

Section 7.4.1.1 (2) Acute toxicity to fish		
Annex Point IIA 7.4.1.1		
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(2)-1. A single death occurred at the lowest concentration (0.096 mg/l) but this incidence was within historical control limits and the death was not considered related to treatment.
4.2.4	Concentration/response curve	The 96-hour dose-response slope was 4.8.
4.2.5	Other effects	None
4.3	Results of controls	
4.3.1	Number/percentage of animals showing adverse effects	[REDACTED]
4.3.2	Nature of adverse effects	[REDACTED]
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	<i>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.</i> [REDACTED]
5.2	Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i> [REDACTED]
		X

Section 7.4.1.1 (2)	Acute toxicity to fish
Annex Point IIA 7.4.1.1	
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	■
Acceptability	<i>acceptable</i>
Remarks	
COMMENTS FROM OTHER MEMBER STATE	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table 7.4.1.1(3)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0.096	0/20	0/20	1/20	1/20
0.18	0/20	1/20	4/20	4/20
0.31	2/20	5/20	6/20	6/20
0.57	20/20	20/20	20/20	20/20
1.00	20/20	20/20	20/20	20/20

Table 7.4.1.1(3)-2

LC50

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	0.39	0.34	0.28	0.28
95% confidence limits	(0.31-0.57)	(0.30-0.40)	(0.23-0.34)	(0.23-0.34)

Section 7.4.1.1(3)		Acute toxicity to fish	
Annex Point IIA 7.4.1.1			
	1. REFERENCE		Official use only
1.1 Reference	Sword, M. C. and Stuerman, L. (1994) Static-Renewal Acute Toxicity of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow (<i>Pimephales promelas</i>) in Dilution Water Amended with 10 mg/l Humic Acid BC Laboratories, Columbia, MO, U. S. Report No. 41236 (unpublished). [Ref No: A7 (LON 3477)]		X
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>		
1.2.1 Data owner	<i>Give name of company</i> ADBAC Joint Venture		
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 TSCA 797.1400 Year: 1993 <i>(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")</i>		
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>		
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>		
	3. MATERIALS AND METHODS		
	<i>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.</i>		
3.1 Test material	Alkyldimethylbenzylammonium Chloride		
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> ██████████ ██████████		

Section 7.4.1.1(3) Acute toxicity to fish			
Annex Point IIA 7.4.1.1			
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] [REDACTED]	
3.1.4	Purity	Give purity in g/kg, g/l, %w/w or % v/v active substance [REDACTED] [REDACTED]	
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] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.2.2	Test organisms	Fathead minnow (<i>Pimephales promelas</i>) [REDACTED] [REDACTED]	
3.2.3	Test system	[REDACTED] [REDACTED]	
3.2.4	Test conditions	Static, daily renewal [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.2.5	Duration of the test	96 hours	
3.2.6	Test parameter	Mortality	

Section 7.4.1.1(3) Acute toxicity to fish		
Annex Point IIA 7.4.1.1		
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
4.2.4	Concentration/response curve	The 96-hour dose-response slope was 14.
4.2.5	Other effects	None
4.3	Results of controls	
4.3.1	Number/percentage of animals showing adverse effects	[REDACTED]
4.3.2	Nature of adverse effects	[REDACTED]
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	<i>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.</i> [REDACTED]
5.2	Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i>
5.2.1	LC0	Not stated but 0.53 mg/l (measured) showed no effects or mortality

Section 7.4.1.1(3) Annex Point IIA 7.4.1.1	Acute toxicity to fish
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table A7.4.1.1(3)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0.30	0/20	0/20	0/20	0/20
0.53	0/20	0/20	0/20	0/20
0.98	16/20	16/20	17/20	18/20
1.80	20/20	20/20	20/20	20/20
3.20	20/20	20/20	20/20	20/20

