Section A1 Applicant

Annex Point IIA1

1.1 Applicant

[redacted]

1.2 Manufacturer of Active Substance (if different)

[redacted]

Section A1 Applicant

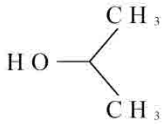
Annex Point IIA1

[redacted]

1.3	**Manufacturer of Product(s) (if different)**	See 1.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2014/03/04
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	-
	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*

Section A2 Identity of Active Substance

Subsection (Annex Point)			Official use only
2.1	Common name (IIA2.1)	2-Propanol	
2.2	Chemical name (IIA2.2)	Propan-2-ol	
2.3	Manufacturer´s development code number(s) (IIA2.3)	not applicable	
2.4	CAS No and EC numbers (IIA2.4)		
2.4.1	CAS-No	67-63-0	
2.4.2	EC-No	200-661-7 (EINECS)	
2.4.3	Other	EC No: 603-117-00-0 RTECS No: NT8050000	X
2.5	Molecular and structural formula, molecular mass (IIA2.5)		
2.5.1	Molecular formula	C_3H_8O	
2.5.2	Structural formula	 CC(OH)C (= SMILES code)	
2.5.3	Molecular mass	60.09 g/mol	
2.6	Method of manufacture of the active substance (IIA2.1)	The dominant manufacturing process of propan-2-ol is the weak acid process. In this process propene gas is absorbed in, and reacted with, 60% sulfuric acid and the resulting sulfates hydrolyzed in a single step process. Another important manufacturing process is catalytic hydration of propene with water. Hydration can be gas-phase with a phosphoric acid catalyst, mixed phase with a cation-exchange resin catalyst or liquid phase using a tungsten catalyst.	
2.7	Specification of the purity of the active substance, as appropriate (IIA2.7)	g/kg: — ; g/l: — ; % w/w: 99.9 ; % v/v: Min. 99.0 / 99.997	X

Section A2 Identity of Active Substance

2.8 Identity of impurities and additives, as appropriate (IIA2.8)

Impurities of marketed propan-2-ol may vary depending on the purity grade (p.a. or technical product), on manufacturers handling and on single production specifications represented by a lot number.
Impurities other than water are volatile components as well as acid contents in variable compositions.

H_2O	Max. 5000 ppm
Organic acids	Max. 30 ppm
Other organic impurities	Max. 3000 ppm
Non volatile matter	Max. 50 ppm

2.8.1 Isomeric composition

not applicable

2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)

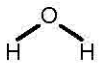
not applicable

Section A2 Identity of Active Substance

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2014/03/04
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	-
	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	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8 *fill in one form for each impurity/additive*

