Section 3.8(1) Annex Point III-A 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,N-Didecyl-N,N-dimethylammonium Chloride (DDAC) Stability in Ethanol and Isopropanol. Huntingdon Life Sciences Ltd, Huntingdon. Report No DKG/012. (unpublished) Ref No. D94 (LON 3803)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes The study was designed to comply with 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. Year: 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]	

Section 3.8(1) Annex Point III-A 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5) *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 system		
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 system	[redacted]	
3.4 Chromatography conditions		
3.4.1 Mobile phase	[redacted]	

Section 3.8(1) Annex Point III-A 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
gradient	[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 = -3.97% Isopropanol = -1.11%	
4.1.2 Regression value	0.99994	
4.1.3 % RSD	1.8825	
	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* Under the conditions of the test, the test substance was found to be stable.	
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 3.8(1) Annex Point III-A 3.8	Stability in organic solvents used in biocidal products and identity of relevant breakdown products	
	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 (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*	

Section 3.8(1) Annex Point III-A 3.8	**Stability in organic solvents used in biocidal products and identity of relevant breakdown products**	
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(1) 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(1) Annex Point IIA 3.9	Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature
	[redacted]

Section 3.9(1) Annex Point IIA 3.9	Partition coefficient n-octanol-water including effect of pH (5 to 9) and temperature	
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 acceptable	
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 Dodigen 1881 AS (Bardac 22 AS) in accordance with OECD-Guideline 113. Report No. B 012/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D95 (LON 3449)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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")*	
	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 3.10 (1) **Annex Point IIA 3.10**		**Thermal stability, identity of relevant breakdown products**	
		[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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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**	In the three tests conducted in sealed glass-crucibles in air atmosphere and in the other two tests conducted in nitrogen atmosphere no endothermal or exothermal peaks were observed.	
		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 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]	

Section 3.10 (1) **Annex Point IIA 3.10**	**Thermal stability, identity of relevant breakdown products**	
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 (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 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 Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC-Guideline A.16. Report No. B 022/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D96 (LON 3446)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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* DD 00/004	
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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 self-ignition temperature of the test substance was observed approximately at 195°C. The maximum temperature to which the sample was exposed was 500°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]	
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 self-ignitable according to the Directive	X

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)**	
	[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 (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*	

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 Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC-Guideline A.10. Report No. B 021/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D97 (LON 3447)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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")*	
	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 (2) **Annex Point IIA 3.11**		**Flammability including auto-flammability and identity of combustion products (Determination of Flammability)**	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* DD 00/004	
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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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.	X

Section 3.11 (2) Annex Point IIA 3.11		Flammability including auto-flammability and identity of combustion products (Determination of Flammability)	
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	
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	[redacted]
	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 3.11 Annex Point IIA.3.1	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:	[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 acceptable	
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 3.12 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]	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	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The Applicant justification is acceptable.	
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, S. (2001) Determination of the Surface Tension of an Aqueous Solution of Dodigen 1881 AS (Bardac 22 AS) in accordance with OECD-Guideline 115. Report No. B 023/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D98 (LON 3448)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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; 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	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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 27.0 mN/m at 20°C and a concentration of 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 considered to be surface active.	
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 (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 3.14 (1) Annex Point IIA 3.14	Viscosity	
	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. (2003) Determination of the Viscosity of Bardac 22/Dodigen 1881 in accordance with OECD Guideline 114 Report No. B 019/2003; for Clariant GmbH, Industriepark Höechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D135 (LON 3660)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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. 114 –Viscosity of liquids Year: 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 3.14 (1) **Annex Point IIA 3.14**		**Viscosity**	
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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Method**	OECD Guideline No. 114 -Viscosity of liquids	
		4. RESULTS	
4.1	**Results**	Kinematic viscosity: 24.5 mm^2/s @ 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]	
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 kinematic viscosity of [redacted] was found to be 24.5 mm^2/s @ 20°C.	
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 3.14 (1) Annex Point IIA 3.14	Viscosity	
	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 (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 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 Dodigen 1881 AS (Bardac 22 AS) in accordance with EEC-Guideline A.14. Report No. B 024/2001; for Clariant GmbH, Industriepark Hoechst, Frankfurt, Deutschland (sponsor); from AllessaChemie GmbH – Werk Cassella-Offenbach, Analytik, Frankfurt, Deutschland testing facility (unpublished). Ref No. D99 (LON 3445)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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.	
	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	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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5). *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 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 test substance is not classified as explosive.	
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 3.15 (1) Annex Point IIA 3.15	Explosive properties	
	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 (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*	

