Section 7.4.1.3 (2) Annex Point IIA 7.4.1.3	Growth inhibition test on algae
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Not 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 7.4.1.3 (3) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
	1. REFERENCE	Official use only
1.1 Reference	Desjardins, D., T.Z. Kendall, R. L. VanHoven and H.O. Krueger (2003). Bardac 2280: A 96-Hour Toxicity Test with the freshwater Alga (*Selenastrum capricornutum*) Using Natural Surface Water. Wildlife International, Ltd., Easton, MD, U.S.A. Report Number 289A-153. (unpublished). Ref No. D66 (LON 3659)	X
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. 201, Council of European Communities Directive Guideline C.3 U.S. EPA OPPTS 850.5400 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	Didecyldimethylammonium Chloride	

Section 7.4.1.3 (3) Annex Point IIA 7.4.1.3		Growth inhibition test on algae	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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* Stable	X
3.1.6	Method of analysis	[redacted]	
3.2	**Testing procedure**		
3.2.1	Dilution water	[redacted]	
3.2.2	Test organisms	Freshwater green algae (*Selenastrum capricornutum)*	
3.2.3	Test system	[redacted]	
3.2.4	Test conditions	Static [redacted]	
3.2.5	Duration of the	96 hours	

Section 7.4.1.3 (3) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
test		
3.2.6 Test parameter	Growth and growth rate	
3.4.7 Monitoring of test substance concentration	[redacted]	
3.4.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results test substance		
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentrations of test substance	[redacted]	
4.2.3 Effect data (Mortality)	96-hr ErC_{50} = 151 (µg/l); 95% confidence limits = (129 – 176) (µg/l) 96-hr EbC_{50} = 145 (µg/l); 95% confidence limits = (122 – 171) (µg/l)	
4.2.4 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Effect data (Mortality) and other effects	[redacted]	
	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.* Results based on cell densities: There was a 6-fold increase in the EC_{50} values in comparison to a concurrent study performed with river water algal medium (the EC_{50}ws found to be 26 µg/l run with the river water algal medium; in this study	

Section 7.4.1.3 (3) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
	the EC_{50} for cell density and biomass were 105 and 145 µg/l respectively). This observation indicates that river water algal medium has potential to mitigate toxicity. Results based on biomass: Based on the growth data, the test substance was found to be algistatic rather than algicidal.	
5.2.1 72-hr EC10 (µg/l) with 95% confidence limits	ErC_{10} = 62 (39- 98) EbC_{10} = 69 (45 - 104)	
5.2.2 72-hr EC50 (µg/l) with 95% confidence limits	ErC_{50} = 130 (103 – 165) EbC_{50} = 137 (110 – 169)	
5.2.3 72-hr EC90 (µg/l) with 95% confidence limits	ErC_{90} = 274 (223 – 336) EbC_{90} = 272 (226 – 327)	
5.2.4 96-hr EC10 (µg/l) with 95% confidence limits	ErC_{10} = not calculable EbC_{10} = 77 (55 – 107)	
5.2.5 96-hr EC50 (µg/l) with 95% confidence limits	ErC_{50} = 151 (129 – 176) EbC_{50} = 145 (122 – 171)	
5.2.6 96-hr EC90 (µg/l) with 95% confidence limits	ErC_{90} = 276 (241 -316) EbC_{90} = 272 (235 – 315)	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the no-observed-effect concentration (NOEC) was found to be 82 µg/l for both biomass production and growth rate.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	X
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	

Section 7.4.1.3 (3) Annex Point IIA 7.4.1.3	Growth inhibition test on algae
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	
Conclusion	
Reliability	[redacted]
Acceptability	*For the purposes of Dir. 98/8, a study on algae growth using natural surface water is not due. Data would not be used in this context.*
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 7.4.1.3 Annex Point III-A.7.4.1.3	Growth inhibition test on algae (marine)	
	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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	*The applicant's justification is acceptable*	
Remarks		

Section 7.4.1.3 Annex Point III-A.7.4.1.3	Growth inhibition test on algae (marine)
	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 7.4.1.4 (1) Annex Point IIA 7.4.1.4		Inhibition to microbial activity	
		1. REFERENCE	Official use only
1.1	**Reference**	Mead, C. (2001) LZ1043 (Didecyldimethylammonium Chloride): Assessment of the inhibitory effect on the respiration of activated sewage sludge. Report No. 102-369 from Safepharm Laboratories Limited, Derby, UK (unpublished). Ref No. D117 (LON 3330)	
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 for its entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes OECD Guideline No. 209 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")*	X
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**	Didecyldimethylammonium Chloride	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition to microbial activity	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
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]	X
3.1.5 Stability	*Describe stability of test material* Stable	X
3.1.6 Method of analysis	[redacted]	
3.1.7 Method of analysis for test substance	[redacted]	
3.18 Reference substance	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Activated sludge of a predominantly domestic sewage	
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	[redacted]	

Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition to microbial activity	
3.2.5 Duration of the test	3 hours	
3.2.6 Test parameter	Inhibition on respiration rate	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	X
	4. RESULTS	
4.1 Limit test	No	
4.2 Results test substance		
4.2.1 Initial concentration of test substance	[redacted]	X
4.2.2 Actual concentrations of test substance	[redacted]	
4.3 Test with reference substance		
4.3.1 Concentrations	[redacted]	
4.3.2 Results	[redacted]	
	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.*	
5.2.1 EC50	3-hour EC_{50} = 11 mg/l	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the no-observed-effect concentration (NOEC) was 5 mg/l.	X
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	

Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition to microbial activity
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
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	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 7.4.2 Annex Point IIA 7.4.2	Bioconcentration	
	1. REFERENCE	Official use only
1.1 Reference	Fackler, P.H. (1990) Bioconcentration and Elimination of ^{14}C-residues by Bluegill (Lepomis machrochirus) Exposed to Didecyldimethylammonium Chloride (DDAC). Report no. 89-7-3043. Springborn Laboratories, Inc., Wareham MA, USA (unpublished). Ref No. D43 (LON 1790)	
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 before 14 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 U.S. EPA Guideline 165-4 Year: 1989 *(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")*	X
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	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA.	X

Section 7.4.2 Annex Point IIA 7.4.2	Bioconcentration	
	[redacted] *(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]	X
3.1.5 Stability	*Describe stability of test material* Stable	X
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Bluegill (*Lepomis macrochirus*) [redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	
3.4.5 Duration of the test	28 days exposure period + 18 days depuration period	
3.2.6 Test parameter	Bioconcentration factor	X
3.2.7 Sampling	[redacted]	

Section 7.4.2 Annex Point IIA 7.4.2	Bioconcentration	
	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	X
3.2.9 Statistics		
	4. RESULTS	
4.1 Limit test	No	
4.2 Results test substance		
4.2.1 Initial concentration of test substance	[redacted]	X
4.2.2 Actual concentrations of test substance	[redacted]	X
4.2.3 Effect data (Mortality)	Five treated fish died during the exposure test and no fish died during depuration.	X
4.2.4 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals showing adverse effects	[redacted]	
4.3.2 Nature of adverse effects	[redacted]	

Section 7.4.2 **Annex Point IIA 7.4.2**	**Bioconcentration**	
	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.*	
5.2.1 Edible tissue	BCF = 38 (predicted 52) Elimination after 14 Days 57% Elimination after 18 Days 38%	X
5.2.2 Non-edible tissue	BCF = 140 (predicted 160) Elimination after 14 Days 71% Elimination after 18 Days 66%	X
5.2.3 Whole-body	BCF = 81 (predicted 95) Elimination after 14 Days 67% Elimination after 18 Days 56%	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Skin tissue showed ^{14}C-residues 2 to 6 times higher than edible tissue portions. The test substance may bind significantly to skin and scales of exposed fish. Of the accumulated ^{14}C-residue in the edible tissue of bluegill exposed 28 days to the test substance, 65.5% was extractable with a polar solvent (methanol), 8.1% was extractable with a nonpolar solvent (hexane) and 25.9% was not extractable with either solvent.	
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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.4.2 Annex Point IIA 7.4.2	Bioconcentration
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable*

Section 7.4.2 Annex Point IIA 7.4.2	Bioconcentration
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*

Table 7. Measured ^{14}C-Residue Concentrations, Calculated as DDAC in the Edible (muscle/skin) and Nonedible (viscera/carcass) Tissue of Bluegill (Lepomis macrochirus) During 28 Days of Continuous Aqueous Exposure to DDAC.

