

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

| | | | |
|------------|--|---|---|
| 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/cm ³ | X |
| 3.3.7 | OH concentration | $5 \cdot 10^{-11}$ to $10 \cdot 10^{-11}$ mol/cm ³ | |
| 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/cm ³ were tested. | |
| 4.3.2 | Mass balance | - | |
| 4.3.3 | k_p^e | - | |
| 4.3.4 | Kinetic order | Pseudo first order/second order | |
| 4.3.5 | k_p^e / k_p^a | - | |
| 4.3.6 | Reaction quantum yield (ϕ_E^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 $k(OH) = 3.3 \cdot 10^{-12}$ cm ³ /mol · sec and a OH radical concentration of $5 \cdot 10^5$ radicals/cm ³). | 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 ₂ O/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
Annex Point IIIA VII 5

Phototransformation in air (measurement), including
identification of breakdown products

5.2 Results and discussion $t_{1/2} = 2.9$ days (based on second order rate constant $k(\text{OH}) = 3.3 \cdot 10^{12}$ $\text{cm}^3/\text{mol} \cdot \text{sec}$ and a OH radical concentration of $5 \cdot 10^5$ radicals/ cm^3). The study is well described and assignable and therefore regarded as valid.

- 5.2.1 k_p^e -
- 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] |

Section A7.3.1/02
Annex Point IIIA VII 5

**Phototransformation in air (measurement), including
identification of breakdown products**

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

Section A7.3.1/03
Annex Point IIIA VII 5Phototransformation in air (measurement), including
identification of breakdown products

| | | 1 REFERENCE |
|-------|--|---|
| 1.1 | Reference | Wallington TJ, Atkinson R, Winer AM, Pitts JN jr (1987) A study of the reaction $\text{NO}_3 + \text{NO}_2 + \text{M} \rightarrow \text{N}_2\text{O}_5 + \text{M}$ ($\text{M}=\text{N}_2, \text{O}_2$). 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 | ████████ |
| 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 $(R-k_0)$ against NO_2 concentration ($R = \text{NO}_3$ radical decay rates; k_0 = 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. |

Official
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Section A7.3.1/03
Annex Point IIIA VII 5
Phototransformation in air (measurement), including identification of breakdown products

| | | |
|------------|--|---|
| 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/cm ³ |
| 4.4.2 | Mass balance | - |
| 4.4.3 | $k(\text{NO}_3)$ | $\leq 2.3 \cdot 10^{-15}$ cm ³ /(molecule · sec) |
| 4.4.4 | Kinetic order | pseudo first order |
| 4.4.5 | k_p^c / k_p^a | - |
| 4.4.6 | Reaction quantum yield (ϕ_E^c) | - |
| 4.4.7 | k_{pE} | - |
| 4.4.8 | Half-life ($t_{1/2E}$) | $t_{1/2}$ ca. 1.45-14.5 days based on NO ₃ radical concentrations of 10-100 ppt ($2.4\text{-}24 \cdot 10^8$ radicals/cm ³). |
| 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 $t_{1/2}$ ranging from ca. 1.45 to ca.14.5 days based on NO ₃ radical |

Section A7.3.1/03
Annex Point IIIA VII 5

Phototransformation in air (measurement), including identification of breakdown products

| | |
|------------------------|--|
| discussion | concentrations of 10-100 ppt ($2.4 - 24 \cdot 10^8$ radicals/cm ³) were determined. Based on the information provided the study can be regarded as valid. |
| 5.2.1 $k(\text{NO}_3)$ | $\leq 2.3 \cdot 10^{-15}$ cm ³ /(molecule · sec) |
| 5.2.2 K_{pE} | - |
| 5.2.3 ϕ_E° | - |
| 5.2.4 $t_{1/2}$ | $t_{1/2}$ ca. 1.45-14.5 days based on NO ₃ radical concentrations of 10 - 100 ppt ($2.4 - 24 \cdot 10^8$ radicals/cm ³) |
| 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 | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

