Section 7.2.3 – Adsorption and mobility in soil, further studies
Annex Point IIA 7.2.3

Section 7.2.3.1(1) **Annex Point IIA 7.2.3.1**		**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**	
		1. REFERENCE	Official use only
1.1	**Reference**	Daly, D. (1989) Soil/Sediment Adsorption-Desorption of ^{14}C-Didecyldimethylammonium Chloride (DDAC). Report No. 37009. ABC Laboratories, Inc., Columbia, MO, USA (Unpublished). Ref No.: D42 (LON 1792)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	The Dialkyl Project	
1.2.2	Criteria for data protection	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 U.S. EPA-FIFRA Guideline N-163-1 1989	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[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. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3	Description	[redacted]	

Section 7.2.3.1(1) **Annex Point IIA 7.2.3.1**		**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**	
3.1.4	Purity	[redacted]	
3.1.5	Stability	The non-radiolabelled 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 system**		
3.2.1	Soil types	sand, sandy loam, silty clay loam, and silt loam	
3.2.2	Soil:water ratio	[redacted]	
3.3	**Test procedure**	[redacted]	
3.3.1	Adsorption	[redacted]	
3.3.3	Desorption	[redacted]	
		4. RESULTS	
4.1	**Results of test compound**		
4.1.1	Initial concentrations of test compound	[redacted]	
4.1.2	Estimated distribution of test compound	96.0% to 99.2% adsorbed to soil	
4.2	**Coefficients**	See table 7.2.3.1(1)-1	
4.3	**Remarks**	Didecyldimethylammonium Chloride has little or no potential for mobility in soil and should not pose an environmental risk for contamination of groundwater	
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 7.2.3.1(1) **Annex Point IIA 7.2.3.1**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**
5.1 Materials and methods	[redacted]
5.2 Results and discussion	[redacted]
5.3 Conclusion	Didecyldimethylammonium Chloride has little or no potential for mobility in soil and should not pose an environmental risk for contamination of groundwater
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]
	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	
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable

Section 7.2.3.1(1) **Annex Point IIA 7.2.3.1**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.2.3.1(1)-1. Adsorption and desorption coefficients.

Soil type	Adsorption coefficient (Kd)	Desorption coefficient (Kd)	Mobility coefficient (adsorption phase) (Koc)	Mobility coefficient (desorption phase) (Koc)
Sand	1,095	591	437,805	236,473
Sandy loam	8,179	2,074	908,757	230,498
Silty clay loam	32,791	8,309	1,599,564	405,328
Silt loam	30,851	7,714	1,469,081	367,334

Soil type	n Adsorption	n Desorption
Sand	1.0264	1.3198
Sandy loam	0.9755	1.6919
Silty clay loam	1.0450	1.5262
Silt loam	0.9776	1.5820

Section 7.2.3.2 Annex Point III-A.7.2.3.2	Mobility – Lysimeter studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	[redacted]	
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	*Agreed with applicant justification*	
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 7.3 Fate and behaviour in air
Annex Point IIA 7.3

Section 7.3.1(1) Annex Point IIA7.3.1		Phototransformation in air (estimation method), including identification of breakdown products	
		1. REFERENCE	Official use only
1.1	**Reference**	Howes, D. (2004) DDAC (CAS RN 7173-51-5) Estimation of Photodegradation Using the Atmospheric Oxidation Program (AOPWIN). (Unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	The Dialkyl Project	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, not required for a computer modelling study.	
2.2	**GLP (only where required)**	No GLP is not required for the use of a computer program.	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	Didecyldimethylammonium Chloride	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Not applicable; calculated endpoint	
3.1.3	Description	Not applicable; calculated endpoint	
3.1.4	Purity	Not applicable; calculated endpoint	
3.1.5	Stability	Not applicable; calculated endpoint	
3.2	**Test procedure**		
3.2.1	Software	AOPWIN v1.88	

Section 7.3.1(1) **Annex Point IIA7.3.1**	**Phototransformation in air (estimation method), including identification of breakdown products**	
3.2.2 Method	(SAR) method	
3.2.3 Structure notation	SMILES notation	
	4. RESULTS	
4.1 Results	Mean atmospheric half life = 0.23 days (2.8 hours)	
4.1.1 Assumptions	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Mean atmospheric half life = 0.23 days (2.8 hours)	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	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		
Results and discussion		