Day	Mean (S.D.) Water Concentration (µg/L)[a]	Mean (S.D.) ^{14}C-Residue Tissue Concentration (µg/kg)[b]		
		Edible	Nonedible	Whole Body
0	66 (1)	TNS	TNS	TNS
3	51 (9)	—[c]	—[c]	—[c]
3	64 (1)[d]	TNS	TNS	TNS
4	92 (7)[d]	1600 (770)	7500 (2100)	3800 (1400)
10	130 (9)	3900 (650)	16000 (3100)	8600 (1600)
11	86 (20)	TNS	TNS	TNS
17	100 (10)	3200 (1000)	14000 (1100)	7500 (990)
24	150 (29)	3200 (1300)	12000 (2900)	6500 (2000)
28	100 (13)	3900 (930)	12000 (3000)	7200 (1800)

TNS = Tissue Not Sampled
[a] Mean and standard deviation (S.D.) based on radiometric analysis of triplicate water samples.
[b] Mean (S.D.) based on analysis of tissue portions of 5 fish.
[c] Sampling delayed to day 4 due to diluter malfunction.
[d] Extra sampling of treated aquaria water, following diluter inconsistency.

Figure 3. A Comparison of Measured Tissue Concentrations of DDAC Versus Those Predicted by the Model for Whole Body in Bluegill (Lepomis macrochirus).

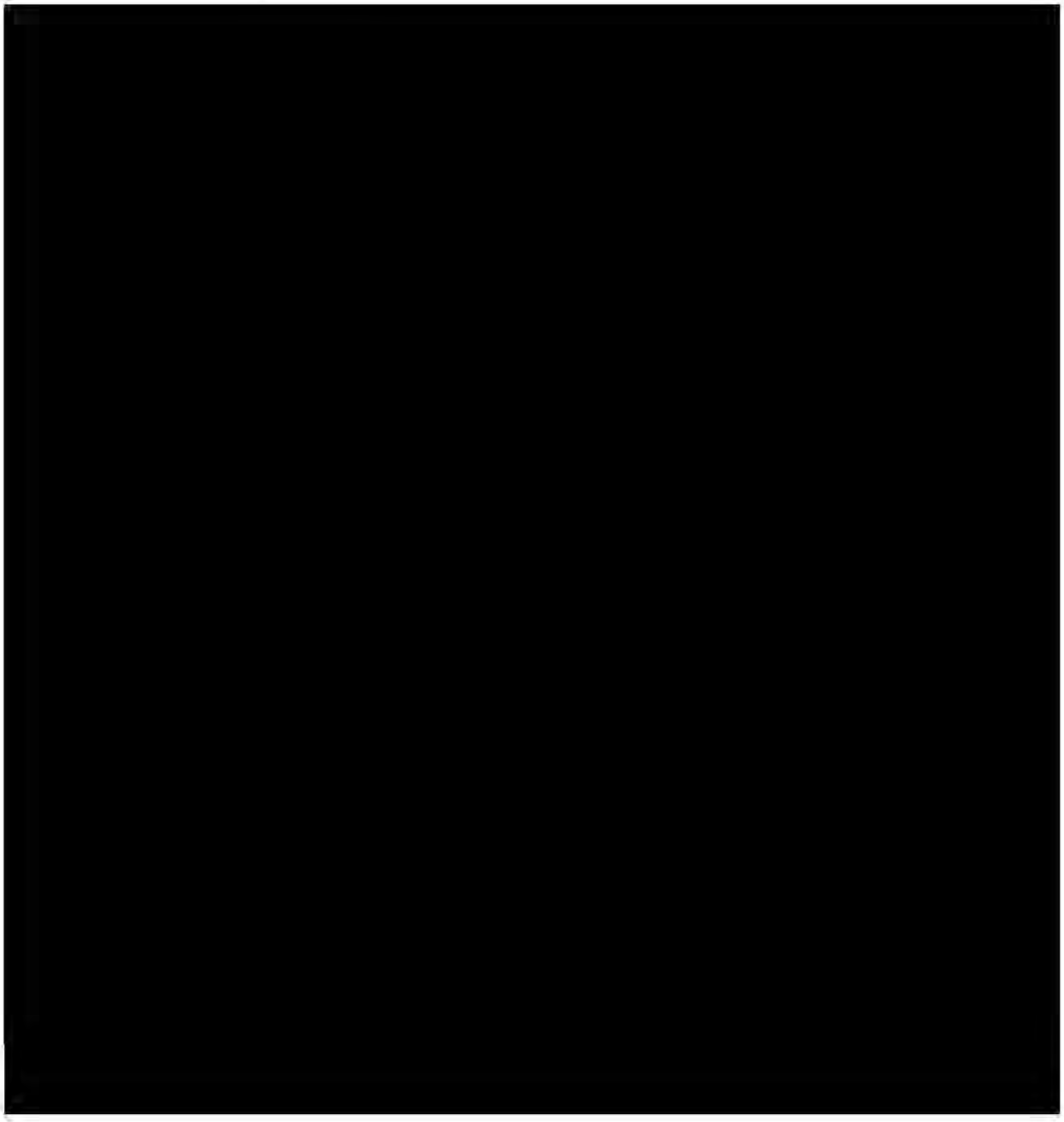

Table 8. Measured ^{14}C-Residue Concentrations, Calculated as DDAC in the Edible (muscle/skin) and Nonedible (viscera/carcass) Tissue of Bluegill (Lepomis macrochirus) During 18 Days Depuration in Flowing, Uncontaminated Water Following 28 Days of Continuous Aqueous Exposure to DDAC.