Subsection							Official use only
2.8.1.1	**Common name**	Water					
2.8.1.2	**Function**	None, impurity					X
2.8.2	**IUPAC name**	Hydrogen dioxide					X
2.8.3	**CAS-No**	7732-18-5					
2.8.4	**EC-No**	231-791-2 (EINECS)					
2.8.5	**Other**						
	CIPAC						
2.8.6	**Molecular formula**	H_2O					
2.8.7	**Structural formula**						
2.8.8	**Molecular mass**	18.0153 g/mol					
2.8.9	**Concentration of the impurity or additive** *typical and range of concentrations*	g/kg	g/l	% w/w <0.01	% v/v Max. 5000 ppm 0.014		X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)								
3.1.1 Melting point								
Melting pt. 1	Handbook data	No data	**result:** -89.5 °C **pressure:** -	Peer-reviewed handbook data	[redacted]	[redacted]	Merck (1996)	X
Melting pt. 2	Handbook data	No data	**result:** -89.5°C **pressure:** -	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
3.1.2 Boiling point								
Boiling pt. 1	Handbook data	No data	**result:** 82.5 °C **pressure:** 1013 hPa	Peer-reviewed handbook data	[redacted]	[redacted]	Merck (1996)	X
Boiling pt. 2	Handbook data	No data	**result:** 82.3 °C **pressure:** 1013 hPa	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
3.1.3 Bulk density/ relative density								
Rel. density 1	Handbook data	No data	0.785 at 20°C	Peer-reviewed handbook data	[redacted]	[redacted]	Merck (1996)	X
Rel. density 2	Handbook data	No data	0.785 at 20°C	Peer-reviewed handbook data	[redacted]	[redacted]	Sax (1984)	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
Rel. density 3	Handbook data	No data	0.7809 at 25°C	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
3.2 Vapour pressure (IIA3.2)								
Vapour pressure 1	Handbook data	No data	**result:** 57.8 hPa (5.775 Pa) **temperature:** 25 °C	Acceptable handbook data	[redacted]	[redacted]	Riddick et al (1986)	X
Vapour pressure 2	Calculated from Riedel's regression equation	No data	**result:** 60.5 hPa **temperature:** 25 °C	Handbook data	[redacted]	[redacted]	Daubert & Danner (1985)	X
Vapour pressure 3	Calculated from Antoine-type equation	No data	**result:** 60.73 hPa **temperature:** 25 °C	Handbook data	[redacted]	[redacted]	Yaws (1997)	X
3.2.1 Henry´s Law Constant (Pt. I-A3.2)								
Henry's Law Const. 1	GC	No data	**Measured (at 25 °C):** **result:** 0.80 Pa · m³/mol	Study well documented, meets generally accepted scientific principles	[redacted]	[redacted]	Snider & Dawson (1985) [redacted]	X
Henry's Law Const. 2	Calculation using HENRYWIN v3.10	-	**Calculated (at 25 °C):** **result:** 0.76 Pa · m³/mol (bond method) 1.16 Pa · m³/mol (group	Generally accepted calculation method	[redacted]	[redacted]	[redacted]	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			method)					
Henry's Law Const. 3	Handbook data	No data	**result:** 0.82 Pa · m³/mol	Reliable handbook data	[redacted]	[redacted]	Howard (1990)	X
Henry's Law Const. 4	No data	No data	**result:** 0.82 Pa · m³/mol	Only result presented	[redacted]	[redacted]	Taft et al. (1985), [redacted]	X
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Visual inspection	-	liquid	Peer-reviewed handbook data	[redacted]	[redacted]	Sax (1984)	X
	ASTM D4176	99.9% m/m	Liquid; clear & free from suspended matter	Certificate of analysis	[redacted]	[redacted]	[redacted]	X
3.3.2 Colour	Visual inspection	-	colorless	Peer-reviewed handbook data	-	[redacted]		X
	ASTM D1209	99.9% m/m	Pt-Co 0	Certificate of analysis, (Platinum-Cobalt scale 0: means that substance is colourless)	[redacted]	[redacted]	[redacted]	X
3.3.3 Odour	Olfactory assessment	-	slight	Peer-reviewed handbook data	[redacted]	[redacted]		X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	Shell Method Series (SMS) 547	99.9% m/m	Initial diluted odor: 4 (= same as reference solution odour)	Certificate of analysis, (reference substance: Propan-2-ol (Isopropyl Alcohol)	[redacted]	[redacted]	[redacted]	X
3.4 Absorption spectra (IIA3.4)								
UV/VIS	Handbook data	No data	For propan-2-ol as a solvent in UV/VIS spectrophotometry a cut-off point of 210 nm is given. Therefore, no absorption between 290 nm and 750 nm is expected.	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
	According Eur. Pharm.	99.997%	Abs 230 nm: 0.09 Abs 250 nm: 0.01 Abs 270 nm: -0.01 Abs 290 nm: -0.01 Abs 310 nm: -0.01 Spectrum is consistent with the proposed structure. No absorption maximum >210 nm	Internal report of manufacturer to applicant	[redacted]	[redacted]	[redacted]	X
	UV-Vis	99.997%	Spectrum is consistent with the proposed structure. No absorption	Internal report of applicant. Brenntag sales 2-propanol of	[redacted]	[redacted]	[redacted]	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			maximum >210 nm	SASOL				
	Lambda 35 (Perkin-Elmer), Serie-Nr. 101N2012803 incl. Software UVWinlab V2.85.04	99.997% 99.9% m/m	Spectrum is consistent with the proposed structure for quality from both sources	Internal report of applicant	[redacted]	[redacted]	[redacted]	X
IR	liquid film	No data	3346, 3334, 2972, 2933, 2907, 2884, 2722, 2659, 2521, 2408, 2387, 2198, 1903, 1766, 1467, 1409, 1379, 1368, 1341, 1309, 1162, 1130, 1110, 954, 818, 660, 654, 490, 436 cm^{-1}	Compilation of data	[redacted]	[redacted]	SDBS (2007)	X
	Europ.Pharm. /USP	99.997%	Spectrum is consistent with the proposed structure compared with reference spectrum	Internal report of manufacturer to applicant	[redacted]	[redacted]	[redacted]	X
	FT-IR Photometer Paragon 1000 (Perkin-Elmer), Serie-Nr. 39543 incl. Software Spectrum BX 5.0.1	99.997% 99.997%	Spectrum is consistent with the proposed structure for quality from both sources	Internal report of applicant	[redacted]	[redacted]	[redacted]	X
NMR	^{1}H-NMR at 300 MHz ^{13}C-NMR at 75.5 MHz	No data	ppm in $CDCl_3$ CH3: 1.22 (d) CH: 4.04 (sep) ppm in $CDCl_3$	Compilation of data	[redacted]	[redacted]	Gottlieb et al. (1997)	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			CH3: 25.14 CH: 64.50					
	^{1}H-NMR at 399 MHz	99.997%	Spectrum is consistent with the proposed structure	Internal report of applicant	[redacted]	[redacted]	[redacted]	X
	^{1}H-NMR at 399 MHz ^{13}C-NMR at 100 MHz	99.9 %m/m	Spectrum is consistent with the proposed structure	Internal report of manufacturer to applicant	[redacted]	[redacted]	[redacted]	X
MS	Handbook data	No data	45(100), 43(19), 27(17), 29(12), 41(7), 31(6), 19(6), 42(5), 44(4), 59(3)	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
	Europ.Pharm. /USP	99.997%	Spectrum is consistent with the proposed structure	Internal report of manufacturer to applicant	[redacted]	[redacted]	[redacted]	X
	Not specified	99.997	Spectrum is consistent with the proposed structure compared to reference spectrum	Internal report of applicant. Brenntag sales 2-propanol of SASOL	[redacted]	[redacted]	[redacted]	X
	Not specified	99.9 %m/m	Spectrum is consistent with the proposed structure compared to reference spectrum	Internal report of manufacturer to applicant	[redacted]	[redacted]	[redacted]	X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.5 Solubility in water (IIA3.5)	Handbook data	No data	**result:** infinitely in aqua **temperature:** - **pH:** -	Acceptable handbook data; Note: Episuite database cite this source with 1000 g/L at 25°C	[redacted]	[redacted]	Riddick et al. (1986)	X
	Handbook data	No data	Miscible	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
	Handbook data	No data	Miscible with water	Peer-reviewed handbook data	[redacted]	[redacted]	Merck (1996)	X
3.6 Dissociation constant (-)	Handbook data	No data	-3.2	Acceptable handbook data	[redacted]	[redacted]	Riddick et al. (1986)	X
3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1)	Handbook data	No data	**result:** miscible with acetone, alcohol and ether **temperature:** -	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)			Scientifically unjustified, see Justification for non-submission.	Expert judgement	[redacted]	[redacted]		X

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.9 Partition coefficient n-octanol/water (IIA3.6)								
log P_{ow} 1	GC	No data	**result:** 0.05 **temperature:** - **pH:** -	Generally accepted determination method without detailed documentation	[redacted]	[redacted]	Dillingham et al. (1973)	X
log P_{ow} 2	Measured, no further information	No data	**result:** 0.05 **temperature:** - **pH:** -	Original literature not available	[redacted]	[redacted]	Hansch et al. (1995)	X
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	-	-	Scientifically unjustified, see Justification for non-submission.	Expert judgement	[redacted]	[redacted]		
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	Handbook data	No data	**result:** 455°C (autoignition)	Peer-reviewed handbook data	[redacted]	[redacted]	Sax (1984)	
	Handbook data	No data	**result:** 399°C (ignition temperature)	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	
3.12 Flash-point (IIA3.9)								
Flash-point 1	Handbook data	No data	12°C (closed cup)	Acceptable handbook data	[redacted]	[redacted]	Riddick et al. (1986)	

