

Section A1

Applicant

Annex Point IIA1

1.1 Applicant

[Redacted text block for 1.1 Applicant]

1.2 Manufacturer of Active Substance (if different)

[Redacted text block for 1.2 Manufacturer of Active Substance]

Section A1

Applicant

Annex Point IIA1

[Redacted text block]

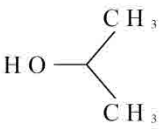
[Redacted text block]

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

Section A2 Identity of Active Substance

Subsection
(Annex Point)

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			
2.5	Molecular and structural formula, molecular mass (IIA2.5)				
2.5.1	Molecular formula	C ₃ H ₈ O			
2.5.2	Structural formula	 <chem>CC(O)C</chem> (= 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	% v/v
				99.9	Min. 99.0 99.997

Official
use only

X

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 ₂ O	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	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPporteur MEMBER STATE	
Date	2014/03/04
Materials and methods	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	-
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Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
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 ₂ O				
2.8.7	Structural formula					
2.8.8	Molecular mass	18.0153 g/mol				
2.8.9	Concentration of the impurity or additive <i>typical and range of concentrations</i>	g/kg	g/l	% w/w	% v/v	X
				<0.01	Max. 5000 ppm 0.014	

Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPporteur MEMBER STATE	
Date	2008/06/10
Materials and methods	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	-
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
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Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 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		■	Merck (1996)	X
Melting pt. 2	Handbook data	No data	result: -89.5°C pressure: -	Peer-reviewed handbook data		■	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		■	Merck (1996)	X
Boiling pt. 2	Handbook data	No data	result: 82.3 °C pressure: 1013 hPa	Peer-reviewed handbook data		■	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		■	Merck (1996)	X
Rel. density 2	Handbook data	No data	0.785 at 20°C	Peer-reviewed handbook data		■	Sax (1984)	X
Rel. density 3	Handbook data	No data	0.7809 at 25°C	Peer-reviewed handbook data		■	CRC (2001)	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
3.2 Vapour pressure (IIA3.2)								
Vapour pressure 1	Handbook data	No data	result: 57.8 hPa (5.775 Pa) temperature: 25 °C	Acceptable handbook data		■	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		■	Daubert & Danner (1985)	X
Vapour pressure 3	Calculated from Antoine-type equation	No data	result: 60.73 hPa temperature: 25 °C	Handbook data		■	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 · m ³ /mol	Study well documented, meets generally accepted scientific principles		■	Snider & Dawson (1985)	X
Henry's Law Const. 2	Calculation using HENRYWIN v3.10	-	Calculated (at 25 °C): result: 0.76 Pa · m ³ /mol (bond method) 1.16 Pa · m ³ /mol (group method)	Generally accepted calculation method		■		X
Henry's Law Const. 3	Handbook data	No data	result: 0.82 Pa · m ³ /mol	Reliable handbook data		■	Howard (1990)	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
Henry's Law Const. 4	No data	No data	result: 0.82 Pa · m ³ /mol	Only result presented	█	█	Taft et al. (1985), █	X
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Visual inspection	-	liquid	Peer-reviewed handbook data	█	█	Sax (1984)	X
	ASTMD4176	99.9% m/m	Liquid; clear & free from suspended matter	Certificate of analysis	█	█	█	X
3.3.2 Colour	Visual inspection	-	colorless	Peer-reviewed handbook data	█	█		X
	ASTM D1209	99.9% m/m	Pt-Co 0	Certificate of analysis, (Platinum-Cobalt scale 0: means that substance is colourless)	█	█	█	X
3.3.3 Odour	Olfactory assessment	-	slight	Peer-reviewed handbook data	█	█		X
	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))	█	█	█	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	
3.4 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	█	█	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	█	█	█	X
		UV-Vis	99.997%	Spectrum is consistent with the proposed structure. No absorption maximum >210 nm	Internal report of applicant. Brenntag sales 2-propanol of SASOL	█	█	█	X
		Lambda 35 (Perkin-Elmer), Serie-Nr. 101N2012803 incl. Software UVWinlab	99.997% 99.9% m/m	Spectrum is consistent with the proposed structure for quality from both sources	Internal report of applicant	█	█	█	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
V2.85.04								
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	█	█	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	█	█	█	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	█	█	█	X
NMR	¹ H-NMR at 300 MHz	No data	ppm in CDCl ₃ CH ₃ : 1.22 (d) CH: 4.04 (sep) ppm in CDCl ₃ CH ₃ : 25.14 CH: 64.50	Compilation of data	█	█	Gottlieb et al. (1997)	X
	¹³ C-NMR at 75.5 MHz							
	¹ H-NMR at 399 MHz	99.997%	Spectrum is consistent with the proposed structure	Internal report of applicant	█	█	█	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
	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	█	█	█	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	█	█	CRC (2001)	X
	Europ.Pharm. /USP	99.997%	Spectrum is consistent with the proposed structure	Internal report of manufacturer to applicant	█	█	█	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	█	█	█	X
	Not specified	99.9 %m/m	Spectrum is consistent with the proposed structure compared to reference spectrum	Internal report of manufacturer to applicant	█	█	█	X
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	█	█	Riddick et al. (1986)	X
	Handbook data	No data	Miscible	Peer-reviewed	█	█	CRC (2001)	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
	Handbook data	No data	Miscible with water	handbook data Peer-reviewed handbook data	█ █	█	Merck (1996)	X
3.6	Dissociation constant (-)	Handbook data	No data	-3.2	Acceptable handbook data	█ █	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	█ █	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	█	█		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	█	█	Dillingham et al. (1973)	X
	log P _{ow} 2	Measured, no further information	No data	result: 0.05 temperature: - pH: -	Original literature not available	█	█	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	█	█			
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	█	█	Sax (1984)		
	Handbook data	No data	result: 399°C (ignition temperature)	Peer-reviewed handbook data	█	█	CRC (2001)		
3.12 Flash-point (IIA3.9)									
Flash-point 1	Handbook data	No data	12°C (closed cup)	Acceptable handbook data	█	█	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
Flash point 2	Handbook data	No data	12°C	Peer-reviewed handbook data	[REDACTED]	[REDACTED]	Sax (1984)	
3.13 Surface tension (IIA3.10)								X
Surface tension 1	Handbook data	No data	result: 20.93 mN/m temperature: 25°C	Peer-reviewed handbook data	[REDACTED]	[REDACTED]	CRC (2001)	
Surface tension 2	Prolabo tensiometer, which employs the Wilhelmy plate principle	>99.7%	result: 21.22 mN/m temperature: 25°C result: 21.74 mN/m temperature: 20°C	Study well documented, meets generally accepted scientific principles	[REDACTED] data	[REDACTED]	Vazquez et al. (1995)	
	Calculation of surface tension according to Vasquez et al. (1995)	1g/L	result: 71.55 mN/m temperature: 20°C	Coefficients for calculation have been read from two figures which may lead to some uncertainties	[REDACTED]	[REDACTED]	[REDACTED]	
Surface tension 3	Langmuir trough and Wilhemly plate	16.7 g/L aqueous solution Spectrophotometric grade 99+%	result: 62 mN/m temperature: Room temperature	Study well documented, meets generally accepted scientific principles. Value given as log mole fraction: -2.3	[REDACTED]	[REDACTED]	Kataoka & Cremer (2006)	