Day	Mean (S.D.) Water Concentration (µg/L)[a]	Mean (S.D.) ^{14}C-Residue Tissue Concentration (µg/kg)[b]		
		Edible	Nonedible	Whole Body
3	< 11	3100 (870)	9300 (3200)	5300 (1600)
7	< 11	3600 (1300)	8900 (1500)	5600 (1100)
14	< 11	1700 (410)	3600 (1000)	2400 (630)
18	< 11	2400 (1100)	4200 (1900)	3100 (1500)

[a] Mean and standard deviation (S.D.) based on radiometric analysis of triplicate water samples.

[b] Mean (S.D.) based on analysis of tissue portions of 5 fish.

Section 7.4.3.1 Annex Point III-A.7.4.3.1	**Prolonged toxicity to fish**	
	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 [X] **Limited exposure [ ]**	**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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	*Accepted*	
Conclusion	[redacted]	
Remarks		

Section 7.4.3.1 Annex Point III-A.7.4.3.1	Prolonged toxicity to fish
	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 7.4.3.2 (1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
	1. REFERENCE	Official use only
1.1 Reference	Hooftman, R.N., H.Q.M. de Vette and B.Borst (2001). Early Life Stage Test under intermittent flow-thorugh conditions with Didecyldimethylammonium Chloride and the fish species, *Brachydanio rerio* (OECD Guideline No. 210). Report No. 99-9048-03. TNO Chemistry, Delft, The Netherlands (unpublished). Ref No. D118 (LON 3373)	
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. 210 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	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted] [redacted]	

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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]	X
3.1.5 Stability	*Describe stability of test material* Stable	X
3.2 Test procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organism	Zebra fish (*Brachydanio rerio*) [redacted]	
3.2.3 Test system	[redacted] intermittent flow-through system [redacted]	
3.2.4 Test conditions	[redacted]	
3.2.5 Exposure period	34 days	
3.2.6 Test parameter	Hatching, mortality, morphological and behavioural development, body weight and body length	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	
3.3. Environmental parameters		

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
3.3.1 pH	[redacted]	
3.3.2 Lowest oxygen concentration	[redacted]	
3.3.3 Temperature	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results of test substance		
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentration of test substance	[redacted]	
4.2.3 Hatching	The test substance had no effect on hatching.	
4.2.4. Mortality	See table 7.4.3.2(1)-2. All fish died at a test substance concentration of 320 µg/l.	
4.2.5 Behavioural observations	At 100 µg/l fish were observed swimming on the surface. No other observations were made at any other test substance concentrations.	
4.2.6 Morphological observations	No morphological observations were made.	
4.2.7 Body lengths	See table 7.4.3.2(1)-3. The test substance had no effect on body lengths.	
4.2.8 Body weights	See table 7.4.3.2(1)-3 Body weights appeared to increase at 100 µg/l.	
4.3 Statistics		
4.3.1 LC_{50}	81µg/l (95% confidence interval = 70 – 93µg/l)	X
4.3.2 NOEC	32µg/l	X
4.3.3 LOEC	100µg/l	X
4.4 Remarks		X
	5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	**Effects on reproduction and growth rate on an appropriate species of fish**	
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.* All fish died at a test substance concentration of 320 µg/l. At 100 µg/l fish were observed swimming on the surface. No morphological observations were made. The test substance did not affect body length, but body weight increased at 100 µg/l.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* LC_{50} = 81 µg/l NOEC = 32 µg/l LOEC = 100 µg/l	X
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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	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*	

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	**Effects on reproduction and growth rate on an appropriate species of fish**
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 7.4.3.2(1)-1. Actual test substance concentration. Results of the Liquid Scintillation Countings in percentage of dosed amount of radioactivity at various exposure days

[redacted]

Table 7.4.3.2(1)-2. Mortality data

Dose concentration (µg/l)	% eggs hatched after 6 days	% mortality after 34 days
0	100	2.5
1.0	100	8.8
3.2	100	1.2
10	100	5.0
32	100	6.2
100	100	66
320	100	100