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
	Interpolation	1 g/L	**result:** 72.11 mN/m	Value derived by linear interpolation of surface tension of a 16.7 g/L solution and pure water (72.75 mN/m)	[redacted]	[redacted]	[redacted]	
Surface tension 4	Calculation of surface tension according to Tahery & Modarress (2005)	1 g/L	**result:** 72.73 mN/m (ideal case) **temperature:** 20°C **result:** 72.72 mN/m (incl. deviation form ideal case) **temperature:** 20°C	Values for pure substance and water taken from Vasquez et al. 1995	[redacted]	[redacted]	Tahery & Modarress (2005), [redacted]	
Surface tension 5	OECD 115; EU A.5	1g/L, 99.7% (m/m)	**result:** 70.7 mN/m **temperature:** 22 °C		[redacted]	[redacted]	[redacted]	X
3.14 Viscosity (-)	Handbook data	No data	**result:**2.038 mPA · s **temperature:** 25°C	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	X
3.15 Explosive properties (IIA3.11)	Handbook data	No data	Lower explosive limit in air: 2.0% Upper explosive limit in air: 12.7%	Peer-reviewed handbook data	[redacted]	[redacted]	CRC (2001)	
3.16 Oxidizing properties (IIA3.12)			Scientifically unjustified, see Justification for non-	Expert judgement	[redacted]	[redacted]		

Section A3 Physical and Chemical Properties of Active Substance

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/06/10
3.1.1 Melting point Melting pt. 1 Melting pt. 2	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Date	2008/06/10
[redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Date	2008/06/10
3.1.3	[redacted]

Conclusion	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/09/25
3.2 [redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/09/25
3.2.1 [redacted]	[redacted]

Date	2008/06/10
3.3.3 [redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	-
Date	2008/06/10
3.4 [redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.4 [redacted]	[redacted]

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.4 [redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Date	2008/06/10
3.4	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.5	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10

3.6	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.7	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.8	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Date	2008/06/10
[redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/01/25
3.11	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Date	2008/06/10
3.13 [redacted]	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/06/10
3.14 [redacted] **(-)**	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
Date	2008/01/25
3.15 [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	

Section A3.6 Dissociation constant

Annex Point IIA3

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	
References:	[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	2008/09/25
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 A3.8 Annex Point IIA3.2	Stability in organic solvents used in b.p. and identity of relevant breakdown products

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure [ ]	Other justification [X]	
Detailed justification:	[redacted]	
References:	[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	2008/09/25
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 A3.16 Oxidizing properties

Annex Point IIA3.12

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	
References:	[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	2008/09/25
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 A3.17 Reactivity towards container material

Annex Point IIA3.13

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	
References:	[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	2008/09/25
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 A4.1 Analytical Methods for Detection and Identification

Annex Point IIA4.1 Determination of components in propan-2-ol

Official use only

	1 REFERENCE	
1.1	**Reference**	Council of Europe (2005) EUROPEAN PHARMACOPOEIA 5.0 Monograph Isopropyl alcohol. 01/2005: 0970; p 1841-1842 (published)
1.2	**Data protection**	No
1.2.1	Data owner	-
1.2.2	Criteria for data protection	-
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No
2.2	**GLP**	[redacted]
2.3	**Deviations**	-
	3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	
3.1.1	Enrichment	Not applicable
3.1.2	Cleanup	Not applicable
3.2	**Detection**	GC/FID
3.2.1	Separation method	a. Test solution (a): substance to be determined (propan-2-ol) b. Test solution (b): 1.0 mL of 2-butanol were diluted to 50.0 mL with the test substance. 5.0 mL of this solution was further diluted to 100.0 mL with test solution (a) c. Reference solution (a): 2-butanol (0.5 mL) and 0.5 mL of propanol were diluted to 50.0 mL with the test substance. 5.0 mL of this solution were further diluted to 50 mL with test substance (a) d. Reference solution (b): 100 µL of benzene were diluted to 100.0 mL with the test substance. 0.20 µl of this solution were further diluted to 100.0 mL with the test substance (a) GC conditions - Material: fused silica - Size: 30 m in length, 0.32 mm in diameter - Stationary phase: poly[(cyanopropyl)(phenyl)][dimethyl]siloxane (film thickness: 1.8 µm) Carrier gas: helium for chromatography Auxiliary gas: nitrogen for chromatography or helium for Chromatography: linear velocity: 35 cm/s; split ratio: 1:5; temperature column: 40°C (0-12 min), 40-240°C (12-32 min), 240°C (32-42 min); injection port: 280°C; detector : 280°C; injection volume: 1 µL
3.2.2	Detector	FID
3.2.3	Standard(s)	2-butanol and benzene
3.2.4	Interfering	No data

	substance(s)	
3.3	**Linearity**	
3.3.1	Calibration range	No data
3.3.2	Number of measurements	No data
3.3.3	Linearity	No data
3.4	**Specifity: interfering substances**	No data
3.5	**Recovery rates at different levels**	No data
3.5.1	Relative standard deviation	No data
3.6	**Limit of determination**	System suitability (reference solution b) Resolution: minimum 10 between the peak (propanol) and the second peak (2-butanol) Limits -benzene (test solution (a)): not more than half the area of the corresponding peak in the chromatogram obtained with reference solution (b) (2 ppm), after the sensitivity has been adjusted so that the height of the peak due to benzene in the chromatogram obtained with reference solution (b) represents at least 10% of the full scale of the recorder -total of other impurities apart from 2-butanol (test solution (b)): not more than 3 times the area of the peak due to 2-butanol in the chromatogram obtained with test solution (b) (0.3%), after the sensitivity has been adjusted so that the height of the 2 peaks following the principle peak in the chromatogram obtained with reference solution (a) represents at least 50% of the full scale of the recorder
3.7	**Precision**	No data
3.7.1	Repeatability	No data
3.7.2	Independent laboratory validation	No data

