Section 7.4.3.4/01
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an invertebrate species
Daphnia magna STRAUS

		[redacted]	
5.2	**Results and discussion**	[redacted]	x
		[redacted]	
5.2.1	NOEC	[redacted]	
5.2.2	LOEC	[redacted]	
5.2.3	EC_{50} (EC_x)	[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	2014/02/13
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.4.3.4/01
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an invertebrate species
Daphnia magna STRAUS

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

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Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

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1 REFERENCE

1.1	**Reference**	Hermens J, Broekhuyzen E, Canton H, Wegman R (1985) Quantitative structure activity relationship and mixture toxicity studies of alcohols and chlorohydrocarbons: effects on growth of *Daphnia magna*. Aquat Toxicol 6, 209-217 (published) 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 6502 'Determination of the chronic toxicity with *Daphnia magna*' Dutch Standard Organization, Delft (1980) which is comparable to OECD guideline 202.
2.2	**GLP**	[redacted]
2.3	**Deviations**	The test duration was 16 days.

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**	

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Daphnia magna STRAUS

3.4.1 Dilution water

Criteria	Details
Source	Dutch Standard Water according to Canton and Sloof (1982) Toxicity and accumulation studies of Cd (Cd^{2+}) with freshwater organisms of different trophic levels. Ecotoxicol Environ Safe 6, 113-128
Salinity	No data
Hardness	ca. 1 mmol/L
pH	No data
Ca / Mg ratio	No data
Na / K ratio	No data
Oxygen content	No data
Conductance	No data
TOC	No data
Holding water different from dilution water	No data

3.4.2 Test organisms

Criteria	Details
Species	*Daphnia magna*
Strain / Clone	Not stated
Source	No data
Age	<1 d
Breeding method	No data
Kind of food	*Chlorella* spec.
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 (aim of the study was to examine the growth of the daphnids)

3.4.4 Test system

Criteria	Details
Test type	Semi-static
Renewal of test solution	renewing rate: 3 times a week (no further information)
Volume of test vessels	1 L
Volume/animal	67 mL/animal

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Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

		Number of animals/vessel	15	
		Number of vessels/ concentration	2	
		Test performed in closed vessels due to significant volatility of TS	No data	
3.4.5	Test conditions	**Criteria**	**Details**	
		Test temperature	19 ± 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	16 d		x
3.4.7	Test parameter	Growth (measured as length)		
3.4.8	Examination / Sampling	At the start of the experiment and after 16 days the length of the daphnids was measured.		
3.4.9	Monitoring of TS concentration	Yes. Just before and after renewal of the test solution the actual concentrations were determined		
3.4.10	Statistics	Student's t-test		
		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	Just before and after renewal of the test solution the actual concentrations were determined (no further information)		
4.2.3	Effect data	16 d $NOEC_{Growth}$ = 141 mg/L (at $p < 0.001$).		

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Effects on reproduction and growth rate with an invertebrate species
Daphnia magna STRAUS

		No further information	
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 6502 (1980) which is comparable to OECD guideline 202. In deviation of the standard procedure the test duration was 16 d. The test was conducted in 1 L flasks and 15 daphnids (tests conducted in duplicate: 30 daphnids per concentration). The test solution was renewed 3 times a week and the actual concentration of the test substance measured analytically. The decrease of the concentration till renewing the solutions was maximally 20%. At the start of the experiment and after 16 days the length of the daphnids was measured. The NOEC was tested with Student's t-test at $p<0.001$.	
5.2	**Results and discussion**	In the chronic study with *Daphnia magna* a 16 d $NOEC_{Growth}$ =141 mg/L was determined in respect to growth (endpoint length). Mortality or reproduction was not subject of the study. No information is provided about the mortality of parent animals at test termination. As the study was conducted according to a national standard method with an acceptable modification (test duration: 16 d) and the information provided the study can be regarded as valid. 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. The analytical monitoring of test substance concentrations showed that the actual measured concentrations were in all cases ≥80% of initially applied.	x
5.2.1	NOEC	16 d $NOEC_{Growth}$ = 141 mg/L	
5.2.2	LOEC	-	
5.2.3	EC_{50} (EC_x)	-	
5.3	**Conclusion**	[redacted]	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	