Table 7.4.3.2(1)-3. Growth of eggs/larvae of fish exposed to test substance

Dose concentration (µg/l)	No. fish	Mean final length (cm)	Mean final dry weight (mg)
0	78	1.32±0.17	1.83±0.09
1.0	73	1.36±0.15	2.32±0.44
3.2	79	1.30±0.14	1.96±0.18
10	76	1.31±0.19	2.31±0.83
32	75	1.34±0.15	2.11±0.27
100	27	1.30±0.25	3.49±1.71
320	0	n/d	n/d

n/d no data (all fish had died)

Section 7.4.3.3 Bioaccumulation in an aquatic organisms
Annex Point IIA 7.4.3.3

Section 7.4.3.3.1 (1) **Annex Point IIA 7.4.3.3.1**	**Bioaccumulation in fish**	
	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 [ ]** **Other justification [ ]**	
Detailed justification:		
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	*The summary of a study on fish bioconcentration was originally provided by the Applicant in the present section instead of in 7.4.2. The RMS has moved the study summary to Section 7.4.2, as more appropriate.* *The non submission of data for the present section is deemed justified due to other existing data (7.4.2).*	
	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 7.4.3.3.2 Annex Point III-A.7.4.3.3.2	**Bioaccumulation in an appropriate invertebrate species**	
	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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	*Acceptable*	
Remarks		

Section 7.4.3.3.2 Annex Point III-A.7.4.3.3.2	Bioaccumulation in an appropriate invertebrate species
	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 7.4.3.4(1) Annex Point IIA 7.4.3.4	**Effects on reproduction and growth rate with *Daphnia magna***	
	1. REFERENCE	Official use only
1.1 Reference	Hooftman, R.N. and H.Q.M. de Vette. (2001) Intermittent Flow Through Reproduction Test with Didecyldimethylammonium Chloride and *Daphnia magna*. TNO Report V99.1171. TNO Nutrition and Food Research, Department of Environmental Toxicology, The Netherlands (unpublished). Ref No. D7 (LON 3323)	
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 211 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")*	X
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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]	X
3.1.5 Stability	*Describe stability of test material* Stable	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	*Daphnia magna*	
3.2.3 Test system		
3.2.4 Test conditions	Intermittent flow through system [redacted]	
3.2.5 Duration of the test	21 days	
3.2.6 Test parameter	Mortality and Reproduction	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results test substance		X
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentrations of test substance	[redacted]	X
4.2.3 Effect data (Mortality)	All daphnids in the 56 µg/l treatment were dead by day 2; 50% of daphnids in 32 µg/l treatment were dead by day 9, with little other mortality.	
4.2.4 Other effects	Throughout the test, small green animals were observed swimming on the bottom in the 32 µg/l treatment and incidentally in other treatments.	X
4.3 Results of controls	[redacted]	
	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 2.1 above are relevant in this table.* [redacted]	X
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	X
5.2.1 NOEC/LOEC	Reproductive effect: NOEC = 0.018 mg/l LOEC = 0.032 mg/l Survival effect: NOEC = 0.010 mg/l	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
	LOEC = 0.018 mg/l Condition effect: NOEC = 0.018 mg/l LOEC = 0.032 mg/	
5.2.2 EC50 reproduction LC50	0.018mg/l < EC_{50} for reproduction < 0.056 mg/l LC_{50} = 0.023 mg/l (95% confidence limit 0.0034 - 0.0057 mg/l)	X
5.3 Conclusion		
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	X
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	**Effects on reproduction and growth rate with *Daphnia magna***
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*

Table 7.4.3.4(1)-1. Actual test substance concentration. Results of the Liquid Scintillation Countings in percentage of dosed amount of radioactivity at various exposure days

[redacted]

Table 7.4.3.4(1)-2. Average cumulative number of young per female daphnia at day 21

Concentration (µg/l)	cumulative number of young per living female	
	determined	% of control
0.0	129.5 ± 8.5	-
3.2	119.7 ± 19.4	92
5.6	120.4 ± 17.7	93
10.0	128.3 ± 8.1	99
18.0	119.3 ± 8.6	92
32.0	91.9 ± 10.0*	71
56.0	0	

*: Significantly less (two-tailed Dunnet test; p = 0.01) than control reproduction.

