Competent Authority Report

DOCUMENT III-A

Study Summaries Active Substance

Section 7

Rapporteur Member State: Italy

December 2012

SECTION 7

ECOTOXICOLOGICAL PROFILE INCLUDING ENVIRONMENTAL FATE

Introduction

The read across of data from biocidal active substances of similar chemical structure for the purpose of safety evaluation is not a new concept. Bridging studies on several identical endpoints (non volatile, water soluble, hydrolytically stable, readily biodegradable, immobile in soil), are provided in the Tables below for N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate (Bardap 26) and Didecyldimethylammonium Chloride (DDAC). The presence of hydrophobic side chains in both substances results in similar movement and fate characteristics (adsorption, degradation).

The tables below show results of the bridging studies.

Environmental fate: Bridging studies to DDAC		
Study	**Bardap 26**	**DDAC**
Vapour pressure	non volatile (1.8×10^{-6} Pa, 20°C)	non volatile (5.9×10^{-6} Pa, 20 °C)
Solubility in water	highly soluble	highly soluble
Hydrolysis	hydrolytically stable	hydrolytically stable
Biodegradation	95 % (CAS)	>95% (STP simulation)
	partial mineralisation (34 %; OECD 301B)	readily biodegradable (77.5 %; OECD 301B)
Henry's constant	3.03x10-11Pa.m3/mol (monomer)	4.27x10-9 Pa.m3/mol
Partition coefficient	Not determined as the substance is ionic and surface active.	Not determined as substance is ionic and surface active
Adsorption	immobile (calculated) Koc: 122'000	immobile (measured) Koc > 400'000

For the endpoints:

7.4.3.3.1	Bioaccumulation in fish
7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish
7.4.3.4	Effects on reproduction and growth rate with an appropriate invertebrate species
7.4.3.5.1	Effects on soil dwelling organisms
7.5.1.1	Inhibition of soil microbial activity
7.5.1.3	Acute toxicity to terrestrial plants
7.5.3.1.2	Avian short-term toxicity

tests have been conducted with the chemical and structural analog, Didecyldimethylammonium Chloride.

The proposal for read across of N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate with data of Didecyldimethylammonium Chloride was widely discussed between the Applicant and the RMS. In this process also, additional data were provided in support of the read across.

Except for the issue of read across for bird studies, which was accepted without further discussion at the begininning of the evaluation process and is addressed in section A7.5.3.1.2, the rational for the acceptance/refusal of the read across of studies 7.4.3.3.1, 7.4.3.2, 7.4.3.4, 7.4.3.5.1, 7.5.1.1 and 7.5.1.3, is reported in Doc IIA, Appendix I.

Section 7.1 Fate and behaviour in water
Annex Point IIA 7.1 – headline only

Section 7.1.1 Degradation, initial studies
Annex Point IIA 7.1.1 – headline only

Section 7.1.1.1 Abiotic
Annex Point IIA 7.1.1.1 – headline only

Section 7.1.1.1.1 (1) **Annex Point IIA 7.1.1.1.1**	**Hydrolysis as a function of pH and identification of breakdown products**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) Determination of abiotic degradation: Hydrolysis as a function of pH. [redacted]. Project No: 102/383 (unpublished) Lonza Report No.: 3381	
1.1 Data protection	Yes	
1.1.1 Data owner	Lonza AG	
1.1.2 Criteria for data protection	Data submitted 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 Directive 92/69/EEC, C.*7* 2001	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethly)ammonium Propionate	
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: Bardap 26 tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Test procedure	Sample solutions were prepared in stoppered glass flasks at a nominal concentration of 4g/l in the buffer solutions at pH4, pH7 and pH9, using	

Section 7.1.1.1.1 (1) Annex Point IIA 7.1.1.1.1	Hydrolysis as a function of pH and identification of breakdown products
	a 1% methanol co-solvent. The solutions were shielded from light and maintained at 50.0 ± 0.5°C for 5 days.
	4. RESULTS
4.1 Results of test substance	
4.1.1 Initial concentration of test substance	[redacted]
4.1.2 Actual concentrations of test substance	[redacted]
4.2 Degradation %	[redacted]
4.3 Half life	[redacted]
4.4 Remarks	[redacted]
	5. APPLICANT'S SUMMARY AND CONCLUSION
5.1 Materials and methods	The study was carried out in accordance with Directive 92/69/EEC, C.*7* guidelines. Buffers used were pH 4, 7, and 9. Samples were incubated at 50°C for 5 days and shielded from light.
5.2 Results and discussion	No degradation occurred during the incubation period.
5.3 Conclusion	N,N-Didecyl-N-methylpoly(oxyethly)ammonium Propionate is hydrolytically stable at 25°C at pH 4, 7 and 9 for over 1 year.
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	No
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.1.1.1.1 (1) Annex Point IIA 7.1.1.1.1	Hydrolysis as a function of pH and identification of breakdown products
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.1.1.1.2 Annex Point IIA 7.1.1.1.2	Phototransformation in water including identity of the products of transformation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 7.1.1.1.2(1) **Annex Point IIA 7.1.1.1.2**	**Phototransformation in water including identity of the products of transformation**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1989) Determination of the Photolysis Rate of Didecyldimethylammonium Chloride (DDAC) in pH 7 Buffered Solution at 25 °C. Report No. 37005. [redacted] (Unpublished). Ref No.: D37 (LON 1793)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	U.S. EPA-FIFRA N-161-2 1988	
2.2 GLP (only where required)	[redacted]	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable under the conditions of this study.	
3.2 Testing procedure	A study using ^{14}C-Didecyldimethylammonium Chloride (DDAC) at a nominal concentration of 10 µg/ml was conducted at 25°C in aqueous solution buffered at pH 7. The test substance was exposed to a xenon arc light source for 30 days; controls were kept in the dark for 30 days.	
3.2.1 Light source	[redacted]	
3.2.2 Light spectrum	[redacted]	
3.2.3 Light intensity	[redacted]	
3.2.4 Sensitiser	[redacted]	
	4. RESULTS	
4.1 Results of test		

