringmann G, Kuehn R (1977) Befunde der Schadwirkung wassergefährdender Stoffe gegen *Daphnia magna*. Z Wasser Abwasser-Forsch 10, 161-166 (published) Bringmann G, Kuehn R (1982) Results of toxic action of water pollutants on *Daphnia magna* Straus tested by improved standardized procedure. Z Wasser Abwasser-Forsch 15, 1-6 (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. Study conducted according to national standard method (German DIN 38412 part 11: *Daphnia* short-term test, 1982, draft)
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	-
3.1.2	Specification	Propanol-(2)
3.1.3	Purity	No data
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	Although the test substance is moderately volatile the test vessels were only loosely covered with filter paper.
3.1.6	Method of analysis	No analytical monitoring performed.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**). The test vessels were only loosely covered with filter paper. Based on the short exposure period no significant losses due to volatilisation are assumed.
3.3	**Reference substance**	No data
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details
Source	Artifical fresh water prepared according to DIN 38412 part 11

Section A7.4.1.2/02 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

Alkalinity	-
Hardness	-
pH	8.0
Ca / Mg ratio	2.5 mmol/L
Na / K ratio	10:1
Oxygen content	maximum
Conductance	-
Holding water different from dilution water	Yes. Holding water: distilled water; Dilution water: prepared acc. to DIN 38412 part 11

3.4.2 Test organisms

Criteria	**Details**
Species	*Daphnia magna*
Strain	IRCHA
Source	Laboratory culture
Age	≤24 h
Breeding method	Continuous culture: daily females were transferred to freshly prepared culture glasses; young animals were separated by sieving (DIN filter: 0.315 mm); culture glasses were covered with watch glasses on white tables; cultures were feed daily with dry food (Mikrozell); on Monday and Friday the tape water of all cultures was renewed and also the culture vessels on Friday; for breeding tape water was used (hardness: 16° d.H., pH 7.6 - 7.7); daphnids were cultured at 20 °C; light intensity: E = 2.5 W/m²; photoperiod: 9 h light and 15 h dark.
Kind of food	Dry food 'Mikrozell'
Amount of food	30 g/L tap water were suspended; 10 mL of the suspension were added to the culture glasses
Feeding frequency	Daily
Pretreatment	No
Feeding of animals during test	No

3.4.3 Test system

Criteria	**Details**
Renewal of test solution	No
Volume of test vessels	50 mL
Volume/animal	2 mL/animal

Section A7.4.1.2/02 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

		Number of animals/vessel	10	
		Number of vessels/ concentration	2	
		Test performed in closed vessels due to significant volatility of TS	No. The test vessels were only loosely covered with filter paper.	
3.4.4	Test conditions	**Criteria**	**Details**	
		Test temperature	20 °C	
		Dissolved oxygen	At the beginning: oxygen saturated dilution water; at the end: measurement of oxygen (DO ≥ 2 mg/L)	
		pH	At the beginning: pH 8 of dilution water; after addition of test substance pH not adjusted; at the end: checking whether pH fulfills validity criteria (8.0 ± 0.2)	
		Adjustment of pH	No.	
		Aeration of dilution water	Yes. Till saturation.	
		Quality/Intensity of irradiation	Light intensity: E = 2.5 W/m^2	
		Photoperiod	9 h light/15 h dark	
3.4.5	Duration of the test	24 h		x
3.4.6	Test parameter	Immobilisation		
3.4.7	Sampling	No information		
3.4.8	Monitoring of TS concentration	No		
3.4.9	Statistics	The EC_{50} values were determined graphically based on the experimental results.		
		4 RESULTS		
4.1	**Limit Test**	No information		
4.1.1	Concentration	-		
4.1.2	Number/ percentage of animals showing adverse effects	-		
4.1.3	Nature of adverse effects	-		
4.2	**Results test substance**			
4.2.1	Initial concentrations of test substance	No data		

Section A7.4.1.2/02 **Acute toxicity to invertebrates**
Annex Point IIA7.2 *Daphnia magna* STRAUS

