Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in ethanol solution.	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5 Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 Method of analysis	[redacted]	X
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Semi-continuous activated sludge (SCAS)	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	X
3.2.5 Duration of the test	3 days	
3.2.6 Test parameter	Acute microbial toxicity	X
3.2.7 Monitoring of test substance concentration	[redacted]	X

Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
3.2.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results test substance		
4.2.1 Stock solution concentrations	[redacted]	
4.2.2 Actual concentrations of test substance	[redacted]	
4.2.3 Effect data (Mortality)	Threshold inhibition level (Unacclimated microbes) > 10 mg/l Threshold inhibition level (Acclimated microbes) > 20 mg/l	X
4.2.4 Other effects	None	
4.3 Results of controls		
4.3.1 Number/ percentage of animals/ species showing adverse effects	[redacted]	X
4.3.2 Nature of 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.*	
5.2.1 Threshold inhibition level	Threshold inhibition level (Unacclimated microbes) > 10 mg/l Threshold inhibition level (Acclimated microbes) > 20 mg/l	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate*	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	

Section 7.4.1.4 (2) **Annex Point IIA 7.4.1.4**	**Inhibition on microbiological activity**
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	Accepted
Reliability	[redacted]
Acceptability	In this test the effect of ADBAC on the DO depletion in comparison of the glucose control was measured after 3 days exposure. The study does not follow a standard guideline. The results, limited to the unacclimated sludge, can be accepted as additional information.
Remarks	
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 7.4.2 (1) **Annex IIA Point 7.4.2**	**Bioconcentration**	
	1. REFERENCE	Official use only
1.1 Reference	Fackler, P. H. (1989) Bioconcentration and Elimination of 14C-Residues by Bluegill (*Lepomis macrochirus*) Exposed to Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). Springborn Life Sciences, Inc., Wareham MA, USA. Report No. 89-1-2921 (unpublished). [Ref No: A45 (LON 1866)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Joint Venture	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA OPP 165-4 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	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN	X

	68424-85-1) in aqueous solution was tested.	
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* The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	*Lepomis macrochirus*	X
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	Test temperature: 17°C	
3.2.5 Duration of the test	35 days	
3.2.6 Test parameter	BCF and Elimination	
3.2.7 Monitoring of test substance concentration	[redacted]	X
3.2.8 Statistics		
	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 BCF	BCF = 79	X
4.2.4 Other effects (Mortality)	Two treated fish (in a population of 190) died	
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	*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 BCF	BCF = 79	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The substance has low potential to bioaccumulate.	
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
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 7.4.2-1. Measured ^{14}C-residue concentrations calculated as ADBAC in the edible (muscle/skin) and nonedible (viscera/carcass) tissue of bluegill (*Lepomis macrochirus*) during 35 days of continuous aqueous exposure to ^{14}C-ADBAC at a mean measured water concentration of 0.076 (± 0.024) mg/L and during an additional 21 days depuration in flowing, untreated water.

Day	Mean (S.D.) Water Concentration (mg/L)[a]	Mean (S.D.) ^{14}C-Residue Tissue Concentration (mg/kg)[b]		
		Edible	Nonedible	Whole Body
Exposure Period				
0	0.036 (0.002)	---	---	---
1	0.057 (0.005)	0.10 (0.021)	1.1 (0.35)	0.49 (0.14)
3	0.074 (0.010)	0.30 (0.19)	2.1 (0.57)	1.1 (0.34)
7	0.081 (0.013)	0.99 (0.11)[c]	7.1 (1.1)	3.2 (0.54)[c]
8	0.076 (0.009)[d]	---[e]	---	---
9	0.088 (0.004)	---	---	---
10	0.65 (0.001)	1.3 (0.27)	6.3 (1.2)	3.3 (0.61)
14	0.062 (0.0023)	2.1 (0.21)	11 (1.6)	5.5 (0.82)
21	0.13 (0.039)	2.2 (0.44)	12 (3.6)	6.34 (1.8)
23	0.083 (0.008)	---	---	---
28	0.088 (0.022)	2.5 (0.22)	11 (2.0)	5.8 (0.90)
35	0.079 (0.008)	3.4 (0.81)	13 (1.2)	6.6 (2.4)
Depuration Period				
1	<0.014	0.78 (0.96)[d]	1.7 (2.6)[c,d]	1.2 (1.8)[c,d]
3	<0.014	2.6 (0.10)	11 (0.50)	5.9 (0.28)
7	<0.014	2.6 (0.24)	8.6 (1.1)	5.0 (0.65)
10	<0.014	2.3 (0.08)	7.6 (0.74)	4.4 (0.36)
14	<0.014	2.2 (0.24)	7.1 (0.61)	4.2 (0.25)
21	<0.014	2.4 (0.47)	5.3 (1.3)	3.7 (0.75)