Section 7.1.1.1.2(1) Annex Point IIA 7.1.1.1.2	Phototransformation in water including identity of the products of transformation	
substance		
4.1.1 Initial concentration of test substance	[redacted]	
4.2 Direct Photolyis		
4.2.1 Half Life	[redacted]	
4.2.2 Degradation %	[redacted]	
4.3 Indirect Photolyis		
4.3.1 Half Life	[redacted]	
4.3.2 Degradation %	[redacted]	
4.3.3 Rate constant	[redacted]	
4.3.4 Breakdown Products	[redacted]	
4.4 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	A study using ^{14}C-Didecyldimethylammonium Chloride (DDAC) at a nominal concentration of 10 µg/ml was conducted at 25°C in aqueous solution buffered at pH 7. The test substance was exposed to a xenon arc light source for 30 days; controls were kept in the dark for 30 days. The study was carried out in accordance with U.S. EPA-FIFRA N-161-2.	
5.2 Results and discussion	The test substance was found to be photolytically stable in the absence of a photosensitiser. An accurate estimate of the photolysis rate constants and the half-life for solutions containing no photosensitiser and all dark controls (both sensitised and nonsensitised) could not be determined since no significant degradation of the test substance was detected during the 30 day evaluation period. Essentially all of the ^{14}C-moiety not present as parent compound was found in a single degradate.	
5.2.1 Direct photolysis	[redacted]	
5.2.2 Indirect photolysis	[redacted]	
5.2.3 Half life	[redacted]	

Section 7.1.1.1.2(1) Annex Point IIA 7.1.1.1.2	Phototransformation in water including identity of the products of transformation	
5.3 Conclusion	The test substance is photolytically stable in the absence of a photosensitising agent. In the presence of the energy from a xenon arc lamp and the photosensitising agent, acetone, it appears that Didecyldimethylammonium Chloride breaks down to form a single degradate.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
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 OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 7.1.1.2 Biotic
Annex Point IIA 7.1.1.2 – headline only

Section 7.1.1.2.1(1) Annex Point IIA 7.1.1.2.1	**Ready Biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2004) ^{14}C-Radiolabelled N,N-Didecyl-N-methyl poly(oxyethyl) Propionate, Assessment of Ready Biodegradability – Modified Sturm Test, Report No. LZA/246. [redacted]. (Unpublished) Lonza Report No.: 3835	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC Procedure C.4-C, OECD Procedure 301B, U.S. EPA OPPTS 853.3110.	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	N,N-didecyl–N-methyl-poly(oxyethyl)ammonium Propionate	
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: ^{14}C-radiolablled N,N-didecyl-N-methyl-poly(oxyethyl)ammonium Propionate was tested.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Test procedure		
3.2.1 Test system	[redacted]	
3.2.2 Contact time	[redacted]	
3.2.3 Positive control	[redacted]	

Section 7.1.1.2.1(1) Annex Point IIA 7.1.1.2.1	**Ready Biodegradability**	
	[redacted]	
3.2.4 Negative controls	[redacted]	
	4. RESULTS	
4.1 Test substance concentration	[redacted]	
4.2 Control results		
4.2.1 % Biodegradation	[redacted]	
4.2.2 $^{14}CO_2$ production	[redacted]	
4.3 Test substance results	[redacted]	
4.4 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with Directive 92/69/EEC Procedure C.4-C, OECD Procedure 301B and U.S. EPA OPPTS 853.3110. Mineral salts inoculated with activated sludge were treated with ^{14}C- N,N-didecyl-N-methyl-poly(oxyethyl)ammonium Propionate and incubated with 29 days.	
5.2 Results and discussion	Mean cumulative $^{14}CO_2$ production was equivalent to 10% after 4 days and progressed rapidly until Day 8. The rate of biodegradation then slowed. 34% biodegradation had occurred by Day 29, where the biodegradation curve was still on the upward trend, confirming a continuing mineralisation of the test substance.	
5.3 Conclusion	Under the strict terms and conditions of the OECD Test Guidelines for ready biodegradability the test substance cannot be termed readily biodegradable. However, the biodegradation curve was still on the upward trend at the termination of the test after 29 days, confirming a continuing mineralisation of the test substance.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion		

Section 7.1.1.2.1(1) Annex Point IIA 7.1.1.2.1	**Ready Biodegradability**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*acceptable*
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.1.1.2.1(2) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) Bardap 26 (LZ1524.1): Assessment of Ready Biodegradability; CO_2 Evolution Test. [redacted] Project No.: 102/381. [redacted] Lonza Report No. 3405	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 301B "Ready Biodegradability; CO_2 Evolution Test" 1992	
2.2 GLP **(only where required)**	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecylmethylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Test procedure		
3.2.1 Test system	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Innoculum concentration	[redacted]	
3.2.4 Control substance	[redacted]	
3.2.5 Exposure period	[redacted]	
3.2.6 Incubation conditions	[redacted]	

Section 7.1.1.2.1(2) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
3.2.7 Sampling times	[redacted]	
3.2.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Test substance concentration	[redacted]	
4.2 CO_2 evolution	[redacted]	
4.3 % Biodegradation	[redacted]	
4.4 DOC concentration	[redacted]	
4.5 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with OECD Guideline 301B "Ready Biodegradability; CO_2 Evolution Test". Samples of activated sludge mixed with culture medium were dosed with Didecyldimethylpoly(oxyethyl)ammonium Propionate, sodium benzoate or a mixture of both. Evolved CO_2 was collected in vessels containing 0.05M NaOH aqueous solution.	
5.2 Results and discussion	Samples dosed with Didecyldimethylpoly(oxyethyl)ammonium Propionate showed 0% biodegradation after 28 days.	
5.3 Conclusion	Didecyldimethylpoly(oxyethyl)ammonium Propionate is not readily biodegradable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion		

