Section 3.11 Annex Point IIA.3.11	Autoflammability	
	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:	*This end-point is a Core Data Requirement* [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	[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*	

Section 3.11 Annex Point IIA.3.11	Autoflammability
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 3.12 **Annex Point IIA.3.12**	**Flash point**	
	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.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The Applicant justification is accepted	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 3.12 Annex Point IIA.3.12	Flash point
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 3.13 (1) **Annex Point IIA 3.13**	**Surface tension**	
	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).* Schneider, (2001) S. Determination of the surface tension of an aqueous solution (1 g/l) of Barquat MB AS in accordance with OECD-Guideline 115 [and according to EEC-Guideline A.5]. Clariant GmbH, Germany. Report No. B 082/2001 (unpublished). [Ref No: A76 (LON 3537)]	
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 A5 and OECD Guideline No. 115 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]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.13 (1) **Annex Point IIA 3.13**	**Surface tension**	
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 A5; OECD Guideline No. 115	
	4. RESULTS	
4.1 Results	The surface tension of the aqueous solution of the test substance was found to be 31.3 mN/m at 20°C (concentration 1 g/l), therefore the test substance is considered to be surface active.	
	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 classified as a surfactant.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	

Section 3.13 (1) **Annex Point IIA 3.13**	**Surface tension**	
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 3.14 Annex Point IIIA.3.14	Viscosity	
	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.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	27/04/2006	
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 3.15 (1) **Annex Point IIA 3.15**	**Explosive properties**	
	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 explosive properties of Barquat MB AS in accordance with EEC-Guideline A.14. Clariant GmbH, Frankfurt, Germany. Report no. B 020/2001 (unpublished). [Ref No: A77 (LON 3392)]	
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 A14 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]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 3.15 (1) Annex Point IIA 3.15		Explosive properties	
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 92/69EEC, Method A14	
		4. RESULTS	
4.1	**Results**	Under the conditions of the test, the test substance is found not to be sensitive to flame, shock or friction.	
		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 does not possess explosive properties.	
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]	

Section 3.15 (1) **Annex Point IIA 3.15**	**Explosive properties**	
	(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] ▪ [redacted] ▪ [redacted] ▪ [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*	

Section 3.15 (1) Annex Point IIA 3.15	Explosive properties	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 3.16 **Annex Point IIA.3.16**	**Oxidising properties**	
	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	*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*	

Section 3.16 **Annex Point IIA.3.16**	**Oxidising properties**	
data submission [ ]	*agreed on the delayed data submission.)*	
	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 3.17 Annex Point IIA. 3.17	Reactivity towards container material	Official use only
	Chemical compatibility towards container material Test method: Chemical compatibility according to Test Guideline AV 90.1, TRV 002, A and B Date of investigation: a) June 1992 b) April 1986 c) October 1996 Reference: Internal data of manufacturer Test substance: a) [redacted]0 (50% Alkyldimethylbenzylammonium Chloride (ADBAC)) b) [redacted] (50% Alkyldimethylbenzylammonium Chloride (ADBAC)) c) [redacted] (50% Alkyldimethylbenzylammonium Chloride (ADBAC)) d) [redacted] (80% Alkyldimethylbenzylammonium Chloride (ADBAC)) Test material: a) Polyethylene, Type Hostalen GM6255 b) Polyethylene, Type Hostalen GM 7745 Results: Tests A and B positive Resistance against the test materials confirmed. Metals: Experience in use, shows that 316 l stainless steel is satisfactory at normal handling temperatures. For higher temperatures (which make for easier handling of the 80% products), stainless steel, containing 6% or more molybdenum (Rolled alloys AL-6XN, Avesta 254-SMO, INCO 25-6 mO), provides significantly more corrosion resistant. Because these alloys are more expensive; overall economics must be considered for their use. Plastic: PVC, polyolefin, Teflon, Kynar, Kalrez and vinyl ester are satisfactory to temperatures recommended by manufacturer. Natural rubber, neoprene and Buna-N should be avoided. It is recommended that specific applications be pre-tested.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	27/04/2006	

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*

Section 4.1 (1) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Criteria for data protection		
2.1 Guideline study		
2.2 GLP (only where required)		
2.3 Deviations		
3.1 Test material		
3.1.1 Lot/Batch number		
3.1.2 Specification		

Section 4.1 (1) Annex Point IIA 4.1		Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)
		[redacted]
3.1.3	Description	
3.1.4	Purity	
3.1.5	Stability	
3.2	**Chromatograph details**	
3.2.1	Chromatograph	
3.2.2	Column	
3.2.3	Integrator	
3.3	**Chromatography conditions**	
3.3.1	Flow rate	
3.3.2	Temperature	
3.3.3	Injection volume	
3.4	**Remarks**	
4.1	**Chromatography results**	

Section 4.1 (1) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)
4.2 Remarks	[redacted]

Section 4.1 (1) Annex Point IIA 4.1		Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	Materials and methods	[redacted]	
5.2	Results and discussion		
5.3	Conclusion		
5.3.1	Reliability		x
5.3.2	Deficiencies		

Section 4.1 (1) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)**
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
Date	
Materials and Methods	

Section 4.1 (1) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers)
Results and discussion	[redacted]
Conclusion	
Reliability	
Acceptability	

[redacted]

Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted]	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Criteria for data protection		
2.1 Guideline study		
2.2 GLP (only where required)		
2.3 Deviations		
3.1 Test material (standards)		X
3.1.1 Lot/Batch number		
3.1.2 Purity		X
3.1.3 Stability		
3.1 Test material (production batches)		X