4.2.2 Actual concentrations of test substance: No analytical monitoring.

4.2.3 Effect data (Immobilisation): EC_{50}, NOEC and EC_{100} values after 24 h

	EC_{50}	95 % c.l.	EC_0	EC_{100}
24 h [mg/L]	9714 (n)	-	5102 (n)	>10 000 (n)
48 h [mg/L]				

n-nominal concentrations

4.2.4 Concentration / response curve: No data

4.2.5 Other effects: No data

4.3 Results of controls: No information

4.4 Test with reference substance: No information

4.4.1 Concentrations: -

4.4.2 Results: -

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The study was conducted according to the draft of the German DIN 38412 part 11: *Daphnia* short-term test (1982). Twenty daphnids ≤ 24 h old were exposed to 2-propanol per concentration step. The test vessels were only loosely covered with filter paper. Based on the short exposure period no significant losses due to volatilisation are assumed. However, analytical monitoring was not performed.

5.2 Results and discussion

Validity criteria	fulfilled	Not fullfilled
Immobilisation of control animals <10%	**No data**	**No data**
Control animals not staying at the surface	**No data**	**No data**
Concentration of dissolved oxygen in all test vessels >3 mg/l	**No data**	**No data**
Concentration of test substance ≥80% of initial concentration during test	**No data**	**No data**

The study was conducted according to national standard method. Deviations from this procedure were not reported. Therefore the validity criteria can be considered as fulfilled. x

Propan-2-ol was found to be toxic towards *Daphnia magna* in the static test at a concentration of 9714 mg/L nominal (24 h EC_{50}).

No information on dose-response relationship is available.

Although propan-2-ol shows a moderate volatility from aqueous solution (**cf. Doc III A3.2.1**) the test vessels were only loosely covered with filter paper. But based on the short exposure period (24 h) no significant losses due to volatilisation are assumed. However, analytical monitoring of test substance concentration was not performed.

5.2.1 24 h EC_0: 5102 mg/L (nominal)

Section A7.4.1.2/02 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

5.2.2	24 h EC_{50}	9714 mg/L (nominal)
5.2.3	24 h EC_{100}	>10 000 mg/L (nominal)
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	2008/06/30
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	

Acute toxicity to invertebrates

Section A7.4.1.2/03 *Daphnia magna* STRAUS

Annex Point IIA7.2

Official use only

		1 REFERENCE
1.1	**Reference**	Calleja MC, Personne G, Geladi P (1993) The predictive potential of a battery of ecotoxicological tests for human acute toxicity, as evaluated with the first 50 MEIC chemicals. Altern Lab Anim 21, 330-349 (published) Calleja MC, Personne G, Geladi P (1994) Comparative toxicity of the first 50 multicentre evaluation of *in vitro* cytotoxicity chemicals to aquatic non-vertebrates. Arch Environ Contam Toxicol 26, 69-78 (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 202 '*Daphnia magna*, acute immobilization test and reproduction test' (1984)
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	-
3.1.2	Specification	Isopropyl alcohol and isopropanol, respectively
3.1.3	Purity	Min. 99.7 %
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	Due to the volatility of the substance glass vials capped with poly-ethylene were used in the test. The vials were filled to the brim and covered tightly, thus avoiding any air-space.
3.1.6	Method of analysis	No analytical monitoring.
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**). Therefore, glass vials capped with polyethylene were used in the test. The vials were filled to the brim and covered tightly, thus avoiding any air-space.
3.3	**Reference substance**	No
3.3.1	Method of analysis for reference substance	-

Acute toxicity to invertebrates

Section A7.4.1.2/03 *Daphnia magna* STRAUS

Annex Point IIA7.2

3.4 Testing procedure

Dilution water

Criteria	Details
Source	No information
Alkalinity	No information
Hardness	No information
pH	No information
Ca / Mg ratio	No information
Na / K ratio	No information
Oxygen content	No information
Conductance	No information
Holding water different from dilution water	No information

