Section 7.1.1.2.1(4) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	Corby, J. E. (1992) Semi-Continuous Activated Sludge (SCAS) Removability Test - Hyamine 3500-80. Report No. 91-065. Roy F. Weston, Inc., Lionville, PA, U. S. (Unpublished) [Ref No.: A3 (LON 2302)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Joint Venture	
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 OECD Guideline 302 A	X
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 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	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	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 7.1.1.2.1(4) **Annex Point IIA 7.1.1.2.1**		**Ready biodegradability**	
3.2	**Test procedure**	[redacted]	
3.2.1	Test system	Activated sludge, [redacted]	
3.2.2	Acclimation period	7 days	
3.2.3	Test period	7 days	
		4. RESULTS	
4.1	**% Carbon removed**	See Table 7.1.1.2.1(4)-1 Ca 100% after 7 days	
4.2	**Remarks**	The test substance was readily biodegradable.	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	X
5.3	**Conclusion**	The average percent SOC removal for ADBAC was >100%.	
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	[redacted]	
		Evaluation by Competent Authorities	
		EVALUATION BY RAPPORTEUR MEMBER STATE	

Section 7.1.1.2.1(4) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**
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 7.1.1.2.1(4)-1. % Carbon removed

Days	Test 1	Test 2
1	100.59	102.96
2	98.22	106.51
3	100.00	104.73
4	98.22	100.59
5	100.59	102.96
6	101.18	104.73
7	102.96	102.96

Section 7.1.1.2.1(5) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
	1. REFERENCE	Official use only
1.1 Reference	Van Dievoet, F. and V. Bouillon. (2005) Biodegradability Test Report According to OECD 301 B – Modified. Report No. ST49132.01.01, dated January 19, 2004 for Stephan Europe, Voreppe, France; from BfB Oil Research S.A., Gembloux, Belguim. (Unpublished) Ref. No. A113 (LON 3960)	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Issues Steering Committee	
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	Yes OECD Guideline 301B	
2.2 GLP (only where required)	No. However, this study was conducted in accordance with ISO 17025 Regulations.	
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. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[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.	

Section 7.1.1.2.1(5) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
3.1.5 Stability	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).	
3.2 Reference Compound	[redacted]	
3.3 Test procedure	[redacted]	
3.3.1 Test system	[redacted]	
3.3.2 Inoculum	[redacted]	
3.3.3 Contact time	28 days, in dark	
3.3.4 Temperature range	22 ± 2 °C	
3.3.5 Test concentrations	Test substance: 5 mg carbon/l [redacted]	
	4. RESULTS	
4.1 Kinetics	See Table 7.1.1.2.1(5)-1.	
4.2 Remarks	The results indicated that 95.5% total CO_2 was produced in test vessels, compared to 88.9% in the reference standard. CO_2 production in the blank (inoculum control) was 39.2 mg. The pH measured at the start and end of the test period was 7.3 and 7.8, respectively. The temperature throughout the test ranged from 20.8 to 21.4°C.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and	[redacted]	

Section 7.1.1.2.1(5) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
methods	[redacted]	
5.2 Results and discussion	[redacted]	X
5.3 Conclusion	The test material was determined to be readily biodegradable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
Remarks		
	COMMENTS FROM	
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 7.1.1.2.1(5)-1: Test Results

Day	Reference Substance		Test Substance	
	% CO_2 Produced	% CO_2 Total	% CO_2 Produced	% CO_2 Total
0	[redacted]		0.0	0.0
1			1.2	1.2
3			1.0	2.2
6			9.5	11.6
8			16.0	27.7
10			20.2	47.9
13			17.4	65.3
15			7.5	72.8
17			5.1	77.9
20			3.9	81.8
22			1.6	83.5
24			4.4	87.8
28			1.8	89.6
29			5.8	95.5

Section 7.1.1.2.3 Annex Point IIIA.7.1.1.2.3	Biodegradation in seawater	
	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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.1.2 Rate and route of degradation in aquatic systems including identification of metabolites and degradation products
Annex Point IIA 7.1.2 – headline only