Section 4.1(2) **Annex Point IIA 4.1**		**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
		[redacted]	
3.1.1	Lot/Batch number		
3.1.2	Specification		
3.1.3	Description		
3.1.4	Purity		
3.1.5	Stability		
3.2	**Test procedure**		
3.3	**Test system**		
3.3.1	Chromatography		

Section 4.1 (2) Annex Point IIA 4.1		Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD	
	system	[redacted]	
3.3.2	Column		
3.3.3	Detector		
3.3.4	Mobile phase and gradient		
3.3.5	Conditions		
4.1	**Results**		
4.1.1	Precision (repeatability and replicate injections)		

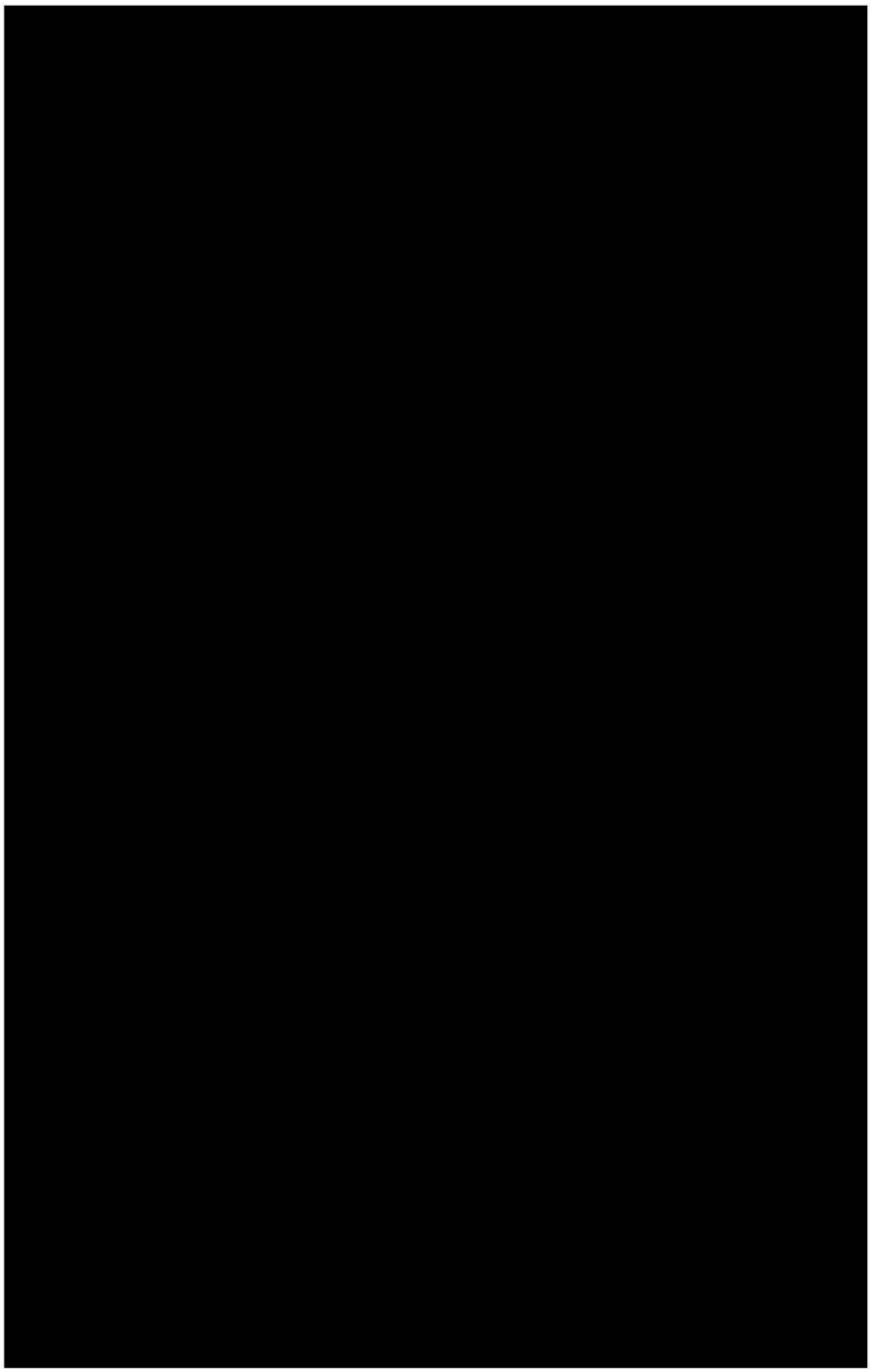
Section 4.1(2) Annex Point IIA 4.1		Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD	
		[redacted]	
4.1.2	Accuracy		
4.1.3	Non-analyte interference		
4.1.4	Sensitivity		
4.1.5	Specificity		