Section 7.3.1(1) Annex Point IIA7.3.1	**Phototransformation in air (estimation method), including identification of breakdown products**
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 7.3.2 Annex Point III-A.7.3.2	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [ ]	
Detailed justification:	[redacted]	
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	*Agreed with applicant justification*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 7.3.2 Annex Point III-A.7.3.2	Fate and behaviour in air, further studies
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 7.4.1.1(1) Annex Point IIA 7.4.1.1		Acute toxicity to fish	
		1. REFERENCE	Official use only
1.1	**Reference**	LeLievre, M. K. (1990) Evaluation of Didecyldimethylammonium Chloride (DDAC) in a Static Acute Toxicity Test with Coho Salmon, *Oncorhynchus kisutch*. SLI Report No. 90-4-3290, Study No. 11696.0887.6101.156. Springborn Laboratories, Inc., Wareham, MA, USA (unpublished). Ref No. D5 (LON 1788)	
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 OECD Guideline No. 203 Year: 1990 *(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. [redacted]	X

Section 7.4.1.1(1) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	(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 Preparation of test substance solution for poorly soluble and volatile test substances	[redacted]	
3.3 Testing procedure		
3.3.1 Dilution water	[redacted]	
3.3.2 Test organisms	Coho Salmon (*Oncorhynchus kisutch*) [redacted]	
3.3.3 Test system	[redacted]	
3.3.4 Test conditions	Static [redacted]	

Section 7.4.1.1(1) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	[redacted]	
3.3.5 Duration of the test	96 hours	
3.3.6 Test parameter	Mortality	
3.3.7 Monitoring of test substance concentration	[redacted]	
3.3.8 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)	Refer to Table 7.4.1.1 (1)-1 96-hour LC_{50} = 1.0 mg/l (95% confidence interval of 0.59 – 1.5 mg/l)	X
4.2.4 Other effects	[redacted]	
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 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	

Section 7.4.1.1(1) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
5.2.1 LC50	96-hour LC_{50} = 1.0 mg/l (95% confidence interval of 0.59 – 1.5 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 0.59 mg/l.	
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*	
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 7.4.1.1(1)-1 Mortality data

Mean measured concentration (mg/l)	Percent Mortality at:			
	24 hours	48 hours	72 hours	96 hours
0	0	0	0	0
0.59	0	0	0	0
0.98	30	40	40	40

1.5	100	100	100	100
2.5	100	100	100	100
4.4	100	100	100	100

Section 7.4.1.1 (2) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	1. REFERENCE	Official use only
1.1 Reference	LeLievre, M. K. (1990) Evaluation of Didecyldimethylammonium Chloride (DDAC) in a Static Acute Toxicity Test with Bluegill Sunfish, *Lepomis macrochirus* SLI Report No. 89-10-3111, Study No. 11696.0887.6107.100. Springborn Laboratories, Inc., Wareham, MA, USA (unpublished). Ref No. D4 (LON 1786)	
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 FIFRA Guideline No. 72-2 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")*	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 7.4.1.1 (2) Annex Point IIA 7.4.1.1	Acute toxicity to 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):*	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]	
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 Sunfish (*Lepomis macrochirus*) [redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	Static [redacted]	X

Section 7.4.1.1 (2) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
3.2.5 Duration of the test	96 hours	
3.2.6 Test parameter	Mortality	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	
	4. RESULTS	X
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)	Refer to Table 7.4.1.1 (2)-1 96-hour LC_{50} = 0.32 mg/l (95% confidence interval of 0.25 – 0.42 mg/l)	
4.2.4 Other effects	[redacted]	
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 2.1above are relevant in this table.* [redacted]mination. The LC_{50} was calculated based on measured concentrations.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	

Section 7.4.1.1 (2) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
5.2.1 LC50	96-hour LC_{50} = 0.32 mg/l (95% confidence interval of 0.25 – 0.42 mg/l)	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the no-observed-effect concentration (NOEC) was 0.1 mg/l.	
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]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	*Not acceptable.* [redacted]	

Section 7.4.1.1 (2) Annex Point IIA 7.4.1.1	Acute toxicity to fish
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 7.4.1.1 (2)-1 Mortality data