3.4.2 Test organisms

Criteria	Details
Species	*Daphnia magna*
Strain	No informmation
Source	No information
Age	No information
Breeding method	No information
Kind of food	No information
Amount of food	No information
Feeding frequency	No information
Pretreatment	No information
Feeding of animals during test	No information

3.4.3 Test system

Criteria	Details
Renewal of test solution	No
Volume of test vessels	No information
Volume/animal	No information
Number of animals/vessel	No information
Number of vessels/ concentration	≥ 3
Test performed in closed vessels due to significant volatility of TS	Yes. Due to the volatility of the substance glass vials capped with polyethylene were used in the test. The vials were filled to the brim and covered tightly, thus avoiding any air-space.

Acute toxicity to invertebrates

Section A7.4.1.2/03 *Daphnia magna* STRAUS

Annex Point IIA7.2

3.4.4 Test conditions

Criteria	Details
Test temperature	No information
Dissolved oxygen	No information
pH	No information
Adjustment of pH	No information
Aeration of dilution water	No information
Quality/Intensity of irradiation	No information
Photoperiod	No information

3.4.5 Duration of the test: 24 hours x

3.4.6 Test parameter: Immobilisation

3.4.7 Sampling: No information

3.4.8 Monitoring of TS concentration: No.

3.4.9 Statistics: EC_{50} values and the corresponding 95% confidence limits were calculated using the Trimmed Spearman-Karber method (Hamilton et al. 1977)

4 RESULTS

4.1 Limit Test: No information

4.1.1 Concentration: -

4.1.2 Number/ percentage of animals showing adverse effects: -

4.1.3 Nature of adverse effects: -

4.2 Results test substance

4.2.1 Initial concentrations of test substance: No information

4.2.2 Actual concentrations of test substance: Not measured.

4.2.3 Effect data (Immobilisation): EC_{50} values of the two tests performed:

	EC_{50} [mg/L]	95 % c.l.	EC_0	EC_{100}
Test 1, 24 h	9307 (n)	-	-	-
Test 2, 24 h	9554 (n)	-	-	-

n: nominal

Section A7.4.1.2/03 **Acute toxicity to invertebrates**
Daphnia magna STRAUS
Annex Point IIA7.2

4.2.4	Concentration / response curve	Not available	
4.2.5	Other effects	No information	
4.3	**Results of controls**	No information	
4.4	**Test with reference substance**	No information	
4.4.1	Concentrations	-	
4.4.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The study was conducted according to OECD guideline 202 '*Daphnia magna*, acute immobilization test and reproduction test' (1984). Due to the volatility of the substance glass vials capped with polyethylene were used in the test. The vials were filled to the brim and covered tightly, thus avoiding any air-space. At least three replicates were conducted. Further details are not reported in the publication.

5.2 Results and discussion

Validity criteria	fulfilled	Not fullfilled
Immobilisation of control animals <10%	**No data**	**No data**
Control animals not staying at the surface	**No data**	**No data**
Concentration of dissolved oxygen in all test vessels >3 mg/l	**No data**	**No data**
Concentration of test substance ≥80% of initial concentration during test	**No data**	**No data**

Details of the test performance are not reported. Deviations from guideline were not stated. Even though the information is very limited it can be assumed that the validity criteria were fulfilled. x

Propan-2-ol was found to be toxic towards *Daphnia magna* in the static test in the range between 9300 to 9550 mg/L (24 h EC_{50}).

No data for the dose-response relationship are available.

Due to the moderate volatility (**cf. Doc III A3.2.1**) of the substance glass vials capped with polyethylene were used in the test. The vials were filled to the brim and covered tightly, thus avoiding any air-space. Due to this fact significant changes of test substance concentrations during the test duration (24 h) are not to be expected. Analytical monitoring of test substance concentration was not performed. Due to the test design and short exposure time analytical monitoring seems not necessary.