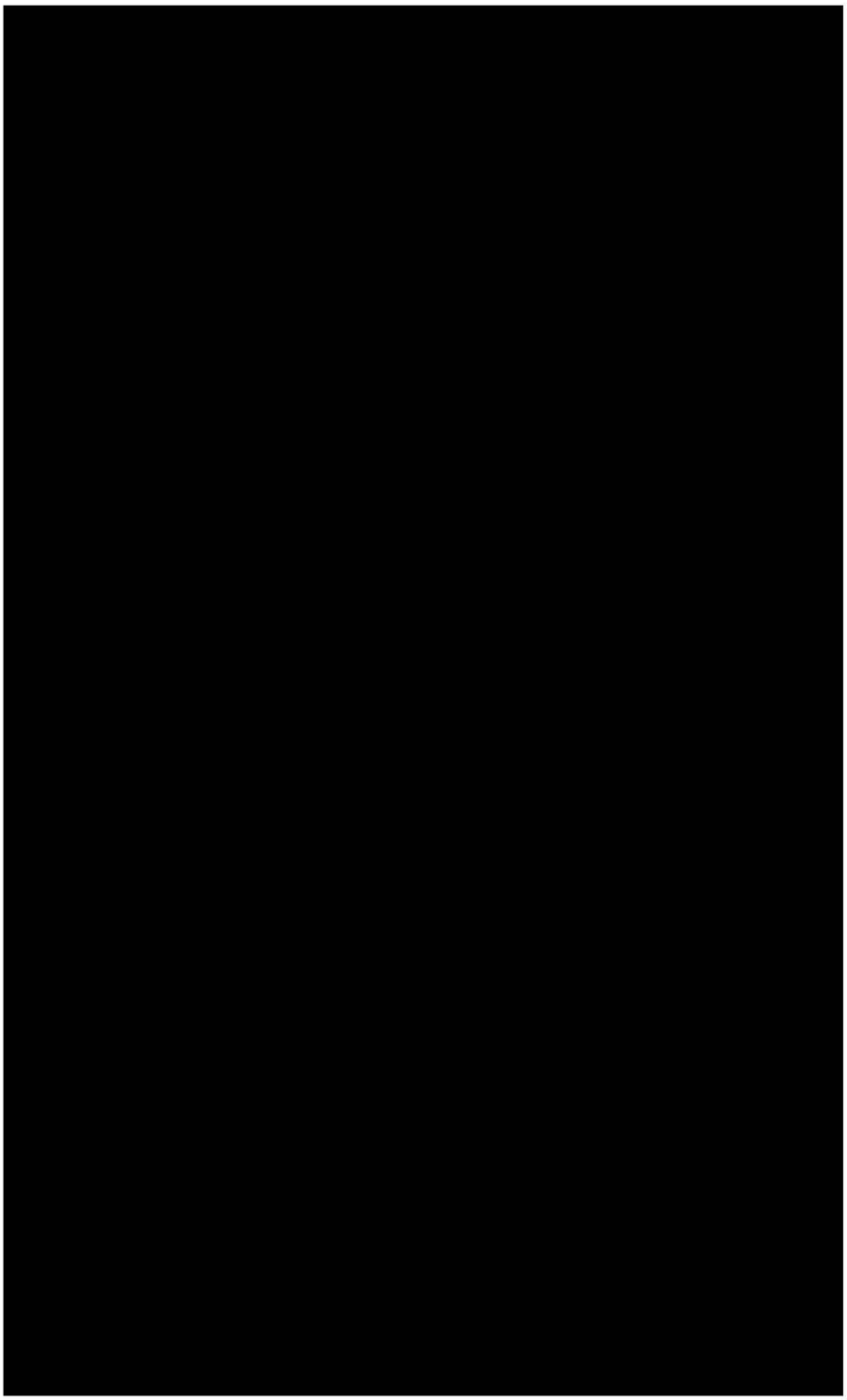
Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
	[redacted]	
4.2 Remarks		
5.1 Materials and methods		X
5.2 Results and discussion		X
5.3 Conclusion		X
5.3.1 Reliability		X

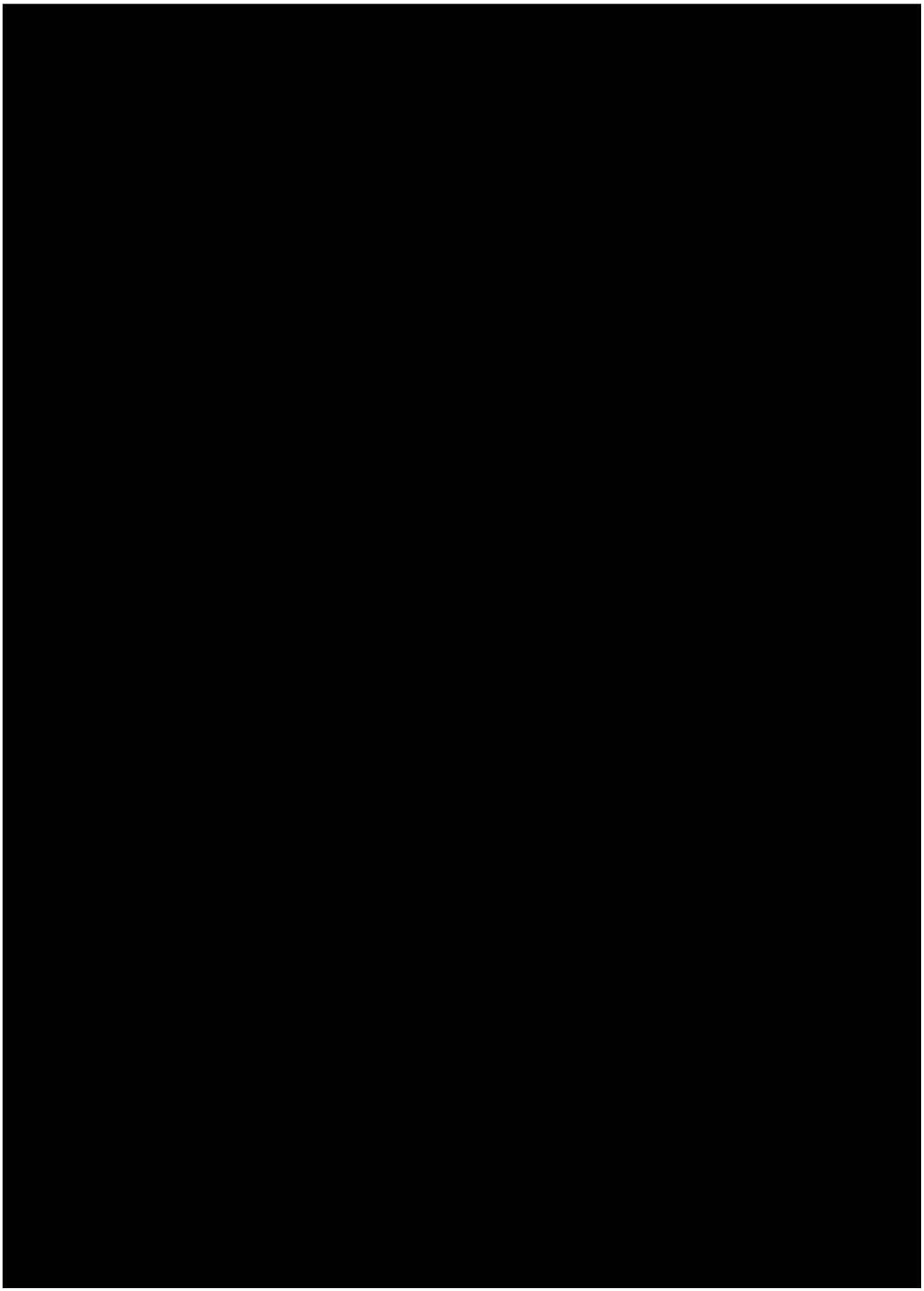
Section 4.1(2) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD**	
5.3.2 Deficiencies	[redacted]	X