Section 7.1.1.2.1(2) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*acceptable*
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.1.1.2.1(2)-1. CO_2 Evolution (Inorganic Carbon Concentration (mg))

Day	**Control**		**Sodium benzoate**		**Test material**		**Sodium benzoate and test material**
	R1	**R2**	**R1**	**R2**	**R1**	**R2**	**R1**
[redacted]							

R1, R2: Replicas 1 and 2
All values are the sum of the two CO_2 absorber vessels for each sample.

Table 7.1.1.2.1(2)-2. % Biodegradation

Day	**Sodium benzoate**	**Test material**	**Sodium benzoate and test material**
[redacted]			

Table 7.1.1.2.1(2)-3. DOC concentration (mg C/l)

Sample	**Day 0**		**Day 28**		
	mg C/l	**% nominal C**	**mg C/l**	**% initial C**	**% degradation**
[redacted]					

R1, R2: Replicas 1 and 2

Section 7.1.1.2.2 **Annex Point IIA.7.1.1.2.2**	**Inherent biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1989) [redacted] Bardap 26: Assessment of Biodegradability in a Zahn-Wellens-Test. [redacted] Project No.: V-89-273. [redacted]. Lonza Report No. 2889	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG and Clariant AG (former Hoechst AG)	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 302 B "Inherent Biodegradability; Zahn-Wellens-Test" 88/302/EWG (Part C), Official Journal L 133, 30.9.1988 1981	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecylmethylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Test procedure		
3.2.1 Test system	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Innoculum concentration	[redacted]	
3.2.4 Control substance	[redacted]	

Section 7.1.1.2.2 Annex Point IIA.7.1.1.2.2	Inherent biodegradability	
3.2.5 Exposure period	[redacted]	
3.2.6 Incubation conditions	[redacted]	
3.2.7 Sampling times	[redacted]	
	4. RESULTS	
4.1 Test substance concentration	[redacted]	
4.3 % Biodegradation	[redacted]	
4.5 Remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was carried out in accordance with OECD Guideline 3012 "Inherent Biodegradability; Zahn-Wellens-Test". Samples of activated sludge mixed with culture medium were dosed with Didecyldimethylpoly(oxyethyl)ammonium Propionate. Based on the measured DOC concentrations at distinct time points, the % elimination and % biodegradation was calculated. The results were corrected against the blank values obtained at time 0 days.	
5.2 Results and discussion	80% elimination or 57 % biodegradation was reached after 15 days. Thereafter, no significant increase in biodegradation or elimination was observed until the termination of the test after 28 days. This can be attributed to the potential toxic properties of the test substance at the high initial test concentration of 303 mg C/l. Didecyldimethylpoly(oxyethyl)ammonium Propionate can be termed as inherently biodegradable.	
5.3 Conclusion	Didecyldimethylpoly(oxyethyl)ammonium Propionate is not readily biodegradable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No control substance and no blank values reported. Not performed to GLP. Overall poor reporting. The results are not representative as the used starting concentration of 303 mg C/l (corresponding to approx. 534 mg test substance/l) is far above the toxic limit for activated sludge organisms (3-hour EC50 = 11 mg test substance/l).	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		

Section 7.1.1.2.2 **Annex Point IIA.7.1.1.2.2**	**Inherent biodegradability**
Results and discussion	
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Not acceptable*
Remarks	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Table 7.1.1.2.2-1. Analytical results (% elimination and biological degradation)

Day	**Test material**	
	Elimination	**Biological Degradation**
[redacted]		

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	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 (1) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation – Primary sewage biodegradation**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1989) Evaluation of biodegradability of Bardap 26 (Disinfectant QAV) in the OECD-Confirmatory-Test Project No. 417/89 (B). [redacted] (Unpublished). Lonza Report No. 1308	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG and Clariant AG (formal Hoechst AG)	
1.2.2 Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD, Paris 1981, Test Guideline 303 A 1981	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecylmethylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable at room temperature	
3.2 Test system		
3.2.1 Test system	[redacted]	
3.2.2 Control	[redacted]	

Section 7.1.2.1.1 (1) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation – Primary sewage biodegradation	
3.2.3 Source	[redacted]	
3.3 Test procedure		
3.3.1 Acclimation period	[redacted]	
3.3.2 Test period	[redacted]	
3.3.3 Test condition	[redacted]	
3.3.4 Sampling intervals	[redacted]	
	4. RESULTS	
4.1 Dose concentration	[redacted]	
4.2.1 Primary degradation	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was conducted according to OECD Test Guideline 303 A, Confirmatory Test, Paris 1981.	
5.2 Results and discussion	Didecylmethylpoly(oxyethyl)ammonium Propionate showed a mean primary degradation from the 21. day of incubation of >95 %.	
5.3 Conclusion	Didecylmethylpoly(oxyethyl)ammonium Propionate biodegrades well in aerobic conditions and is considered to be readily removed during the biological sewage treatment process.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[redacted]	
Materials and Methods		
Results and discussion		
Conclusion	[redacted]	

