Section A4.2/01 Analytical Methods for Detection and Identification

Annex Point IIA, IV.4.2 *b) Residues in Air*

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schoknecht U, Wegener R, Horn W, Jann O (2002a), Emission of Biocides from Treated Materials, Environ Sci Pollut Res Int 2003; 10(3): 154-61. Schoknecht U, Wegner R, Horn W, Jann O (2002b): Biozidemissionen aus Materialien, Forschungsbericht (UFO-Plan 299 67 410) – part two: materials and methods.	
1.2	**Data protection**	No	
1.2.1	Data owner		
1.2.2	Companies with letter of access		
1.2.3	Criteria for data protection	Data submitted on existing A.S. for the purpose of its entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	-	
		3 MATERIALS AND METHODS	
3.1	**Preliminary treatment**	-	
3.1.1	Extraction	Active sampling of a defined volume of air on PU-foam plugs (sorbent) and subsequent desorption with acetone/n-hexane	X
3.1.2	Cleanup	-	
3.2	**Detection**	-	
3.2.1	Separation method	Gas chromatography	
3.2.2	Detector	MS (in SIM-Mode)	
3.2.3	Standard(s)	Reference Standard: OIT-Standard, THOR GmbH Internal standard: 4-(4'-Chlorobenzoyl)pyridine	
3.2.4	Interfering substance(s)	-	
3.3	**Linearity**	-	
3.3.1	Calibration range	0.1 – 60 ng/µl (OIT)	X
3.3.2	Number of measurements	7 measurements in double	
3.3.3	Linearity	$R^2 = 0.9999$	

Section A4.2/01 Analytical Methods for Detection and Identification

Annex Point IIA, IV.4.2 *b) Residues in Air*

3.4	**Specifity: interfering substances**	No specific interference. Sampling tubes have to be checked for possible background signals by procedures specified.
3.5	**Recovery rates at different levels**	Recovery (Elution/n-Hexane): 60.1 +/- 6.5 % Recovery (Ultrasonic bath/ n-Hexane): 82.3 +/- 5.5 %. Recovery (Soxhlet (50 cycles)/n-Hexan): 86.9 +/- 2.0 %
3.5.1	Relative standard deviation	For deviations refer to table on recoveries above.
3.6	**Limit of determination**	LOD of 0.5 µg/m³ for sample volume of 15 m³.
3.7	**Precision**	
3.7.1	Repeatability	Not applicable/not needed as results were calculated using the internal standard method in comparison with calibration curves
3.7.2	Independent laboratory validation	-

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	Determination of semi volatile organic compounds in indoor and test chamber air by active sampling on PU-foam sorbent, chemical desorption and GC/MS detection.
4.2	**Conclusion**	This method has been successfully validated for OIT and is therefore considered suitable to support registration data and also as a method for post registration monitoring and surveillance. This analytical method is suitable for the determination of OIT emissions of different product types.
4.2.1	Reliability	2
4.2.2	Deficiencies	no

Section A4.2/01 Analytical Methods for Detection and Identification

Annex Point IIA, IV.4.2 *b) Residues 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	*31/01/11*
Materials and methods	The applicant has submitted two studies for this method: 1) a research article which only gives a summary of the method and does not contain sufficient details on the validation data 2) a study in German with a brief summary in English The validation data are not complete in a number of areas, as follows: **3.1.1: Extraction** The applicant must state the defined volume of air used and the time period. A relative humidity of 50 % and temperature of 23°C appears to have been used (this would need to be confirmed). Recoveries at 35°C and a relative humidity of 80 % also need to be investigated. The exact details used to extract the active must then be given. **3.2: Detection:** The ion(s) used for monitoring must be given. **3.3: Linearity**: No results on the linearity, including an example calibration graph appear to have been given. **3.5 Recovery**: The precise fortification levels and recoveries are required. The breakthrough volume must also be addressed. **3.6: Limit of determination:** How this limit was determined must be addressed. The LOQ quoted is acceptable in terms of the Concentration C, as defined in the 'additional guidance on: TNsG on data requirements for analytical methods for detetction and identification.
Conclusion	While the validation data for this method are incomplete a method for air is not required. The vapour pressure is not ≥ 0.01 Pa and the application method does not include spraying.
Reliability	3. The issues identified must be addressed if the method was required in the future.
Acceptability	Not acceptable. However, a method is not required.
Remarks	A method is not required for 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*

Section A4.2/01 Analytical Methods for Detection and Identification

Annex Point IIA, IV.4.2 *b) Residues in Air*

Remarks