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
Date	

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 4.1(3)(a) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted]	X
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Criteria for data protection		
2.1 Guideline study		
2.2 GLP (only where required)		
2.3 Deviations		
3.1 Test and reference materials		
3.1.2 Test substance (Production batch of technical grade)		X0
3.1.2.1 Lot/Batch number		
3.1.2.2 Specification		
		X1
3.1.2.3 Description		

Section 4.1(3)(a) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)**	
3.1.2.4 Purity	[redacted]	X2
3.1.2.5 Stability		
3.1.1 Reference Standards		X3
3.1.1.1 Lot/Batch number		X3
3.1.1.2 Purity		X3
3.1.1.3 Stability		
3.2 Validation procedure		X4
3.3 HPLC-ELSD for determination of the active substance		
3.3.1 Instrument Conditions		
3.3.2 Linearity		X5

Section 4.1(3)(a) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)	
3.3.3 Precision (repeatability)	[redacted]	X6
3.3.4 Specificity		X7
4.1 Results		X8
5.1 Materials and methods		X
5.2 Results and discussion		

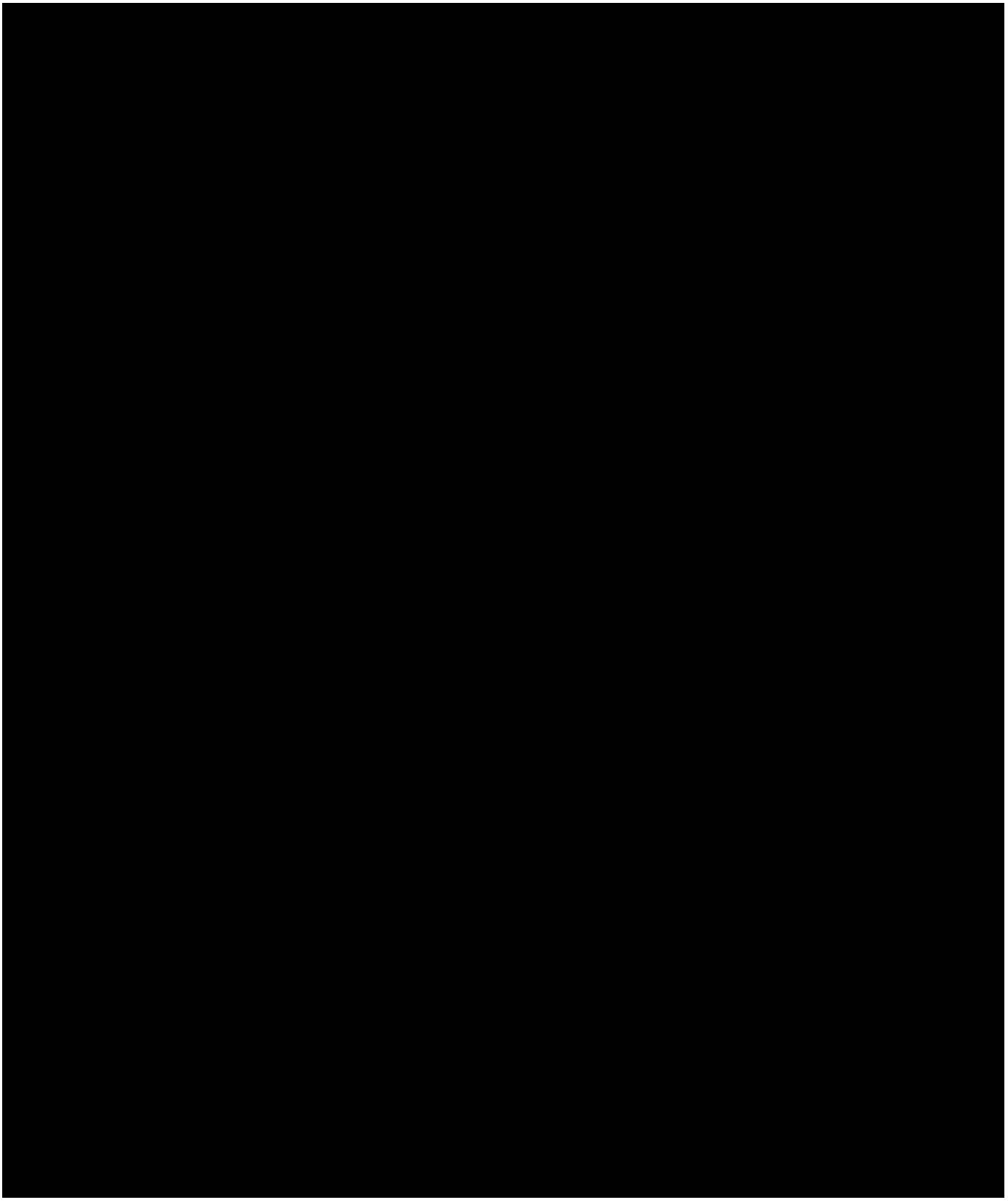
Section 4.1(3)(a) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)**
5.3 Conclusion	[redacted]
5.3.1 Reliability	
5.3.2 Deficiencies	
Date	
Materials and Methods	
Results and discussion	