Section 7.1.2.1.1 (1) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation – Primary sewage biodegradation**
Reliability	[redacted]
Acceptability	*Acceptable*
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.1.2.1.1(2) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation – Ultimate sewage biodegradation**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2009) [C]Bardap 26: Biodegradatoin in Activated Sludge. Project No. 289E-120 [redacted] (Unpublished). Lonza Report No. 4352	
1.2 Data protection	Yes	
1.2.1 Data owner	Lonza AG	
1.2.2 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No Not specified 2009	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	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	Didecylmethylpoly(oxyethyl)ammonium Propionate	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecylmethylpoly(oxyethyl)ammonium Propionate, in aqueous/alcohol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The non-radiolabelled a.s., Didecylmethylpoly(oxyethyl)ammonium Propionate, 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 at room temperature, *e.g.* at least two years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Test system		X

Section 7.1.2.1.1(2) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation – Ultimate sewage biodegradation	
3.2.1 Test system	[redacted]	
3.2.2 Control	[redacted]	
3.2.3 Source	[redacted]	
3.3 Test procedure		
3.3.1 Acclimation period	[redacted]	
3.3.2 Test period	[redacted]	
3.3.3 Test condition	[redacted]	
3.3.4 Sampling intervals	[redacted]	
3.4 Statistics	[redacted]	
	4. RESULTS	
4.1 Dose concentration	[redacted]	
4.2 Radioactive distributions		

Section 7.1.2.1.1(2) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation – Ultimate sewage biodegradation**	
4.2.1 CO_2	[redacted]	
4.2.2 Extracts	[redacted]	
4.2.3 Solids	[redacted]	
4.3 Statistics		
4.3.1 1st order non-linear function kinetic analysis	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was not conducted to any specified guideline. Two 1 gallon jugs, with gas trapping systems, containing 2 and 1 litres of either biotic or abiotic activated sludge, respectively, were dosed with 50 µg/l radiolabelled test substance.	
5.2 Results and discussion	At test termination (28 days) 86% of the radioactivity was evolved as $^{14}CO_2$, 0.0% was recovered in the extracts and 5.79% remained in the solid. 6.34% of a polar metabolite was detected after 28 days. In the abiotic sample 101.88% of the radioactivity was recovered in the extracts and 3.01% remained in the solid.	X
5.3 Conclusion	Didecylmethylpoly(oxyethyl)ammonium Propionate biodegrades in a waste water treatment plant die-away silmulation test under aerobic conditions with a removal half life DT_{50} of 4.7 hours and a high conversion rate to CO_2.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[redacted]	

Section 7.1.2.1.1(2) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation – Ultimate sewage biodegradation**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Not acceptable as key study. Study is acceptable as supplementary information.
Remarks	Study is not GLP compliant.
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

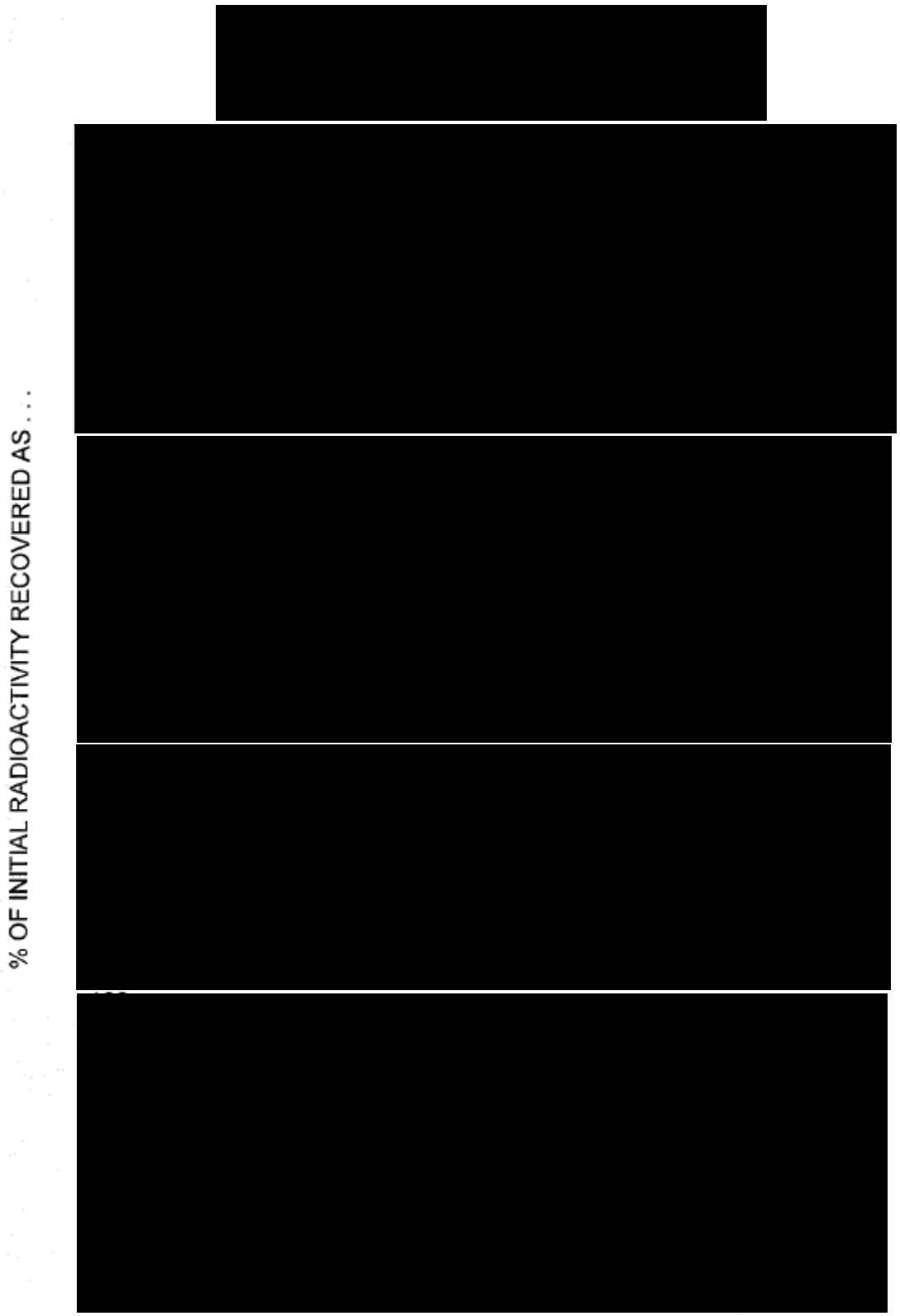
Table 7.1.2.1.1(2)-1. Radioactive distributions (% total radioactivity)