5.2.1	EC_0	-	
5.2.2	24 h EC_{50}	9307 - 9554 mg/L (24 h immobilisation test)	x
5.2.3	EC_{100}	-	
5.3	**Conclusion**	[redacted]	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	

Acute toxicity to invertebrates

Section A7.4.1.2/03 *Daphnia magna* STRAUS

Annex Point IIA7.2

[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	2008/06/30
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*

Acute toxicity to invertebrates

Section A7.4.1.2/03 *Daphnia magna* STRAUS

Annex Point IIA7.2

Remarks

Section A7.4.1.2/04 Acute toxicity to invertebrates

Annex Point IIA7.2 *Crangon crangon*

Official use only

1 REFERENCE

1.1	**Reference**	Blackman RAA (1974) Toxicity of oil-sinking agents. Mar Pollut Bull 5, 116-118 (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. The study was conducted according to the method described by Portmann & Connor (1968) The toxicity of several oil-spill removers to some species of fish and shellfish. Mar Biol 1, 322-329.
2.2	**GLP**	[redacted]
2.3	**Deviations**	Yes. In contrast to the toxicity test of Portmann & Connor the test solution was renewed every 6, 12, or 24 h depending on the volatility of the test substance.

3 MATERIALS AND METHODS

3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	Isopropyl alcohol
3.1.3	Purity	Purity not stated
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	
3.1.6	Method of analysis	No analytical monitoring
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**). Test concentrations were renewed every 6, 12, or 24 h depending on the volatility of the test substance.
3.3	**Reference substance**	No information
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	

Dilution water

Criteria	Details
Source	No information
Alkalinity	No information
Hardness	No information

Section A7.4.1.2/04 Acute toxicity to invertebrates

Annex Point IIA7.2 *Crangon crangon*

pH	No information
Ca / Mg ratio	No information
Na / K ratio	No information
Oxygen content	No information
Conductance	No information
Holding water different from dilution water	No information

3.4.2 Test organisms

Criteria	**Details**
Species	*Crangon crangon*
Strain	No information
Source	No information
Age	No information
Breeding method	No information
Kind of food	No information
Amount of food	No information
Feeding frequency	No information
Pretreatment	No information
Feeding of animals during test	No information

3.4.3 Test system

Criteria	**Details**
Renewal of test solution	Test concentrations were renewed every 6, 12, or 24 h depending on the volatility of the test substance
Volume of test vessels	No information
Volume/animal	No information
Number of animals/vessel	20
Number of vessels/ concentration	No information
Test performed in closed vessels due to significant volatility of TS	No. However, test concentrations were renewed every 6, 12, or 24 h depending on the volatility of the test substance.

3.4.4 Test conditions

Criteria	**Details**
Test temperature	No information
Dissolved oxygen	No information
pH	No information
Adjustment of pH	No information
Aeration of dilution water	No information

Section A7.4.1.2/04 Acute toxicity to invertebrates

Annex Point IIA7.2 *Crangon crangon*

	Quality/Intensity of irradiation	No information
	Photoperiod	No information

3.4.5	Duration of the test	96 h
3.4.6	Test parameter	mortality
3.4.7	Sampling	No information
3.4.8	Monitoring of TS concentration	No
3.4.9	Statistics	Results were plotted, and 48 h and 96 h values calculated using the method of Litchfield (1949). The ranges given are those from the extreme curves fitted to the upper and lower 95% confidence limits of the plotted values for the estimated time to reach 50% mortality. The curves were fitted by eye.

4 RESULTS

4.1	**Limit Test**	No information
4.1.1	Concentration	-
4.1.2	Number/ percentage of animals showing adverse effects	-
4.1.3	Nature of adverse effects	-
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Not stated
4.2.2	Actual concentrations of test substance	No analytical monitoring performed
4.2.3	Effect data (Immobilisation)	Data presented below were converted from those given as ppm (v/v) in the report.

48 and 96 h LC_{50} (including 95 % c.l.)

	LC_{50}	**95 % c.l.**	**LC_0**	**LC_{100}**
48 h [mg/L]	1100 (n)	700 - 1530	-	-
96 h [mg/L]	900 (n)	590 - 1300	-	-

n: nominal concentrations

4.2.4	Concentration / response curve	Not available
4.2.5	Other effects	No information
4.3	**Results of controls**	Results of the controls were taken into account. No further data provided.