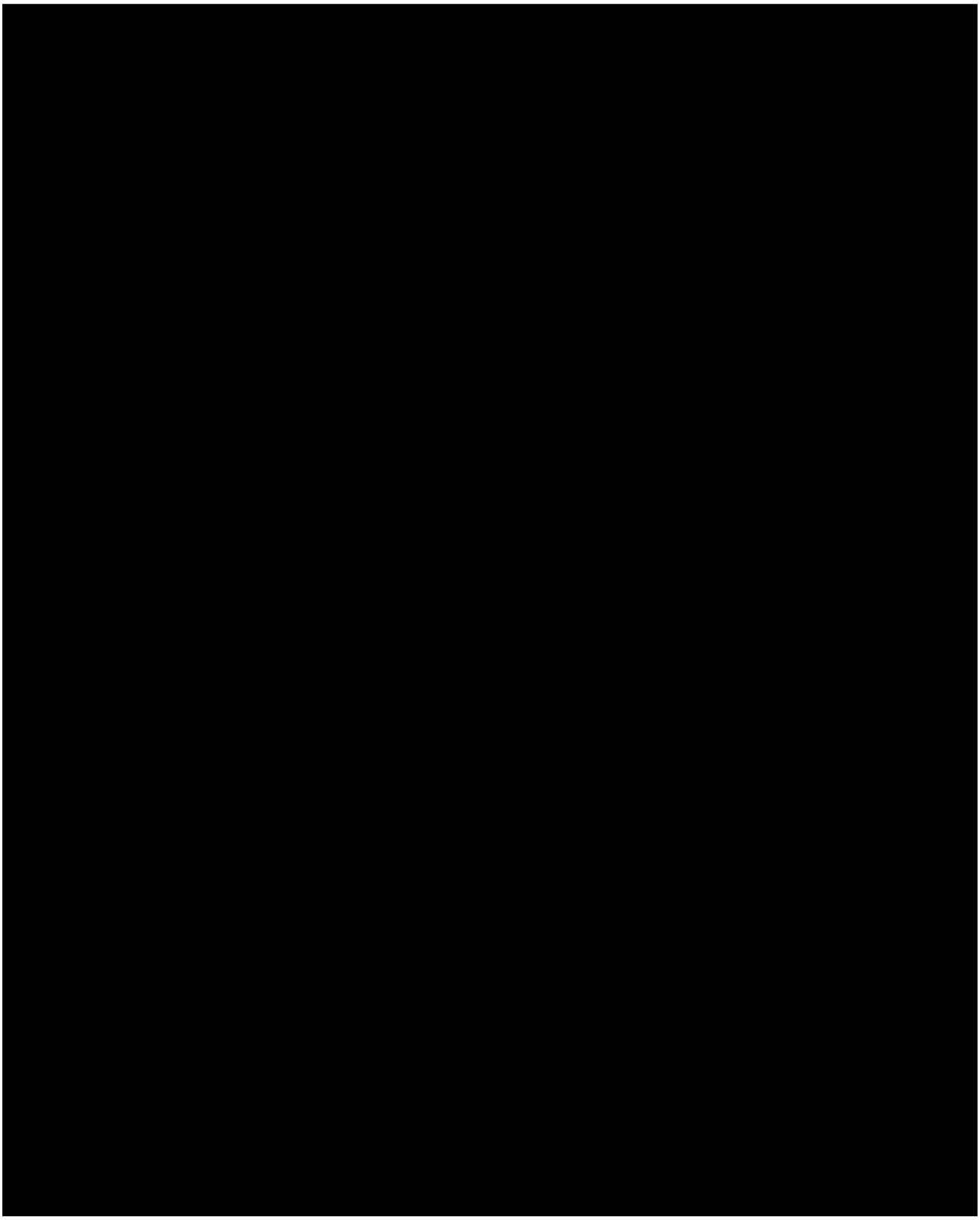
Section 4.1(3)(a) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)
Conclusion Reliability	[redacted]