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/cm ³) | 1.4×10^{12} |
| Test concentrations (molecule/cm ³) | 3.9×10^{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 ($R=(t-t_0)^{-1} \times \ln([\text{NO}_3]_0/[\text{NO}_3]_t)$) were determined. Based on pseudo-first order decay the rate constant can be determined graphically via $R=k_0 + k$ [reactant] |

Table A7_1_1_2-2: Description of test system

| Criteria | Details |
|--|---|
| Laboratory equipment | No details 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 wavelength 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*

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1 REFERENCE

1.1 Reference [REDACTED] (1984) Acute toxicities of organic chemicals to fathead minnows (*Pimephales promelas*), [REDACTED]
[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]
[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

3.4.2 Test organisms

| | |
|---|---|
| pH | 7.09 - 7.87 |
| Oxygen content | 6.6 - 6.7 mg/L |
| Conductance | No data |
| Holding water different from dilution water | No data. |
| Criteria | Details |
| Species/strain | <i>Pimephales promelas</i> (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: <i>Artemia</i> 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 LC₅₀ and EC₅₀ was made by using the "trimmed Spearman-Kärber" 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 17000 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 |

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA7.1

Pimephales promelas

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 LC₅₀ 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 EC₅₀ values were determined also (96 h EC₅₀ = 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 examining 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 LC₅₀ = 6550-10400 mg/L; 96 h EC₅₀ = 6120-9540 mg/L).

| | fulfilled | Not fulfilled |
|---|-----------|---------------|
| 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 | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

Section A7.4.1.1/02 Acute toxicity to fish

Annex Point IIA7.1 *Pimephales promelas*

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1 REFERENCE

1.1 Reference [REDACTED] (1983) Estimating the acute toxicity of narcotic industrial chemicals to fathead minnows. [REDACTED]
[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]
[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 CaCO ₃ |
| Hardness | 56.3 mg/L as CaCO ₃ |

Section A7.4.1.1/02

Acute toxicity to fish

Annex Point IIA7.1

Pimephales promelas

3.4.2 Test organisms

| | |
|---|--|
| pH | 7.5 |
| Oxygen content | > 60% of saturation |
| Conductance | No data |
| Holding water different from dilution water | No |
| Criteria | Details |
| Species/strain | <i>Pimephales promelas</i> |
| 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 LC₅₀ was calculated using the trimmed Spearman-Kärber 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 LC₅₀ 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 fulfilled |
|---|-----------|---------------|
| 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.

Propan-2-ol showed a very low acute toxicity towards *Pimephales promelas* (96 h LC₅₀=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 LC₀

5.2.2 LC₅₀

96 h LC₅₀ = 9640 and 10000 mg/L (effective)

5.2.3 LC₁₀₀

5.3 Conclusion

[REDACTED]

5.3.1 Other Conclusions

5.3.2 Reliability

[REDACTED]

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

██████████ A7.4.1.1/03 Acute toxicity to fish
Annex Point IIA7.1 *Oryzias latipes*

Official
use only

1 REFERENCE

- 1.1 Reference** ██████████ (1998) Final Report, Acute Toxicity Test on *Oryzias latipes* to 2-Propanol. ██████████
██████████
- ██████████ 2007 Chemical Risk Information Platform (CHRIP) Total Search System for Chemical Substances: 2-Propanol; ██████████
██████████
- 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. ██████████
- 2.2 GLP** ██████████
- 2.3 Deviations** None

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 ██████████
- 3.1.4 Composition of Product ██████████
██████████
- 3.1.5 Further relevant properties ██████████
██████████
██████████
██████████
██████████
██████████
██████████
- 3.1.6 Method of analysis ██████████
- 3.2 Preparation of TS solution for poorly soluble or volatile test substances** ██████████
██████████
- 3.3 Reference substance** Yes: copper sulfate pentahydrate
- 3.3.1 Method of analysis for reference No data