DDAC	Biotic				Abiotic
	1 hr	3 hrs	Day 3	Day 28	mean
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Table 7.1.2.1.1(2)-2. Kinetic analysis

Process	F-value	R^2	Compartment A	
			A (%)	K_1 (hrs^{-1})
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Figure 7.1.2.1.1(2)-1



Section 7.1.2.1.1(3) Annex Point IIIA 7.1.2.1.1	Aerobic biodegradation – Ultimate sewage biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 7.1.2.1.1(4) **Annex Point IIA 7.1.2.1.1**	**Aerobic biodegradation**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) Didecyldimethylammonium Chloride (DDAC): Dieaway in Activated Sludge. Project No. 289E-112. [redacted] (Unpublished). Ref No.: D60 (LON 3438)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No Not specified 2001	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	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	Bardac 2280 with radiolabelled Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The non-radiolabelled a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Test system		
3.2.1 Test system	[redacted]	

Section 7.1.2.1.1(4) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation	
	[redacted]	
3.2.2 Control	[redacted]	
3.2.3 Source	[redacted]	
3.3 Test procedure		
3.3.1 Acclimation period	[redacted]	
3.3.2 Test period	[redacted]	
3.3.3 Test condition	[redacted]	
3.3.4 Sampling intervals	[redacted]	
3.4 Statistics	[redacted]	
	4. RESULTS	
4.1 Dose concentration	[redacted]	
4.2 Radioactive distributions		
4.2.1 CO_2	[redacted]	
4.2.2 Extracts	[redacted]	
4.2.3 Solids	[redacted]	
4.3 Statistics		
4.3.1 2 compartment function kinetic analysis	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	The study was not conducted to any specified guideline. Two 1 gallon jugs, with gas trapping systems, containing 2 litres of either biotic or abiotic activated sludge were dosed with 16 µg/l radiolabelled test	

Section 7.1.2.1.1(4) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation	
	substance.	
5.2 Results and discussion	At test termination (28 days) 93.3% of the radioactivity was evolved as $^{14}CO_2$, 1.32% was recovered in the extracts and 3.28% remained in the solid. One major metabolite was identified. In the abiotic sample 92.22% of the radioactivity was recovered in the extracts and 1.5% remained in the solid.	
5.3 Conclusion	Didecyldimethylammonium Chloride biodegrades in aerobic conditions	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion		
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Table 7.1.2.1.1(2)-1. Radioactive distributions (% total radioactivity)

	Biotic				Abiotic
DDAC	**1 hr**	**12 hrs**	**Day 7**	**Day 28**	**mean**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

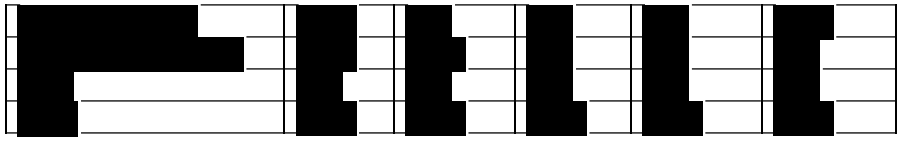


Table 7.1.2.1.1(2)-2. 2 compartment functions kinetic analysis

Process	F-value	R^2	Compartment A		Compartment B	
			A (%)	K_1 (hrs^{-1})	B (%)	K_1 (hrs^{-1})

Section 7.1.2.1.2 Annex IIIA Point 7.1.2.1.2	Anaerobic biodegradation	
	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		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

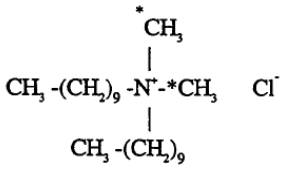
Section 7.1.2.2 Biodegradation in freshwater
Annex Point IIA 7.1.2.2 – headline only

Section 7.1.2.2.1 **Annex Point IIIA.7.1.2.2.1**	**Aerobic aquatic degradation study**	
	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]	

Section 7.1.2.2.1 Annex Point IIIA.7.1.2.2.1	Aerobic aquatic degradation study
Evaluation of applicant's justification	
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.1.2.2.2 Annex Point IIIA.7.1.2.2.2	Water/sediment degradation study	
	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]	

Section 7.1.2.2.2 Annex Point IIIA.7.1.2.2.2	Water/sediment degradation study
Evaluation of applicant's justification	
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	**A Water/sediment degradation study**	
	1. Reference	Official use only
1.1 Reference	[redacted] (2000) A water/sediment study of didecyldimethylammonium chloride (DDAC) using [^{14}C]-DDAC. [redacted] Study No. IMW-99-9048-01 (unpublished). Ref. No. D65 (LON 3255)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. Guidelines and Quality Assurance	
2.1 Guideline study	Yes. Dutch CTB guideline Section G.2.1, German BBA guideline for the registration of pesticides, part IV, 5-1, the EU Commission Directive 95/36/EC and SETAC-Europe Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides. The study design is in general agreement with the current OECD 308 guideline.	
2.2 GLP	Yes	
2.3 Deviations	No	
	3. Materials and Methods	
3.1 Test material	[^{14}C]-Didecyldimethylammonium Chloride (DDAC) Structure:  *Position of label Non-radiolabelled – DDAC (provided as Bardac 22, a trade name for DDAC).	