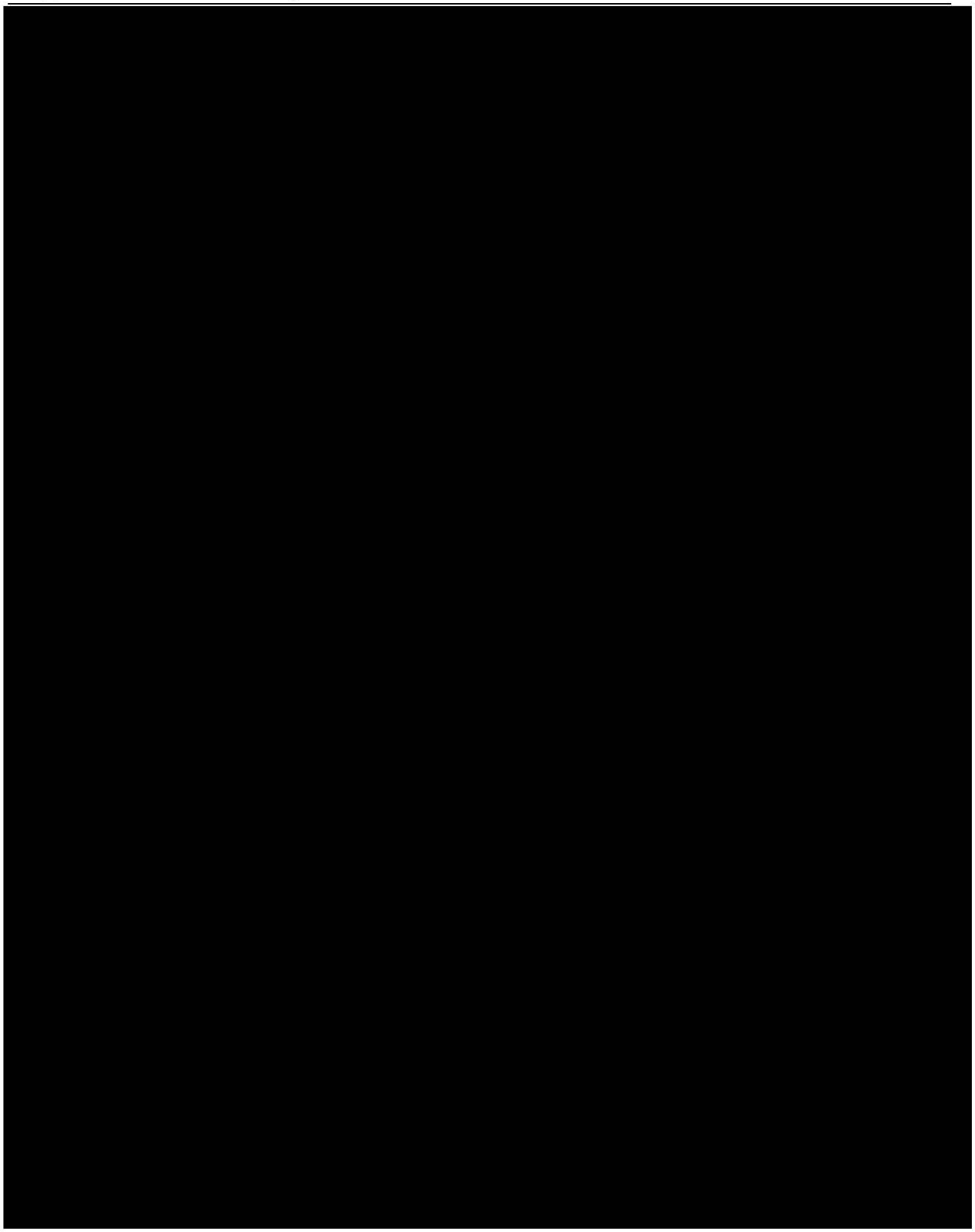
Section 4.1(3)(a) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)
Acceptability	[redacted]

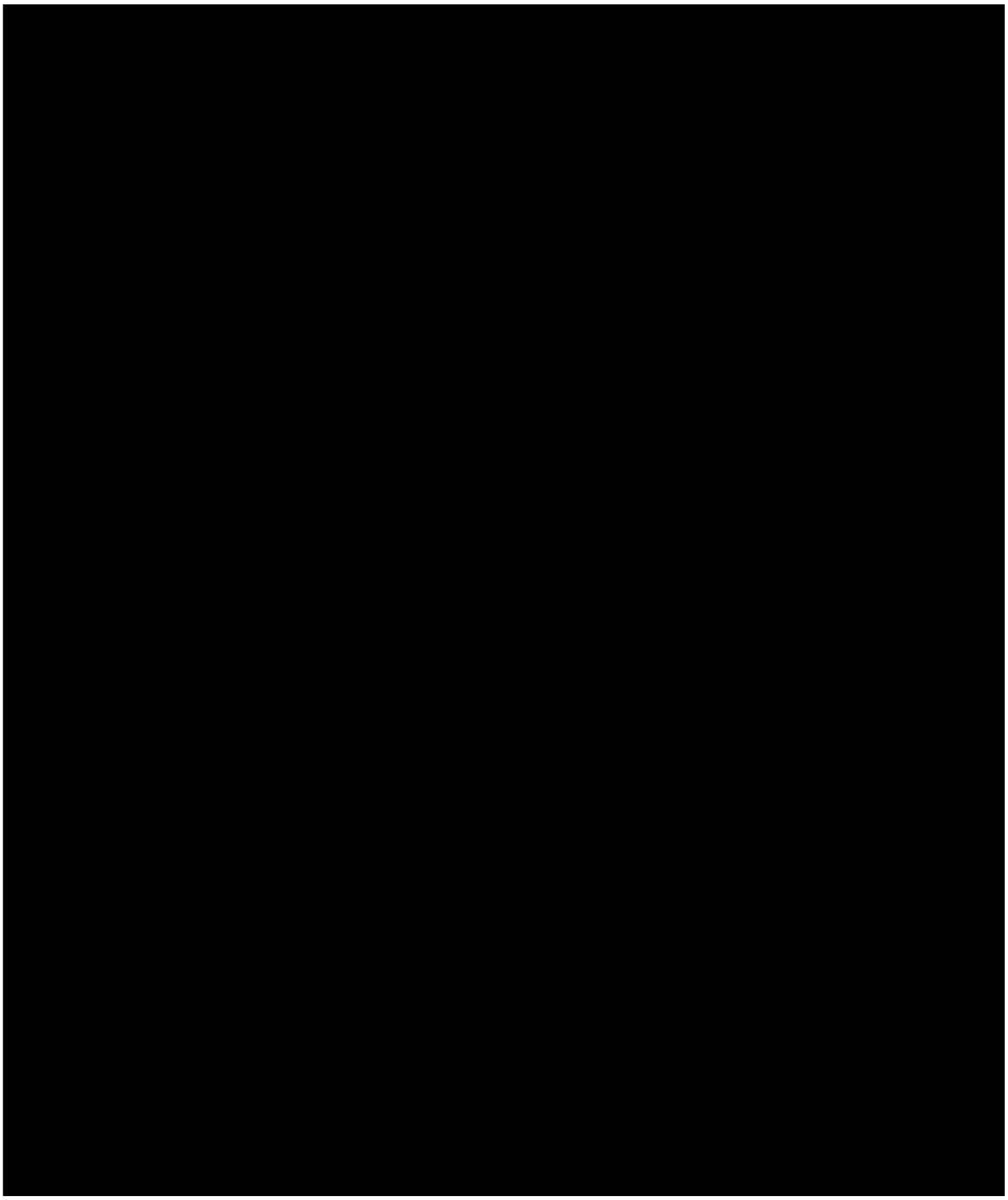
Section 4.1(3)(a) **Annex Point IIA 4.1**	**Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – Active Substance (HPLC-ELSD)**
Remarks	
	COMMENTS 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*