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] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.2 Test organisms

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.3 Test system

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

██████████ A7.4.1.1/03 Acute toxicity to fish
Annex Point IIA7.1 *Oryzias latipes*

| | | |
|-------|--------------------------------|------------|
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| 3.4.4 | Test conditions | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| | ██████████ | ██████████ |
| 3.4.5 | Duration of the test | ██████████ |
| 3.4.6 | Test parameter | ██████████ |
| 3.4.7 | Sampling | ██████████ |
| 3.4.8 | Monitoring of TS concentration | ██████████ |
| 3.4.9 | Statistics | ██████████ |

4 RESULTS

| | | |
|------------|--|----------------|
| 4.1 | Limit Test | ██████████ |
| 4.1.1 | Concentration | ██████████ |
| 4.1.2 | Number/ percentage of animals showing adverse effects | ██████████ |
| 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 |

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

- 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 LC₅₀ = 0.930 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

5.2 Results and discussion

| | | | |
|--|--|--|--|
| | | | |
| | | | |
| | | | |
| | | | |

5.2.1 LC₀

5.2.2 LC₅₀

5.2.3 LC₁₀₀

5.3 Conclusion

█ A7.4.1.1/03 **Acute toxicity to fish**
Annex Point IIA7.1 *Oryzias latipes*

- 5.3.1 Other Conclusions
- 5.3.2 Reliability █
- 5.3.3 Deficiencies █



| Evaluation by Competent Authorities | |
|---|---|
| <i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i> | |
| EVALUATION BY RAPPOREUR MEMBER STATE | |
| Date | 2014/02/12 |
| Materials and Methods | █ |
| Results and discussion | █ |
| Conclusion | █ |
| Reliability | █ |
| Acceptability | █ |
| Remarks | █ |
| COMMENTS FROM ... | |
| Date | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

Section A7.4.1.2/01 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]
[REDACTED] 2007 Chemical Risk Information Platform (CHRIP) Total Search System for Chemical Substances: 2-Propanol; [REDACTED]
[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]
[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]
[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

3.4.3 Test system

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.4 Test conditions

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [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










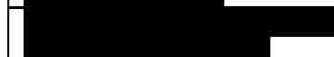

Annex Point IIA7.2 *Daphnia magna* STRAUS

| | | |
|------------|---|--|
| 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


5.2 Results and discussion


| | | |
|---|---|---|
|  |  |  |
|  |  | |
|  |  | |
|  |  | |
|  |  | |



Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2

Daphnia magna STRAUS

5.2.1 EC₀

[REDACTED]

5.2.2 EC₅₀

[REDACTED]

5.2.3 EC₁₀₀

[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 STRAUSOfficial
use only**1 REFERENCE**

- 1.1 Reference** Bringmann G, Kuehn R (1977) Befunde der Schadwirkung wasser-gefährdender 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** ■
- 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 | Artificial 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

3.4.2 Test organisms

| | |
|---|--|
| 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 |
| Criteria | Details |
| Species | <i>Daphnia magna</i> |
| 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/m ² ; 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 |
| Criteria | Details |
| Renewal of test solution | No |
| Volume of test vessels | 50 mL |
| Volume/animal | 2 mL/animal |

3.4.3 Test system

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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Test temperature</td> <td>20 °C</td> </tr> <tr> <td>Dissolved oxygen</td> <td>At the beginning: oxygen saturated dilution water; at the end: measurement of oxygen (DO ≥ 2 mg/L)</td> </tr> <tr> <td>pH</td> <td>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)</td> </tr> <tr> <td>Adjustment of pH</td> <td>No.</td> </tr> <tr> <td>Aeration of dilution water</td> <td>Yes. Till saturation.</td> </tr> <tr> <td>Quality/Intensity of irradiation</td> <td>Light intensity: E = 2.5 W/m²</td> </tr> <tr> <td>Photoperiod</td> <td>9 h light/15 h dark</td> </tr> </tbody> </table> | 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 |
| 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 | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | |

x

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) EC₅₀, NOEC and EC₁₀₀ 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 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 national standard method. Deviations from this procedure were not reported. Therefore the validity criteria can be considered as fulfilled.

