Section 3.4(1) **Annex Point IIA 3.4.1**		**Absorption spectra (UV/Vis)**	
		1. REFERENCE	Official use only
1.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Sydney, P. (2006) N-Alkyl(C_{12}-C_{16})-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) (Supplied As Barquat MB 80): Ultraviolet/Visible Absorption Spectrum. Huntingdon Life Sciences, Ltd. Report No. ADB0030/062227 (unpublished) [Ref No. A121 (LON 3996)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Guideline 101 1981 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2	**GLP (only where required)**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	

Section 3.4(1) **Annex Point IIA 3.4.1**		**Absorption spectra (UV/Vis)**	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	OECD Guideline 101 – UV-VIS Absorption Spectra, Adopted by the Council on 12 May 1981.	
		4. RESULTS	
4.1	**Results**	No absorption maxima were found at wavelengths greater than 400 nm. The spectra from 200 - 400 nm for ADBAC in purified water, 0.1M aqueous hydrochloric acid and 0.1M aqueous sodium hydroxide are summarized in Table 3.4.1(1)-1. It was not possible to calculate the bandwidth for any of the peaks present in the spectra, as none of the peaks could be resolved sufficiently from the others to allow measurement at half the absorbance maximum value.	
4.2	**Discussion**	The ultraviolet/visible absorption spectra were consistent with the assigned structure of ADBAC.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 3.4(1) **Annex Point IIA 3.4.1**		**Absorption spectra (UV/Vis)**	
		[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	The ultraviolet/visible absorption spectra were consistent with the assigned structure of ADBAC.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	

Section 3.4(1) Annex Point IIA 3.4.1	**Absorption spectra (UV/Vis)**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (SPECIFY)
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 3.4.1(1)-1: UV-visible absorption spectra results.

Solvent	Absorbance (A)	λ_{max} (nm)	E
Purified water	1.116	209	229
	0.957	214(sh)	197
	0.556	252(sh)	6.35
	0.812	257	9.27
	0.965	262	11.0
	0.754	269	8.61
0.1M aqueous HCl	1.129	209	232
	0.982	214(sh)	202
	0.536	253(sh)	6.12
	0.782	257	8.93
	0.927	263	10.6
	0.721	269	8.23
0.1M aqueous NaOH	0.618	217	*
	0.541	252(sh)	6.18
	0.793	257	9.06
	0.940	263	10.7
	0.731	269	8.35

sh = shoulder
* not calculated as below the lower wavelength limit of this solvent matrix

Section 3.4(2) Annex Point IIA 3.4.1	Absorption spectra (IR and NMR) and mass spectrum, molar extinction at relevant wavelengths	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Petrovic P. (2001) Characterization of the Structure of Barquat MB AS. Clariant GmbH, Frankfurt, Germany. Unpublished report no. B 016/2001 (unpublished) [Ref No: A78 (LON 3386)] Young, S. (2004) N-Alkyl(C12-16)-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC): Mass Spectrum. Huntingdon Life Sciences, Huntingdon. Report NO.: ADB022/042073 (unpublished) [Ref No: A93 (LON 3791)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Standard Operating Procedures of the testing facility 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines	

Section 3.4(2) **Annex Point IIA 3.4.1**		**Absorption spectra (IR and NMR) and mass spectrum, molar extinction at relevant wavelengths**	
		are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	Standard Operating Procedures of the testing facility	
		4. RESULTS	
4.1	**Results**	IR: The recorded IR spectrum does not show any absorption bands which are in disagreement with the proposed structure NMR: The ^{1}H-NMR spectra of the test substance corresponds with the proposed structure. Mass spectrum: The mass spectra produced are consistent with the proposed structure.	
4.2	**Discussion**	The recorded spectra of the test substance correspond with the proposed structure.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 3.4(2) **Annex Point IIA 3.4.1**	**Absorption spectra (IR and NMR) and mass spectrum, molar extinction at relevant wavelengths**	
	[redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3 Conclusion	[redacted]	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.5 Annex Point IIA 3.5	Solubility in water	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Fischer, A. (2001) Determination of the water solubility of Barquat MB AS. Clariant GmbH, Frankfurt, Germany. Unpublished report no. B 015/2001 (unpublished). [Ref No: A42 (LON 3383)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 105 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	x
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant*	

Section 3.5 **Annex Point IIA 3.5**	**Solubility in water**	
	[redacted]	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Method	The water solubility was determined in the pH range 5 to 9 (5.5 to 8.2) in accordance with OECD Guideline No. 105 using the addition method because of the sticky nature of the test substance.	
	4. RESULTS	
4.1 Water solubility	pH5.5: 409 g/l pH 6.5: 431 g/l pH 6.9: 403 g/l pH 8.2: 379 g/l All measurements are carried out at 20°C.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 3.5 **Annex Point IIA 3.5**	**Solubility in water**	
	[redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3 Conclusion	The test substance is highly soluble in water in the pH range 5 to 9.	
5.3.1 Reliability	[redacted]	x
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	