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	**A Water/sediment degradation study**	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. [redacted]	
3.1.3 Purity	[redacted]	
3.1.4 Stability	The non-radiolabelled a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, e.g. at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.5 Further relevant properties	[redacted]	
3.1.6 Composition of Product	[redacted]	
3.1.7 Specific chemical analysis	[redacted]	
3.2 Reference substance	[redacted]	
3.2.1 Initial concentration of reference substance	[redacted]	
3.3 Testing procedure	The route and rate of aquatic degradation of [^{14}C]-DDAC was investigated in two representative natural aerobic water/anaerobic sediment systems under laboratory conditions at a temperature of 20°C.	

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	A Water/sediment degradation study	
3.3.1 Test media	[redacted]	
3.3.2 Test system	[redacted]	
3.3.3 Test conditions	[redacted]	
3.3.4 Method of preparation of test solution	[redacted]	
3.3.5 Initial TS concentration	[redacted]	
3.3.6 Duration of test	[redacted]	

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	A Water/sediment degradation study	
3.3.7 Sampling	[redacted]	
3.3.8 Liquid scintillation counting	[redacted]	
3.3.9 Chromatographic analysis	[redacted]	

[1] The extraction solvent was modified to acetone:ultrapure water:acetic acid (80:10:10) for the last extraction of the 7 day samples and for all subsequent samples

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	**A Water/sediment degradation study**
	[redacted]
3.3.10 Controls	[redacted]
3.3.11 Statistics	[redacted]
	4. Results
4.1 Recovery and distribution	[redacted]
4.2 Degradation of test substance	[redacted]
	5. Applicant's Summary and conclusion
5.1 Materials and methods	The study was designed to meet the Dutch CTB (Section G.2.1), the German BBA (Part IV, 5-1) and SETAC-Europe guidelines, along with

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	**A Water/sediment degradation study**	
	EU Commission Directive 95/36/EC. The study design is in general agreement with the current OECD 308 guideline. The route and rate of aquatic degradation of [^{14}C]-DDAC was investigated in two representative natural aerobic water/anaerobic sediment systems under laboratory conditions at a temperature of 20°C. The study was conducted in accordance with GLP and was reported in 2000.	
5.2 Results and discussion	The recovery and distribution of the applied radioactivity from the water/sediment systems was generally unacceptable in the study ranging overall from 69.1 to 96.3%. At the 0 day sampling interval the recovery in both water/sediment systems was < 80%. The applied radioactivity quickly dissipated to the sediment layer; radioactivity in the water layer comprised < 5% by 14 days. The total amount of carbon dioxide evolved after 120 days was 7.8% (TNO) and 15.4% (Kromme Rijn). No significant metabolites were observed.	
5.3 Conclusion	The active substance DDAC quickly dissipated from the water layer to the sediment layer. Overall, major methodological deficiencies limit the usefulness of the study and the information that can be reliably derived.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	Yes, deficiencies listed below: 1) Mass balance: the recovery of applied radioactivity was generally below levels considered to be acceptable. 2) Sample work up: procedural recovery of applied radioactivity during work up of the sample extracts, although not detailed in the report, were indicated to have been at levels below that considered to be acceptable.	
	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		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.1.2.2.2 (1) Annex Point IIIA XII.2.1	A Water/sediment degradation study
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Table A7.1.2.2.2 (1)-1: Test system characterisation

Table C1: [redacted]

Figure A7.1.2.2.2 (1)-1: [redacted]

Figure 1 [redacted]

Table A7.1.2.2.2 (1)-2: Recovery and distribution of applied radioactivity from the water/sediment systems

[redacted]

Figure A7.1.2.2.2 (1)-2: [redacted]

Figure A7.1.2.2.2 (1)-3: [redacted]

Table A7.1.2.2.2 (1)-3: [redacted]

Table A7.1.2.2.2 (1)-4: [redacted]

Section 7.1.3 **Annex IIA Point 7.1.3**	**Adsorption/desorption screening test**	
	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	[redacted].	

Section 7.1.3 Annex IIA Point 7.1.3	Adsorption/desorption screening test
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.1.4 Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary
Annex Point IIA 7.1.4 – headline only

Section 7.1.4 **Annex Point IIIA.7.1.4**	**Studies on adsorption and desorption in water/sediment systems**	
	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.)*	

Section 7.1.4 Annex Point IIIA.7.1.4	Studies on adsorption and desorption in water/sediment systems
	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	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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 *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]	

Section 7.1.4.1 Annex Point IIIA.7.1.4.1	Field study on accumulation in the sediment
Evaluation of applicant's justification	
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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

Section 7.2.1 **Annex IIIA Point 7.2.1**	**Aerobic degradation in soil, initial study**	
	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
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	

Section 7.2.1 Annex IIIA Point 7.2.1	Aerobic degradation in soil, initial study
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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

Section 7.2.2.1 **Annex IIIA Point 7.2.2.1**	**The 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 *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	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 7.2.2.1 Annex IIIA Point 7.2.2.1	The 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
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.2.2.2 Annex Point IIIA.7.2.2.2	Field soil dissipation and accumulation	
	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]	

Section 7.2.2.2 Annex Point IIIA.7.2.2.2	Field soil dissipation and accumulation
Evaluation of applicant's justification	
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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 *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]	

Section 7.2.2.3 Annex Point IIIA.7.2.2.3	Extent and nature of bound residues
Evaluation of applicant's justification	
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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 *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
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		