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 3.15 (2) Annex Point IIA 3.15	Explosive 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 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 acceptable	

Section 3.15 (2) Annex Point IIA 3.15	Explosive properties
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 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]	

Section 3.16 Annex Point IIA.3.16	Oxidising properties	
	[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 acceptable	
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
	Reactivity towards container material: Chemical compatibility according to test guideline AV 90.1, TRV 002, A and B Date of investigation: a) [redacted] b) [redacted] Reference: Internal data of manufacturer Test substance: a) [redacted] Didecyldimethylammonium Chloride (DDAC)) b) [redacted] Didecyldimethylammonium Chloride (DDAC)) Test material: a) Polyethylene, Type Hostalen GM 6255 b) Polyethylene, Type Hostalen GM 7746 c) Polyethylene, Type Hostalen GM 7745 Results: Tests A and B positive. Resistance against the test materials confirmed. Metals: Tests have shown that stainless steel is satisfactory at normal handling temperatures. For higher temperatures, stainless steel, containing 6% or more molybdenum (Rolled alloys AL-6XN, Avesta 254-SMO, INCO 25-6MO) provides significantly more corrosion resistant. Because these alloys are more expensive; overall economics must be considered for their use. Plastics: 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	[redacted]	
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		
3.1.3 Description		
3.1.4 Purity		
3.1.5 Stability		

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]
3.2 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	
4.2 Remarks	
5.1 Materials and methods	
5.2 Results and discussion	
5.3 Conclusion	

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

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)**
Materials and Methods	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	

Table 4.1(1)-1. Other analytical methods included in this study

[redacted]

Table 4.1(1)-2. Alkyl chain Length Distribution of Quaternary Ammonium Chlorides – Chromatography results

[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)	
	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 Lot/Batch number		
3.1.2 Specification		
3.1.3 Description		
3.1.4 Purity		
3.1.5 Stability		

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)	
3.2 Test substance	[redacted]	
3.2.1 Concentration		
3.2.2 Vehicle		
3.3 Chromatograph details		
3.3.1 Autosampler		
3.3.2 Pump		
3.3.3 Conductivity detector		
3.3.4 Column		
3.3.5 Data capture system		
3.4 Chromatography conditions		
3.4.1 Mobile phase gradient		
3.4.2 Mobile phases		
3.4.3 Flow rate		
3.4.4 Temperature		
3.4.5 Injection volume		
3.5 Remarks		
4.1 Chromatography results		
4.2 Remarks		

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)	
	[redacted]	
5.1 Materials and methods		
5.2 Results and discussion		
5.3 Conclusion		
5.3.1 Reliability		
5.3.2 Deficiencies		
Evaluation by Competent Authorities		
	[redacted]	
Date		
Materials and Methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability		

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)**
Remarks	[redacted]
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	

Table 4.1(2)-1. Chromatography results

[redacted]

Section 4.1(3) 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]	Official use only
1.1 Reference		
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(3) **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 system		
3.3.2 Column		

Section 4.1(3) **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**	
3.3.3 Detector	[redacted]	
3.3.4 Mobile phase and gradient		
3.3.5 Conditions		
4.1 Results		
4.1.1 Precision (repeatability and replicate injections)		