Table 7.4.1.1(3)-2

LC50

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	0.81	0.81	0.79	0.77

Section 7.4.1.1 (4)		Acute toxicity to fish	
Annex Point IIA 7.4.1.1			
1. REFERENCE		Official use only	
1.1 Reference	Sword, M. C. and Stuerman, L. (1994) Static-Renewal Acute Toxicity of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow (<i>Pimephales promelas</i>) in Dilution Water Amended with 20 mg/l Humic Acid. ABC Laboratories, Columbia, MO, U. S. Report No. 41235 (unpublished). [Ref No: A8 (LON 3478)]	X	
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>		
1.2.1 Data owner	<i>Give name of company</i> ADBAC Joint Venture		
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 TSCA 797.1400 Year: 1993 <i>(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")</i>		
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>		
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>		
3. MATERIALS AND METHODS			
<i>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.</i>			
3.1 Test material	Alkyldimethylbenzylammonium Chloride		
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> ██████████ ██████████	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 (4) Acute toxicity to fish		
Annex Point IIA 7.4.1.1		
	[REDACTED] <i>(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):</i>	
3.1.3	Description <i>If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)</i> [REDACTED] [REDACTED]	
3.1.4	Purity <i>Give purity in g/kg, g/l, %w/w or % v/v active substance</i> [REDACTED] [REDACTED]	
3.1.5	Stability <i>Describe stability of test material</i> Stable	
3.1.6	Method of analysis [REDACTED]	
3.2	Testing procedure	
3.2.1	Dilution water [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	
3.2.2	Test organisms Fathead minnow (<i>Pimephales promelas</i>) [REDACTED] [REDACTED]	
3.2.3	Test system [REDACTED] [REDACTED]	
3.2.4	Test conditions Static, daily renewal [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [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] [REDACTED]	
3.2.8	Statistics [REDACTED] [REDACTED] [REDACTED]	

Section 7.4.1.1 (4)		Acute toxicity to fish	
Annex Point IIA 7.4.1.1			
	4. RESULTS		
4.1	Limit test	No	
4.2	Results test substance		
4.2.1	Initial concentration of test substance		
4.2.2	Actual concentrations of test substance		
4.2.3	Effect data (Mortality)	Refer to Table 7.4.1.1(4)-1	
4.2.4	Concentration/ response curve	The 96-hour dose-response slope was 15.	
4.2.5	Other effects	None	
4.3	Results of controls		
4.3.1	Number/percentage of animals showing adverse effects		
4.3.2	Nature of adverse effects		
	5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	<i>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.</i>	
5.2	Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i>	
5.2.1	LC0	Not stated but 0.99 mg/l (measured) showed no effects or mortality	
5.2.2	LC50	LC ₅₀ (96hr) = 1.4 mg/l (95% confidence limit = 0.99 and 1.8 mg/l) Dose response slope = 15 Refer to Table 7.4.1.1(4)-2	

Section 7.4.1.1 (4)		Acute toxicity to fish	
Annex Point IIA 7.4.1.1			
5.2.3	LC100	Not stated but 100% mortality observed at 3.2 mg/l (measured).	
5.3	Conclusion	<i>Subsections for NOAEL, LOAEL etc. if appropriate</i> Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.99 mg/l.	
5.3.1	Reliability	<i>Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4</i> [REDACTED]	
5.3.2	Deficiencies	[REDACTED] <i>(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)</i>	
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Materials and Methods	[REDACTED]		
Results and discussion	[REDACTED]		
Conclusion	[REDACTED]		
Reliability	[REDACTED]		
Acceptability	<i>Not acceptable:</i> [REDACTED]		
Remarks	[REDACTED]		
COMMENTS FROM OTHER MEMBER STATE			

Section 7.4.1.1 (4)	Acute toxicity to fish
Annex Point IIA 7.4.1.1	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table A7.4.1.1(4)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0/20	0/20	0/20	0/20	0/20
0/20	0/20	0/20	0/20	0/20
0/20	0/20	0/20	0/20	0/20
1.8	19/20	19/20	19/20	19/20
3.2	20/20	20/20	20/20	20/20

Table 7.4.1.1(4)-2

LC50

LC50 ppm (mg/l)	24hr	48hr	72hr	96hr
	1.4	1.4	1.4	1.4

Section 7.4.1.1 (5) Acute toxicity to fish		
Annex Point IIA 7.4.1.1		
1. REFERENCE		Official use only
1.1 Reference	Pate, H.O. and D.O. McIntyre (1991). Daily Static-Renewal Acute 96-hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. Battelle Columbus Division, Columbus, OH, U. S. Report No. SC890051 (unpublished). [Ref No: A8b (LON 1864)]	
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>	
1.2.1 Data owner	<i>Give name of company</i> ADBAC Joint Venture	
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 Subdivision E, Guideline 72-1, Hazard evaluation: Wildlife and aquatic organisms Year: 1990 <i>(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")</i>	
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>	
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>	
3. MATERIALS AND METHODS		
<i>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.</i>		
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> [REDACTED] [REDACTED]	