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 EC₅₀).

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 EC₀ 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 EC₅₀ 9714 mg/L (nominal)
5.2.3 24 h EC₁₀₀ >10 000 mg/L (nominal)

5.3 Conclusion

5.3.1 Reliability

5.3.2 Deficiencies

[REDACTED]

[REDACTED]

[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

Results and discussion

[REDACTED]

Conclusion

Reliability

Acceptability

Remarks

[REDACTED]

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

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

| | | 1 | REFERENCE |
|------------|--|--|--|
| 1.1 | Reference | | <p>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. <i>Altern Lab Anim</i> 21, 330-349 (published)</p> <p>Calleja MC, Personne G, Geladi P (1994) Comparative toxicity of the first 50 multicentre evaluation of <i>in vitro</i> cytotoxicity chemicals to aquatic non-vertebrates. <i>Arch Environ Contam Toxicol</i> 26, 69-78 (published)</p> |
| 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 ' <i>Daphnia magna</i> , acute immobilization test and reproduction test' (1984) |
| 2.2 | GLP | | |
| 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 polyethylene 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 | - | |

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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 | <i>Daphnia magna</i> |
| 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 | 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

EC₅₀ values and the corresponding 95% confidence limits were calculated using the Trimmed Spearman-Kärber 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)EC₅₀ 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

Acute toxicity to invertebrates**Section A7.4.1.2/03***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 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 |

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.

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 EC₅₀).

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) |
| 5.2.3 | EC ₁₀₀ | - |

5.3 Conclusion

| | | |
|-------|--------------|---|
| 5.3.1 | Reliability | █ |
| 5.3.2 | Deficiencies | █ |

x

x

Section A7.4.1.2/03 **Acute toxicity to invertebrates**
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 | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |

Section A7.4.1.2/03 **Acute toxicity to invertebrates**
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
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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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Species</td> <td><i>Crangon crangon</i></td> </tr> <tr> <td>Strain</td> <td>No information</td> </tr> <tr> <td>Source</td> <td>No information</td> </tr> <tr> <td>Age</td> <td>No information</td> </tr> <tr> <td>Breeding method</td> <td>No information</td> </tr> <tr> <td>Kind of food</td> <td>No information</td> </tr> <tr> <td>Amount of food</td> <td>No information</td> </tr> <tr> <td>Feeding frequency</td> <td>No information</td> </tr> <tr> <td>Pretreatment</td> <td>No information</td> </tr> <tr> <td>Feeding of animals during test</td> <td>No information</td> </tr> </tbody> </table> | Criteria | Details | Species | <i>Crangon crangon</i> | 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 |
| Criteria | Details | | | | | | | | | | | | | | | | | | | | | | | |
| Species | <i>Crangon crangon</i> | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Renewal of test solution</td> <td>Test concentrations were renewed every 6, 12, or 24 h depending on the volatility of the test substance</td> </tr> <tr> <td>Volume of test vessels</td> <td>No information</td> </tr> <tr> <td>Volume/animal</td> <td>No information</td> </tr> <tr> <td>Number of animals/vessel</td> <td>20</td> </tr> <tr> <td>Number of vessels/concentration</td> <td>No information</td> </tr> <tr> <td>Test performed in closed vessels due to significant volatility of TS</td> <td>No. However, test concentrations were renewed every 6, 12, or 24 h depending on the volatility of the test substance.</td> </tr> </tbody> </table> | 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. | | | | | | | | |
| 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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Test temperature</td> <td>No information</td> </tr> <tr> <td>Dissolved oxygen</td> <td>No information</td> </tr> <tr> <td>pH</td> <td>No information</td> </tr> <tr> <td>Adjustment of pH</td> <td>No information</td> </tr> <tr> <td>Aeration of dilution water</td> <td>No information</td> </tr> </tbody> </table> | Criteria | Details | Test temperature | No information | Dissolved oxygen | No information | pH | No information | Adjustment of pH | No information | Aeration of dilution water | No information | | | | | | | | | | |
| 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 LC₅₀ (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 shellfish. 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 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 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 LC₅₀) and 900 mg/L (96 h LC₅₀).