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	A method for the determination of possible impurities occurring in propan-2-ol is described. For the detection a glass capillary gas chromatography method coupled with FID was developed.
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

Section A4.1 Analytical Methods for Detection and Identification

Annex Point IIA4.1 Determination of components in propan-2-ol

JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data [X]	**Technically not feasible [ ]**	**Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**		

Detailed justification:

[redacted]

References:

[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	2013/09/04
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	Comments from other Member State *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4.2/02 Analytical Methods for Detection and Identification

Annex Point IIA4.2 *Additional information*

	ADDITIONAL INFORMATION	Official use only
Results	[redacted]	
References	WHO (1990) Environmental Health Criteria 103, 2-Propanol. IPCS, World Health Organization 1990.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/12/01
Evaluation of results	[redacted]
Conclusion	[redacted]
Remarks	-
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of results	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A4.2a
Annex Point 4.2

Analytical Methods for Detection and Identification
Determination of propan-2-ol in soil

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]		
References:			

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/04/16
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 A4.2b Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-2-ol in air*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Occupational Safety & Health Administration (OSHA) (1997) Analytical Method No 109, 200 Constitution Avenue, NW Washington, DC 20210, published.	X1
1.2	**Data protection**	No	
1.2.1	Data owner	OSHA, Organic Methods Evaluation Branch, OSHA Salt Lake Technical Center Salt Lake City, UT 84115-1802	
1.2.2	Criteria for data protection	Not applicable	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**		
3.1.1	Enrichment	Samples are collected using a personal sampling pump calibrated, with the sampling device attached, to within 25± at the recommended flow rate. [Note of the applicant: Original citation from method, assumed to be ±25%, after review of several other OSHA guidelines]	
		Samples are collected by drawing a known volume of air through a 400-mg and a 200-mg Anasorb® 747 sampling tube. The sampling tubes (11-cm × 8-mm o.d. × 6-mm i.d.) are connected in series with silicone tubing prior to sampling. The adsorbent beds are held in place with a glass wool plug at the front, and a foam plug at the rear of the adsorbent bed. For this evaluation, commercially prepared sampling tube sets were purchased from SKC, Inc. (catalog no. 226-82). The recommended air volume and sampling rate are 18 L at 0.05 to 0.2 L/min and 3 L at 0.2 L/min for long-term and short-term samples, respectively.	
		The breakthrough determinations at high humidity are 22.6 L for 0.2 L/min at 84% RH and 29.0 L for 0.05 L/min at 77% RH. The breakthrough determinations at low humidity are 29.8 L for 0.2 L/min at 12% RH and 37.6 L for 0.05 L/min at 13% RH.	X2
3.1.2	Cleanup	Samples are desorbed with a 60/40 N,N-dimethylformamide/carbon disulfide solution. The average desorption efficiency for isopropyl alcohol from Anasorb® 747 for 0.05, 0.1 and 0.2 times the target concentration were 100.2%, 102.9%, and 103.6% respectively.	X3
3.2	**Detection**		
3.2.1	Separation method	The sample is separated via gas chromatography, Hewlett-Packard 5890A Series II Gas Chromatograph equipped with a 7673A Automatic Sampler was used. A GC column capable of separating isopropyl alcohol from the desorption solvent, internal standard and any potential interferences. A 60-m × 0.32-mm i.d. capillary DB-5 with a 1.0-µm df (J&W Scientific, Folsom, CA) was used in the evaluation. An electronic integrator or some other suitable means of measuring peak areas. A Waters 860 Networking Computer System was used in this evaluation.	

Section A4.2b Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-2-ol in air*

		GC conditions zone temperatures: 60° (column), hold 4 min, ramp at 10°/min to 160°, hold 4 min 210° (injector) 225° (detector) run time: 18 min column gas flow: 2.9 mL/min (hydrogren) septum purge: 1.9 mL/min (hydrogen) injection size: 1.0 µL (19:1 split) column: 60-m x 0.32-mm i.d. capillary DB-5 (1.0 µm df) retention times: 4.4 min (isopropyl alcohol) 16.6 min (*p*-cymene)	
3.2.2	Detector	The concentration is determined by a flame ionization detector (FID). **FID conditions** hydrogen flow: 38 mL/min air flow: 450 mL/min makeup flow: 30 mL/min (nitrogen)	
3.2.3	Standard(s)	An internal standard (ISTD) calibration method is used.	X4
3.2.4	Interfering substance(s)	There are no known compounds that will severely interfere with the collection of isopropyl alcohol on Anasorb® 747. In general, the presence of other contaminant vapours in the air will reduce the capacity of Anasorb® 747 to collect isopropyl alcohol.	
3.3	**Linearity**		
3.3.1	Calibration range	0.34- 3.4 µg/ml or 1.02-10.2 µg/sample	X5
3.3.2	Number of measurements	10 data points	
3.3.3	Linearity	Yes	
3.4	**Specifity: interfering substances**	Not applicable	
3.5	**Recovery rates at different levels**	The recovery of isopropyl alcohol from samples used in the 19-day storage test remained above 100.2%.	
3.5.1	Relative standard deviation	Relative standard deviations are determined from six replicate injections of isopropyl alcohol standards at 0.5, 0.75, 1, 1.5 and 2 times the target concentrations. After assuring that the RSDs satisfy the Cochran test for homogeneity at the 95% confidence level, the RSDP is calculated to be 0.71% and 0.61% for the target concentration with 3 L and 18 L, respectively.	