Table 7.4.3.4(1)-3. Average cumulative number of young per initial number of females

Concentration (µg/l)	cumulative number of young per living female	
	determined	% of control
0.0	123.8 + 13.45	-
3.2	113.6 + 17.60	92
5.6	113.7 + 15.30	92
10.0	121.1 + 4.79	98
18.0	107.0 + 13.88	86
32.0	42.3 + 11.58*	34
56.0	0	

* Significantly lower than control reproduction (two-tailed paired t-test)

Section 7.4.3.5 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk
Annex Point IIA 7.4.3.5- headline only

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
	1. REFERENCE	Official use only
1.1. Reference	England, D.C. and T. Leak (1995). Chronic Toxicity of Sediment-Incorporated Didecyldimethylammonium Chloride (DDAC)to Chironomus tentans. Final report No. 41005. ABC Laboratories, Columbia, MO, USA (unpublished). Ref No. D63 (LON 2941)	
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 before 14 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 American Society for Testing Materials (1992) ASTM Document No E 1383-93 U.S. EPA-600/3-75-009 American Society for Testing Materials (1992) ASTM Document No E 729-88a Standard Methods for the Examination of Water and Wastewater, American Public Health Association, Washington DC, 17th edition 1995 *(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")*	

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**		**Effects on sediment dwelling organisms**	
		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**	Didecyldimethylammonium Chloride	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
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]	X
3.1.5	Stability	*Describe stability of test material* Stable	X
3.2	**Testing procedure**		
3.2.1	Test organism	*Chironomus tentans*	
3.2.2	Source	[redacted]	
3.2.3	Worm weights	[redacted]	
3.2.4	Soil	Sediment from an agriculture pond	
3.2.5	Soil pH	[redacted]	
3.2.6	Dilution water	[redacted]	
3.2.7	Temperature	[redacted]	
3.2.8	Light	[redacted]	
3.3.	**Test procedure**		

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1	Effects on sediment dwelling organisms	
3.3.1 Duration of test	28 days	
3.3.2 Test parameters	Mortality, growth and body weight	
3.3.3 Control	[redacted]	
3.3.4 Test method	[redacted]	X
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	
	4. RESULTS	
4.1 Observations		
4.1.1 Mortality	Survival of test organisms, including survival to successful emergence, was reduced as a result of exposure to the highest sediment concentration of the test substance.	
4.1.2. Other effects	Adverse effects on growth as determined by day 14 larval weights and time of emergence were observed as a result of exposure to sediment concentrations above 1000 mg/kg. Although a 14-day LC50 could not be determined due to insufficient mortality, the 14-day EC50 based on total adverse effects was found to be 1287 mg/kg. The 28-day LC_{50} was 2085 mg/kg.	X
4.2 Result test substance	The test substance was found to have adverse effects on the test organisms.	
4.2.1 Initial test substance concentration	126, 249, 501, 1000 and 1999 mg/kg	X
4.2.2 Actual substance concentration	150, 260, 530, 1000 and 2200 mg/kg	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1	Effects on sediment dwelling organisms	
	[redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant* The 14-day and 28-day NOEC was found to be 530 mg/kg, based on the growth and emergence success. The 28-day LC_{50} was 2085 mg/kg.	X
5.2.1 LC50	See table 7.4.3.5.1.(1)-1	
5.2.2 NOEC/LOEC/ MATC	See table 7.4.3.5.1.(1)-1	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on the results of this study, the test substance was found to have adverse effects on the test organisms.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	X
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1	Effects on sediment dwelling organisms
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*

Table 7.4.3.5.1(1)-1 LC50/EC50, NOEC/LOEC and MATC (mg a.s./kg dw)

	Day 14	Day 28
LC50 mg/kg	>1000	2085
(95% confidence limits mg/kg)	-	(1000-2200)
EC50 mg/kg	1287	2085
(95% confidence limits mg/kg)	(1137-1483)	(1000-2000)
NOEC (mg/kg)	530[1]	530[2]
LOEC (mg/kg)	1000[1]	1000[2]
MATC (mg/kg)	728[1]	728[2]

[1] - Based on Growth (larval weights)
[2] - Based on time to emergence

Table 7.4.3.5.1(1)-2 Chemical screening of control sediments

Section 7.4.3.5.1 Annex Point III-A.7.4.3.5.1	Second and third study on effects on sediment dwelling organisms	
	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 [ ]**	X
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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Date	**EVALUATION BY RAPPORTEUR MEMBER STATE** [redacted]	

Section 7.4.3.5.1 Annex Point III-A.7.4.3.5.1	Second and third study on effects on sediment dwelling organisms
Evaluation of applicant's justification	[redacted]
Conclusion	A "second and third study on effects on sediment dwelling organisms"is not required.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.5.2 Annex Point III-A.7.4.3.5.2	Aquatic plant toxicity	
	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** [ ]	X
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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.4.3.5.2 Annex Point III-A.7.4.3.5.2	Aquatic plant toxicity
Conclusion	A study on aquatic plant toxicity is not required.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.5 Effects on terrestrial organisms
Annex Point IIA 7.5- headline only