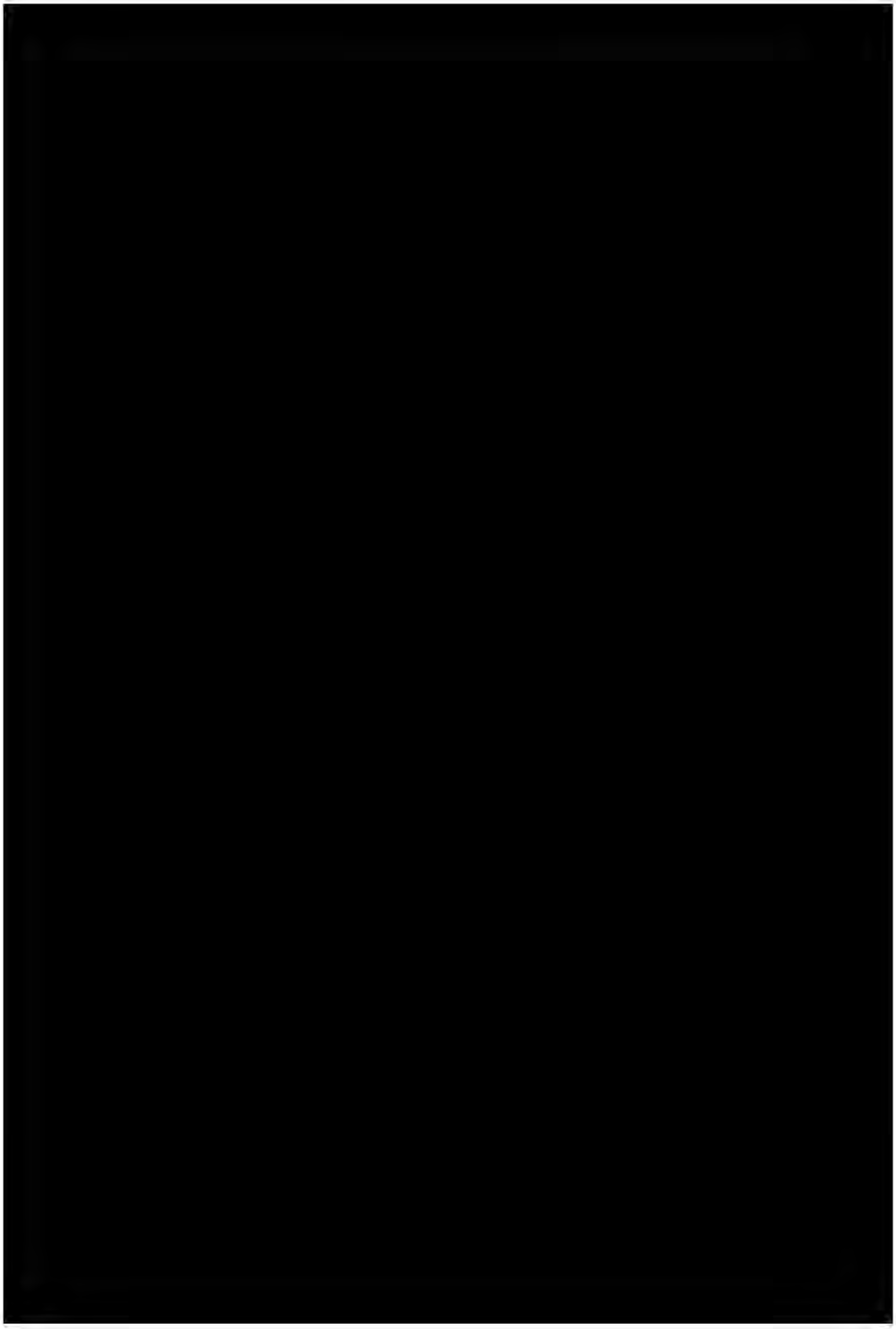
Section 4.1(3) Annex Point IIA 4.1		Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – **HPLC-ELSD**
		[redacted]
4.1.2	Accuracy	
4.1.3	Non-analyte interference	
4.1.4	Sensitivity	
4.1.5	Specificity	