Mean measured concentration (over the 96hours) (mg a.s./l)	Cumulative mortality (%)			
	24 hours	48 hours	72 hours	96 hours
0	0	0	0	0
0.10	0	0*	0*	0*
0.18	0	20	20	20
0.29	20	30	30	30
0.55	90	90	90	90
1.0	100	100	100	100

* one fish showing darkened pigmentation

Table 7.4.1.1.(2)-2

Mean measured concentration (over the 96hours) (mg a.s./l)	Dissolved Oxygen (% saturation)				
	0 hours	24 hours	48 hours	72 hours	96 hours
[redacted]					

Section 7.4.1.1(3) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	1. REFERENCE	Official use only
1.1 Reference	Putt, A.E. (1994) Didecyldimethylammonium Chloride (DDAC)—Static Acute Toxicity to Fathead Minnow (*Pimephales promelas*) with and without the Presence of Humic Acid. Report No. 94-1-5122 Springborn Laboratories, Inc., Wareham, MA, USA (unpublished). Ref No. D56 (LON 2937)	
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	U.S. EPA OPPTS 850.1085 Year: 1993 *(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 7.4.1.1(3) Annex Point IIA 7.4.1.1		Acute toxicity to 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):*	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]	
3.2	**Testing procedure**		
3.2.1	Dilution water	[redacted]	
3.2.2	Test organisms	Fathead Minnow (*Pimephales promelas*) [redacted]	
3.2.3	Test system	[redacted]	
3.2.4	Test conditions	[redacted] The test and control solutions were renewed at 48 hours of exposure. [redacted]	X

Section 7.4.1.1(3) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	[redacted]	
3.2.5 Duration of the test	96 hours	
3.2.6 Test parameter	Mortality	
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		
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentrations of test substance	[redacted]	
4.2.3 Effect data (Mortality)	Refer to Table 7.4.1.1.(3)-1 LC_{50} = 0.19 mg/l (0.16 to 0.27 mg/l) – Dilution water test LC_{50} = 0.77 mg/l (0.65 to 1.0 mg/l) - + 10 mg/l humic acid test LC_{50} = 1.2 mg/l (0.94 to 1.6 mg/l) - + 20 mg/l humic acid test	
4.2.4 Other effects	[redacted]	

Section 7.4.1.1(3) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
	[redacted]	
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 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC50	Dilution water test: LC_{50} = 0.19 mg/l (95% confidence limits 0.16 to 0.27 mg/l) +10 mg/l humic acid test: LC_{50} = 0.77 mg/l (95% confidence limits 0.65 to 1.0 mg/l) +20 mg/l humic acid test: LC_{50} = 1.2 mg/l (95% confidence limits 0.94 to 1.6 mg/l)	
5.3 Conclusion	Based on concentration-effect relationship observed, the no-observed-effect concentration (NOEC) was: Dilution water test: NOEC = 0.092 mg/l +10 mg/l humic acid test: NOEC = 0.40 mg/l +20 mg/l humic acid test: NOEC = 0.94 mg/l [redacted]	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	

Section 7.4.1.1(3) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
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	Accepted	
Reliability	[redacted]	
Acceptability	*For the use in the risk assessment, only the results from the test with dilution water are considered.*	
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 7.4.1.1(3)-1 Mortality data

Mean measured concentration (mg a.s./l)		**Cumulative Mortality (%):**			
		24 hours	**48 hours**	**72 hours**	**96 hours**
Dilution water test	0	0	0	0	0
	0.054	0	0	0	0

	0.092	0	0	0	0
	0.16	0	15	15	15
	0.27	90	95	95	100
	0.46	100	100	100	100
10 mg/l humic acid test	0	0	0	0	0
	0 + 10 mg/l	0	0	0	0
	0.40	0	0	0	0
	0.65	0	10	10	10
	1.0	100	100	100	100
	1.6	100	100	100	100
	2.6	100	100	100	100
20 mg/l humic acid test	0	0	0	0	0
	0 + 20 mg/l	0	0	0	0
	0.35	0	0	0	0
	0.51	0	0	0	0
	0.94	0	0	0	0
	1.6	100	100	100	100
	2.5	100	100	100	100

Table 7.4.1.1(3)-2 Concentration of DDAC (mg DDAC equivalents/l) in replicates A and B in the test without humic acid .