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Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/07/04
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.4/03 Effects on reproduction and growth rate with an invertebrate species
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Official use only

1 REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Huels AG
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No. [redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	No data

3 METHOD

3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	No information
3.1.2	Specification	2-Propanol
3.1.3	Purity	No data
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	No information
3.1.6	Method of analysis	No data
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	No data
3.3	**Reference substance**	No data
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Testing procedure**	
3.4.1	Dilution water	

Criteria	Details
Source	No data
Salinity	No data
Hardness	No data
pH	No data
Ca / Mg ratio	No data

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Na / K ratio	No data
Oxygen content	No data
Conductance	No data
TOC	No data
Holding water different from dilution water	No data

3.4.2 Test organisms

Criteria	**Details**
Strain / Clone	No data
Source	No data
Age	No data
Breeding method	No data
Kind of food	No data
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

No data

3.4.4 Test system

Criteria	**Details**
Test type	No data
Renewal of test solution	No data
Volume of test vessels	No data
Volume/animal	No data
Number of animals/vessel	No data
Number of vessels/ concentration	No data
Test performed in closed vessels due to significant volatility of TS	No data

3.4.5 Test conditions

Criteria	**Details**
Test temperature	No data
Dissolved oxygen	No data
pH	No data
Adjustment of pH	No data
Aeration of dilution water	No data
Quality/Intensity of	No data

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		irradiation	
		Photoperiod	No data
3.4.6	Duration of the test	21 days	
3.4.7	Test parameter	No data	
3.4.8	Examination / Sampling	No data	
3.4.9	Monitoring of TS concentration	No	
3.4.10	Statistics	No data	
		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	Analytical monitoring not performed.	
4.2.3	Effect data	21 d NOEC = 30 mg/L 21 d EC_{29} = 100 mg/L 21 d EC_{50} >100 mg/L (no further information available).	
4.2.4	Concentration / response curve	No data	
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**	Chronic toxicity towards *Daphnia magna* was tested according to a proposal of the Federal Environmental Protection Agency 'Prolonged	

Section 7.4.3.4/03 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

		toxicity-test with *Daphnia magna*'. Further information is not available.
5.2	**Results and discussion**	The chronic toxicity of propan-2-ol towards *Daphnia magna* was tested according to a proposal of the Federal Environmental Agency. The following results are available: 21 d NOEC=30 mg/L, 21 d EC_{29}=100 mg/L, and 21 d EC_{50}>100 mg/L. No further information is available. The original study is not available and the data given not assignable.
5.2.1	NOEC	21 d NOEC=30 mg/L
5.2.2	LOEC	
5.2.3	EC_{50} (EC_x)	21 d EC_{29}=100 mg/L, and 21 d EC_{50}>100 mg/L.
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/06/30
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*

Section 7.4.3.4/03 Effects on reproduction and growth rate with an invertebrate species
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Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.4/04
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an invertebrate species
Daphnia magna STRAUS

Official use only

1 REFERENCE

1.1	**Reference**	De Wolf W, Canton JH, Deneer JW, Wegman RCC, Hermens JLM (1988) Quantitative structure-activity relationships and mixture-toxicity studies of alcohols and chlorohydrocarbons: reproducibility of effects on growth and reproduction of *Daphnia magna*. Aquat. Toxicol. 12, 39-49
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. However, the study was conducted according to the Dutch standard method NEN 6502 (1980) which is comparable to OECD guideline 202.
2.2	**GLP**	[redacted]
2.3	**Deviations**	Not applicable

3 METHOD

3.1	**Test material**	Propanol-2
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, 2% KOH on chromosorb), direct water injection
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 accumulation studies of Cd (Cd^{2+}) with freshwater organisms of different