Section 7.5.1 Terrestrial toxicity, initial tests
Annex Point IIA 7.5.1- headline only

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**	
	1. REFERENCE	Official use only
1.1 Reference	DeVette, H.Q.M., R. Hanstveit and J.A. Schoonmade. (2001) The assessment of the ecological effects of Didecyldimethylammonium Chloride (Guidelines OPPTS 850.5100 Soil Microbial Community Test, OECD 216 and OECD 217 and CTB section H.4.1). Study No.: IMW-99-9048-05. TNO Chemistry, Delft, The Netherlands (unpublished). Ref No. 119 (LON 3378)	
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 Guidelines 216 and 217 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")*	X
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant*	

Section 7.5.1.1(1) Annex Point IIA 7.5.1.1	Inhibition to microbial activity	
	[redacted]	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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]	X
3.1.5 Stability	*Describe stability of test material* Stable	X
3.2 Test conditions		
3.2.1 Soil	Sandy loam and low humic content sand	
3.2.2 Source	[redacted]	
3.2.3 Soil additive	[redacted]	
3.3 Test procedure		
3.3.1 Duration of test	28 days	
3.3.2 Test parameters	Nitrite, nitrate, ammonium and carbon dioxide formation	
3.3.3 Control	[redacted]	
3.3.4 Test method	[redacted]	X
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	X
	4. RESULTS	
4.1 Nitrogen metabolism		

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**	
4.1.1 Nitrate formation	See table 7.5.1.1(1)-1 No significant reduction in nitrate formation was observed.	X
4.1.2 Nitrite formation	See table 7.5.1.1(1)-2 No significant reduction in nitrite formation was observed.	X
4.1.3 Ammonium formation	See table 7.5.1.1(1)-3 The test substance caused an increase in ammonium formation.	
4.2 Carbon metabolism		
4.2.1 Microbial biomass	See table 7.5.1.1(1)-4 Values were considered to be characteristic for the soil types.	
4.2.2 Carbon content	See table 7.5.1.1(1)-4 Values were considered to be characteristic for the soil types.	
4.2.3 Carbon dioxide formation	See table 7.5.1.1(1)-5 No significant reduction in carbon dioxide formation was observed.	
4.3 Remarks	Didecyldimethylammonium Chloride can be characterised as having no long-term influence on nitrogen or carbon transformations in soils.	
	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.* The test substance had no effect on the production of nitrates, nitrites and carbon dioxide. The rate of ammonium production increased.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Didecyldimethylammonium Chloride can be characterised as having no long-term influence on nitrogen or carbon transformations in soils.	X
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 7.5.1.1(1) Annex Point IIA 7.5.1.1	Inhibition to microbial activity
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	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)*

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**
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 7.5.1.1(1)-1. Nitrate formation

Dose concentration (µg/g)	**Mean nitrate formation rate (mg/kg dry weight/day)**				**% reduction**			
	Low humic content sand		**Sandy loam**		**Low humic content sand**		**Sandy loam**	
Day	**5**	**28**	**5**	**28**	**5**	**28**	**5**	**28**
0	2.71	2.19	4.86	1.09	-	-	-	-
10	2.93	1.94	5.26	0.97	-8.0	11.4	-8.2	10.7
100	2.26	2.12	5.04	0.89	16.5	2.89	-3.8	18.2
1000	2.89	1.93	3.65	1.10	-6.6	11.7	24.8	-0.61

Table 7.5.1.1(1)-2. Nitrite formation

Dose concentration (µg/g)	**Mean nitrite formation rate (mg/kg dry weight/day)**				**% reduction**			
	Low humic content sand		**Sandy loam**		**Low humic content sand**		**Sandy loam**	
Day	**5**	**28**	**5**	**28**	**5**	**28**	**5**	**28**
0	0.35	0.02	0.80	0.02	-	-	-	-
10	0.38	0.02	0.81	0.01	-8.1	6.7	-1.2	10.7
100	0.34	0.02	0.81	0.02	4.5	4.1	-1.4	0.8
1,000	0.35	0.06	0.79	0.02	0.6	-135.4	0.8	-9.3

Table 7.5.1.1(1)-3. Ammonium formation

Dose concentration (µg/g)	**Mean ammonium formation rate (mg/kg dry weight/day)**				**% reduction**			
	Low humic content sand		**Sandy loam**		**Low humic content sand**		**Sandy loam**	
Day	**5**	**28**	**5**	**28**	**5**	**28**	**5**	**28**
0	2.36	0.29	1.66	0.10	-	-	-	-
1,000	4.33	0.40	3.09	0.10	-83.8	-86.5	-39.1	-6.2