Section 7.2.2.4 Annex Point IIIA.7.2.2.4	Other soil degradation studies (e.g. photolysis)
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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 **Annex Point IIIA 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**	
	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 [X]** **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		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.2.3.1 Annex Point IIIA 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]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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	[redacted] (1989) Soil/Sediment Adsorption-Desorption of ^{14}C-Didecyldimethylammonium Chloride (DDAC). Report No. 37009. [redacted] (Unpublished). Ref No.: D42 (LON 1792)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA-FIFRA Guideline N-163-1 1989	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
	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	Bardac 22 with radiolabelled Didecyldimethylammonium Chloride	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The non-radiolabelled a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Test system		

Section 7.2.3.1(1) **Annex Point IIA 7.2.3.1**		**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**	
3.2.1	Soil types	[redacted]	
3.2.2	Soil:water ratio	[redacted]	
3.3	**Test procedure**	Aqueous ^{14}C-Didecyldimethylammonium Chloride (DDAC) was equilibrated with four soil types and adsorption and desorption coefficients and constants were determined.	
3.3.1	Adsorption	[redacted]	
3.3.3	Desorption	[redacted]	
		4. RESULTS	
4.1	**Results of test compound**		
4.1.1	Initial concentrations of test compound	[redacted]	
4.1.2	Estimated distribution of test compound	[redacted]	
4.2	**Coefficients**	[redacted]	
4.3	**Remarks**	[redacted]	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	^{14}C- Didecyldimethylammonium Chloride was equilibrated with four soil types and adsorption and desorption coefficients and constants were determined. A 1:200 soil:water ratio was used. Soil types were: sand, sandy loam, silty clay loam, and silt loam. Adsorption: One-gram samples of soil were placed into bottles; triplicate aliquots of each standard solution were added to bottles. Soil suspensions were shaken in dark environmental chamber at 25 ºC for 24 hours. Suspensions were then centrifuged and supernatants and soil were separated. Desorption: Soil samples from the adsorption phase were shaken with 0.01 m $CaCl_2$ for 24 hours in dark environmental chamber at 25 ºC. Suspensions were then centrifuged and supernatants and soil were separated. Sand samples were extracted with DMF-acetic acid for radioanalysis; all other soil types were combusted for radioanalysis. The study was carried out in accordance with U.S. EPA-FIFRA Guideline N-163-1 guidelines.	
5.2	**Results and**	Sand had the lowest adsorption and desorption coefficients and adsorption phase mobility coefficient. Sandy loam had the lowest	

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	
discussion	desorption phase mobility coefficient. Silty clay loam had the highest coefficients.	
5.3 Conclusion	Didecyldimethylammonium Chloride has little or no potential for mobility in soil and should not pose an environmental risk for contamination of groundwater	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

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

Soil type	Adsorption coefficient (Kd)	Desorption coefficient (Kd)	Mobility coefficient (adsorption phase) (Koc)	Mobillity coefficient (desorption phase) (Koc)
[redacted]				

Section 7.2.3.2 Annex Point IIIA.7.2.3.2	Mobility – Lysimeter studies	
	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		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

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 **Annex Point IIIA.7.3.1**	**Phototransformation in air**	
	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		
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 7.3.1 Phototransformation in air Annex Point IIIA.7.3.1
Remarks

Section 7.3.2 Annex Point IIIA.7.3.2	Fate and behaviour in air, further studies	
	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		
Conclusion	[redacted]	
Remarks		

Section 7.3.2 Annex Point IIIA.7.3.2	Fate and behaviour in air, further studies
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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	[redacted] (2001). Bardap 26: Acute toxicity to common carp *Cyprinus carpio*. [redacted] Project No. 102/370 (unpublished). LONZA Report No. 3404	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted 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 Directive 92/69/EEC, Method C1 and OECD Guideline No. 203 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	

Section 7.4.1.1 (1) Annex Point IIA 7.4.1.1	**Acute toxicity to fish**	
3.1.4 Purity	[redacted]	
3.1.5 Stability	[redacted]	X
3.1.6 Method of analysis		
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	X
3.2.2 Test organisms	[redacted]	
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	X
3.2.9 Statistics	[redacted]	X
	4. Results	
4.1 Limit test	[redacted]	
4.1.1 Concentration	[redacted]	X
4.1.2 Number/percentage of animals showing adverse effects	[redacted]	X
4.1.3 Nature of adverse effects	[redacted]	X
4.2 Results test substance		
4.2.1 Initial concentration of test substance	[redacted]	X
4.2.2 Actual concentrations of test substance	[redacted]	
4.2.3 Effect data (Mortality)	[redacted]	
4.2.4 Other effects	[redacted]	X

Section 7.4.1.1 (1) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
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.* The study was conducted according to the Directive 92/69/EEC, Method C1 and OECD Guideline No. 203.The test system was semi-static and *Cyprinus carpio* was used as test organism.	X
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC0	LC_0 = 0.39 mg a.s./l	
5.2.2 LC50	LC_{50} = 0.62 mg a.s./l	X
5.2.3 LC100	LC_{100} = 1.26 mg a.s./l	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be 0.39 mg/l.	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.4.1.1 (1) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	[redacted]
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.4.1.1.(1)-1 Cumulative mortality

Nominal concentration (mg a.s./l)	Cumulative Mortality						% Mortality
	3 hours	6 hours	24 hours	48 hours	72 hours	96 hours	96 hours
[redacted]							

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	[redacted] (2001). Bardap 26: A 96 hour flow-through acute toxicity test with the bluegill (*Lepomis macrochirus*). [redacted] Project No. 289A-154 (unpublished). LONZA Report No. 3439	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted 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 EPA OPPTS 850.1075 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	