Section 7.4.3.4/04 **Effects on reproduction and growth rate with an invertebrate species**
Annex Point IIIA XIII 2.4
Daphnia magna STRAUS

	trophic levels. Ecotoxicol Environ Safe 6, 113-128
Salinity	No data
Hardness	Approx. 1 mmol/L
pH	No data
Ca / Mg ratio	No data
Na / K ratio	No data
Oxygen content	No data
Conductance	No data
TOC	No data
Holding water different from dilution water	No data

3.4.2 Test organisms

Criteria	**Details**
Species	*Daphnia magna*
Strain / Clone	Strain not stated
Source	No data
Age	<1 d
Breeding method	No data
Kind of food	*Chlorella* spec.
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 (aim of the study was to examine the growth of the daphnids)

3.4.4 Test system

Criteria	**Details**
Test type	Semi-static
Renewal of test solution	renewing rate: 3 times a week (no further information)
Volume of test vessels	1 L
Volume/animal	67 mL/animal
Number of animals/vessel	15
Number of vessels/ concentration	2
Test performed in closed vessels due to significant	No data

Section 7.4.3.4/04 **Annex Point IIIA XIII 2.4**

Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

		volatility of TS	
3.4.5	Test conditions	**Criteria**	**Details**
		Test temperature	19 ± 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	Until control daphnids produced four broods.	x
3.4.7	Test parameter	Reproduction and growth	
3.4.8	Examination / Sampling	At the start and at the end of the experiment the length of the daphnids was measured.	
3.4.9	Monitoring of TS concentration	Yes. Just before and after renewal of the test solution the actual concentrations were determined.	
3.4.10	Statistics	Student's t-test ($p < 0.01$)	
		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	Just before and after renewal of the test solution the actual concentrations were determined. Concentrations were 80 - 104% of calculated amount. Decrease during the test was average 9% (Maximum 26%).	
4.2.3	Effect data	$NOEC_{Reproduction}$ = 1408 mg/L $NOEC_{Growth}$ = 774 mg/L (at $p < 0.01$). No further information.	
4.2.4	Concentration / response curve	Not available	
4.2.5	Other effects	No data	

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Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

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 6502 (1980) which is comparable to OECD guideline 202. In deviation of the standard procedure the test duration was not specified. The experiment was terminated when control daphnids released their fourth brood. The test was conducted in 1 L flasks and 15 daphnids (tests conducted in duplicate: 30 daphnids per concentration). The test solution was renewed 3 times a week and the actual concentration of the test substance measured analytically. The decrease of the concentration till renewing the solutions was maximally 26% (average 9%). At the start and at the end of the experiment the length of the daphnids was measured. The NOEC was tested with Student's t-test at $p<0.01$.	x
5.2	**Results and discussion**	In the chronic study with *Daphnia magna* a NOEC = 1408 mg/L was determined for reproduction ($NOEC_{Growth}$ = 774 mg/L). No information is provided about the mortality of parent animals at test termination. As the study was conducted according to a national standard method with an acceptable modification (test duration: until control daphnids released their fourth brood). The information provided the study can be regarded as valid. 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. The analytical monitoring of test substance concentrations showed that the actual measured concentrations were in all cases ≥80% of initally applied and a decrease over time of average 9% was observed. Note that Verschueren (1996) "Handbook of environmental data on organic chemicals" cited a $NOEC_{Reproduction}$ of 2100 mg/L ($NOEC_{Growth}$ = 757 mg/L) from the same author De Wolf et al. (1986) "Chronische Toxiciteit van mengsels en struktuuraktiviteitsrelaties con chemicalien...) RIVM No 842052001, The Netherlands (internal report in dutch, not available). Wether these value is a typo or an error when converting log (µmol/L) to mg/L can not be evaluated as the reference is not at hand.	x
5.2.1	NOEC	$NOEC_{Reproduction}$ = 1408 mg/L $NOEC_{Growth}$ = 774 mg/L	x
5.2.2	LOEC	-	
5.2.3	EC_{50}	-	
5.3	**Conclusion**	[redacted]	

Section 7.4.3.4/04 **Effects on reproduction and growth rate with an invertebrate species**
Annex Point IIIA XIII 2.4
Daphnia magna STRAUS