[a] Mean and standard deviation (S.D.) based on radiometric analysis of triplicate samples.
[b] Mean (S.D.) based on analysis of tissue portion of 5 fish.
[c] N = 4
[d] Analyses not validated by Quality Assurance samples.
[e] --- = Measurements not required at stated time interval.

Table 7.4.2-2. Measured ^{14}C-residue concentrations calculated as ^{14}C-ADBAC in the edible (muscle) and nonedible (viscera/carcass) tissue of bluegill (*Lepomis macrochirus*) during 56 days of continuous aqueous exposure to untreated control water.

Figure 3. A comparison of measured tissue concentration of ^{14}C-ADBAC versus those predicted by the model for whole body in bluegill (*Lepomis macrochirus*).

edicted

			Official use only
		Laboratories for Rohm and Haas Company, Philadelphia, PA, USA. Report no. 23-42. (unpublished). [Ref No: A86 (LON 1099)]	X
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		2. GUIDELINES AND QUALITY ASSURANCE	

Section 7.4.2 (2) Annex IIA Point 7.4.2		Bioconcentration	
2.1	**Guideline study**	No guidelines were available at the time of the study An in-house method of [redacted] was used 1971 *(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)*	
2.3	**Deviations**	Not applicable *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	**Test material**	[redacted]	X
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	X
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in ethanol solution.	
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted] Refer to Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein, for specifications of percent active substance, purity and typical impurities.	X
3.1.5	Stability	*Describe stability of test material* The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	

Section 7.4.2 (2) **Annex IIA Point 7.4.2**	**Bioconcentration**	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Bluegill sunfish	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	Flow-through. [redacted]	
3.2.5 Duration of the test	6 weeks	
3.2.6 Test parameter	Bioconcentration and Elimination	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Sampling	[redacted]	
3.2.9 Statistics	[redacted]	

Section 7.4.2 (2) Annex IIA Point 7.4.2	Bioconcentration	
	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 BCF	BCF = 42.5 for carcass BCF = 103 for viscera	X
4.2.4 Other effects (Mortality)	After 24 days of continuous exposure (and 10 days of no exposure) fish from the low exposure level died. This was a direct consequence of a common fish disease and was not caused by the test substance.	
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.*	
5.2.1 BCF @ 0.196 ppm exposure level	BCF = 42.5 for carcass BCF = 103 for viscera	X
5.2.2 Elimination	The time for 50% of labelled test substance to be eliminated from the fish was found in all cases to be less than a week. Potential of the test substance to accumulate in fish is low and the residue in fish exposed to the test substance is rapidly eliminated from fish body.	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The substance has low potential to bioaccumulate. The residue in fish exposed to the test substance is rapidly eliminated from the fish body.	X

Section 7.4.2 (2) **Annex IIA Point 7.4.2**	**Bioconcentration**	
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]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	*Not acceptable*	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	