Section 7.1.2.1 Biological sewage treatment
Annex Point IIA 7.1.2.1 – headline only

Section 7.1.2.1.1 **Annex IIIA Point 7.1.2.1.1**	**Aerobic biodegradation**	
	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	

Section 7.1.2.1.1 **Annex IIIA Point 7.1.2.1.1**	**Aerobic biodegradation**
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	Applicant's justification is acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2.1.1 (1) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation**	
	[redacted]	Official use only
1.1 Reference	Schaefer, E.C. (2001) Didecyldimethylammoniumchloride (DDAC): Dieaway in Activated Sludge. Project No. 289E-112. Wildlife International, Inc., Easton, MA, USA (unpublished). [Ref No.: A101 (LON 3438)]	
1.2 Data protection	Yes	
Data owner	The Dialkyl Project	
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	
	Guidelines and Quality Assurance	
1.3 Guideline study	No Not specified 2001	X
1.4 GLP (only where required)	Yes	
1.5 Deviations	No	
	Materials and Methods	
1.6 Test material	Didecyldimethylammonium Chloride	
Lot/Batch number	[redacted]	
Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted]	
Description	[redacted]	
Purity	[redacted]	
Stability	Stable	
1.7 Test system		
Test system	Biotic activated sludge [redacted]	

Section 7.1.2.1.1 (1) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation**	
Control	[redacted]	
Source	[redacted]	
1.8 Test procedure		
Acclimation period	[redacted]	
Test period	28 days	
Test condition	[redacted]	
Sampling intervals	[redacted]	
1.9 Statistics	[redacted]	
	Results	
1.10 Dose concentration	[redacted]	
1.11 Radioactive distributions		
CO_2	See Table 7.1.2.1.1(1)-1 The amount of $^{14}CO_2$ increased over time reaching 93.3% after 28 days. No $^{14}CO_2$ evolved in the abiotic sample.	
Extracts	See Table 7.1.2.1.1(1)-1 The amount of parent and metabolite decreased over time reaching 1.32% of metabolite and 0% of metabolite after 28 days. In the abiotic sample radioactivity was found as an average 92.2% parent and 0% metabolite.	
Solids	See Table 7.1.2.1.1(1)-1 The amount of radioactivity in the solid varied from 1.71 – 5.32% with 3.28% found after 28 days. 1.5% of the radioactivity was present as solid in the abiotic sample.	
1.12 Statistics		
2 compartment function kinetic analysis	See Table 7.1.2.1.1(1)-2	
	Applicant's Summary and conclusion	

Section 7.1.2.1.1 (1) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation	
1.13 Materials and methods	[redacted]	
1.14 Results and discussion	[redacted]	
1.15 Conclusion	Didecyldimethylammonium Chloride biodegrades in aerobic conditions	
Reliability	[redacted]	X
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	*The study was not conducted to any specified guideline.*	

Section 7.1.2.1.1 (1) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation**
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 stat*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.1.2.1.1(1)-1. Radioactive distributions (% total radioactivity)

	Biotic				**Abiotic**
DDAC	**1 hr**	**12 hrs**	**Day 7**	**Day 28**	**mean**
CO_2	12.36	65.83	88.36	93.30	N/A
Extracts – parent	65.21	9.72	1.56	1.32	92.22
Extracts – metabolite	20.10	13.37	1.02	0.00	0.00
Solid	1.71	3.58	5.32	3.28	1.50
Total	99.38	92.50	96.26	97.90	93.72

N/A – Not Applicable

Table 7.1.2.1.1(1)-2. 2 compartment functions kinetic analysis

			Compartment A		**Compartment B**	
Process	**F-value**	**R^2**	**A (%)**	**K_1 (hrs^{-1})**	**B (%)**	**K_1 (hrs^{-1})**
$^{14}CO_2$ production	539.9	0.990	65.9 ± 5.8	0.2 ± 0.003	26.4 ± 5.6	0.014 ± 0.005
Loss of parent	1423.9	0.996	47.4 ± 9.7	1.1 ± 0.29	59.1 ± 10.1	0.17 ± 0.03