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/07/04
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

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Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an invertebrate species

Daphnia magna STRAUS

Remarks

Section A7.5.1.1 Annex Point IIA 7.5	Inhibition to microbial activity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification: [redacted] Reference:		
Undertaking of intended data submission [ ]	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/07/03	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.5.1.3 Acute toxicity to plants

Annex Point IIIA XIII 3.4 *Lactuca sativa*

Official use only

		1 REFERENCE
1.1	**Reference**	Reynolds T (1979) An anomalous effect of isopropanol on lettuce germination. Plant Sci Lett 15, 25-28 (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.
2.2	**GLP**	[redacted]
2.3	**Deviations**	-
		3 METHOD
3.1	**Test material**	Propan-2-ol
3.1.1	Lot/Batch number	-
3.1.2	Specification	Isopropanol
3.1.3	Purity	Purity not stated
3.1.4	Composition of Product	-
3.1.5	Further relevant properties	-
3.1.6	Method of analysis	No information
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 information
3.3.1	Method of analysis for reference substance	-
3.4	**Testing procedure**	
3.4.1	Dilution water	Not applicable
3.4.2	Test plants	*Lactuca sativa* L cv. Great Lakes
3.4.3	Test system	Seeds of *Lactuca sativa* were incubated at 30°C for 3 days on 0.5% agar containing various concentrations of isopropanol. To allow greater hypocotyls growth normal bench level fluorescent lighting (1 W/m²) was used instead of high-intensity fluorescent lighting (17 W/m²).No further details provided.

Section 7.5.1.3 Acute toxicity to plants
Annex Point IIIA XIII 3.4 *Lactuca sativa*

3.4.4	Test conditions	Plant: seeds of Lactuca sativa; incubation at 30 °C for 3 days on 0.5% agar; light intensity: 1 W/m² (no further details reported)	
3.4.5	Test duration	3 days (germination)/6 days hypocotyl and root growth	x
3.4.6	Test parameter	Seed germination, hypocotyl and root growth	
3.4.7	Sampling	No information	
3.4.8	Method of analysis of the plant material	No information	
3.4.9	Quality control	Controls were conducted. No further information.	
3.4.10	Statistics	No information	
		4 RESULTS	
4.1	**Results test substance**		
4.1.1	Applied initial concentration	No information	
4.1.2	Phytotoxicity rating	Isopropanol inhibited the germination of lettuce seeds (*Lactuca sativa*) by 50% after 3 days of incubation at an isopropanol concentration of 35 mM (= 2100 mg/L). However, when the concentration of the test substance was increased above 300 mM (=18000 mg/L) the percentage of germination started to rise reaching a maximum of 62% at 440 mM (= 26440 mg/L) after which the germination again decreased. Growth of the hypocotyl and to a lesser extent the root showed similar behavior. At no time the growth of the plants exposed to the test substance exceed that of the controls. A growth stimulation of the test substance was not observed.	
4.1.3	Plant height	No information	
4.1.4	Plant dry weights	No information	
4.1.5	Root dry weights	No information	
4.1.6	Root length	No information	
4.1.7	Number of dead plants	Not applicable	
4.1.8	Effect data	3 d ED_{50} = 2100 mg/L (=35 mM (endpoint germination))	
4.1.9	Concentration / response curve	Not available	
4.1.10	Other effects	-	
4.2	**Results of controls**	No information	
4.2.1	Number/ percentage of plants showing adverse effects	-	
4.2.2	Nature of adverse effects	-	
4.3	**Test with reference**	Not performed	