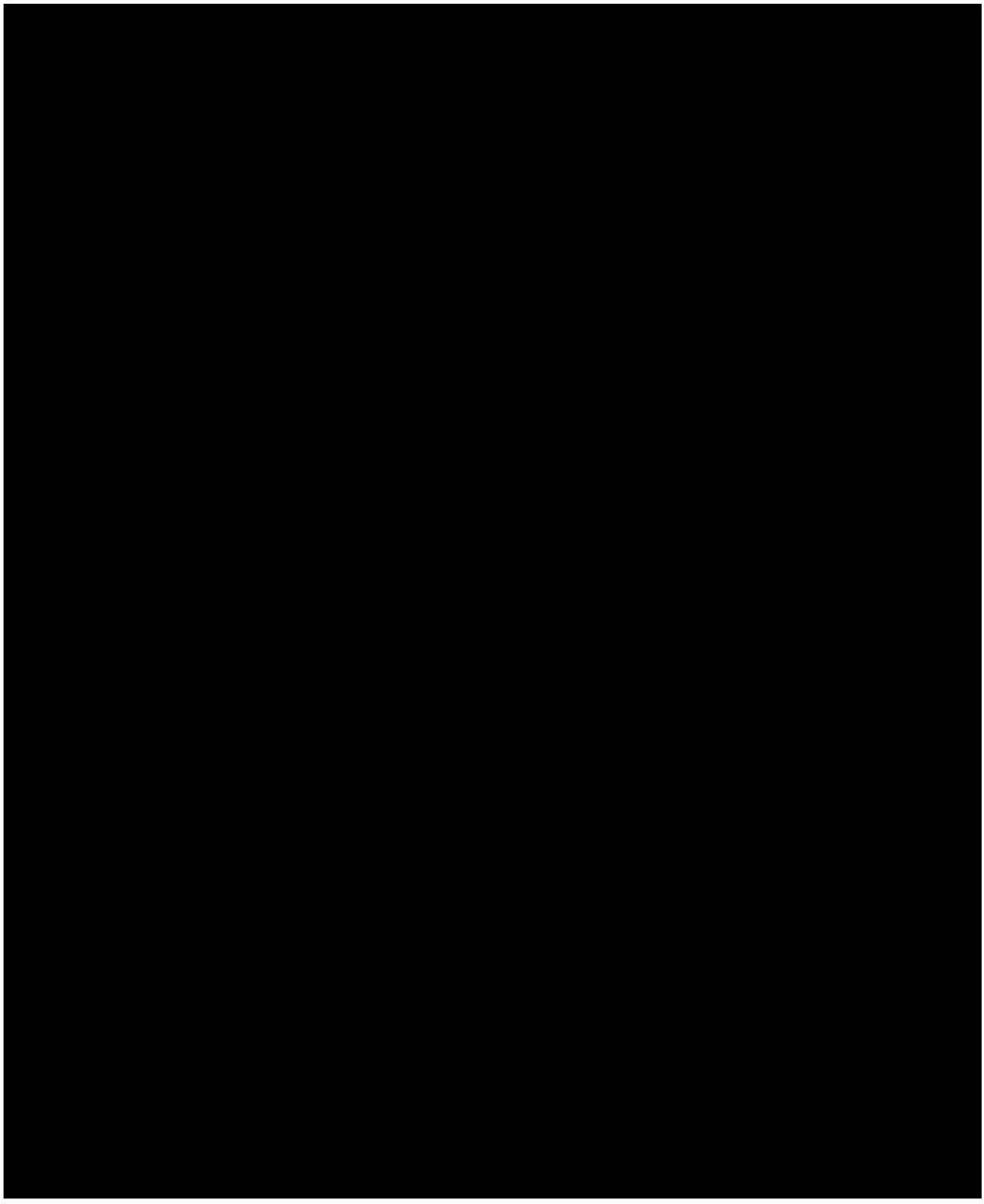
[redacted]