Section 7.4.1.1 (5) Acute toxicity to fish			
Annex Point IIA 7.4.1.1			
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. Alkyldimethylbenzylammonium Chloride was tested. <i>(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):</i>	X
3.1.3	Description	<i>If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)</i> [REDACTED]	
3.1.4	Purity	<i>Give purity in g/kg, g/l, %w/w or % v/v active substance</i> [REDACTED]	X
3.1.5	Stability	<i>Describe stability of test material</i> Stable	
3.1.6	Method of analysis	[REDACTED]	
3.2 Testing procedure			
3.2.1	Dilution water	[REDACTED]	
3.2.2	Test organisms	Rainbow trout (<i>Oncorhynchus mykiss</i>) supplied [REDACTED]	
3.2.3	Test system	[REDACTED]	
3.2.4	Test conditions	Static, daily renewal [REDACTED]	
3.2.5	Duration of the test	96 hours	

Section 7.4.1.1 (5)		Acute toxicity to fish	
Annex Point IIA 7.4.1.1			
3.2.6	Test parameter	Mortality	
3.2.7	Monitoring of test substance concentration	[REDACTED] [REDACTED] [REDACTED] [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] ¹	
4.2.3	Effect data (Mortality)	Refer to Table 7.4.1.1(5)-1	
4.2.4	Other effects	Three hours after test initiation, three fish in the 1.354 mg/l dose group were swimming erratically on the water surface. No mortality or non-lethal toxic symptoms occurred in test substance concentration of 0.619 mg/l during the 96-hour exposure.	
4.3	Results of controls		
4.3.1	Number/percentage of animals showing adverse effects	[REDACTED] [REDACTED] [REDACTED] [REDACTED]	
4.3.2	Nature of adverse effects	[REDACTED]	
5. APPLICANT'S SUMMARY AND CONCLUSION			
5.1	Materials and methods	<i>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.</i> [REDACTED] [REDACTED] [REDACTED] [REDACTED]	

Section 7.4.1.1 (5)		Acute toxicity to fish
Annex Point IIA 7.4.1.1		
5.2 Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i>	
5.2.1 LC0	LC ₀ (96hr) = 0.619 mg/l	
5.2.2 LC50	LC ₅₀ (96hr) = 0.930 mg/l (95% confidence limit = 0.866 to 0.984 mg/l) Refer to Table 7.4.1.1(5)-2	
5.2.3 LC100		
5.3 Conclusion	<i>Subsections for NOAEL, LOAEL etc. if appropriate</i>	
	Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.619 mg/l.	
5.3.1 Reliability	<i>Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4</i>	
5.3.2 Deficiencies	<i>(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)</i>	
Evaluation by Competent Authorities		
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date		
Materials and Methods		
Results and discussion		
Conclusion		
Reliability		
Acceptability	<i>Acceptable</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE		
Date	<i>Give date of the comments submitted</i>	

Section 7.4.1.1 (5)	Acute toxicity to fish
Annex Point IIA 7.4.1.1	
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table 7.4.1.1(5)-1

Mortality data

Concentration (mg/l)	Percent Mortality at:			
	24 hours	48 hours	72 hours	96 hours
1.354	10	95	100	100
1.204	0	60	100	100
1.029	0	5	30	60
0.864	0	0	25	40
0.619	0	0	0	0

Table 7.4.1.1(5)-2

LC50

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	>1.354	1.175	1.1066	0.930
95% confidence limits	not determined	(1.029-1.354)	(0.864-1.204)	(0.866-0.984)

Section 7.4.1.1	
Annex Point IIIA.7.4.1.1	
	Acute toxicity to fish (marine)
	COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.4.1.2(1)		Acute toxicity to invertebrates	
Annex Point IIA 7.4.1.2			
		1. REFERENCE	Official use only
1.1 Reference	Pate, H. O. and D. O. McIntyre (1991). Daily Static-Renewal Acute 48-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to <i>Daphnia magna</i> . . Report No. SC890052. Battelle Columbus Division, Columbus, OH, U. S (unpublished). [Ref No: A68 (LON 0097)]		
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>		
1.2.1 Data owner	<i>Give name of company</i> ADBAC Joint Venture		
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 Subdivision E, Guideline 72-2 Hazard evaluation: Wildlife and aquatic organisms 1990 <i>(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")</i>		
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>		
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>		
		3. MATERIALS AND METHODS	
		<i>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.</i>	
3.1 Test material	Alkyldimethylbenzylammonium Chloride		
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> ████████████████████		