Section A4.2b **Analytical Methods for Detection and Identification**

Annex Point 4.2 *Determination of propan-2-ol in air*

3.6	**Limit of determination**	The detection limit of the analytical procedure and of the overall procedure are 7.05 pg and 0.587 µg per sample (13.3 ppb or 32.6 µg/m^3), respectively. The reliable quantitation limit (~LOQ) is 1.96 µg per sample (44.4 ppb or 108.9 µg/m^3). The reliable quantitation limit is 0.266 ppm (0.653 mg/m^3) when 3 L is sampled.
3.7	**Precision**	The precision of the overall procedure at the 95% confidence level for the ambient temperature 19-day storage test (at the target concentration) is ±10.1%. This includes an additional 5% for sampling error.
3.7.1	Repeatability	The precision of the overall procedure at the 95% confidence level for the ambient temperature 19-day storage test (at the target concentration) is ±10.1%. This includes an additional 5% for sampling error.
3.7.2	Independent laboratory validation	Six samples were collected from a test atmosphere using two Anasorb® 747 tubes, 400 mg and 200 mg, in series. The isopropyl alcohol concentration of the test atmosphere was 405 ppm. They were sampled at 0.2 L/min for 90 minutes. The relative humidity was 80% at 22°. The samples were submitted to an OSHA Salt Lake Technical Center service branch, along with a draft copy of this method. The samples were analyzed after being stored for 3 days at 4°. Sample results were corrected for desorption efficiency. No sample result for isopropyl alcohol had a deviation greater than the precision of the overall procedure.

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	The analytical method No. 109 by OSHA can be used for the determination of propan-2-ol in air samples. Samples of 3-18 L were enriched via Anasorb® 747 tubes and were analysed via GC/FID. The range investigated was from 1.02 to 10.2 µg/sample. The precision of the analytical and overall procedure were 0.61% and 10.1%, respectively. The desorption efficiency are reported to be 100.2%, 102.9%, and 103.6% for 0.05, 0.1 and 0.2 times the target concentration respectively. The LOD and LOQ are 0.587 (13.3 ppb or 32.6 µg/m^3) and 1.98 µg (44.4 ppb or 108.9 µg/m^3) per sample, respectively.
4.2	**Conclusion**	[redacted]
4.2.1	Reliability	[redacted]
4.2.2	Deficiencies	[redacted]

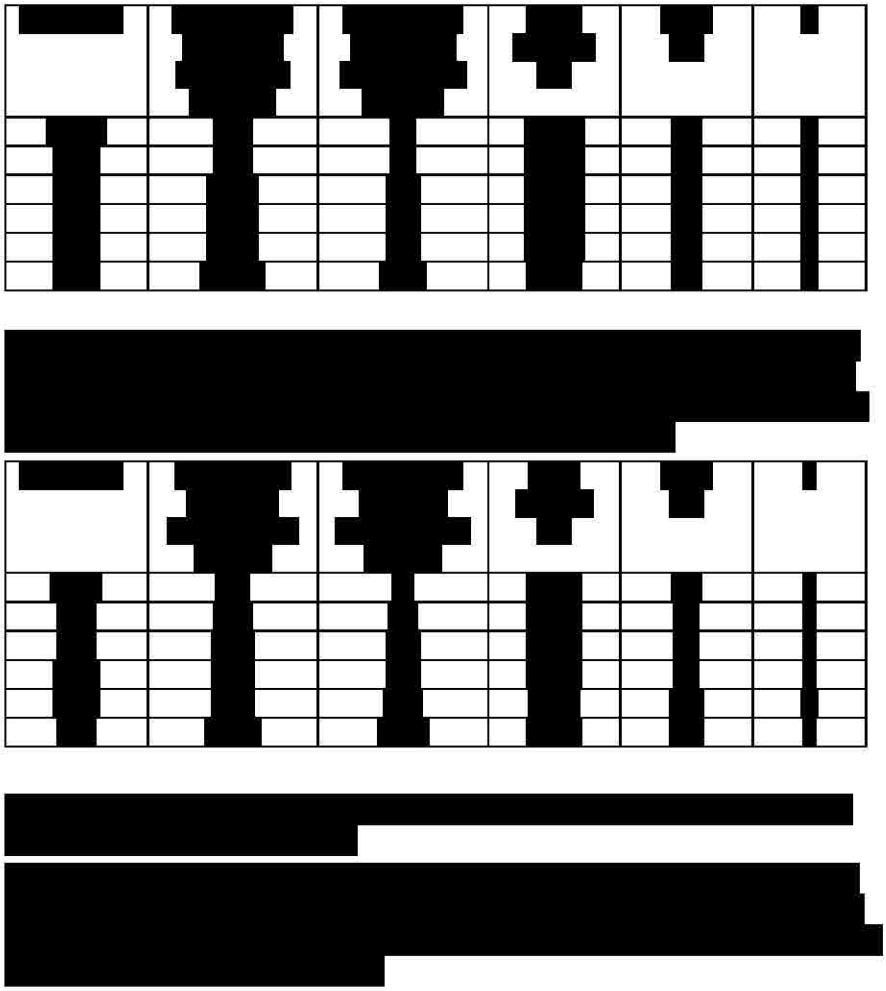
Section A4.2b Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-2-ol in air*

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2013-03-12
Materials and methods	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A4.2b Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-2-ol in air*



	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	

Section A4.2c Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-2-ol in water*

	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]		
References:	[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	2008/04/16
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 A4.2d Analytical Methods for Detection and Identification

Annex Point 4.2

Determination of propan-2-ol in animal and human body fluids and tissues

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	[redacted]	
References:	[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	2008/04/16
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 A4.3 **Annex Point 4.3**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, in/on food or feedstuffs and other products where relevant**

	JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data [ ]	**Technically not feasible** [ ]	**Scientifically unjustified** [X]	
Limited exposure [X]	**Other justification** [ ]		
Detailed justification:	[redacted]		
References:			

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/04/16
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 A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Bactericide, fungicide and virucide	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Obligate or facultative pathogenic or deteriorating bacteria (including mycobacteria, excluding bacterial spores), fungi and viruses (including enveloped and non-enveloped viruses) contaminating any surfaces - inanimate and animate or other matrices	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Mammalia (direct and indirect), food and feed, cosmetics and pharmaceutical products, any product susceptible to microbial deterioration	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**	Irreversible inactivation by an active substance final concentration usually in a range from 50 up to 80%. The active substance may be used at lower concentrations if combined with other active substances, such as alcohols or others or if used for specified purposes requiring limited effectiveness.	
5.3.1	**Effects on target organisms (IIA5.3)**	See following summary table.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	See Doc III section B5, 5.3	
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	Propanol-2-ol exhibits an unspecific mechanism of effect. It affects the outer cell membrane causing alteration of membrane fuidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular/virus activity resulting in the cell's or virus' inactivation.	
5.4.2	**Time delay**	Rapid inactivation of the target micro-organisms/viruses without time delay due to the unspecific mode of action (topical disinfectant); time required for sufficient inactivation strongly dependent on the formulation, concentrations of propan-2-ol contained in the applied biocidal product, the type of target organisms and on the specific use conditions, , e.g. presence of organic material at the application site.	