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
Surface tension 4	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)				
Surface tension 5	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 from ideal case) temperature: 20°C	Values for pure substance and water taken from Vasquez et al. 1995			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]	X
3.14 Viscosity (-)	Handbook data	No data	result: 2.038 mPA · s temperature: 25°C	Peer-reviewed handbook data			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			CRC (2001)	
3.16 Oxidizing properties (IIA3.12)			Scientifically unjustified, see Justification for non- submission.	Expert judgement				

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
3.17 Reactivity towards container material (IIA3.13)			Scientifically unjustified, see Justification for non- submission.	Expert judgement	■	■		

Date	2008/06/10
	
	
	
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Conclusion	
	
Reliability	
Acceptability	
Remarks	

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Conclusion

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Acceptability

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Remarks

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Conclusion

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Reliability

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Acceptability

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Conclusion	[REDACTED]
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Conclusion	[Redacted]
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Date	2008/06/10
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Date	2008/01/25
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Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
Date	COMMENTS FROM ... <i>Give date of comments submitted</i>
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Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 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:	<div style="background-color: black; width: 100px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 700px; height: 15px; margin-bottom: 5px;"></div> <div style="background-color: black; width: 500px; height: 15px;"></div>	
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Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/09/25
Evaluation of applicant's justification	<div style="background-color: black; width: 200px; height: 15px;"></div>
Conclusion	<div style="background-color: black; width: 60px; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 10px; height: 15px;"></div>
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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 <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
Detailed justification:	<div style="background-color: black; width: 100%; height: 100px;"></div>	
References:	<div style="background-color: black; width: 100%; height: 20px;"></div>	

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	<div style="background-color: black; width: 100%; height: 20px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 20px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 20px;"></div>
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A3.10 Thermal stability, identity of relevant breakdown products
Annex Point IIA3.7

JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
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 <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>
Limited exposure <input type="checkbox"/>	Other justification <input checked="" type="checkbox"/>	
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	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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:	<div style="background-color: black; width: 100%; height: 100%; min-height: 100px;"></div>		
References:	<div style="background-color: black; width: 100%; height: 100%; min-height: 20px;"></div>		

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	<div style="background-color: black; width: 100%; height: 15px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A4.1

Analytical Methods for Detection and Identification

Annex Point IIA4.1

Determination of components in propan-2-ol

	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	██████████	
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	

Official
use only

Section A4.1**Analytical Methods for Detection and Identification****Annex Point IIA4.1**

Determination of components in propan-2-ol

	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	Specificity: 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

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

Section A4.1
Annex Point IIA4.1

Analytical Methods for Detection and Identification

Determination of components in propan-2-ol

JUSTIFICATION FOR NON-SUBMISSION OF DATA

Official
use only

Other existing data **Technically not feasible** **Scientifically unjustified**
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	2013/09/04
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]
Remarks	[REDACTED]
Comments from other Member State (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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