Section A7.4.1.2/04 Acute toxicity to invertebrates

Annex Point IIA7.2 *Crangon crangon*

4.4	**Test with reference substance**	No information
4.4.1	Concentrations	-
4.4.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The study was conducted according to Portmann & Connor (1968) The toxicity of several oil-spill removers to some species of fish and shell-fish. Mar Biol 1, 322-329. Solvents used in the toxicity test were renewed every 6, 12, or 24 h depending on the volatility of the test substance. 20 animals per exposure tank were used. No further information provided.

5.2 Results and discussion

Validity criteria	fulfilled	Not fullfilled
Immobilisation of control animals <10%	**No data**	**No data**
Control animals not staying at the surface	**No data**	**No data**
Concentration of dissolved oxygen in all test vessels >3 mg/l	**No data**	**No data**
Concentration of test substance ≥80% of initial concentration during test	**No data**	**No data**

The documentation is insufficient and therefore the study is regarded as invalid.

Propan-2-ol was found to be toxic towards *Crangon crangon* in the static test at propan-2-ol concentrations of 1100 (48 h LC_{50}) and 900 mg/L (96 h LC_{50}).

No data for the dose-response relationship are available.

The influence of the moderate volatility (**cf. Doc IIIA3.2.1**) of the substance is assumed to be negligible due to the semi-static test conditions.

5.2.1	LC_0	-
5.2.2	LC_{50}	48 h: 1100 mg/L nominal (reported in the report as 1400 ppm v/v) 96 h: 900 mg/L nominal (reported in the report as 1150 ppm v/v)
5.2.3	LC_{100}	-
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted] x
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** [redacted]

Section A7.4.1.2/04 Acute toxicity to invertebrates

Annex Point IIA7.2 *Crangon crangon*

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 A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

Official use only

1 REFERENCE

1.1	**Reference**	Lilius H, Isomaa B, Holmstrom T (1994) A comparison of 50 reference chemicals to freshly isolated rainbow trout hepatocytes and *Daphnia magna*. Aquat Toxicol 30, 47-60 (published) Lilius H, Hästabacka T, Isomaa B (1995) A comparison of the toxicity of 30 reference chemicals to *Daphnia magna* and *Daphnia pulex*. Environ Toxicol Chem 14, 2085-2088 (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 202 '*Daphnia* sp., acute immobilisation test and reproduction test' (1993)
2.2	**GLP**	[redacted]
2.3	**Deviations**	Yes.The toxicity tests were performed in 100-mL polpropylene vessels, with 50 mL liquid in each. Twenty neonates (<24 h) were introduced inti vessels containing different concentrations of the test chemical, and the vessels were closed with polyethylene caps.

3 MATERIALS AND METHODS

3.1	**Test material**	Isopropyl alcohol
3.1.1	Lot/Batch number	-
3.1.2	Specification	-
3.1.3	Purity	Reagent grade
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	The tests were conducted in test vessels filled to the half and capped with polyethylene to prevent volatilization
3.1.6	Method of analysis	No analytical monitoring
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**). Test performed in half filled vessels capped with polyethylene to prevent volatilisation.
3.3	**Reference substance**	No information
3.3.1	Method of analysis for reference substance	No analytical monitoring
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