Table 7.5.1.1(1)-4. Biomass and carbon content

Parameter	**Low humic content sand**	**Sandy loam**
Microbial biomass (µgC/g)	142	14
Carbon content (mgC/g)	55	9
Carbon content assumed to be in the biomass (%)	0.3	1.6

Table 7.5.1.1(1)-5. Carbon dioxide production

	Mean carbon dioxide formation rate (mg/kg dry weight/day)	**% reduction**

Dose concentration (µg/g)	Low humic content sand		Sandy loam		Low humic content sand		Sandy loam	
Day	**5-8**	**25-28**	**5-8**	**25-28**	**5-8**	**25-28**	**5-8**	**25-28**
0	284.0	28.6	237.9	25.7	-	-	-	-
10	327.3	25.3	216.3	31.2	-15.2	11.6	9.1	-21.5
100	292.3	8.7	260.4	31.3	-2.9	69.6*	-9.5	-22.0
1,000	261.9	104.3	181.6	31.4	7.8	-264.8	23.6	-22.3

* not statistically significant

Section 7.5.1.2 (1) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	1. REFERENCE	Official use only
1.1. Reference	Henzen, L. (1999). The acute toxicity of DDAC to the worm species *Eisenia fetida* in a 14 day test (OECD Guideline No 207). TNO Nutrition and Food Research Institute. (unpublished) Ref. No.: D88 (LON 3153)	
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 before 14 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 207 1999 *(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	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.5.1.2 (1) Annex Point IIA 7.5.1.2		Acute toxicity test to earthworms or other soil non-target organisms	
3.1.2	Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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]	X
3.1.5	Stability	*Describe stability of test material* Stable	X
3.2	**Testing procedure**		
3.2.1	Test organism	*Eisenia fetida*	
3.2.2	Source	[redacted]	
3.2.3	Worm weights	[redacted]	
3.2.4	Soil	Artificial soil containing sphagnum peat, kaolin clay and fine industrial sand [redacted]	
3.2.5	Soil pH	[redacted]	
3.2.6	Soil water content	[redacted]	
3.2.7	Temperature	[redacted]	
3.2.8	Light	[redacted]	
3.3	**Test procedure**		
3.3.1	Duration of test	14 days	
3.3.2	Test parameters	Mortality, body weight, morphological and behavioural observations	
3.3.3	Control	[redacted]	
3.3.4	Test method	[redacted]	X
3.3.5	Sampling	[redacted]	X

Section 7.5.1.2 (1) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
3.3.6 Statistics	[redacted]	
	4. RESULTS	
4.1 Observations		
4.1.1 Mortality	No adverse effects were observed LC50 > 1000 mg a.s./kg dry weight soil	
4.1.2. Body weight	No adverse effects were observed	
4.1.3 Morphological observations	No adverse effects were observed	
4.1.4 Behavioural observations	No adverse effects were observed	
4.2 Remarks	The test substance had no adverse effects on worms.	
	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.* The test substance had no effect on mortality, body weights, morphological development or behavioural development.	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Didecyldimethylammonium Chloride can be characterised as having no long-term influence on earthworms.	X
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 7.5.1.2 (1) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	The study is 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 7.5.1.2(2) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	1. REFERENCE	Official use only
1.1 Reference	Rodgers, M. H. (2004). N-Alkyl (C12-16)-N,N-Dimethyl –N-Benzylammonium Chloride (ADBAC) Acute Toxicity (LC_{50}) to the Earthworm. HLS. Report No.: ADB023/033976 (unpublished). Ref No. D133 (LON 3799)	X
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 207 for Testing Chemicals "Earthworm, acute toxicity tests" Directive 88/302/EEC, Part C, Methods for determination of ecotoxicity, "Toxicity for earthworms: Artificial soil test". 1988 *(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	Alkyldimethylbenzylammonium Chloride – Read Across Study	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.5.1.2(2) **Annex Point IIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(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* Stable	
3.1.6 Method of analysis	[redacted]	
3.2 Test procedure	[redacted]	
3.2.1 Test organisms	Earthworms *Eisenia foetida foetida* [redacted]	
3.2.2 Test system	Artificial OECD 207 soil, [redacted]	
3.2.3 Test conditions	[redacted]	
3.2.4 Duration of the test	14 days	
3.2.5 Test parameter	Mortality, behavioural and pathological signs.	
3.2.6 Sampling	[redacted]	
3.2.7 Monitoring of the test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	