Section 7.4.2 (2) **Annex IIA Point 7.4.2**	**Bioconcentration**
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.4.3.3.1(1)-1: ^{14}C Residues in bluegills under continuous exposure

Day	^{14}C-Residue Concentrations (ppm)			
	Low Exposure Level		High Exposure Level	
	Carcass	Viscera	Carcass	Viscera
1	0.321	0.420	0.801	1.67
2	0.388	0.506	2.09	3.52
3	--	--	--	--
4	0.650	0.360	2.62	5.34
5	0.735	0.452	3.13	9.25
6	0.679	4.60	3.88	7.65
7	4.38	4.09	8.32	19.9
8	0.935	1.48	6.35	26.3
9	1.10	2.46	7.00	23.2
10	--	--	--	--
11	--	--	--	--
12	1.38	2.92	9.45	14.4
13	--	--	--	--
14	1.25	4.72	8.58	20.2
21	1.54	8.13	11.2	16.4
28	Fish died on Day 24		7.62	19.2
42			8.10	108
47			15.8	21.1
48			18.0	94.0
49			19.4	78.6
50			17.8	126
59			21.8	42.3
60			25.3	47.6

-- Samples not taken

Section 7.4.3 Effects on aquatic organisms, further studies
Annex Point IIA 7.4.3 – headline only

Section 7.4.3.1 **Annex Point IIIA.7.4.3.1**	**Prolonged toxicity to fish**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	*Acceptable*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.4.3.1 **Annex Point IIIA.7.4.3.1**	**Prolonged toxicity to fish**
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.2(1) **Annex Point IIA 7.4.3.2**	**Effects on reproduction and growth rate to Fathead minnow**	
	1. REFERENCE	Official use only
1.1 Reference	McIntyre, D. O. and H. O. Pate (1992). Static-Renewal Early Life Stage Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnows. Report No. SC890057. Battelle Columbus Operations, Columbus, OH, U. S (unpublished). [Ref No: A11 (LON 3219)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Joint Venture	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA 72-4(a) 1991 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.4.3.2(1) **Annex Point IIA 7.4.3.2**	**Effects on reproduction and growth rate to Fathead minnow**	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especiallySections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous solution.	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* The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 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	All test solutions were renewed daily and prepared immediately before use. Exposures were conducted without aeration. [redacted]	X

Section 7.4.3.2(1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate to Fathead minnow	
	[redacted]	
3.2.5 Duration of the test	28-day post-hatch (34-day total: egg plus post-hatch exposure)	
3.2.6 Test parameter	Toxicity, mortality, effects on hatchability and growth	
3.2.7 Monitoring of test substance concentration	Sample concentrations of ^{14}C-ADBAC were verified by liquid scintillation counting.	
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)	See Table 7.4.3.1(1)-1 and 7.4.3.2(2)-2 LC_{50} (28 days post hatch) = 94 µg/l	
4.2.4 Other effects		
	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	See Table 7.4.3.2(1)-1 LC_{50} (28 days post hatch) = 94 µg/l	
5.2.2 LOECs/ NOECs	See Table 7.4.3.2(1)-2; An effect on hatching success (68% compared to 89% for controls) was observed at 488.7 µg/l. Therefore, the NOEC for	

Section 7.4.3.2(1) **Annex Point IIA 7.4.3.2**		**Effects on reproduction and growth rate to Fathead minnow**	
		hatchability was 273.7µg*/l	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) for hatchability was found to be 273.7 µg/l, the NOEC for survival was 32.2 µg/l and the NOEC for growth was found to be greater than 32.2 µg/l.	X
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		acceptable	
Remarks		*2.1 The study is consistent with OECD guideline 210, which is the method recommended by TNsG.*	
		COMMENTS FROM OTHER MEMBER STATE	

Section 7.4.3.2(1) **Annex Point IIA 7.4.3.2**	**Effects on reproduction and growth rate to Fathead minnow**
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.4.3.2(1)-1 LC50

