Section A4.1 Analytical Methods for Detection and Identification

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

Official use only

		1 REFERENCE
1.1	**Reference**	Council of Europe (2005) European Pharmacopoeia 5.0. Monograph Propanol. 01/2005: 2036 Corrected; p 2320-2321 (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**	No data
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
3.2.1	Separation method	a. 1 mL of test substance solution was diluted to 100 mL using heptane. 1.0 mL was further diluted with heptane to obtain a test solution of 10 mL (solution a) b. 0.1 mL of acetone was mixed with 0.1 mL of propan-2-ol and diluted to 100 ml with the test solution (solution b) GC conditions Column: material: fused silica; -size: 30 m in length; 0.25 mm in diameter; -stationary phase: poly[(cyanopropyl)(phenyl)][dimethyl] siloxane (film thickness: 1.4 µm); carrier gas: helium; linear velocity: 25 cm/s; split ratio: 1:200; Temperatures: column: 40°C (0-12 min), 40-200°C (12-28 min), 200°C (28-38 min); injection port: 240°C; detector : 240°C; injection volume : 1 µL
3.2.2	Detector	FID
3.2.3	Standard(s)	Acetone and propan-2-ol
3.2.4	Interfering substance(s)	No data
3.3	**Linearity**	No data
3.3.1	Calibration range	No data
3.3.2	Number of measurements	No data
3.3.3	Linearity	No data

Section A4.1 Analytical Methods for Detection and Identification

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

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 (solution b) -resolution: minimum 2.0 between the peaks due to impurities (acetone and 2-propanol) Limits -any impurities: not more than the area of the peak due to propan-1-ol in the chromatogram obtained with solution a (0.1%) -total: no more than three times the area of the peak due to propan-1-ol in the chromatogram obtained with solution a (0.3%) -disregard limit: 0.1 times the area of the peak due to propan-1-ol in the chromatogram obtained with solution a (0.01%)
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-1-ol is described. For the detection a glass capillary gas chromatography method coupled with FID was developed. Acetone and 2-propanol were used as internal standards.
4.2	**Conclusion**	According to the information provided the described analytical method is suitable for checking the purity of propan-1-ol.
4.2.1	Reliability	2
4.2.2	Deficiencies	Study meets generally accepted scientific principles and is described in sufficient details.

Section A4.1 Analytical Methods for Detection and Identification

Annex Point IIA4.1 Determination of components in propan-1-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	2008/03/17
Materials and methods	The given analytical method is an instruction of the Pharmacopeia. No validation data, e.g. Linearity, Repeatability, Recovery rate are included in this instruction. Because the presented method is an official method of Pharmacopeia it is assumed that all validation was performed successfully. Therefore the method is acceptable for the determination of Propan-1-ol. Additionally a justification for non Submission of the validation data was submitted by the applicant.
Conclusion	-
Reliability	-
Acceptability	acceptable
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 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:	None	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2008/07/04
Evaluation of applicant's justification	
Conclusion	Applicant's justification is acceptable
Remarks	none
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*

Section A4.1 Analytical Methods for Detection and Identification

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

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	
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*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	Besides the methods handed in, several other methods are available in the published literature. Two reports are listed below, which summaries some suitable methods. These methods are mainly based on gas chromatography with FID. In the BUA report (BUA 1997) 6 methods are given for air, 12 for water and 4 for biological media. In the Environmental Health Criteria (WHO 1990) 3 methods are given for air, 6 for water and 3 for biological media.	
References	BUA (1997) BUA Report 190 on 1-Propanol (in German), Editor: Beratergremium für umweltrelevante Altstoffe (BUA) der Gesellschaft Deutscher Chemiker, 197p. WHO (1990) Environmental Health Criteria 102, 1-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	2008/08/04
Evaluation of results	The provided data were not evaluated.
Conclusion	For determination of propan-1-ol in air specific study data should be submitted. Analytical methods for the determination of propan-1-ol in water and "biological media" are not deemed necessary.
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-1-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	2008/08/04
Evaluation of applicant's justification	The applicant's justification is conclusive. It should be considered further that propan-1-ol is being notified for in-door use.
Conclusion	No analytical method for the determination of propan-1-ol in soil is required.
Remarks	
	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	
Reliability	*Discuss if deviating from view of rapporteur member state*