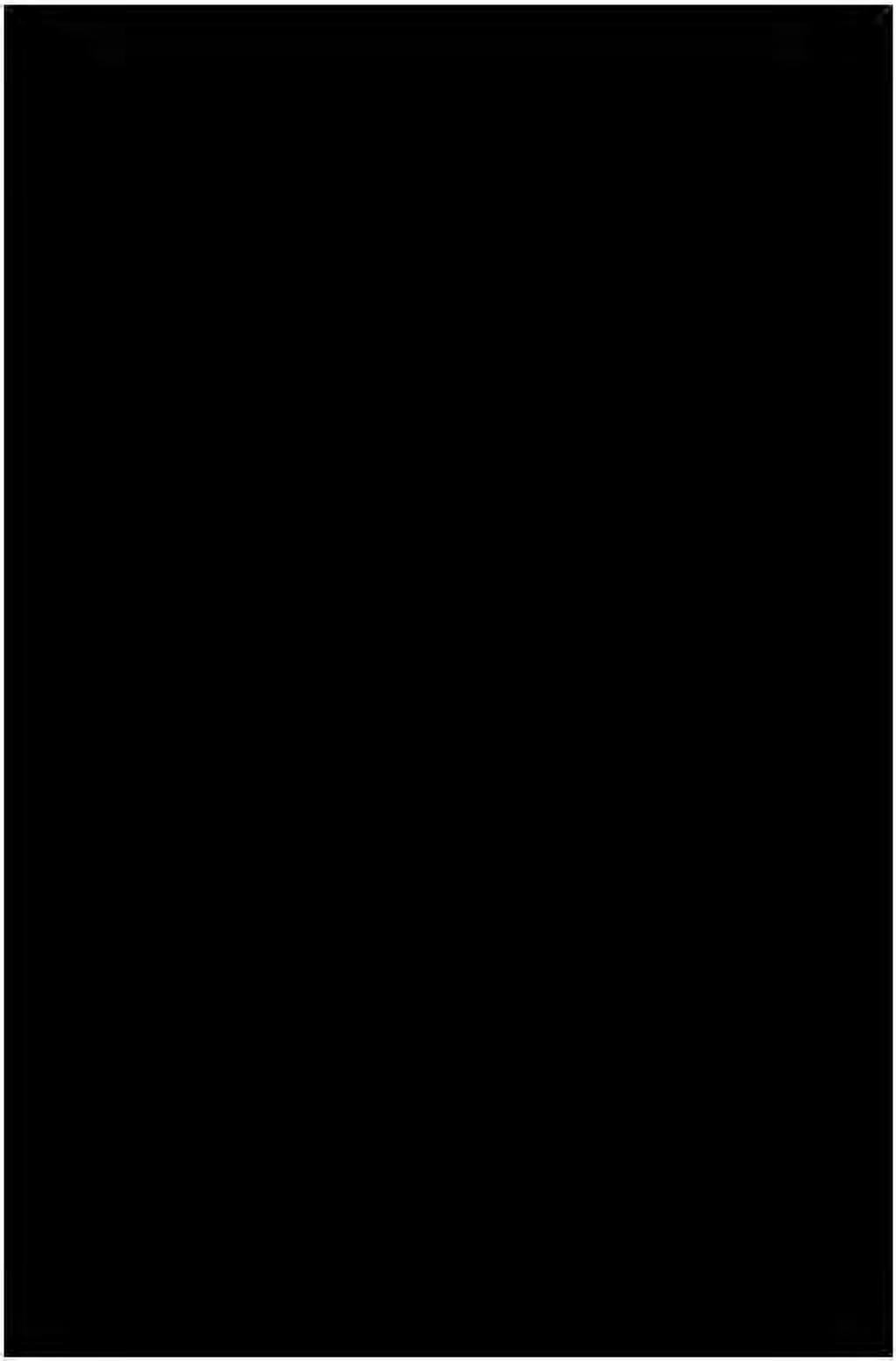
Section 4.1(3) Annex Point IIA 4.1	Analytical methods for the determination of pure active substance and, where appropriate, for relevant degradation products, isomers and impurities of active substances and their additives (e.g. stabilisers) – HPLC-ELSD	
	[redacted]	
4.2 Remarks		
5.1 Materials and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