Nominal concentration (mg a.s./l)	**0 hours**		**48 hours**		**96 hours**		**Mean measured concentration - (% of nominal)**
	A	**B**	**A**	**B**	**A**	**B**	
0	<0.0077	<0.0077	<0.0077	<0.0077	<0.0077	<0.0077	----
	<0.0077	<0.0077	<0.0077	<0.0077	<0.0077	<0.0077	
0.065	0.053	0.051	0.052	0.053	0.054	0.061	0.054 (84)
	0.051	0.053	0.055	0.055	0.051	0.062	
0.11	0.083	0.094	0.093	0.093	0.10	0.098	0.092 (84)
	0.083	0.093	0.093	0.087	0.093	0.099	
0.18	0.16	0.17	0.16	0.15	0.15	0.14	0.16 (88)
	0.16	0.19	0.18	0.15	0.17	0.14	
0.30	0.27	0.28	0.26	0.26	0.27	0.30	0.27 (91)
	0.28	0.27	0.26	0.26	0.28	0.30	
0.50	0.47	0.43	0.45	0.45	0.49	0.47	0.46 (92)
	0.46	0.47	0.44	0.43	0.49	0.46	

Section 7.4.1.1(4) Annex Point IIA 7.4.1.1		Acute toxicity to fish	
		1. REFERENCE	Official use only
1.1	**Reference**	Swigert, J.P., W.C. Graves and M.A. Mank. (1995) An evaluation of Didecyldimethylammonium Chloride (DDAC) in a 96-Hour Flow-Through Acute Toxicity Study with the Fathead Minnow (*Pimephales promelas*), Project No. 289A-124, Wildlife International Ltd., Easton, MD, USA. [Lonza/Molluscicide – Calgon Study] (unpublished). Ref No. D68 (LON 3087)	
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 FIFRA Series 72, Subdivision E ASTM Standard E729-88a Year: 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)**	No data *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	X
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]	X

Section 7.4.1.1(4) Annex Point IIA 7.4.1.1	Acute toxicity to 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):*	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]	
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	*Pimephales promelas*	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	Flow through	
3.2.5 Duration of the test	96 hours	
3.2.6 Test parameter	Mortality	
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		

Section 7.4.1.1(4) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentrations of test substance	[redacted]	
4.2.3 Effect data (Mortality)	After 24 hours of exposure, 100% mortality was observed in the 348 µg a.s./l treatment group. After 96 hours of exposure, mortality in the 224 µg a.s./l treatment group was 70%. See table 7.4.1.1(4)-1	
4.2.4 Other effects	[redacted]	
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 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC0	LC_0 = 122 µg/l	X
5.2.2 LC50	LC_{50} = 195 µg/l	X
5.2.3 LC100	LC_{100} = ca 384 µg/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 122 µg/l and the lowest-oberved – effect concentraiton (LOEC) was 224 µg a.s./l.	
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 7.4.1.1(4) Annex Point IIA 7.4.1.1	Acute toxicity to fish
	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*

Table 7.4.1.1.(4)-1 Mortality data

Mean measured concentration (µg/l)			3 hours		24 hours		48 hours		72 hours		96 hours	
	Replicate	N. of fish exposed	dead	live[1]	dead	live[1]	dead	live[1]	dead	live[1]	dead	live[1]
0	A	10	0	10	0	10	0	10	0	10	0	10
	B	10	0	10	0	10	0	10	0	10	0	10
45	A	10	0	10	0	10	0	10	0	10	0	10
	B	10	0	10	0	10	0	10	0	10	0	10
74	A	10	0	10	0	10	0	10	0	10	0	10
	B	10	0	10	0	10	0	10	0	10	0	10
122	A	10	0	10	0	10	0	10	0	10	0	10
	B	10	0	10	0	10	0	10	0	10	0	10
224	A	10	0	10	0	10	1	9	3	7	7	3
	B	10	0	10	0	10	3	7	5	5	7	3
384	A	10	0	10	10	0	10	0	10	0	10	0
	B	10	0	10	10	0	10	0	10	0	10	0