Section A4.2a Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-1-ol in soil*

Acceptability	*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-1-ol in air*

Official use only

1 REFERENCE

1.1	**Reference**	NIOSH (1994) NIOSH Manual of Analytical Methods (NMAM), Fourth Edition, 8/15/94, Alcohols II, METHOD: 1401, Issue 2, 15 August 1994, 4p (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**	Not applicable. However, the analytical methods used were laid down in the NIOSH manual (1994).
2.2	**GLP**	No data
2.3	**Deviations**	-

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Sampler used for enrichment of air samples: glass tube (7 cm long, 6-mm OD, 4-mm ID; flame-sealed ends) containing two sections of activated (600°C) coconut shell charcoal (front: 100 mg; back: 50 mg) separated by a 2-mm urethane foam plug. A silylated glass wool plug precedes the front section and a 3-mm urethane foam plug follows the back section. The ends of the sampler were broken immediately before sampling started and the sampler was connected to a personal sampling pump. The samples were drawn through the sorbent tube via the personal sampling pump at 0.01 to 0.2 L/min resulting in a total sample size of 1-10 L. The samplers were capped with plastic caps.
3.1.2	Cleanup	The front and back sorbent sections of the sampler tube were placed in separate glass vials (2 mL; PTFE-lined crimp caps). The glass wool and foam plugs were discarded. To each vial 1 mL eluent (1 % propan-2-ol in CS_2) was added. The crimp cap was attached to each vial. The vials were allowed to stand 30 min with occasional agitation. The average desorption efficiency is reported to be 0.89.
3.2	**Detection**	
3.2.1	Separation method	GC/FID: 5 µl injected Temperatures: -injection: 200 °C -detector: 250-300 °C -column: 75 °C Carrier gas: N_2 or H_2; 20 mL/min Column: glass, 3 m x 2-mm ID; 10 % SP-1000 on 80/100 mesh Chromosorb WHP, or equivalent
3.2.2	Detector	FID
3.2.3	Standard(s)	Undecane (0.2 % v/v), hexane (0.1 % v/v) or other suitable standard Internal standard: 1 % propan-2-ol in CS_2

3.2.4	Interfering substance(s)	No data
3.3	**Linearity**	
3.3.1	Calibration range	Range studied: 225-835 mg/m³ (2.5-10 mg/sample)
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**	103.5 % (range studied: 225-835 mg/m³, 2.5-10 mg/sample; not further specified)
3.5.1	Relative standard deviation	0.016
3.6	**Limit of determination**	0.01 mg/per sample
3.7	**Precision**	0.075 (overall precision)
3.7.1	Repeatability	No data
3.7.2	Independent laboratory validation	Not reported

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	In the NIOSH manual of analytical methods the determination of propan-1-ol in air samples is described. A glass tube containing two sections of activated coconut shell charcoal separated by a urethane foam plug was used for sampling. The samples were prepared by placing the front and back sorbent sections of the sampler tube in separate glass vials and adding the standards to each vial. The separation of the sample was performed on glass column GC and analysed by an FID. The range investigated was 225 to 835 mg/m³ (samples: 1-10 L). The LOD is reported to be 0.01 mg/sample.
4.2	**Conclusion**	Based on the information provided the reported determination method is suitable for the detection of propan-1-ol in air. The LOD is reported to be 0.01 mg/sample.
4.2.1	Reliability	2
4.2.2	Deficiencies	The analytical method meets generally accepted scientific principles and is described in sufficient details in the NIOSH manual. However, some experimental and testing data, respectively, were not reported (calibration range, linearity, number of measurements).