Section 3.5 **Annex Point IIA 3.5**	**Solubility in water**	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.6 Annex Point IIIA.3.6	Dissociation constant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	

Section 3.6 Annex Point IIIA.3.6	Dissociation constant
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	The applicant justification is accepted
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	

Section 3.7(1) Annex Point IIA 3.7	Solubility in organic solvents, including the effect of temperature on solubility	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* Young, S. (2004). N-Alkyl(C12-16)-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) Solubility in Ethanol and Isopropanol. Huntingdon Life Sciences, Huntingdon. Report NO.: ADB021/042021 (unpublished). [Ref No: A91 (LON 3792)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, Method A6 2004 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	Yes The test procedure deviated from the specified test guideline due to the unsuitabillity of the test guideline for the determination of substances of high solubility in organic solvents. See 5.1. *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant*	

Section 3.7(1) Annex Point IIA 3.7		Solubility in organic solvents, including the effect of temperature on solubility	
		[redacted] (Note: The expiry date of this substance lot was extended based on documentation provided by the Sponsor prior to study initiation, in order to complete a testing program with this lot).	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	The study was carried out in accordance with Directive 98/8/EC and Directive 92/69/EEC, Method A6 with the exceptions noted in Section 5.1.	
		4. RESULTS	
4.1	**Results**	The test substance dissolved fully at a concentration of 260000 mg/l at 20°C in both ethanol and isopropanol. No further testing was required.	
4.2	**Discussion**	The solubility of the test substance was found to be greater than 250000 mg/l at 20°C in both ethanol and isopropanol.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 3.7(1) Annex Point IIA 3.7		Solubility in organic solvents, including the effect of temperature on solubility	
		[redacted]	
5.2	Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3	Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Solubility is >250000 mg/l at 20°C in both ethanol and isopropanol.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		acceptable	
Remarks			
		COMMENTS FROM OTHER MEMBER STATE	
Date		*Give date of the comments submitted*	
Materials and Methods		*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion		*Discuss if deviating from view of rapporteur member state*	
Conclusion		*Discuss if deviating from view of rapporteur member state*	
Reliability		*Discuss if deviating from view of rapporteur member state*	
Acceptability		*Discuss if deviating from view of rapporteur member state*	

Section 3.7(2) Annex Point IIA 3.7		Solubility in organic solvents, including the effect of temperature on solubility	
		1. REFERENCE	Official use only
1.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* Young, S. (2004) N-Alkyl(C12-16)-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) Solubility in Octanol. Huntingdon Life Sciences, Huntingdon. Report No.: ADB020/042020 (unpublished). [Ref No: A90 (LON 3826)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A6 2004 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2	**GLP (only where required)**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	

Section 3.7(2) Annex Point IIA 3.7		Solubility in organic solvents, including the effect of temperature on solubility	
		[redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	Directive 92/69/EEC, Method A6	
		4. RESULTS	
4.1	**Results**	2.5 g of test substance dissolved completely in 10 ml of octanol.	
4.2	**Remarks**	The solubility of the test substance was found to be at least 250 g/L at 20°C in octanol.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* The solubility of the test substance was found to be >250000 mg/l at 20°C in octanol.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	

Section 3.7(2) Annex Point IIA 3.7	**Solubility in organic solvents, including the effect of temperature on solubility**
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 3.8 (1) Annex Point IIA 3.8		Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
		1. REFERENCE	Official use only
1.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Young, S. (2004) N-Alkyl(C12-16)-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) Stability in Ethanol and IPA Huntingdon Life Sciences, Huntingdon. Report No.: ADB025 (unpublished). [Ref No: A92 (LON 3793)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No A guideline method does not exist for this endpoint; however, the study was designed and conducted to address the data requirement of European Biocidal Products Directive 98/8/EC as set forth in the Technical Guidance Document for Active Substances and Biocidal Products, Final Draft Version 4.3.2 October 2000, Additional Data requirement, Chapter 3, Section 3.8. *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2	**GLP (only where required)**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	

Section 3.8 (1) Annex Point IIA 3.8		Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Test substance preparation**		
3.2.1	Test substance concentration	[redacted]	
3.2.2	Storage temperature	[redacted]	
3.2.3	Storage period	[redacted]	
3.3	**Chromatography**		
3.3.1	Autosampler	[redacted]	
3.3.2	Pump	[redacted]	
3.3.3	Conductivity detector	[redacted]	
3.3.4	Column	[redacted]	
3.3.5	Data capture	[redacted]	
3.4	**Chromatography conditions**		
3.4.1	Mobile phase gradient	[redacted]	