[1]: normal appearance

Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	1. REFERENCE	Official use only
1.1 Reference	Swigert, J.P., W.C. Graves and M.A. Mank (1995). An Evaluation of Didecyldimethylammonium Chloride (DDAC) in a 96-Hour Flow-Through Acute Toxicity Study with the Rainbow Trout (*Oncorhynchus mykiss),* Project No. 289A-125, Wildlife International Ltd., Easton, MD, USA.[Lonza/Molluscicide – Calgon Study] (unpublished). Ref No. D69 (LON 3809)	
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 FIFRA Series 72, Subdivision E ASTM Standard E729-88a Year: 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)*	X
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]	X
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 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
	[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 Preparation of test substance solution for poorly soluble and volatile test substances	[redacted]	
3.3 Testing procedure		
3.3.1 Dilution water	[redacted]	
3.3.2 Test organisms	Rainbow trout (*Oncorhynchus mykiss*) [redacted]	
3.3.3 Test system	[redacted]	
3.3.4 Test conditions	Flow through [redacted]	
3.3.5 Duration of the test	96 hours	
3.3.6 Test parameter	Mortality	
3.3.7 Monitoring of test substance concentration	[redacted]	
3.3.8 Statistics	[redacted]	
	4. RESULTS	

Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
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)	Refer to Table 7.4.1.1 (5)-1 96-hour LC_{50} = 0.466 mg a.s./l (95% confidence interval of 0.38-0.57 mg a.s./l)	
4.2.4 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals showing adverse 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.* The 96-hour LC_{50} of the test substance was found to be 0.466 mg a.s./l and the LC_0 was 0.38 mg a.s./l.	
5.2.1 LC50	96-hour LC_{50} = 0.466 mg a.s./l (95% confidence interval of 0.38-0.57 mg a.s./l)	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the no-observed-effect concentration (NOEC) was 0.38 mg a.s./l and the lowest observed-effect concentration (LOEC) 0.58 mg a.s./lmg/l.	

Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
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*	
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 7.4.1.1(5)-1 Mortality data

Mean measured concentration (mg/l)	Percent Mortality at:				
	3 hours	24 hours	48 hours	72 hours	96 hours
0	0	0	0	0	0
0.23	0	0	0	0	0
0.38	0	0	0	0	0

0.58	0	15	70	100	100
1.0	0	100	100	100	100
1.9	0	100	100	100	100

Section 7.4.1.1 Annex Point III-A.7.4.1.1	Acute toxicity to fish (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 7.4.1.1 Annex Point III-A.7.4.1.1	Acute toxicity to fish (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 7.4.1.2 (1) Annex Point IIA 7.4.1.1	Acute toxicity to invertebrates	
	1. REFERENCE	Official use only
1.1 Reference	LeLievre, M. K. (1990) Evaluation of Didecyldimethylammonium Chloride (DDAC) in a Static Acute Toxicity Test with Daphnids, *Daphnia magna*. SLI Report No. 89-10-3112. Springborn Laboratories, Inc., Wareham, MA, USA (unpublished). Ref No. D6 (LON 1787)	
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 FIFRA Guideline No. 72-2 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")*	
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]	X

Section 7.4.1.2 (1) Annex Point IIA 7.4.1.1	Acute toxicity to invertebrates	
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]	X
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	*Daphnia magna* [redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	Static [redacted]	

Section 7.4.1.2 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to invertebrates**	
	[redacted]	
3.2.5 Duration of the test	48 hours	
3.2.6 Test parameter	Immobilisation	
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]	X
4.2.3 Effect data (Mortality)	Refer to Table 7.4.1.2 (1)-1 48 hour EC_{50} = 0.094 mg/l (95% confidence limits 0.074 to 0.120 mg/l)	X
4.2.4 Other effects	None	
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 2.1above are relevant in this table.* [redacted]	

Section 7.4.1.2 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to invertebrates**	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 EC50	48 hour EC_{50} = 0.094 mg/l (95% confidence limits 0.074 to 0.120 mg/l)	X
5.3 Conclusion	Based on concentration-effect relationship observed, the no-observed-effect concentration 48-hour NOEC was found to be 0.074 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]	
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		
	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 7.4.1.2 (1)-1 Analytical results and mortality data

Nominal concentrations (µg/l)	Measured concentrations (µg/l)			Mean measured concentrations (µg/l)	Percent mortality at:	
	0 hours	24 hours	48 hours		24 hours	48 hours
0	<1.43	<1.42	<1.42	-	5	5
	<1.43	<1.43	<1.42			
	<1.43	<1.43	<1.42			
13	20	13	21	19 (2.9)	0	0
	20	20	21			
	18	22	17			
22	25	39	41	31 (7.1)	5	5
	23	36	32			
	21	35	29			
37	48	63	65	51 (9.6)	0	0
	41	58	46			
	40	57	44			
60	71	66	92	74 (9.7)	0	0
	80	78	79			
	66	59	72			
100	120	140	120	120 (12)	0	100
	100	120	130			
	110	120	130			