		Source	SRW according to OECD 1980/1993
		Alkalinity	-
		Hardness	-
		pH	7.6
		Ca / Mg ratio	-
		Na / K ratio	-
		Oxygen content	-
		Conductance	-
		Holding water different from dilution water	Yes. M4 media according to Elendt and Bias (1990)
3.4.2	Test organisms	**Criteria**	**Details**
		Species	*Daphnia magna*
		Strain	No information
		Source	Department of Biology,Uuniversity of Turku
		Age	<24 h
		Breeding method	Breedin in M4 media, 12:12 h light/dark cycle, breeding temperature 20 +/-2°C
		Kind of food	*Scendesmus* sp.
		Amount of food	-
		Feeding frequency	Every second or third day
		Pretreatment	No information
		Feeding of animals during test	No
3.4.3	Test system	**Criteria**	**Details**
		Renewal of test solution	No
		Volume of test vessels	100 mL
		Volume/animal	2.5 mL/animal
		Number of animals/vessel	20
		Number of vessels/ concentration	≥3
		Test performed in closed vessels due to significant volatility of TS	Yes. Test performed in half filled vessels capped with polyethylene to prevent/minimize volatilisation
3.4.4	Test conditions	**Criteria**	**Details**
		Test temperature	21 ±1 °C
		Dissolved oxygen	No information

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

		pH	No information
		Adjustment of pH	No information
		Aeration of dilution water	No
		Quality/Intensity of irradiation	No information
		Photoperiod	Photoperiod: 12 h dark 12 h light
3.4.5	Duration of the test	24 h	x
3.4.6	Test parameter	Immobility	
3.4.7	Sampling	-	
3.4.8	Monitoring of TS concentration	No	
3.4.9	Statistics	EC_{50} values were calculated using regression analysis after linearisation of dose/response curves by logarithmic transformation of the concentration	
		4 RESULTS	
4.1	**Limit Test**	No information	
4.1.1	Concentration	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	No information	
4.2.2	Actual concentrations of test substance	Concentrations refer to nominal concentration	
4.2.3	Effect data (Immobilisation)	24 h EC_{50}	

	EC_{50}	95 % c.l.	EC_0	EC_{100}
24 h [mg/L]	6850 (n)	-	-	-
48 h [mg/L]	-	-	-	-

n: nominal

4.2.4	Concentration / response curve	No information	
4.2.5	Other effects	No information	
4.3	**Results of controls**	No information	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

4.4	**Test with reference substance**	No information	
4.4.1	Concentrations	-	
4.4.2	Results	-	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Yes. OECD guideline 202 '*Daphnia* sp., acute immobilisation test and reproduction test' (1993). Deviations from guideline: The toxicity tests were performed in 100-mL polpropylene vessels, with 50 mL liquid in each. Twenty neonates (<24 h) were introduced inti vessels containing different concentrations of the test chemical, and the vessels were closed with polyethylene cap.	
5.2	**Results and discussion**		

Validity criteria	fulfilled	Not fulfilled
Immobilisation of control animals <10%	**No data**	**No data**
Control animals not staying at the surface	**No data**	**No data**
Concentration of dissolved oxygen in all test vessels >3 mg/l	**No data**	**No data**
Concentration of test substance ≥80% of initial concentration during test	**No data**	**No data**

		The study was conducted according to OECD guideline 202. Deviations from guideline test design were noted. Further deviations were not reported and therefore it can be assumed that the validity criteria were fulfilled.	x
		Propan-2-ol was found to be toxic towards *Daphnia magna* in the static test at a concentration of 6850 mg/L nominal (24 h EC_{50}).	
		No information is available on the dose-response relationship.	
		The tests were conducted in test vessels filled to the half and capped with polyethylene to prevent/minimize volatilization.	
5.2.1	EC_0	-	
5.2.2	24h EC_{50}	6850 mg/L (nominal)	
5.2.3	EC_{100}	-	
5.3	**Conclusion**	[redacted]	x
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/06/30
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	

This document has been prepared by the competent authority and does not necessarily represent the participant`s opinion.

Section 7.4.1.2/06 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

Official use only

1 REFERENCE

1.1	**Reference**	Hermens J, Canton H, Janssen P, De Jong R (1984) Quantitative structure activity relationship and mixture toxicity studies of chemicals with anaesthetic potency: acute lethal and sublethal toxicity to *Daphnia magna*. Aquat Toxicol 5, 143-154 (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. But the study was conducted according to the Dutch standard method NEN 6501 'Determination of the acute toxicity with *Daphnia magna*' Dutch Standard Organization, Delft (1980).
2.2	**GLP**	[redacted]
2.3	**Deviations**	The test duration was 48 h.