Section A5 Effectiveness against target organisms and intended uses

5.5	**Field of use envisaged (IIA5.5)**	
	MG01: Disinfectants and general biocidal products	Product type PT01: Human hygiene biocidal products Product type PT02: Private area and public health area disinfectants and other biocidal products Product type PT04: Food and feed area disinfectants
5.6	**User (IIA5.6)**	
	Industrial	Propan-2-ol is a common solvent used e.g. in the preparation of medical products and pharmaceuticals (eg, anitseptics; disinfectants; rubbing alcohol; anesthetics, iodine tinctures, bathing solutions for surgical sutures and dressings), oils, gums, waxes, resins, alkaloids, cements, primers, varnishes, paints, printing inks, cosmetics and various aerosol formulations (e.g. hair sprays, floor detergents, show polishes, insecticides, window cleaners, waxes and polishes, paints, automotive products, insect repellents, flea and tick spray, air refreshers, disinfectants) and beverages.
	Professional	Propan-2-ol is used by professionals as a broad-spectrum microbicide in numerous areas.
	General public	Non-professional use as a broad-spectrum microbicide in numerous areas (e.g. surface and skin disinfection).
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**	As propan-2-ol is not specific for just one target the development of sensu strictu true resistances is not to be expected (see IIIB5, 5.11).
5.7.1	**Development of resistance**	True resistances are not reported.
5.7.2	**Management strategies**	n.a.
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	[redacted]

Section A5 Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2009/04/16
Materials and methods	[redacted]
Conclusion	[redacted]

Section A5 Effectiveness against target organisms and intended uses

	[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	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
		Aqueous solution of propan-2-ol	*Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* *Escherichia coli* Representative for Gram negative and Gram positive bacteria.	The bactericidal efficacy of propan-2-ol was characterized following a European standard guideline (EN1276).	Quantitative suspension test employing vegetative bacterial cells in the presence of organic load.	[redacted]	[redacted]
		Aqueous solution of propan-2-ol	*Staphylococcus aureus* *Enterococcus faecium* *Proteus mirabilis* *Pseudomonas aeruginosa* *Mycobacterium terrae* *Candida albicans* *Aspergillus niger* Representative for Gram positive, Gram negative bacteria and yeasts and moulds.	The microbicidal efficacy of propan-2-ol was characterized following an established European test method (Test methods for the antimicrobial activity of disinfectants in food hygiene, 1987).	Quantitative suspension test employing vegetative bacterial and yeast cells and mould conidia in the presence of organic load.	[redacted]	[redacted]
		Aqueous solution of propan-2-ol	*Candida albicans* *Aspergillus niger* Representative for fungi.	The fungicidal efficacy of propan-2-ol was characterized following an established guideline	Employed was a quantitative suspension test in the presence of organic load.	[redacted]	[redacted]

				method (EN1650).			
		Aqueous solution of propan-2-ol	Herpes simplex virus Representative for enveloped viruses.	The virucidal efficacy of propan-2-ol was tested using a well established laboratory method.	Employed was a carrier test method simulating practical conditions by immobilizing the test virus on a glass surface.	[redacted]	[redacted]
		Aqueous solution of propan-2-ol	Feline calicivirus Representative for non-enveloped viruses.	The virucidal efficacy of propan-2-ol was tested using an established guideline method.	Employed was a suspension test.	[redacted]	[redacted]

Section A5.3/01 Annex Point IIA5.3 — Efficacy Data

Gram-positive and gram-negative bacterial cells in the presence of organic load

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection		
1.3	**Guideline study**	Yes, BSEN 1276	
1.4	**Deviations**	See 2.3.4.	X
		2 METHOD	
2.1	**Test Substance (Biocidal Product)**		
2.1.1	Trade name/ proposed trade name	Not applicable	
2.1.2	Composition of Product tested	Propan-2-ol 70% in water	
2.1.3	Physical state and nature	liquid	
2.1.4	Monitoring of active substance concentration	No	
2.1.5	Method of analysis	Not applicable	
2.2	**Reference substance**		
2.2.1	Method of analysis for reference substance	No reference substance tested	
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism	Table 2.3.1.1 Bacterial strains employed to test the efficacy of propan-2-ol	

Species	Strain/source/origin	Representative for
Pseudomonas aeruginosa	ATCC 15442	gram-negative bacteria
Staphylococcus aureus	ATCC 6538	gram-positive bacteria
Enterococcus hirae	ATCC 8043	gram-positive bacteria
Escherichia coli	ATCC 10536	gram-negative bacteria

The suspension contained 1.65 x 10E8 - 3.55 x 10E8 CFUs/ml

2.3.2	Test system	Quantitative suspension test under conditions representative of practical use (e.g. CEN - Phase 2, Step1)
2.3.3	Application of TS	As prescribed by guideline
2.3.4	Test conditions	As prescribed by guideline, 3 different concentrations tested (50, 75% and 100% dilution of 70% propan-2-ol), Glass distilled water was used for dilution instead of sterile hard water; bovine serum albumin at 3g/l served as organic load; test was run at 20°C; as neutralizer to stop the effect of the biocide a solution containing 3 g/l lecithin; 30 g/l polysorbat 80; 5 g/l sodium thiosulfate, 1g/l L-histidin, 30 g/l saponin in tryptone sodium chloride solution was employed
2.3.5	Duration of the test / Exposure time	5 min
2.3.6	Number of replicates performed	As prescribed by guideline
2.3.7	Controls	As prescribed by guideline
2.4	**Examination**	
2.4.1	Effect investigated	Reduction in viability of respective test organism using a quantitative suspension test (phase 2/step1) as prescribed by the guideline EN 1276
2.4.2	Method for recording / scoring of the effect	Determining the number of CFUs of respective test organism in test suspension before and after exposure to the test substance
2.4.3	Intervals of examination	CFUs determined once after termination of exposure
2.4.4	Statistics	As prescribed by guideline
2.4.5	Post monitoring of the test organism	No
		3 RESULTS
3.1	**Efficacy**	In accordance with the guideline EN 1276 the product possesses bactericidal activity against the tested organisms
3.1.1	Dose/Efficacy curve	Not applicable
3.1.2	Begin and duration of effects	
3.1.3	Observed effects in the post monitoring phase	Not applicable
3.2	**Effects against organisms or objects to be protected**	None reported
3.3	**Other effects**	None reported.
3.4	**Efficay of the reference substance**	Not applicable