Section 7.4.1.2(2) Annex Point IIA 7.4.1.2		Acute toxicity to invertebrates	
		1. REFERENCE	Official use only
1.1	**Reference**	Swigert, J.P., W.C. Graves and M.A. Mank. (1995) An evaluation of Didecyldimethylammonium Chloride (DDAC) in a 48-Hour Flow-Through Acute Toxicity Study with the Cladoceran (*Daphnia magna*), Project No. 289A-122, Wildlife International Ltd., Easton, MD, USA.[Lonza/Molluscicide – Calgon Study] (unpublished). Ref No. D67 (LON 2939)	
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 OPP 72-2 Year: 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")*	X
2.2	**GLP (only where required)**	No *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	X
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]	X

Section 7.4.1.2(2) Annex Point IIA 7.4.1.2	Acute toxicity to invertebrates	
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]	
3.1.5 Stability	*Describe stability of test material* Stable	X
3.1.6 Method of analysis for test substance	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	*Daphnia magna*	
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	Flow through	
3.2.5 Duration of the test	48 hours	
3.2.6 Test parameter	Immobility	
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		
4.2.1 Initial concentration of test	[redacted]	

Section 7.4.1.2(2) Annex Point IIA 7.4.1.2	Acute toxicity to invertebrates	
substance		
4.2.2 Actual concentrations of test substance	[redacted]	X
4.2.3 Effect data (Mortality)	See table 7.4.1.2.(2)-1	X
4.2.4 Other effects	[redacted]	
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 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 EC_0	EC_0 = 48 µg/l	X
5.2.2 EC_{50}	EC_{50} = 62 µg/l	X
5.2.3 EC_{100}	EC_{100} = 81 µg/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 48 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]	

Section 7.4.1.2(2) Annex Point IIA 7.4.1.2	Acute toxicity to invertebrates
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*

Table 7.4.1.2 (2)-1 Mortality data *

Mean measured concentration (µg/l a.s./l)	Percent mortality at:	
	24 hours	48 hours
0	0	0
20	0	0
29	0	0
48	0	0
81	0	100

153	95**	100

* up to 48 µg a.s./l treatment, animals appeared to be healthy and normal throughout the study.
** 1 animal lethargic

Section 7.4.1.2 Annex Point III-A.7.4.1.2	Acute toxicity to invertebrates (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 7.4.1.2 Annex Point III-A.7.4.1.2	Acute toxicity to invertebrates (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 7.4.1.3 (1) 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. (2002) Bardac 2280: A 96-Hour Toxicity Test with the Freshwater Alga (*Selenastrum capricornutum*). Study Number 289A-152 Wildlife International, Ltd., Easton, MD, USA (unpublished). Ref No. D57 (LON 3433)	
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 201 U.S. EPA OPPTS Guideline 850.5400 Year: 2000 *(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	

Section 7.4.1.3 (1) 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]	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	*Selenastrum capricornutum* [redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	X

Section 7.4.1.3 (1) **Annex Point IIA 7.4.1.3**	**Growth inhibition test on algae**	
	[redacted]	
3.2.5 Duration of the test	96 hours	
3.2.6 Test parameter	Growth and growth rate	X
3.4.7 Monitoring of test substance concentration	[redacted]	X
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]	X
4.2.3 Effect data (Mortality)	The 0.063 and 0.130 mg/l treatment groups were maximally inhibited after the 96-hour exposure period. By Day 6 of the recovery phase, sufficient growth was observed in all replicates to indicate recovery from exposure. The effects of the test substance are considered to be algistatic rather than algicidal.	
4.2.4 Other effects	[redacted]	
4.3 Results of controls	[redacted]	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]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	