Section 7.1.2.1.2 Annex IIIA Point 7.1.2.1.2	Anaerobic biodegradation	
	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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	

Section 7.1.2.1.2 Annex IIIA Point 7.1.2.1.2	Anaerobic biodegradation
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.1.2.2.1 Annex IIIA Point 7.1.2.2.1	Aerobic aquatic degradation study	
	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	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	Applicant's justification is acceptable	
Remarks		

Section 7.1.2.2 Annex IIIA Point 7.1.2.2	Water/sediment degradation study	
	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	Due to exposure to the anaerobic conditions is lacking, it does not need to provide the study. Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 7.1.2.2.2 **Annex IIIA Point 7.1.2.2.2**	**Water/sediment degradation study**
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 7.1.3 Annex Point IIA.7.1.3	Adsorption/desorption screening test	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** X] **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.1.4 Studies on adsorption and desorption in water/sediment systems
Annex Point IIIA 7.1.4 – headline only

Section 7.1.4.1 **Annex Point IIIA.7.1.4.1**	**Field study on accumulation in the sediment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	

Section 7.1.4.1 Annex Point IIIA.7.1.4.1	Field study on accumulation in the sediment
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2 Fate and behaviour in soil
Annex Point 7.2 – headline only

Section 7.2.1 **Annex IIA Point 7.2.1**	**Aerobic degradation in soil, initial study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	

Section 7.2.1 Annex IIA Point 7.2.1	Aerobic degradation in soil, initial study
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 7.2.2 Aerobic degradation in soil, further studies
Annex Point IIIA 7.2.2 – headline only

Section 7.2.2.1 **Annex IIIA Point 7.2.2**	**Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.2.2.1 Annex IIIA Point 7.2.2	Rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions
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 7.2.2.2 Annex Point IIIA.7.2.2.2	Field soil dissipation and accumulation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** []	**Technically not feasible** [ ] **Scientifically unjustified** [X] **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.2.2.3 Annex Point IIIA.7.2.2.3	Extent and nature of bound residues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.2.2.4 Annex Point IIIA.7.2.2.4	Other soil degradation studies (e.g. photolysis)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]		
	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	The study might be justified but the justification should be reworded on the basis of the statement in TGD (Ch. 3, Part A, Section 7.2.2.4). Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

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

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. and W. Cranor. (1988) Soil/Sediment Adsorption-Desorption of Alkyl Dimethyl Ammonium Chloride. Report No. 35716. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, USA. (Unpublished) [Ref No.: A43 (LON 1867)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Joint Venture	
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 Guideline subdivision N 163-1 1988	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable	

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**	
	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).	
3.2 Test system		
3.2.1 Soil types	sand, sandy loam, clay loam, silt loam	
	4. RESULTS	
4.1 Adsorption coefficient (K_d)	See Table 7.2.3.1(1)-1	
4.2 Mobility coefficient (K_{oc})	See Table 7.2.3.1(1)-1	
4.3 Remarks	The test substance can be classified as immobile in all four soil types.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion		
5.2.1 Sand	K_d=6'172 K_{oc}=6'171'657	
5.2.2 Sandy loam	K_d=5'123 K_{oc}=640'389	
5.2.3 Clay loam	K_d=32'429 K_{oc}=1'663'039	
5.2.4 Silt loam	K_d=10'797 K_{oc}=2'159'346	
5.3 Conclusion	The substance can be classified as immobile in all four soil types.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

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**
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	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 7.2.3.1(1)-1. Adsorption (K_d) and mobility coefficients.(K_{oc})

Soil Types	Adsorption coefficient (K_d)	Mobility coefficient (K_{oc})	Desorption coefficient (K_d)	Mobility coefficient (K_{oc})
Sand	6,172	6,171,657	7173	7137310
Sandy loam	5,123	640,389	96540	12067457
Clay loam	32,429	1,663,039	165556	8490062
Silt loam	10,797	2,159,346	14083	2816590

Section 7.2.3.2 Annex Point IIIA.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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section 7.2.3.2 Mobility – Lysimeter studies Annex Point IIIA.7.2.3.2
Remarks