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

Annex Point 4.2 — *Determination of propan-1-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	2017/03/20
Materials and methods	Applicant's description is accepted. The LOD of 0.01 mg/m³ was estimated not validated in the presented study. The validated LOQ is 225 mg/m³.
Conclusion	The presented method is considered to be not acceptable because the LOQ exceeds the limit of 5.5 mg/m^3 (calculated on basis of the AEL) by factor 40. Furthermore, the validation data are not sufficient for acceptance. The breakthrough volume of 19 L (225 – 835 mg/m³) makes it unlikely that the method can be extrapolated to the requested 5.5 mg/m³. Exposure to workplaces: The analytical procedure described by the participant is applicable for the determination of workers' exposure to workplaces.
Reliability	3
Acceptability	not acceptable
Remarks	Analytical and confirmatory methods for the determination of propan-1-ol in air with sufficient LOQs (≤ 5.5 mg/m^3) are available in Docs IIIA 4_2b_02 and 4_2b_03.
	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 A4.2b/02 Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-1-ol in air*

Official use only

1 REFERENCE

1.1	**Reference**	European Committee for Standardization (2000) Indoor, ambient and workplace air: Sampling and analysis of volatile organic compounds by sorbent tube/thermal desorption/capillary gas chromatography – Part 1: Pumped sampling (ISO 16017-1: 2000)
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**	Not applicable, the EN itself is a guideline
2.2	**GLP**	Not applicable. In the frame of this guideline, however, it is pointed to the fact that adequate quality safety standards should be used.
2.3	**Deviations**	-

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Sampler used for enrichment of air samples: stainless steel tubes (90 mm long, 6.3 mm OD, 5 mm ID, particle size: 0.18 mm to 0.25 mm) are filled with appropriate sorbent (e.g. for propan-1-ol: 300 mg Chromosorb 106 and 500 mg Porapak N, respectively). The sorbent are filled in such a way that the sorption bed lies within the desorption heating zone and the distance to the ends of the tubes is at minimum 14 mm. The sorbent are retained by stainless steel mesh and/or silylated glass wool plug. If more than one sorbent is used in a single sorption tube, the sorbent are arranged in increasing sorption strength and are separated by non-silylated glass wool. The sorbent with the lowest sorption potential reside at the end of the tube close to the sample inlet. The ending of the sorption tube are sealed with metal screw caps coated with PTFE. The air samples (range: 1-10 L) are drawn through the sorption tube via a pump.
3.1.2	Cleanup	Due to the test design, a cleanup is not necessary. The whole sampling tube is subject to thermal desorption (Chromosorb 106: 125°C/Porapak N: 120°C): After the removal of air in the sorption device to avoid chromatographic artefacts, the sampling tube is heated to the desired temperature and the organic substances (e.g. propan-1-ol) are transported via a stream of inert gas (flow: ca. 30-50 mL/min) to the chromatograph. The sampling tube shall be installed inversely to the sampling direction. In some cases it can be necessary to pre-concentrate the desorbed substances via a cryogenic trap (temperatures <-100°C) to minimize peak broadening.
3.2	**Detection**	
3.2.1	Separation method	GC/FID (other detectors can be used if appropriate): Temperatures: -injection: not reported -detector: not reported