Section 7.4.1.3 (1) **Annex Point IIA 7.4.1.3**		**Growth inhibition test on algae**	
5.2.1	EC10	Cell density at 96-hours: E_rC_{10} = 0.014 mg/l (0.009 to 0.021 mg/l) Biomass at 96-hours: E_bC_{10} = 0.013 mg/l (0.0092 to 0.018 mg/l)	X
5.2.2	EC50	Cell density at 96-hours: E_rC_{50} = 0.026 mg/l (0.021 to 0.033 mg/l) Biomass at 96-hours: E_bC_{50} = 0.026 mg/l (0.022 to 0.032 mg/l)	X
5.2.3	EC90	Cell density at 96-hours: E_rC_{90} = 0.051 mg/l (0.042 to 0.062 mg/l) Biomass at 96-hours: E_bC_{90} = 0.054 mg/l (0.046 to 0.063 mg/l)	X
5.3	**Conclusion**	NOAEC for both cell density and biomass was found to be: 24-hour NOAEC = 0.0033 mg/l; 48-, 72- and 96-hour NOAEC = 0.014 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]	
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 7.4.1.3 (1) Annex Point IIA 7.4.1.3	Growth inhibition test on algae
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable*
Remarks	[redacted]

Section 7.4.1.3 (1) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
	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*	

*

Percent inhibition in cell densities over the 96h exposure period.

Day 0 measured concentration (ug/l)	24h	48h	72h	96h
0	---	---	---	---
3.3	15	-1.6	-2.2	-0.93
6.9	25*	-0.77	5.5	6.6
14	22*	7.7	3.0	7.8
30	41*	53*	59*	58*
63	62*	80*	93*	98*
130	70*	89*	98*	99*

* Statistically significantly different from control (Dunnett's test)

Inhibition in cell densities over the 96h exposure period (based on initial measured concentrations).

Time	EC_{10} (ug/l)	EC_{50}(ug/l)	EC_{90}(ug/l)
24h	3.5	45	>130
48h	8.0	30	113
72h	15	27	63

96h	14	26	51

Percent inhibition in mean area under the growth curve over the 96h exposure period.

Day 0 measured concentration (ug/l)	24h	48h	72h	96h
0	---	---	---	---
3.3	21	4.6	-0.97	-1.2
6.9	25*	9.1	5.4	6.1
14	30*	14	5.7	6.6
30	56*	57*	59*	59*
63	87*	86*	92*	96*
130	95*	95*	98*	99*

* Statistically significantly different from control (Dunnett's test)

Inhibition in area under the growth curve over the 96h exposure period.

Time	E_bC_{10} (ug/l)	E_bC_{50}(ug/l)	E_bC_{90}(ug/l)
24h	7	26	96
48h	9.3	27	81
72h	11	27	64
96h	13	26	54

Results at 96 hours based on mean measured concentrations (day 0 and 96) (Additional calculation made by the RMS).

Mean measured concentration (ug/l)	Percent inhibition in cell densities	Percent inhibition in area under the growth curve	$96hEC_{50}$(ug/l)	$96hE_bC_{50}$(ug/l)
0	---	---	To be calculated	To be calculated
2.8	-0.93	-1.2		
5.4	6.6	6.1		
11.2	7.8	6.6		
24.5	58*	59*		
44.8	98*	96*		
103.3	99*	99*		

* Statistically significantly different from control (Dunnett's test)

Section 7.4.1.3 (2) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
	1. REFERENCE	Official use only
1.1 Reference	Scheerbaum, D. (1998) Bardac 22: Alga, Growth Inhibition Test (72hr). Report (Study No. SS061301), for Clariant GmbH, Frankfurt, Germany (sponsor); from Dr.U.Noack-Laboratorium fur Angewandte Biologie, Sarstedt, Germany (unpublished). Ref No. D115 (LON 3011)	
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 OECD Guideline No. 201 Year: 1998 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.4.1.3 (2) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
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
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	*Scenedesmus subspicatus*	
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	72 hours	
3.2.6 Test parameter	Biomass production and growth rate	
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		
4.2.1 Initial concentration of test substance	[redacted]	

Section 7.4.1.3 (2) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
4.2.2 Actual concentrations of test substance		X
4.2.3 Effect data (Mortality)	The test substance was found to inhibit the growth of the green algae at concentrations > 0.2 mg/l (biomass) and > 0.4 mg/l (growth rate).	
4.2.4 Other effects	[redacted]	
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 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 EbC_{50}	EbC_{50} = 0.50 mg/l	
5.2.2 ErC_{50}	ErC_{50} = 0.66 mg/l	
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 0.4 mg/l and 0.2 mg/l for ErC_{50} and EbC_{50} respectively.	
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.)*	X
	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]	