Section A5.3/01 Annex Point IIA5.3 **Efficacy Data**
Gram-positive and gram-negative bacterial cells in the presence of organic load

3.5 Tabular and/or graphical presentation of the summarised results

Table 3.5.1 Reduction of viable cells after exposure to aqueous propan-2-ol solution

Species/strain	Concentration of test product	Viability reduction (cfu/ml)
Pseudomonas aeruginosa	50%	<10E5
	75%	>10E5
	100%	>10E5
Staphylococcus aureus	50%	<10E5
	75%	>10E5
	100%	>10E5
Enterococcus hirae	50%	>10E5
	75%	>10E5
	100%	>10E5
Escherichia coli	50%	<10E5
	75%	>10E5
	100%	>10E5

3.6 Efficacy limiting factors

3.6.1 Occurrences of resistances: None reported

3.6.2 Other limiting factors: None reported

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1 Reasons for laboratory testing

The bactericidal activity of the product was tested using two gram-positive - *Staphylococcus aureus* and *Enterococcus hirea* – and two gram-negative bacterial species - *Pseudomonas aeruginosa* and *Escherichia coli* in accordance with a standard guideline method. The data obtained in this study are relevant for the intended field of use.

4.2 Intended actual scale of biocide application

Not stated

4.3 Relevance compared to field conditions

4.3.1 Application method: The test conditions of the quantitative suspension test (phase 2/step1) in the presence of organic load as proposed by CEN are representative for the actual conditions during practical use of the product.

4.3.2 Test organism: The test organisms used in this study representing both gram-positive and gram-negative bacterial species are appropriate representatives for the target organisms in the intended field of use.

Section A5.3/01 Annex Point IIA5.3 **Efficacy Data** Gram-positive and gram-negative bacterial cells in the presence of organic load

4.3.3	Observed effect	The obtained efficacy result of the test product in this study using 2 gram-positive and 2 gram-negative bacterial species under simulated use conditions in the presence of organic load is important for evaluating the bactericidal activity of the product in the intended field of use.
4.4	**Relevance for read-across**	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The bactericidal activity of propan-2-ol 70% in water was evaluated using a generally accepted quantitative suspension test (phase 2/step1) as prescribed by the guideline EN 1276. Two gram positive (*S.aureus, E.hirea*) as well as two gram negative bacterial species (*P.aeruginosa, E.coli*) were used as test organisms. The suspension test was carried out in the presence of organic load (3g/l bovine serum albumin) to simulate practical conditions as prescribed by the guideline. The test was carried out at 20°C for an exposure time of 5min at various concentrations (50%, 75% and 100%). The reduction in viability was determined via CFU count.
5.2	**Reliability**	[redacted]
5.3	**Assessment of efficacy, data analysis and interpretation**	The results of this study show that 70% propan-2-ol in water tested in the presence of organic load (3g/l bovine albumin) and at an exposure duration of 5min was effective against the bacterial species tested. However, the study showed that the product was not effective against *Staphylococcus aureus*, *E. coli* and *Pseudomonas aeruginosa* at a concentration of 50%. In this case the criteria for efficacy as required by the guideline were not fulfilled. Propan-2-ol concentrations of 75%-100% were effective against all tested organisms used in the study and the criteria for efficacy were fulfilled.
5.4	**Conclusion**	[redacted]
5.5	**Proposed efficacy specification**	

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	2008/09/23
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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Appendix 1: CA-Tables

Section A5.3/02
Annex Point IIA5.3

Efficacy Data

Gram-positive and Gram-negative bacterial cells and fungi in the presence of organic load

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]. Vergelijkend onderzoek naar de desinfekterende werking van alcoholen in de Europese suspensie test. [redacted]
1.2	**Data protection**	Not stated
1.2.1	Data owner	
1.2.2	Criteria for data protection	Not stated
1.3	**Guideline study**	Yes, Test methods for the antimicrobial activity of disinfectants in food hygiene, European Council, 1987.
1.4	**Deviations**	See 2.3.5.

2 METHOD

2.1	**Test Substance (Biocidal Product)**	
2.1.1	Trade name/ proposed trade name	Not applicable
2.1.2	Composition of Product tested	Propan-2-ol (p.a, Merck 9634) at different concentrations in water
2.1.3	Physical state and nature	liquid
2.1.4	Monitoring of active substance concentration	No
2.1.5	Method of analysis	Not applicable
2.2	**Reference substance**	Propan-1-ol and ethanol tested in parallel.
2.2.1	Method of analysis for reference substance	no
2.3	**Testing procedure**	
2.3.1	Test population / inoculum / test organism	Table 2.3.1.1 Bacterial strains employed to test the biocidal efficacy of propan-2-ol

Species/strain	Source/origin	Representative for
Pseudomonas aeruginosa	ATCC 15442	Gram negative bacteria
Staphylococcus aureus	ATCC 6538	Gram positive bacteria
Enterococcus faecium	DVG 8582	Gram positive bacteria
Proteus mirabilis	ATCC 14153	Gram negative

Section A5.3/02 Annex Point IIA5.3 **Efficacy Data** Gram-positive and Gram-negative bacterial cells and fungi in the presence of organic load

		bacteria
Mycobacterium terrae	ATCC 15755	Gram positive bacteria
Candida albicans	ATTC 10231	Yeasts
Aspergillus niger	ATCC 16404	Moulds