Section 3.8 (1) Annex Point IIA 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
	[redacted]	
3.4.2 Mobile phases	[redacted]	
3.4.3 Flow rate	[redacted]	
3.4.4 Temperature	[redacted]	
3.4.5 Injection volume	[redacted]	
	4. RESULTS	
4.1 Results		
4.1.1 Mean percentage differences	Ethanol = 3.68% Isopropanol = 2.15%	
4.1.2 Regression value	0.99923	
4.1.3 %RSD	2.06	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	x

	Ethanol	Isopropanol

Section 3.8 (1) Annex Point IIA 3.8		Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
		[redacted]	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* The mean percentage differences between t=0 and t=14 days (at 55°C) samples were +3.68% and + 2.15% for ethanol on isopropanol respectively.	x
		[redacted]	x
		[redacted]	x
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* The test substance was found to be stable (loss on storage < 5%) for 14 days at 55°C in both ethanol and isopropanol.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	x
5.3.2	Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results.*	

Section 3.8 (1) Annex Point IIA 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products
	If relevant, justify acceptability of study.)
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	not acceptable

Section 3.8 (1) Annex Point IIA 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 3.9 **Annex Point IIA 3.9**	**Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [X]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	

Section 3.9 Annex Point IIA 3.9	Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature	
	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	26/04/2006	

Section 3.9 **Annex Point IIA 3.9**	**Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature**
Evaluation of applicant's justification	[redacted]
Conclusion	THe Applicant justification is accepted
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	

Section 3.10 (1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Keipert, W. (2001) Determination of the thermal stability and stability in air of Barquat MB AS in accordance with OECD-Guideline 113. Clariant GmbH, Frankfurt, Germany. Report no. B 017/2001 (unpublished). [Ref No: A73 (LON 3390)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 113 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	x
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	

Section 3.10 (1) Annex Point IIA 3.10		Thermal stability, identity of relevant breakdown products	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	OECD Guideline No. 113	
		4. RESULTS	
4.1	**Results**	Two samples of the test substance were weighted into glass crucibles. These samples were exposed to a temperature/time gradient while the thermal heat-flow was recorded. No decomposition or chemical transformation was observed below 150°C. An endothermal effect at the temperature ranged from 160°C to 165°C occurs and an exothermal decomposition started at approximately 230°C. Therefore, the test substance was considered to be thermally stable at room temperature.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	

Section 3.10 (1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**	
	[redacted]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The substance is found to be thermally stable.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	x
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]ide and broad shape. The exothermal signal started approximately 230-235 °C	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks	▪ [redacted]	
	COMMENTS FROM OTHER MEMBER STATE	

Section 3.10 (1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.11 (1) **Annex Point IIA 3.11**	**Flammability including auto-flammability and identity of combustion products (Determination of the Relative Self-Ignition Temperature)**	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)* *If necessary, copy field and enter other reference(s).* Keipert, W. (2001) Determination of the relative self-ignition temperature of Barquat MB AS in accordance with EEC-Guideline A.16. Clariant GmbH, Frankfurt, Germany. Report no. B 019/2001 (unpublished) [Ref No: A75 (LON 3389)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, Method A16 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	

Section 3.11 (1) **Annex Point IIA 3.11**		**Flammability including auto-flammability and identity of combustion products (Determination of the Relative Self-Ignition Temperature)**	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	Directive 92/69/EEC, Method A16	
		4. RESULTS	
4.1	**Results**	The temperature/time-curves of sample and oven were recorded simultaneously. The oven temperature was increased beginning at room temperature up to 400°C with rate of 0.5°C/min.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* The substance is not classified as self-ignitable according to the	

Section 3.11 (1) **Annex Point IIA 3.11**	**Flammability including auto-flammability and identity of combustion products (Determination of the Relative Self-Ignition Temperature)**	
	Directive 92/69/EEC, Method A16.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	

Section 3.11 (1) **Annex Point IIA 3.11**	**Flammability including auto-flammability and identity of combustion products (Determination of the Relative Self-Ignition Temperature)**	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.11 (2) **Annex Point IIA 3.11**		**Flammability including auto-flammability and identity of combustion products (Determination of Flammability)**	
		1. REFERENCE	Official use only
1.1	**Reference**	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* Keipert, W. (2001) Determination of the flammability of Barquat MB AS in accordance with EEC-Guideline A.10. Clariant GmbH, Frankfurt, Germany. Report no. B 018/2001 (unpublished). [Ref No: A74 (LON 3384)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes Directive 92/69/EEC, Method A10 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2	**GLP (only where required)**	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3	**Deviations**	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	x
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.11 (2) **Annex Point IIA 3.11**		**Flammability including auto-flammability and identity of combustion products (Determination of Flammability)**	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1).	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	Directive 92/69/EEC, Method A10	
		4. RESULTS	
4.1	**Results**	The test substance did not ignite, therefore, the main test was not performed.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* The substance is not classified as flammable according to the Directive 92/69/EEC, Method A10.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	x

Section 3.11 (2) **Annex Point IIA 3.11**	**Flammability including auto-flammability and identity of combustion products (Determination of Flammability)**	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	