Section 7.5.1.3 Acute toxicity to plants
Annex Point IIIA XIII 3.4 *Lactuca sativa*

	substance		
4.3.1	Concentrations	-	
4.3.2	Results	-	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	In the study only basic data on materials and methods employed were reported, but in the publication there were hints provided on other references. Seeds of *Lactuca sativa* were incubated at 30 °C for 3 days on 0.5% agar containing various concentrations of isopropanol. To allow greater hypocotyls growth normal bench level fluorescent lighting (1 W/m²) was used instead of high-intensity fluorescent lighting (17 W/m²). No further details provided.	
5.2	**Results and discussion**	Propan-2-ol inhibited the germination of lettuce seeds (*Lactuca sativa*) by 50% after 3 days of incubation at a propan-2-ol concentration of 35 mM (= 2100 mg/L). However, when the concentration of the test substance was increased above 300 mM (= 18000 mg/L) the percentage of germination started to rise reaching a maximum of 62% at 440 mM (= 26440 mg/L) after which the germination again decreased. Growth of the hypocotyl and to a lesser extent the root showed similar behavior. At no time the growth of the plants exposed to the test substance exceed that of the controls. A growth stimulation of the test substance was not observed. Based on the measured Henry's Law Constant propan-2-ol is moderately volatile from aqueous solution (**cf. Doc IIIA3.2.1**). So losses of test substance during the test can not be excluded. Analytical monitoring was not performed.	
5.2.1	EC_{20}	-	
5.2.2	EC_{50}	3 d EC_{50} = 2100 mg/L (nominal; germination)	
5.2.3	EC_{80}	-	
5.3	**Conclusion**	[redacted]	
5.3.1	Reliability	[redacted]	x
5.3.2	Deficiencies	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	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 ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.5.5 Annex Point IIA 7.5	Bioconcentration, terrestrial	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	[redacted]	
Reference:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/07/03
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A8 Measures necessary to protect man, animals and the environment

Subsection (Annex Point)			Official use only
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**	
8.1.0	**Methods and precautions concerning placing on the market**	Not applicable.	
8.1.1	**Methods and precautions concerning production, handling and use of the active substance**	In the following only the active substance as manufactured is described. For Exposure controls/Personal protection during handling and use of propan-2-ol containing formulations/products see the respective documents Doc IIIB8. **Advice on safe handling** It is recommended to provide adequate ventilation/extraction system exhaust on the workplace, so that the exposure limit of propan-2-ol will be kept. When using, do not eat, drink or smoke. Avoid contact with eyes. **Advice on protection against fire and explosion** Keep product and empty container away from heat and sources of ignition. Do not smoke - volatile. Take precautionary measures against static discharges. Do not spray on a naked flame or any other incandescent material. **Personal protective equipment** Respiratory protection: If ventilation is inadequate wear respiratory protection. [Gas filter for gases/vapours of organic compounds (boiling point >65 °C, e. g. EN 14387 Type A)] Hand protection: In case of repeated (approx. 50 times/ day) or prolonged (>30 min) exposure it is recommended to use chemical resistant protective gloves (EN 374) Eye protection: If exposure to the eye can not be excluded wear tightly fitting safety goggles (splash goggles) (e.g. EN 166) Body protection: It is recommended to use body protection depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to DIN-EN 465). General safety and hygiene measures: It is recommended to handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended additionally to the stated personal protection	*1 *2

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
		equipment. Avoid inhalation of vapour in high concentration.	
8.1.2	**Methods and precautions concerning storage of the active substance and its formulations**	**Requirements for storage rooms and vessels** Keep container tightly closed in a dry, cool and well-ventilated place. Pay attention to anti-explosion rules. **Advice on storage compatibility** Incompatible with: oxidizing agents, alkaline metals and earth alkaline metals. **Further information on storage conditions** Keep away from food, drink and animal feeding stuffs. Storageclass (VCI): 3 A	
8.1.3	**Methods and precautions concerning transport of the active substance and its formulations**	**Land transport (ADR/RID)** ADR/RID: 3 UN number: 1219 ADR packaging group: II Description of the goods: ISOPROPANOL **Marine transport** IMDG-Code: 3 UN number: 1219 Packaging group: II Marine pollutant: No Exact technical name: ISOPROPANOL **Air transport** ICAO/IATA-DGR: 3 UN/ID number: 1219 ICAO-packaging group: II Exact technical name: ISOPROPANOL	
8.1.4	**Methods and precautions concerning fire of the active substance and its formulations**	**Suitable extinguishing media** Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water-spray **Extinguishing media that must not be used for safety reasons** Full water jet **Special protective equipment for firefighters** Use breathing apparatus with independent air supply.	*3
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)** Fire may produce: Carbon monoxide and carbon dioxide.	
8.3		**Emergency measures in case of an accident (IIA8.3)**	
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if**	**General information** Remove contaminated soaked clothing immediately. If you feel unwell, seek medical advice. **After inhalation** In the event of symptoms move to fresh air and refer for medical	