Analytical Methods for Detection and Identification

Annex Point 4.2

Determination of propan-2-ol in soil

JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>		
Detailed justification:	<div style="background-color: black; width: 100%; height: 15px;"></div> <div style="background-color: black; width: 100%; height: 15px;"></div> <div style="background-color: black; width: 100%; height: 15px;"></div> <div style="background-color: black; width: 100%; height: 15px;"></div> <div style="background-color: black; width: 100%; height: 15px;"></div> <div style="background-color: black; width: 100%; height: 15px;"></div>		
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	<div style="background-color: black; width: 100%; height: 15px;"></div>
Conclusion	<div style="background-color: black; width: 100%; height: 15px;"></div>
Remarks	<div style="background-color: black; width: 100%; height: 15px;"></div>
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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 <i>(specify)</i>
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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 Technically not feasible Scientifically unjustified

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	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
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	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
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 fluidity 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, antiseptics; 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, shoe 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

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

Section 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	<i>Pseudomonas aeruginosa</i> <i>Staphylococcus aureus</i> <i>Enterococcus hirae</i> <i>Escherichia coli</i> 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	<i>Staphylococcus aureus</i> <i>Enterococcus faecium</i> <i>Proteus mirabilis</i> <i>Pseudomonas aeruginosa</i> <i>Mycobacterium terrae</i> <i>Candida albicans</i> <i>Aspergillus niger</i> 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	<i>Candida albicans</i> <i>Aspergillus niger</i> 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.		
		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.		

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
<i>Pseudomonas aeruginosa</i>	ATCC 15442	gram-negative bacteria
<i>Staphylococcus aureus</i>	ATCC 6538	gram-positive bacteria
<i>Enterococcus hirae</i>	ATCC 8043	gram-positive bacteria
<i>Escherichia coli</i>	ATCC 10536	gram-negative bacteria

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

Section A5.3/01
Annex Point IIA5.3

Efficacy Data

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

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	Efficacy 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)
<i>Pseudomonas aeruginosa</i>	50%	<10E5
	75%	>10E5
	100%	>10E5
<i>Staphylococcus aureus</i>	50%	<10E5
	75%	>10E5
	100%	>10E5
<i>Enterococcus hirae</i>	50%	>10E5
	75%	>10E5
	100%	>10E5
<i>Escherichia coli</i>	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 hirae* – 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.

X

5.4 Conclusion

[REDACTED]

5.5 Proposed efficacy specification

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<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	2008/09/23
Materials and methods	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Results and discussion	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
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Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Appendix 1: CA-Tables



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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 desinfecterende 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
<i>Pseudomonas aeruginosa</i>	ATCC 15442	Gram negative bacteria
<i>Staphylococcus aureus</i>	ATCC 6538	Gram positive bacteria
<i>Enterococcus faecium</i>	DVG 8582	Gram positive

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		bacteria
<i>Proteus mirabilis</i>	ATCC 14153	Gram negative bacteria
<i>Mycobacterium terrae</i>	ATCC 15755	Gram positive bacteria
<i>Candida albicans</i>	ATTC 10231	Yeasts
<i>Aspergillus niger</i>	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

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Efficacy Data

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

3 RESULTS

- 3.1 Efficacy** Propan-2-ol exhibited biocidal activity for all organisms tested.
- 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 Efficacy 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 summarized 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)
<i>Pseudomonas aeruginosa</i>	2	20	1.8
		30	>=5
	5	20	2.5
		30	>=5
<i>Staphylococcus aureus</i>	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	0.3
		30	>=5
		40	>=5
<i>Enterococcus faecium</i>	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	<=0.2
		30	>=5

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		40	>=5
<i>Proteus mirabilis</i>	2	20	2.5
		30	>=5
	5	20	2.9
		30	>=5
<i>Mycobacterium terrae</i>	2	30	2.9
		40	>=5
		50	>=5
	5	30	>=5
		40	>=5
		50	>=5
<i>Candida albicans</i>	2	20	<=0.2
		30	>=5
		40	>=5
	5	20	<=0.2
		30	>=5
		40	>=5
<i>Aspergillus niger</i>	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** The microbicidal activity of the product was tested using three Gram positive (*Staphylococcus aureus*, *Mycobacterium terrae* and

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Efficacy Data

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

	laboratory testing	<i>Enterococcus faecium</i>) and two Gram negative bacterial species (<i>Pseudomonas aeruginosa</i> and <i>Proteus mirabilis</i>) as well as two fungal species (<i>Candida albicans</i> and <i>Aspergillus niger</i>). 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 (<i>S. aureus</i> , <i>E. faecium</i> , <i>M. terrae</i>), two gram negative bacterial species (<i>P. aeruginosa</i> , <i>P. mirabilis</i>) and two fungi (<i>A. niger</i> , <i>C. albicans</i>) 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 <i>Aspergillus niger</i> conidia required test substance concentrations of >= 80%.
5.4	Conclusion	[REDACTED]

x

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Efficacy Data

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

5.5 Proposed efficacy specification

[REDACTED]



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