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*





[redacted]

Section 4.1(4)(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)	
1.1 Reference	[redacted]	Official use only 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)		X1
3.1.2.1 Lot/Batch number		
3.1.2.2 Specification		
3.1.2.3 Description		
3.1.2.4 Purity		X2
3.1.2.5 Stability		

Section 4.1(4)(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)	
3.1.1 Reference Standard	[redacted]	X3
3.1.1.1 Lot/Batch number		
3.1.1.2 Purity		
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
		X6

Section 4.1(4)(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]	X7
3.3.4 Specificity		X8
4.1 Results		
5.1 Materials and methods		X
5.2 Results and discussion		
5.3 Conclusion		
5.3.1 Reliability		X
5.3.2 Deficiencies		X

Section 4.1(4)(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)
Evaluation by Competent Authorities	
	[redacted]
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	

Section 4.1(4)(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]
Remarks	

Section 4.1(4)(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)**
	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 4.1(4)(a)-1: HPLC-ELSD Operating Conditions for Determination of Active Substance (DDAC)

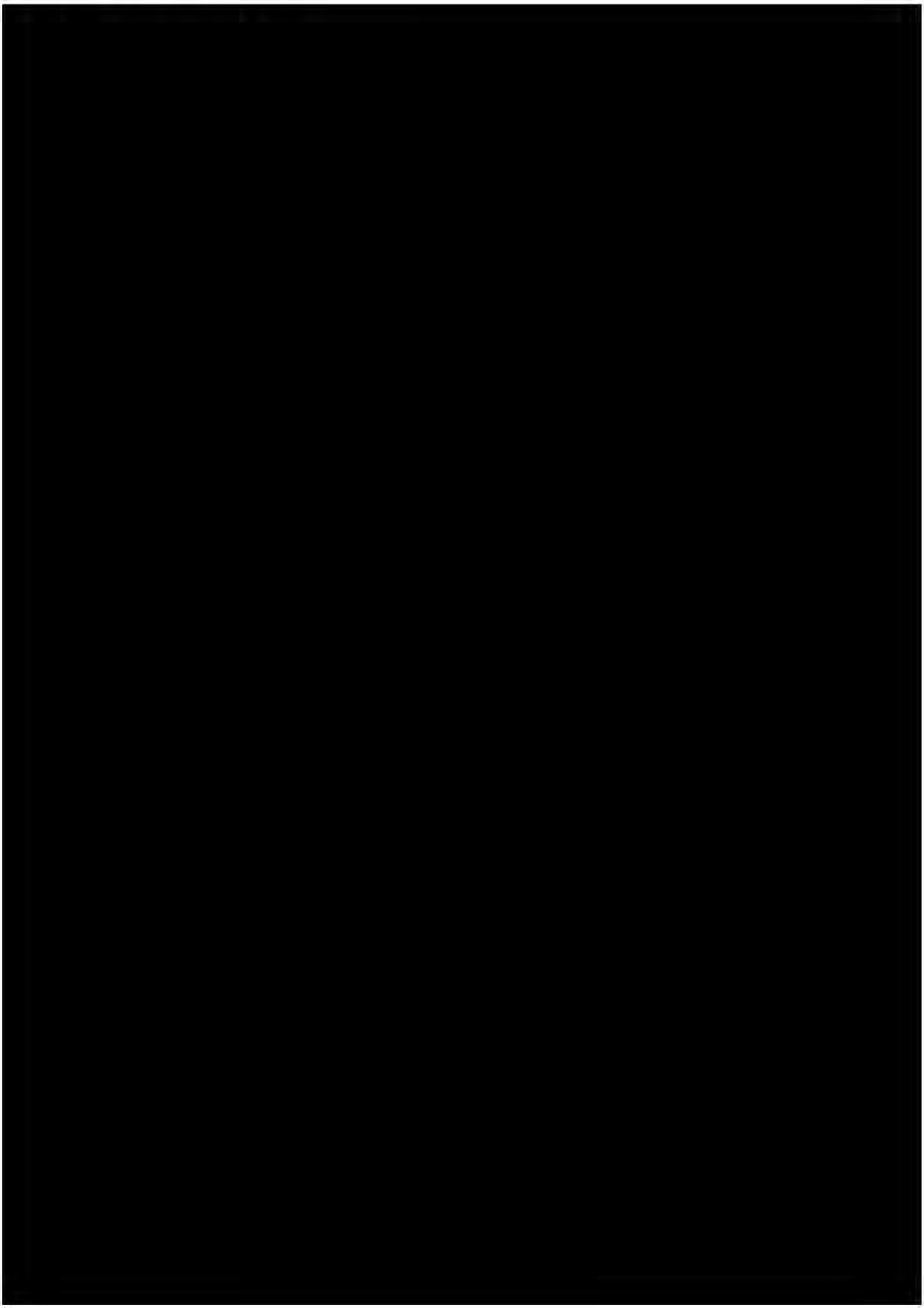
[redacted]