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
	available	treatment. **<u>After contact with eyes</u>** Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist. **<u>After ingestion</u>** Drink plenty of water. Summon a doctor immediately. Induce vomiting only upon the advice of a physician. Attention! Beware, danger of aspiration!	
8.3.2	**Emergency measures to protect the environment**	Not necessary due to ready biodegradability.	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	Not applicable. In case that large amounts of propan-1-ol evaporate, ensure adequate ventilation and keep away sources of ignition.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Propan-2-ol is classified to water contaminating class: 1 - slightly water contaminating. The product is miscible in water, decontamination is not possible.	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Decontamination of soil is not necessary due to volatilisation and ready biodegradability.	
8.5		**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	
8.5.1	**Possibility of re-use or recycling**	Propan-2-ol may be recycled by distillation.	
8.5.2	**Possibility of neutralisation of effects**	The biocidal effects of propan-2-ol may be neutralised by dilution with water.	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal**	As propan-2-ol is highly flammable it is classified as "requiring special supervision", that is as hazardous waste. Waste disposal code: 070604. Contaminated packaging is to be treated in the same way as the product. If there are no official regulations, non-contaminated and	

Section A8 Measures necessary to protect man, animals and the environment

Official use only

completely empty packaging can be treated in the same way as household refuse or recycled.

8.5.4 Conditions for controlled incineration

Propan-2-ol is highly flammable. It may be used as fuel.

8.6 Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)

Man:

Inhalation:

Inhalation of vapours in high concentration can cause narcotic effects.

Skin contact:

Repeated (approx. 50 times/ day) or prolonged (>30 min) exposure may cause skin irritation, due to degreasing properties of the product. The application of skin caring hand creams is recommended in such cases.

Oral intake:

In case of inadvertant ingestion, propan-2-ol is rapidly absorbed. Depending on the amount of product ingested, the person may suffer from symptoms comparable to acute alcohol poisoning which should be treated accordingly.

Eye contact:

Contact with eyes may cause severe irritation.

Non-target organisms:

Propan-2-ol is intended to act non-specifically on all kinds of micro-organisms. At use concentration it is reasonable to assume that propan-2-ol may be harmful to plants and may have effects on animals similarly as man.

8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7)

Not applicable, as the active substance is volatile and readily biodegradable.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/09/24
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
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	

Propan-2-ol

Biocide for Use as Human Hygiene Biocidal Product (PT 1)

Biocide for Use as Private area and Public Health Area Disinfectants and Other Biocidal Products (PT 2)

Biocide for Use as Food and Feed Area Disinfectant (PT 4)

Dossier According to Directive 98/8/EC

Applicant note:

Please refer to the specific part of Doc IIA for "Classification and Labelling" (copy listed below)

1.1 CLASSIFICATION AND LABELLING

1.1.1 Current classification

Propan-2-ol is classified in Directive 67/548/EEC with the No.: 603-117-00-0. This classification is listed below.

Table 0-1 Current classification of propan-2-ol

Classification	As in Directive 67/548/EEC (No.: 603-117-00-0)
Class of danger	F: Highly flammable Xi: Irritating
R phrases	R11 Highly flammable R36 Irritating to eyes R67 Vapours may cause drowsiness and dizziness
S phrases	S2 Keep out of the reach of children S7 Keep container tightly closed S16 Keep away from sources of ignition - No smoking S24/25 Avoid contact with skin and eyes S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

1.1.2 Proposed classification

No other classification is proposed as in Annex I of Directive 67/548/EEC.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2014/04/24
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
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Remarks	