	7-day post hatch	14-day post hatch	21-day post hatch	28-day post hatch
LC50 (µg/l)	198	104	98	94
95% confidence limits (µg/l)	(164-231)	(72-138)	(68-130)	(64-126)

Table 7.4.3.2(1)-2 NOEC and LOEC values

LOEC (µg/l) hatchability	488.7
NOEC (µg/l) hatchability	273.2
NOEC(µg/l) survival	32.2
NOEC (µg/l) growth	>32.2

Table 7.4.3.2(1)-3: Mean measured concentrations of ADBAC in test vessels

[redacted]

Table 7.4.3.2(1)-4: Cumulative percent mortality

Mean Measured Concentration (ug/l)	Cumulative Percent Mortality Days Post-hatch			
	7-day	14-day	21-day	28-day
0	5	5	10	10
32.2	11	26	26	26
75.9	30	35	35	40
134.2	20	44	50	50
186.8	35	55	60	60
273.2	85	90	90	90
488.7	100	100	100	100

Table 7.4.3.2(1)-5: Average dry weight of surviving fry exposed to test substance

Dose concentration (µg/l)	Mean dry weight (mg/fry)[a]
0	0.800
32.2	0.996
75.9	0.972
134.2	1.149
186.8	1.557
273.2	1.908

488.7	n/d

n/d no data (all fish had died)
[a] Total dry weight of fry per replicate/number of surviving fry per replicate.

Section 7.4.3.3 Bioaccumulation in an aquatic organisms
Annex Point IIA 7.4.3.3- headline only

Section 7.4.3.3.1 (1) **Annex Point IIA 7.4.3.3.1**	**Bioaccumulation in fish**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:		
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted] *The non submission of data for the present section is deemed justified due to other existing data (7.4.2 (1).*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.4.3.3.2 Annex Point IIIA.7.4.3.3.2	**Bioaccumulation in an appropriate invertebrate species**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	*Accepted*	

Section 7.4.3.3.2 **Annex Point IIIA.7.4.3.3.2**	**Bioaccumulation in an appropriate invertebrate species**
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
	1. REFERENCE	Official use only
1.1 Reference	McIntyre, D. O. and H. O. Pate. (1992) Daily Static-Renewal Chronic 21-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Daphnia magna. Report No. SC890056. Battelle Columbus Operations, Columbus, OH, U. S. (unpublished). [Ref No: A12 (LON 3220)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Joint Venture	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA 72-4 (b) 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")*	X

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	X
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1) was tested.	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* The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 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]	X

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*	
	[redacted]	
3.2.4 Test conditions	Static daily renewal [redacted]	
3.2.5 Duration of the test	21 days	
3.2.6 Test parameter	Mortality, reproduction and growth	
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)	See Table 7.4.3.4(1)-1	X
4.2.4 Other effects	See Table 7.4.3.4(1)-1 MATC = 4.56 µg/l	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 Mortality	NOECs/LOECs: See Table 7.4.3.4(1)-1	
5.2.2 Reproduction	NOECs/LOECs: See Table 7.4.3.4(1)-1	X
5.2.3 Growth	NOECs/LOECs: See Table 7.4.3.4 (1)-1	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the chronic NOEC for mortality, reproduction and growth was found to be 4.15 µg/l. The maximum acceptable toxicant concentration (MATC) was 4.56 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 7.4.3.4(1) Annex Point IIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*
Materials and Methods	[redacted]

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	**Effects on reproduction and growth rate with *Daphnia magna***
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable* [redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***
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	*Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.4.3.4 (1)1 NOEC and LOEC results

Parameter		Concentration (µg/l)
Mortality*	**NOEC**	≥ 4.15
	LOEC	> 4.15
Reproduction**	**NOEC**	4.15
	LOEC	5.02
Growth**	**NOEC**	≥ 4.15
	LOEC	> 4.15

*Based on the total 22 exposed daphnids /concentration

** based on 7 individually exposed daphnids/concentration

Table 7.4.3.4(1)-2 Mean Measured Concentrations of ADBAC in Test Vessels (ug/L). Standard deviation in parentheses (± SD).