The bacterial suspensions contained approx. 10E8 CFUs/ml, the yeast suspension approx. 10E7 CFUs/ml, the conidial suspension approx. 10E7 CFUs/ml. Stock cultures of all strains but *A. niger* and *M. terrae* were kept on tryptone soy agar. *M. terrae* was kept on Middlebrook 7H10 Agar with 10% OADC whilst *A. niger* was kept on malt extract agar. Working cultures (2 subsequent times 24h growth on TSA at 32°C) were used to prepare suspensions for all bacterial strains (exception *M. terrae*) and the yeast by using glass beads and glass wool filtration. *M. terrae* suspensions were obtained from 7d stock cultures using glass beads and subsequent filtration with glass wool. *A. niger* conidia were harvested from 4d stock cultures using 0.6% Tergitol 7, harvested by centrifugation (20 min @ 2000 g). All suspensions were prepared in saline with 0.1% peptone.

2.3.2	Test system	Quantitative suspension test under conditions representative of practical use (e.g. CEN - Phase 2, Step1)
2.3.3	Application of TS	As prescribed by guideline, diluted in water of standard hardness.
2.3.4	Test conditions	Concentrations tested (20 up to 80% propan-2-ol (v/v)), dilution in sterile hard water; bovine serum albumin at 0.03% served as organic load; test was run at 20°C+/-1°C; dilution in neutralizer solution used to stop the effect of the biocide.
2.3.5	Duration of the test / Exposure time	2 and 5 min
2.3.6	Number of replicates performed	As prescribed by guideline
2.3.7	Controls	As prescribed by guideline
2.4	**Examination**	
2.4.1	Effect investigated	Reduction in viability of respective test organism using a quantitative suspension test (phase 2/step1) as prescribed by the guideline employed.
2.4.2	Method for recording / scoring of the effect	Determining the number of CFUs of respective test organism in test suspension before and after exposure to the test substance
2.4.3	Intervals of examination	CFUs determined once after termination of exposure
2.4.4	Statistics	
2.4.5	Post monitoring of the test organism	No
		3 RESULTS
3.1	**Efficacy**	Propan-2-ol exhibited biocidal activity for all organisms tested.
3.1.1	Dose/Efficacy	Not applicable

	curve	
3.1.2	Begin and duration of effects	
3.1.3	Observed effects in the post monitoring phase	Not applicable
3.2	**Effects against organisms or objects to be protected**	None reported
3.3	**Other effects**	None reported.
3.4	**Efficay of the reference substance**	Propan-1-ol was more effective than propan-2-ol which was more effective than ethanol (exception *A. niger*).
3.5	**Tabular and/or graphical presentation of the summarised results**	Table 3.5.1 Reduction of CFUs/ml after exposure to aqueous propan-2-ol solution

Species/strain	Exposure time (min)	Concentration of test product (%, v/v)	Viability reduction (log RF CFUs/ml)
Pseudomonas aeruginosa	2	20	1.8
		30	>=5
	5	20	2.5
		30	>=5
Staphylococcus aurenus	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	0.3
		30	>=5
		40	>=5
Enterococcus faecium	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	<=0.2
		30	>=5
		40	>=5
Proteus mirabilis	2	20	2.5
		30	>=5
	5	20	2.9
		30	>=5
Mycobacterium	2	30	2.9

terrae		40	>=5
		50	>=5
	5	30	>=5
		40	>=5
		50	>=5
Candida albicans	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	<=0.2
		30	>=5
		40	>=5
Aspergillus niger	2	40	<=0.2
		50	<=0.2
		60	0.6
		70	1.2
		80	2.1
	5	40	<=0.2
		50	0.5
		60	1
		70	1.8
		80	3.2

3.6 Efficacy limiting factors

3.6.1 Occurrences of resistances: None reported

3.6.2 Other limiting factors: None reported

4 RELEVANCE OF THE RESULTS COMPARED TO FIELD CONDITIONS

4.1 Reasons for laboratory testing

The microbicidal activity of the product was tested using three Gram positive (*Staphylococcus aureus, Mycobacterium terrae* and *Enterococcus faecium)* and two Gram negative bacterial species (*Pseudomonas aeruginosa* and *Proteus mirabilis)* as well as two fungal species *(Candida albicans* and *Aspergillus niger)*. The data obtained in this study are relevant for the intended field of use.

4.2 Intended actual scale of biocide application

Not stated

4.3 Relevance compared to field

	conditions		
4.3.1	Application method	The test conditions of the quantitative suspension test (phase 2/step1) in the presence of organic load are representative for the actual conditions during practical use of the product.	
4.3.2	Test organism	The test organisms used in this study representing both gram-positive and gram-negative bacterial as well as fungal species are appropriate representatives for the target organisms in the intended field of use.	
4.3.3	Observed effect	The obtained efficacy result of the test product in this study using 5 different bacterial and 2 fungal species under simulated use conditions in the presence of organic load is important for evaluating the bactericidal activity of the product in the intended field of use.	
4.4	**Relevance for read-across**		
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The bactericidal activity of propan-2-ol in water was evaluated using a generally accepted suspension test (phase 2/step1). Two gram positive (*S. aureus, E. faecium, M. terrae*), two gram negative bacterial species (*P. aeruginosa, P. mirabilis*) and two fungi (*A. niger, C. albicans*) were used as test organisms. The suspension test was carried out in the presence of organic load (0.03% bovine serum albumin) to simulate practical conditions. The test was carried out at 20°C for an exposure time of 2 and 5min at various concentrations (20 - 80%). The reduction in viability was determined per CFU count.	
5.2	**Reliability**	[redacted]	
5.3	**Assessment of efficacy, data analysis and interpretation**	The results of this study show that 30% propan-2-ol in water tested in the presence of organic load (0.03% bovine serum albumin) and at an exposure time of 5min was effective against the bacterial and fungal species tested in the study. However, sufficient effectivity against *Aspergillus niger* conidia required test substance concentrations of >= 80%.	x
5.4	**Conclusion**	[redacted]	
5.5	**Proposed efficacy specification**		

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/09/23
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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	