3 METHOD

3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	Propanol-2
3.1.3	Purity	Purity not stated
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	GC/FID (column: 10% Carbowax 20 M)
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Propan-2-ol is indefinitely miscible with water (**cf. Doc III A3.5**). Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc III A3.2.1**).
3.3	**Reference substance**	No data
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details
Source	Dutch Standard Water according to Canton and Sloof (1982) Toxicity and

Section 7.4.1.2/06 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

	accumulation studies of Cd (Cd^{2+}) with freshwater organisms of different trophic levels. Ecotoxicol Environ Safe 6, 113-128
Salinity	No data
Hardness	ca. 1 mmol/L
pH	No data
Ca / Mg ratio	No data
Na / K ratio	No data
Oxygen content	No data
Conductance	No data
TOC	No data
Holding water different from dilution water	No data

3.4.2 Test organisms

Criteria	**Details**
Species	*Daphnia magna*
Strain / Clone	Not stated
Source	No data
Age	< 2 d
Breeding method	No data
Kind of food	none
Amount of food	No data
Feeding frequency	No data
Pretreatment	No data
Feeding of animals during test	No data

3.4.3 Handling of offspring

Not reported

3.4.4 Test system

Criteria	**Details**
Test type	Static
Renewal of test solution	no
Volume of test vessels	1 L
Volume/animal	40 mL/animal
Number of animals/vessel	25
Number of vessels/ concentration	2

Section 7.4.1.2/06 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna* STRAUS

		Test performed in closed vessels due to significant volatility of TS	No data
3.4.5	Test conditions	**Criteria**	**Details**
		Test temperature	22 ± 1 °C
		Dissolved oxygen	No data
		pH	No data
		Adjustment of pH	No data
		Aeration of dilution water	No data
		Quality/Intensity of irradiation	No data
		Photoperiod	No data
3.4.6	Duration of the test	48 h	
3.4.7	Test parameter	Immobility	
3.4.8	Examination / Sampling	Not explicitely mentioned. Test procedure is described in the NEN report 6501.	
3.4.9	Monitoring of TS concentration	Yes. Effect values are based on nominal quantities.	
3.4.10	Statistics	Estimation of IC50 values by logit transformation according to Brown (1978)	
		4 RESULTS	
4.1	**Range finding test**	No data	
4.1.1	Concentrations	-	
4.1.2	Number/ percentage of animals showing adverse effects	-	
4.1.3	Nature of adverse effects	-	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	No data	
4.2.2	Actual concentrations of test substance	Actual concentrations were determined during the test by gaschromatographic analysis (no further information)	
4.2.3	Effect data	48 d IC_{50} = 2285 mg/L No further information	

Section 7.4.1.2/06 Acute toxicity to invertebrates
Annex Point IIA7.2 *Daphnia magna* STRAUS

4.2.4	Concentration / response curve	Not available
4.2.5	Other effects	No data
4.3	**Results of controls**	No data
4.4	**Test with reference substance**	No data
4.4.1	Concentrations	-
4.4.2	Results	-

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The study was conducted according to the Dutch standard method NEN 6501 (1980). The test was performed in 1 L flasks and 25 daphnids (tests conducted in duplicate: 50 daphnids per concentration). Actual concentration of the test substance was measured analytically. No further information is given.
5.2	**Results and discussion**	In the acute study with *Daphnia magna* a 48 h IC_{50} = 2285 mg/L (4.58 µmol/L) was determined in respect to immobilisation. No information is provided about the mortality of parent animals at test termination. The study was conducted according to a national standard method. No information on dose-response relationship is given. Based on the experimentally determined Henry's Law constant (**cf. Doc III A3.2.1**) a moderate volatilisation from aqueous solution is to be expected.
5.2.1	NOEC	-
5.2.2	LOEC	-
5.2.3	EC_{50} (EC_x)	48 h IC_{50} = 2285 mg/L
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]