Section 7.4.1.2(1)		Acute toxicity to invertebrates	
Annex Point IIA 7.4.1.2			
		[REDACTED]	
3.2.5	Duration of the test	48 hours	
3.2.6	Test parameter	Mortality and immobilisation	
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]	X
4.2.3	Effect data (Mortality)	EC ₅₀ (24hr) = 0.0194 mg/l (95% confidence limits 0.0149 to 0.0272 mg/l) EC ₅₀ (48hr) = 0.0058 mg/l (95% confidence limits 0.0036 to 0.0075 mg/l) Refer to Table 7.4.1.2(1)-1	X
4.2.4	Other effects	None	
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 7.4.1.2(1) Annex Point IIA 7.4.1.2		Acute toxicity to invertebrates	
5. APPLICANT'S SUMMARY AND CONCLUSION			
5.1 Materials and methods	<i>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.</i>		
	[REDACTED]		
5.2 Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i>		X
5.2.1 EC0	Not defined		
5.2.2 EC50	EC ₅₀ (24hr) = 0.0194 mg/l (95% confidence limits 0.0149 to 0.0272 mg/l) EC ₅₀ (48hr) = 0.0058 mg/l (95% confidence limits 0.0036 to 0.0075 mg/l)		X
5.2.3 EC100	Not stated but 100% mortality observed at 0.0227 mg/l (measured).		
5.3 Conclusion	<i>Subsections for NOAEL, LOAEL etc. if appropriate</i> Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be less than 0.006 mg/l.		
5.3.1 Reliability	<i>Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4</i>		X
	[REDACTED]		
5.3.2 Deficiencies	[REDACTED] <i>(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)</i>		
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Materials and Methods	[REDACTED]		

Section 7.4.1.2(1) Annex Point IIA 7.4.1.2	Acute toxicity to invertebrates
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table A7.4.1.2(1)-1

Mortality data

Mean measured concentration (mg/l)	Percent Mortality at:	
	24 hours	48 hours
0.0516	100	100
0.0272	100	100
0.0227	65	100
0.0149	25	95
0.0060	5	53
0.0	0	10

Section 7.4.1.2 Acute toxicity to invertebrates (marine)**Annex Point IIIA.7.4.1.2****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)		Growth inhibition test on algae	
Annex Point IIA 7.4.1.3			
		1. REFERENCE	Official use only
1.1 Reference	Mayer, P, H. Oldersma and J. A. Schoonmade (2001). Determination of the effect of Alkyldimethylbenzylammonium Chloride (ADBAC) on the growth of fresh water green alga <i>Selenastrum capricornutum</i> (OECD Guideline No. 201 and EU C.3). TNO Chemistry, Delft, The Netherlands. Report no. 99-9072-03 (unpublished). [Ref No: A48 (LON 3374)]		
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>		
1.2.1 Data owner	<i>Give name of company</i> ADBAC Issues Steering Committee		
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 "Algal Growth Inhibition Test" 2001 <i>(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")</i>		
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>		
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>		
		3. MATERIALS AND METHODS	
		<i>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.</i>	
3.1 Test material	██████████		
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> ██████████ ██████████		

Section 7.4.1.3(1)		Growth inhibition test on algae	
Annex Point IIA 7.4.1.3			
5.3.2	Deficiencies	<input type="checkbox"/>	<i>(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)</i>
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPporteur MEMBER STATE			
Date			
Materials and Methods	[REDACTED]		
Results and discussion	[REDACTED]		
Conclusion	[REDACTED]		
Reliability		<input type="checkbox"/>	
Acceptability			<i>Acceptable</i>
Remarks			
COMMENTS FROM OTHER MEMBER STATE			

Section 7.4.1.3(1) Annex Point IIA 7.4.1.3	Growth inhibition test on algae
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Table 7.4.1.3(1)-1. 72-Hour Effect Concentrations for Growth Rate and Area Under the Growth Curve (AUC).

Parameter	EC ₁₀ (ug a.i./l)	EC ₅₀ (ug a.i./l)	EC ₉₀ (ug a.i./l)
Growth Rate (E _r C)	9.0	49	270
AUC (E _b C)	<1.2	14	57

Table 7.4.1.3(1)-2. Mean Values of cell algal densities (10⁴ cells/ml corrected for background)

Time (hours)	Measured concentrations of ADBAC (ug a.i./l)E _b C ₁₀ (ug/l)							
	E _b C ₅₀ (ug/l)							
	E _b C ₉₀ (ug/l)							
	0	0	1.2	5.1	11	22	98	382
0	1.0	1.0	--	--	--	--	--	--
23	4.8	4.7	4.6	4.4	3.6	3.8	0.7	0.6
47	24.3	24.0	21.9	19.6	16.0	7.1	0.7	0.1
71	111.2	110.9	96.0	82.9	66.3	29.3	0.9	-3.0

-- Not determined

Table 7.4.1.3(1)-3. The area under the growth curve (A) and the percentage reduction in growth (I_A) after 72 hours of exposure to ADBAC