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 LC₀ -

5.2.2 LC₅₀ 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 LC₁₀₀ -

5.3 Conclusion

5.3.1 Reliability

5.3.2 Deficiencies

[REDACTED]

[REDACTED]

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

Section A7.4.1.2

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 <i>Daphnia magna</i> . <i>Aquat Toxicol</i> 30, 47-60 (published) Lilius H, Hästabačka T, Isomaa B (1995) A comparison of the toxicity of 30 reference chemicals to <i>Daphnia magna</i> and <i>Daphnia pulex</i> . <i>Environ Toxicol Chem</i> 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 ' <i>Daphnia</i> sp., acute immobilisation test and reproduction test' (1993) | | | | |
| 2.2 | GLP | ██████████ | | | | |
| 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 into 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 | <table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 50%;">Criteria</th> <th style="width: 50%;">Details</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table> | Criteria | Details | | |
| Criteria | Details | | | | | |
| | | | | | | |

Section A7.4.1.2

Acute toxicity to invertebrates

Annex Point IIA7.2

Daphnia magna

3.4.2 Test organisms

| | |
|--|--|
| 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) |
| Criteria | Details |
| Species | <i>Daphnia magna</i> |
| Strain | No information |
| Source | Department of Biology, University of Turku |
| Age | <24 h |
| Breeding method | Breeding in M4 media, 12:12 h light/dark cycle, breeding temperature 20 +/- 2°C |
| Kind of food | <i>Scenedesmus</i> sp. |
| Amount of food | - |
| Feeding frequency | Every second or third day |
| Pretreatment | No information |
| Feeding of animals during test | No |
| 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 |
| Criteria | Details |
| Test temperature | 21 ±1 °C |
| Dissolved oxygen | No information |

3.4.3 Test system

3.4.4 Test conditions

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 EC₅₀

| | 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 into 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.

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 EC₅₀).

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 EC₀

-

5.2.2 24h EC₅₀

6850 mg/L (nominal)

5.2.3 EC₁₀₀

-

5.3 Conclusion

[Redacted]

5.3.1 Reliability

[Redacted]

5.3.2 Deficiencies

[Redacted]

x

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 | 2008/06/30 |
| Materials and Methods | [REDACTED] |
| Results and discussion | [REDACTED] |
| Conclusion | [REDACTED] |
| Reliability | [REDACTED] |
| Acceptability | [REDACTED] |
| Remarks | [REDACTED] |
| COMMENTS FROM ... | |
| Date | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

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Section 7.4.1.2/06
Annex Point IIA7.2

Acute toxicity to invertebrates
Daphnia magna STRAUS

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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 |

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Section 7.4.1.2/06
Annex Point IIA7.2