		-column: in general temperature programmed in the range between 50-250°C with 5°C/min and an initial holding time of 10 min at 50°C. Carrier gas: He Columns: fused silica/dimethylsiloxane (50 m x 0.22 mm; 1 to 5 µm) or Cyanopropyl column (50 m, 7% cyanopropyl, 7% phenyl, 86% methyl-siloxane
3.2.2	Detector	FID or other detector if appropriate
3.2.3	Standard(s)	Propan-1-ol (10 µg/mL up to 10 mg/mL)
3.2.4	Interfering substance(s)	Substances having the same or nearly the same retention time as the substance under investigation (not further specified).
3.3	**Linearity**	
3.3.1	Calibration range	10 µg/mL up to 10 mg/mL
3.3.2	Number of measurements	As ≥ 5 concentrations are to be measured, single measurement is sufficient
3.3.3	Linearity	ca. 0.5 µg/m³-100 mg/m³
3.4	**Specifity: interfering substances**	Substances having the same or nearly the same retention time as the substance under investigation (not further specified).
3.5	**Recovery rates at different levels**	Assumed to be 100%
3.5.1	Relative standard deviation	Not reported
3.6	**Limit of determination**	In general ca. 0.5 µg/m³
3.7	**Precision**	In general: 1.3-5.9% (Chromosorb)
3.7.1	Repeatability	In general: 3.7-16.7%
3.7.2	Independent laboratory validation	Not reported
		4 APPLICANT'S SUMMARY AND CONCLUSION
4.1	**Materials and methods**	In the guideline DIN EN ISO 16017-1 the determination of propan-1-ol in air samples (indoor, ambient and workplace air) is described. The air samples (range: 1-10 L) are drawn through a sorption tube (e.g. for propan-1-ol: 300 mg Chromosorb 106 and 500 mg Porapak N, respectively) via a pump. Due to the test design, a cleanup is not necessary. The whole sampling tube is subject to thermal desorption (Chromosorb 106: 125°C/Porapak N: 120°C): After the removal of air in the sorption device to avoid chromatographic artefacts, the sampling tube is heated to the desired temperature and the organic substances are transported via a stream of He to the chromatograph. In some cases it can be necessary to pre-concentrate the desorbed substances via a cryogenic trap to minimize peak broadening. Separation and identification of the compounds of interest is done via GC/FID (other detectors can be used if appropriate). The procedure is suitable for concentrations ranging from 0.5 µg/m³ to 100 mg/m³.
4.2	**Conclusion**	Based on the information provided the reported determination method is

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

Annex Point 4.2 *Determination of propan-1-ol in air*

suitable for the detection of propan-1-ol in air.

4.2.1 Reliability 1

4.2.2 Deficiencies No

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2010/01/12
Materials and methods	Applicant's version is acceptable.
Conclusion	The EN ISO 16017-1:2000 method is acceptable for the quantification of propan-1-ol in air. The proposed limit of quantification is 0.5 µg/m³.
Reliability	1
Acceptability	acceptable
Remarks	no
	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 A4.2b/03 Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-1-ol in air*

Official use only

1 REFERENCE

1.1	**Reference**	Deutsches Institut für Normung e.V. (2004) Indoor Air – Part 6: Determination of volatile organic compounds in indoor and test chamber air by active sampling on Tenax TA sorbent, thermal desorption and gas chromatography using MS/FID (ISO 16000-6:2004)
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**	Not applicable, the DIN itself is a guideline
2.2	**GLP**	Not applicable. In the frame of this guideline, however, it is pointed to the fact that adequate quality safety standards should be used.
2.3	**Deviations**	-

3 MATERIALS AND METHODS

3.1	**Preliminary treatment**	
3.1.1	Enrichment	Sampler used for enrichment of air samples: stainless steel tubes (90 mm long, 6.0 mm OD, 5 mm ID; particle size: 0.18 to 0.25 mm) are filled with >=200 mg Tenax TA. For filling the tube, first a plug deactivated glass wool or a stainless steel mesh is introduced at one end of the tube. Subsequently the sorbent is filled in. Thereafter, a further plug consisting of glass wool or stainless steel mesh is introduced to retain the sorbent in the tube. The ending of the sorption tube are sealed with metal screw caps coated with PTFE. The air samples are drawn through the sorption tube via a pump (50 mL/min to 200 ml/min; sample volume: 1-5 L).
3.1.2	Cleanup	Due to the test design, a cleanup is not necessary. The whole sampling tube is subject to thermal desorption (temperature: 120-160°C aliphatic alcohols; desorption time: 5-15 min; flow: 30-50 mL/min). The desorbed VOCs were passed through a cold trap (-30°C to 280°C)/sorbent filled trap and flushed into the gas chromatograph via an inert gas stream (transfer-line temperature: 220°C).
3.2	**Detection**	
3.2.1	Separation method	GC/FID and/or MS: Temperatures: -injection: not reported -detector: not reported -column: temperature programmed (not further specified) Carrier gas: He, Ar, N2 Columns: in general capillary columns (100% dimethylpolysiloxane; 30-60 m x 0.25 to 0.32 mm i.d.; film thickness: 0.25 to 0.33 µm)
3.2.2	Detector	FID and/or MS
3.2.3	Standard(s)	Propan-1-ol (10 µg/mL up to 10 mg/mL) or toluene
3.2.4	Interfering	Substances having the same or nearly the same retention time as the