Section 7.3 Fate and behaviour in air
Annex Point IIA 7.3 – headline only

Section 7.3.1 (1) **Annex Point IIIA 7.3.1**	**Phototransformation in air (estimation method), including identification of breakdown products**	
	1. REFERENCE	Official use only
1.1 Reference	Howes. D.A., (2003). Estimation of Photodegradation using the Atmospheric Oxidation Program (AOPWIN). (Unpublished)	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Issues Steering Committee	
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	
2.2 GLP (only where required)	No Not required	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	Not applicable; calculated endpoint	
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 Procedure	[redacted]	

Section 7.3.1 (1) **Annex Point IIIA 7.3.1**	**Phototransformation in air (estimation method), including identification of breakdown products**	
	[redacted]	
	4. RESULTS	
4.1 Results	Refer to Table 7.3.1(1)-1 ADBAC has an atmospheric half-life of 0.25 days or 3.0 hours	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test substance is predicted to be rapidly phototransformed in air.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	

Section 7.3.1 (1) **Annex Point IIIA 7.3.1**	**Phototransformation in air (estimation method), including identification of breakdown products**
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	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 7.3(1)-1

N-alkyl- species	Rate constant, k: cm^3/mol-sec	Half-life: days; hours
$C_{12}H_{25}$	40.7784 x 10^{-12}	0.262; 3.148
$C_{14}H_{29}$	43.6045 x 10^{-12}	0.245; 2.944
$C_{16}H_{33}$	46.4306 x 10^{-12}	0.230; 2.764

Section 7.3.2 Annex Point IIIA.7.3.2	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [X]	**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	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 7.3.2 Annex Point IIIA.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**	Pate. H.O. and D.O. McIntyre (1991). Daily Static-Renewal Acute 96-hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Bluegill Sunfish. Battelle Columbus Division, Columbus, OH, U. S. Report No. SC890050 (unpublished). [Ref No: A8a (LON 1865)]	
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 Subdivision E, Guideline 72-1, Hazard Evaluation: Wildlife and Aquatic Organisms 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")*	
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	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 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
	Alkyldimethylbenzylammonium Chloride was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	X
3.1.5 Stability	*Describe stability of test material* Stable	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	Bluegill sunfish (*Lepomis macrochirus*) [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	
3.2.6 Test parameter	Mortality	

Section 7.4.1.1 (1) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	
3.2.9 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	
4.2.4 Other effects	Immobilisation and erratic swimming were noted for some fish in the 0.56 mg/l (nominal) group.	
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]	

Section 7.4.1.1 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC0	Not stated but 0.455 mg/l (measured) showed no effects or mortality	
5.2.2 LC50	LC_{50} (96hr) = 0.515 mg/l (95% confidence limit = 0.456 to 0.638 mg/l) Refer to Table 7.4.1.1(1)-2	
5.2.3 LC100	Not stated but 100% mortality observed at 0.638 mg/l (measured).	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.456 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		
	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*	

Section 7.4.1.1 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.4.1.1(1)-1 Mortality data*

Concentration (mg/l)	**Percent Mortality at:**			
	24 hours	**48 hours**	**72 hours**	**96 hours**
0.6384	100	100	100	100
0.515	30	50	50	50
All other dose levels	0	0	0	0

Table 7.4.1.1(1)-2 LC50

LC50 (mg/l)	**24hr**	**48hr**	**72hr**	**96hr**
	0.540	0.515	0.515	0.515
95% confidence limits	(0.456-0.638)	(0.456-0.638)	(0.456-0.638)	(0.456-0.638)

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	Sword, M. C. and Stuerman, L. (1994) Static-Renewal Acute Toxicity of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow (*Pimephales promelas*). ABC Laboratories, Columbia, MO, U. S. Report No. 41237 (unpublished). [Ref No: A6 (LON3476)]	
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 TSCA 797.1400 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	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	X

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	
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	Static, daily renewal [redacted]	
3.4.5 Duration of the test	96 hours	
3.2.6 Test parameter	Mortality	
3.2.7 Monitoring of test substance concentration	[redacted]	