[redacted]

Table 7.4.3.4(1)-3. Number of Young per Adult

[redacted]

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

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
	1. REFERENCE	Official use only
1.1 Reference	England, D. C. and T. Leak (1995). Chronic Toxicity of Sediment-Incorporated ADBAC to *Chironomus tentans*. Report No. 41004. ABC Laboratories, Inc., Columbia, MO, U.S.A (unpublished). [Ref No: A13 (LON 3221)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Joint Venture	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA 72-4 (b) ASTM Document E 1383-93 and U.S. EPA-600/3-75-009 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	Alkyldimethylbenzylammonium Chloride	

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Non-radiolabelled active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	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* The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Midge (*Chironomus tentans*) [redacted]	
3.2.3 Test system	[redacted] treated sediment [redacted]	
3.2.4 Test conditions	[redacted]	

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
	[redacted]	
3.2.5 Duration of the test		
3.2.6 Test parameter	Mortality, toxicity	X
3.2.7 Monitoring of test substance concentration		X
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]	X
4.2.2 Actual concentrations of test substance	[redacted]	X
4.2.3 Effect data (Mortality)	See Table 7.4.3.5.1(1)-1	
4.2.4 Concentration/ response curve	Concentration-response slopes were calculated to be 5.13 for day 14 and 4.22 for day 28.	
4.2.5 Other effects	On Day 14, the 520 and 1200 mg/kg treatment levels had significantly lower larval weights (wet and dry) than controls. There was a general decrease in mean larval weight with increasing sediment concentration of ADBAC, but the difference was not statistically significant for the	

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1	Effects on sediment dwelling organisms	
	120 or 260 mg/kg treatments. See Table 7.4.3.5.1(1)-1	
4.3 Results of controls		
4.3.1 Number/ percentage of animals showing adverse effects	[redacted]	
4.3.2 Nature of adverse effects		
	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 Mortality	LC50/NOECs/LOECs/MATC : See Table 7.4.3.5.1(1)–1	X
5.2.2 Growth	LC50/NOECs/LOECs/MATC: See Table 7.4.3.5.1(1)–2	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the chronic NOEC for the test substance was found to be 520 mg/kg of sediment.	X
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]	

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable for NOEC and LOEC.*
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.4.3.5.1(1)-1 Mortality data / survival

Parameters (mg/kg)	Day 14	Day 28
LC50	548	479
95% confidence limits	458-656	377-600
NOEC	260	520
LOEC	520	1200
MATC	368	790

Table 7.4.3.5.1(1)-2

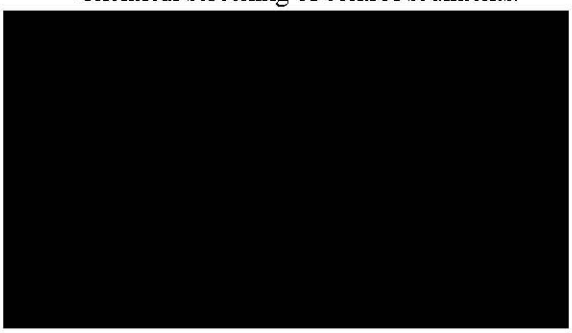
Parameters (mg/kg)	Day 14 - Growth data	Day 28 - Emergence
NOEC	260	520
LOEC	520	1200

Table 7.4.3.5.1(1)-3

Measured sediment concentration (mg/kg) in analytical replicates

Table 7.4.3.5.1(1)-4

Chemical screening of control sediments.



Section 7.4.3.5.1 **Annex Point IIIA.7.4.3.5.1**	**Second and third study on effects on sediment dwelling organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	X X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	