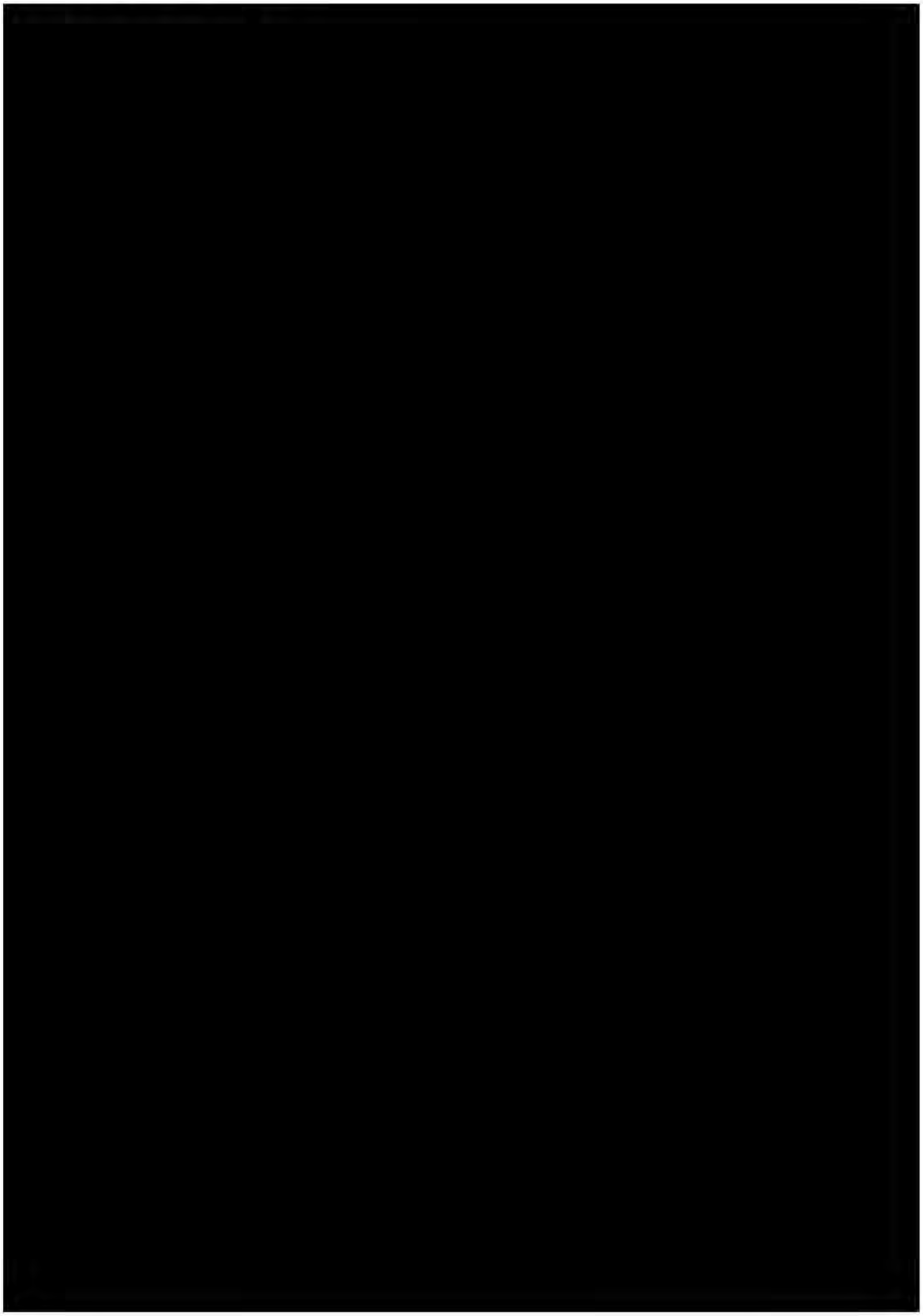
Table 4.1(4)(a)-2: Liquid Chromatography-Mass Spectrometry (LC-MS) Operating Conditions for the Active Substance (DDAC)