Parameter	Measured concentrations of ADBAC (ug a.i./l)							
	0	0	1.2	5.1	11	22	98	382
A	1974	1956	1726	1511	1203	552	-14	-43
I _A	0	0	12	23	39	72	101	102

Section 7.4.1.3

Growth inhibition test on algae (marine)

Annex Point IIIA.7.4.1.3

COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date

Evaluation of applicant's
justification

Conclusion

Remarks

Section 7.4.1.4 (1)		Inhibition on microbiological activity	
Annex Point IIA 7.4.1.4			
		1. REFERENCE	Official use only
1.1 Reference	<i>Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages)</i> <i>If necessary, copy field and enter other reference(s).</i>	Mayer, P, H., J. A. Schoonmade and A. O. Hanstveit (2001). Screening of the Effect of Alkyldimethylbenzylammonium Chloride on the Respiration Rate of Activated Sludge (OECD Guideline No. 209). TNO Nutrition and Food Research, Delft, The Netherlands. Report no. 99-9072-04 (unpublished). [Ref No: A49 (LON 3324)]	
1.2 Data protection	Yes <i>(indicate if data protection is claimed)</i>		
1.2.1 Data owner	<i>Give name of company</i> ADBAC Issues Steering Committee		
1.2.2 Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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. 209 "Activated Sludge, Respiration Inhibition Test" 2001 <i>(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")</i>		X
2.2 GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>		
2.3 Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>		
		3. MATERIALS AND METHODS	
		<i>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.</i>	
3.1 Test material	Alkyldimethylbenzylammonium Chloride		X
3.1.1 Lot/Batch number	<i>List lot/batch number where relevant</i> ██████████		

Section 7.4.1.4 (1)		Inhibition on microbiological activity	
Annex Point IIA 7.4.1.4			
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] <i>(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):</i>	X
3.1.3	Description	<i>If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)</i> [REDACTED]	
3.1.4	Purity	<i>Give purity in g/kg, g/l, %w/w or % v/v active substance</i> [REDACTED]	
3.1.5	Stability	<i>Describe stability of test material</i> Stable	
3.1.6	Method of analysis	[REDACTED]	
3.2 Testing procedure			
3.2.1	Dilution water	[REDACTED]	
3.2.1	Test organisms	Activated sludge, domestic	
3.2.2	Test system	[REDACTED] [REDACTED]	X
3.2.3	Test conditions	[REDACTED] [REDACTED]	X
3.2.4	Duration of the test	3 hours	
3.2.5	Test parameter	Inhibition on respiration rate	X
3.2.6	Monitoring of test substance concentration	[REDACTED]	
3.2.7	Statistics	[REDACTED]	X
4. RESULTS			
4.1	Limit test	No	
4.2 Results test substance			
4.2.1	Initial concentration of test substance	[REDACTED]	

Section 7.4.1.4 (1)		Inhibition on microbiological activity	
Annex Point IIA 7.4.1.4			
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date		[REDACTED]	
Materials and Methods		[REDACTED]	
Results and discussion		[REDACTED]	
Conclusion		[REDACTED]	
Reliability		[REDACTED]	
Acceptability		acceptable	
Remarks		[REDACTED]	
COMMENTS FROM OTHER MEMBER STATE			
Date		<i>Give date of the comments submitted</i>	
Materials and Methods		<i>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</i>	
Results and discussion		<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion		<i>Discuss if deviating from view of rapporteur member state</i>	
Reliability		<i>Discuss if deviating from view of rapporteur member state</i>	
Acceptability		<i>Discuss if deviating from view of rapporteur member state</i>	

Section 7.4.1.4 (2)		Inhibition on microbiological activity	
Annex Point IIA 7.4.1.4			
		1. REFERENCE	Official use only
1.1	Reference	Corby J.E. (1992) Determination of the Acute Toxicity of Chemicals and Wastewaters to Aquatic Microorganisms. Roy F. Weston, Inc., Lionville, PA, USA. Report No. 91-062 (unpublished). [Ref No: A62]	
1.2	Data protection	Yes <i>(indicate if data protection is claimed)</i>	
1.2.1	Data owner	<i>Give name of company</i> ADBAC Joint Venture	
1.2.2	Criteria for data protection	<i>Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:</i> 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 Modification to a five day biochemical oxygen demand analysis 1992 <i>(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")</i>	X
2.2	GLP (only where required)	Yes <i>(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)</i>	
2.3	Deviations	No <i>(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")</i>	
		3. MATERIALS AND METHODS	
		<i>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.</i>	
3.1	Test material	██████████	
3.1.1	Lot/Batch number	<i>List lot/batch number where relevant</i> ██████████	