Section 4.1(3)(b) and **Section 4.1(3)(c),** describing analytical methods for impurities and process solvents in commercially available technical concentrate Maquat MC1412-50% (C_{12-16}-ADBAC nominal content: 50% w/w), contain commercially sensitive information. Therefore, both sections have been moved into the ***Confidential Data.***

Section 4.2a(1) Annex Point IIA 4.2		**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**	
		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).* Brewin, S. (2003). Alkydimethylbenzylammonium Chloride (ADBAC: CAS RN 68424-85-1). Validation of methodology for the determination of residues in soil. Report No. ADB016/033181. Huntingdon Life Sciences, Ltd. (Unpublished). [Ref No.: A65 (LON 3703)]	
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 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 2003 *(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]	

Section 4.2a(1) **Annex Point IIA 4.2**		**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**	
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 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).	
3.1.6	Test procedure	Soil samples were extracted with methanol:water (90:10 v:v) containing 0.01 m ammonium formate and 0.1% formic acid. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
3.1.7	Soil types	Sandy loam and clay loam	
3.1.8	Calibration standards	0.5 – 20 ng/ml; Linearity = 0.9991	
3.1.9	Validation range	0.01 to 0.1 mg/kg (5 replicates/concentration)	
		4. RESULTS	
4.1	**Accuracy data**	See Table 4.2a(1)-1	
4.2	**Limit of quantitation (LOQ)**	0.01 mg/kg	
4.3	**Limit of detection (LOD)**	0.5 ng/ml (equivalent to 0.005 mg/kg in soil)	
4.4	**Remarks**	The test substance can be accurately determined in soil at a limit of quantitation of 0.01 mg/kg. The limit of detection of the test substance in soil was 0.005 mg/kg using this method.	
		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*	

Section 4.2a(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil**	
	relevant in this table. The study was carried out in accordance with 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines to validate analytical methods in clay loam and sandy loam soil samples. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The mean recovery of Alkyldimethylbenzylammonium Chloride in clay loam was 82% (cv 5.4%) and 84% in sandy loam (cv 4.7%). The limit of quantitation was 0.01 mg/kg and the limit of detection was 0.005 mg/kg.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* 0.01 mg/kg of the test substance can be accurately detected in soil.	
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 4.2a(1) Annex Point IIA 4.2	Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (a) Soil
Materials and Methods	[redacted]
Results and discussion	
Conclusion	

Section 4.2a(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(a) Soil**
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*

Table 4.2a(1)-1. Recovery data

Clay loam			Sandy loam		
Recovery range (%)	**Mean recovery (%)**	**CV (%)**	**Recovery range (%)**	**Mean recovery (%)**	**CV (%)**
76-90	82	5.4	78-91	84	4.7

Section 4.2b Annex Point IIA.4.2b	Analytical methods for environmental media (air)	
	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]	X
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	27/04/2006	
Evaluation of applicant's justification	[redacted]	
Conclusion	The Applicant justification is accepted	

Section 4.2b **Annex Point IIA.4.2b**	**Analytical methods for environmental media (air)**
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 4.2c(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) 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).* Brewin, S. (2003) Alkydimethylbenzylammonium Chloride (ADBAC: CAS RN 68424-85-1). Validation of methodology for the determination of residues in drinking, ground and surface water. Report No. ADB017/033171. Huntingdon Life Sciences, Ltd. (Unpublished) [Ref No.: A82 (LON 3698)]	
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 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 2003 *(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	*List lot/batch number where relevant*	

Section 4.2c(1) **Annex Point IIA 4.2**		**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) Water**	
number		[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 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	**Test procedure**	Water samples were partitioned with 0.1 m heptanesulfonic acid and dichloromethane, then concentrated by rotary evaporation and redissolved in 0.1% formic acid in methanol. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
3.2.1	Water types	Drinking, ground and surface water	
3.2.2	Calibration standards	1.0 – 50 ng/ml; Linearity = 0.9963	
3.2.3	Validation range	0.1 – 1.0 µg/L (5 replicates/concentration)	
		4. RESULTS	
4.1	**Accuracy data**	See Table 4.2c(1)-1	
4.2	**Limit of quantitation (LOQ)**	0.1 µg/L	
4.3	**Limit of detection (LOD)**	1.0 ng/ml (equivalent to 0.01 µg/L in drinking, ground and surface water)	
4.4	**Remarks**	The test substance can be accurately determined in water at a limit of quantitation of 0.1 µg/L. The limit of detection of the test substance in water was 1.0 µg/ml using this method.	

Section 4.2c(1) **Annex Point IIA 4.2**		**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) Water**	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 and	**Materials 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.* The study was carried out in accordance with 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines to validate analytical methods in drinking, ground and surface water samples. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* The mean recovery of Alkyldimethylbenzylammonium Chloride in drinking water was 92% (cv 8.1%), surface water was 82% (cv 6.8%) and ground water was 88% (cv 8.0%). The limit of detection was 1.0 ng/ml (equivalent to 0.01 µg/L). The limit of quantitation was 0.1 µg/L.	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* 0.1 µg/L of the test substance can be accurately detected in water.	
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 4.2c(1) Annex Point IIA 4.2	Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water
Materials and Methods	[redacted]
Results and discussion	
Conclusion	