Acute toxicity to invertebrates

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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Species</td> <td><i>Daphnia magna</i></td> </tr> <tr> <td>Strain / Clone</td> <td>Not stated</td> </tr> <tr> <td>Source</td> <td>No data</td> </tr> <tr> <td>Age</td> <td>< 2 d</td> </tr> <tr> <td>Breeding method</td> <td>No data</td> </tr> <tr> <td>Kind of food</td> <td>none</td> </tr> <tr> <td>Amount of food</td> <td>No data</td> </tr> <tr> <td>Feeding frequency</td> <td>No data</td> </tr> <tr> <td>Pretreatment</td> <td>No data</td> </tr> <tr> <td>Feeding of animals during test</td> <td>No data</td> </tr> </tbody> </table> | Criteria | Details | Species | <i>Daphnia magna</i> | 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 |
| Criteria | Details | | | | | | | | | | | | | | | | | | | | | | |
| Species | <i>Daphnia magna</i> | | | | | | | | | | | | | | | | | | | | | | |
| 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 | <table border="1"> <thead> <tr> <th>Criteria</th> <th>Details</th> </tr> </thead> <tbody> <tr> <td>Test type</td> <td>Static</td> </tr> <tr> <td>Renewal of test solution</td> <td>no</td> </tr> <tr> <td>Volume of test vessels</td> <td>1 L</td> </tr> <tr> <td>Volume/animal</td> <td>40 mL/animal</td> </tr> <tr> <td>Number of animals/vessel</td> <td>25</td> </tr> <tr> <td>Number of vessels/ concentration</td> <td>2</td> </tr> </tbody> </table> | 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 | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | | | |

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Section 7.4.1.2/06
Annex Point IIA7.2

Acute toxicity to invertebrates

Daphnia magna STRAUS

| | | | |
|-------|-----------------|--|----------------|
| 3.4.5 | Test conditions | Test performed in closed vessels due to significant volatility of TS | No data |
| | | 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 explicitly 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 IC₅₀ = 2285 mg/L
No further information

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Section 7.4.1.2/06 **Acute toxicity to invertebrates**
Annex Point II A7.2 *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 IC₅₀ = 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 EC₅₀ (EC_x) 48 h IC₅₀ = 2285 mg/L

5.3 Conclusion [REDACTED]

5.3.1 Reliability [REDACTED]

5.3.2 Deficiencies [REDACTED]

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| Evaluation by Competent Authorities | |
|---|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted. | |
| EVALUATION BY RAPPORTEUR MEMBER STATE | |
| Date | 2008/12/05 |
| Materials and Methods | [REDACTED] |
| Results and discussion | [REDACTED] |
| Conclusion | [REDACTED] |
| Reliability | [REDACTED] |
| Acceptability | [REDACTED] |
| Remarks | [REDACTED] |
| COMMENTS FROM ... (specify) | |
| Date | <i>Give date of comments submitted</i> |
| Materials and Methods | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i> |
| Results and discussion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Conclusion | <i>Discuss if deviating from view of rapporteur member state</i> |
| Reliability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Acceptability | <i>Discuss if deviating from view of rapporteur member state</i> |
| Remarks | |

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA7.3 *Selenastrum capricornutum*

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1 REFERENCE

- 1.1 Reference** [REDACTED] (1998) Final Report, Growth Inhibition Test Using *Selenastrum capricornutum* to 2-Propanol. [REDACTED]
[REDACTED]
- [REDACTED] 2007 Chemical Risk Information Platform (CHRIP) Total Search System for Chemical Substances: 2-Propanol; [REDACTED]
[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 [REDACTED]
- 3.1.3 Purity [REDACTED]
- 3.1.4 Composition of Product [REDACTED]
- 3.1.5 Further relevant properties [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
- 3.1.6 Method of analysis [REDACTED]
- 3.2 Preparation of TS solution for poorly soluble or volatile test substances** [REDACTED]
[REDACTED]
- 3.3 Reference substance** Potassium dichromate
- 3.3.1 Method of analysis for reference No data

Section A7.4.1.3/01 **Growth inhibition test on algae**
Annex Point IIA7.3 *Selenastrum capricornutum*

substance

3.4 **Testing procedure**

3.4.1 Culture medium Culture medium indicated in the OECD guideline

3.4.2 Test organisms

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.3 Test system

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.4 Test conditions

| | |
|------------|------------|
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

3.4.5 Duration of the test

[REDACTED]

3.4.6 Test parameter

[REDACTED]