[redacted]

Table 4.1(4)(a)-3: Summary of Validation of Methods for Determination of the Active Substance (DDAC)

[redacted]





Section 4.1(4)(b) and **Section 4.1(4)(c),** describing analytical methods for impurities and process solvents in commercially available technical concentrate [redacted], 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) Didecyldimethylammonium Chloride (DDAC: CAS RN 7173-51-5) Validation of Methodology for the Determination of Residues in Soil. Report No. ADB014/033180. Huntingdon Life Sciences, Ltd. (Unpublished) Ref No.: D46 (LON 3701)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
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 exiting a.s. for the purpose of its entry into Annex I.	
	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	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.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
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., DDAC, 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 seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**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).	
3.2.1	Soil types	Sandy loam and clay loam	
3.2.2	Calibration standards	1.0 - 50 ng/ml	x
3.2.3	Validation range	0.01-0.1 mg/kg	
		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)**	0.2 ng/ml (equivalent to 0.002 mg/kg in soil)	
4.4	**Remarks**	Didecyldimethylammonium Chloride can be accurately determined in soil at a limit of quantitation of 0.01 mg/kg. The limit of detection of Didecyldimethylammonium Chloride in soil was 0.002 mg/kg for this method.	
		5. APPLICANT'S SUMMARY AND 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**	
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.* 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 Didecyldimethylammonium Chloride in clay loam was 81% (cv 6.4%) and 99% in sandy loam (cv 4.4%). The limit of quantitation was 0.01 mg/kg and the limit of detection was 0.002 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	[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**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	3.2.2.Calibration was actually performed in the range 0.2/20 ng/ml
	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 4.2a(1)-1. Recovery data

Clay loam			Sandy loam		
Recovery range (%)	**Mean recovery (%)**	**CV (%)**	**Recovery range (%)**	**Mean recovery (%)**	**CV (%)**
73 - 88	81	6.4	92 - 106	99	4.4

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** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **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 acceptable.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 4.2b Annex Point IIA.4.2b	Analytical methods for environmental media (air)
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	