	substance(s)	substance under investigation (not further specified). However, this does not apply to MS as it is a highly sensitive, substance specific method.
3.3	**Linearity**	
3.3.1	Calibration range	10 µg/mL up to 10 mg/mL
3.3.2	Number of measurements	As ≥ 5 concentrations are to be measured, single measurement is sufficient
3.3.3	Linearity	ca. 1 µg/m³- several mg/m³
3.4	**Specifity: interfering substances**	Substances having the same or nearly the same retention time as the substance under investigation (not further specified).
3.5	**Recovery rates at different levels**	>95%, for C6 -C16
3.5.1	Relative standard deviation	Not reported
3.6	**Limit of determination**	In general ca. 1 µg/m³
3.7	**Precision**	
3.7.1	Repeatability	≤ 15%
3.7.2	Independent laboratory validation	Conducted (results not reported)
		4 APPLICANT'S SUMMARY AND CONCLUSION
4.1	**Materials and methods**	In the guideline DIN EN ISO 16000-6 the determination of propan-1-ol in air samples (indoor air, test chamber) is described. The air samples (range: 1-5 L) are drawn through a sorption tube containing Tenax TA via a pump. Due to the test design, a cleanup is not necessary. The whole sampling tube is subject to thermal desorption. The desorbed VOCs were passed through a cold trap (-30°C to 280°C)/sorbent filled trap and flushed into the gas chromatograph via an inert gas stream (transfer-line temperature: 220°C). Separation and identification of the compounds of interest is done via GC/FID and/or MS. The procedure is suitable for concentrations ranging from 1 µg/m³ to several mg/m³.
4.2	**Conclusion**	Based on the information provided the reported determination method is suitable for the detection of propan-1-ol in air.
4.2.1	Reliability	2
4.2.2	Deficiencies	Yes. Some details are not reported (recovery rates, precision, repeatability).

Section A4.2b/03 Analytical Methods for Detection and Identification

Annex Point 4.2 *Determination of propan-1-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	2010/01/12
Materials and methods	Applicant's version is acceptable.
Conclusion	Applicant's version is adopted. GC-MS is suitable as confirmatory method. The proposed limit of quantification is 1 µg/m³.
Reliability	2
Acceptability	acceptable
Remarks	none
	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-1-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	2008/08/04
Evaluation of applicant's justification	In general, the applicant's justification for non-submission of analytical methods for determination of propan-1-ol in water is conclusive. [redacted]
Conclusion	No analytical method is required for the determination of propan-1-ol in drinking water or surface water.
Remarks	none
	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	
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*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-1-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	2008/08/01
Evaluation of applicant's justification	The applicant's justification is conclusive.
Conclusion	No analytical methods are required for the determination of propan-1-ol in body tissues or body fluids.
Remarks	none
	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-1-ol in animal and human body fluids and tissues*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*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	2008/08/01
Evaluation of applicant's justification	The applicant's justification is conclusive.
Conclusion	Analytical methods for the determination of residues of propan-1-ol in food or feeding stuffs are not deemed necessary.
Remarks	none
	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	
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	