Section 7.4.1.1 (2) Annex Point IIA 7.4.1.1	**Acute toxicity to fish**	
3.1.4 Purity	[redacted]	
3.1.5 Stability	[redacted]	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	[redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	X
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	
3.2.9 Statistics	[redacted]	X
	4. RESULTS	
4.1 Limit test	[redacted]	X
4.1.1 Concentration	[redacted]	
4.1.2 Number/percentage of animals showing adverse effects	[redacted]	
4.1.3 Nature of adverse effects	[redacted]	
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)	[redacted]	
4.2.4 Other effects	[redacted]	
4.3 Results of controls		

Section 7.4.1.1 (2) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
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.* The study was conducted according to the EPA OPPTS 850.1075.The test system was flow through and *Lepomis macrochirus* was used as test organism.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC0	LC_0 = 0.19 mg a.s./l	X
5.2.2 LC50	LC_{50} = 0.52 mg a.s./l	X
5.2.3 LC100	LC_{100} = 0.77 mg a.s./l	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be 0.19 mg/l.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* 1. Reliable without restriction; guideline study. Key study	
5.3.2 Deficiencies	*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.4.1.1 (2) **Annex Point IIA 7.4.1.1**	**Acute toxicity to fish**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.4.1.1.(2)-1 Cumulative mortality

[redacted]	[redacted]					[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	0	0	0	0	0	0

Section 7.4.1.1 **Annex Point IIIA.7.4.1.1**	**Acute toxicity to fish (marine)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	*Acceptable*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 7.4.1.2 (1) Annex Point IIA 7.4.1.2	Acute to toxicity to invertebrates	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001). Bardap 26: Acute toxicity to *Daphnia manga*. [redacted] Project No. 102/371 (unpublished). LONZA Report No. 3403	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted 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 Directive 92/69/EEC, Method C2 and OECD Guideline No. 202 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	

Section 7.4.1.2 (1) **Annex Point IIA 7.4.1.2**	**Acute to toxicity to invertebrates**	
	[redacted]	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	[redacted]	X
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	X
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	X
3.2.9 Statistics	[redacted]	X
	4. RESULTS	
4.1 Limit test	[redacted]	
4.1.1 Concentration	[redacted]	X
4.1.2 Number/percentage of animals showing adverse effects	[redacted]	X
4.1.3 Nature of adverse effects	[redacted]	X
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)	[redacted]	

Section 7.4.1.2 (1) Annex Point IIA 7.4.1.2	Acute to toxicity to invertebrates	
4.2.5 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals showing adverse effects	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* The study was conducted according to the Directive 92/69/EEC, Method C2 and OECD Guideline No. 202. The test system was semi-static and *Daphnia magna (crustacea)* was used as test organism.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 LC0	LC_0 = 0.039 mg a.s./l measured/nominal	X
5.2.2 LC50	LC_{50} = 0.07 mg a.s./l measured/nominal	X
5.2.3 LC100	LC_{100} = 0.22 mg a.s./l measured/nominal	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be 0.039 mg/l.	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.4.1.2 (1) Annex Point IIA 7.4.1.2	Acute to toxicity to invertebrates
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.4.1.2(1)-1 Cumulative immobilisation

[redacted]

Table A7_4_1_2(1)-2: Effect data

	EC_{50} [1]	95 % c.l.	EC_0 [1,2]	EC_{100} [1,2]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[1] [redacted]

[2] [redacted]

Section 7.4.1.2 **Annex Point IIIA.7.4.1.2**	**Acute toxicity to invertebrates (marine)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**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)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 7.4.1.3 (1) Annex Point IIA 7.4.1.3	Growth inhibition test on algae	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001). Bardap 26: Algal inhibition test. Project No. 102/380 (unpublished). LONZA Report No. 3412	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted 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 Directive 92/69/EEC, Method C3 and OECD Guideline No. 201 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	

Section 7.4.1.3 (1) Annex Point IIA 7.4.1.3	**Growth inhibition test on algae**	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	X
3.2.2 Test organisms	[redacted]	
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	X
3.2.9 Statistics	[redacted]	X
	4. RESULTS	
4.1 Limit test	[redacted]	
4.1.1 Concentration	[redacted]	X
4.1.2 Number/percentage of animals/species showing adverse effects	[redacted]	X
4.1.3 Nature of adverse effects	[redacted]	X
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)	[redacted]	
4.2.5 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage	[redacted]	

Section 7.4.1.3 (1) Annex Point IIA 7.4.1.3		Growth inhibition test on algae	
of animals showing 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.* The study was conducted according to the Directive 92/69/EEC, Method C3 and OECD Guideline No. 201. *Scenedesmus subspicatus* was the test organism.	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* The results are expressed as time-weight values due to the decline in measured test concentration over the 72-hour study period. This is considered to be due to adsorption of the test material to algal cells. Adsorption was not a factor in the pre-study stability analysis since no algal cells were present.	X
5.2.1	EbC_{50}	EbC_{50} = 0.15 mg a.s./l calculated	X
5.2.2	ErC_{50}	ErC_{50} = 0.34 mg a.s./l calculated	X
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be 0.044 mg a.s./l.	X
5.3.1	Reliability	[redacted]	
5.3.2	Deficiencies	*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	

Section 7.4.1.3 (1) Annex Point IIA 7.4.1.3	Growth inhibition test on algae
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.4.1.3 (1)-1 **Inhibition of Growth Rate and Biomass**

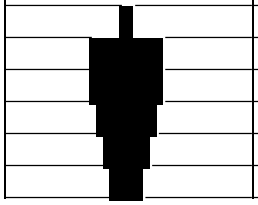
Nominal concentration (mg a.s./l)	Time-weighted mean measured concentrations (mg a.s./l)	Area Under Curve at 72 hr	% Inhibition	Growth Rate	% Inhibition
					

Fig 7.4.1.3 (1)-1 [redacted]

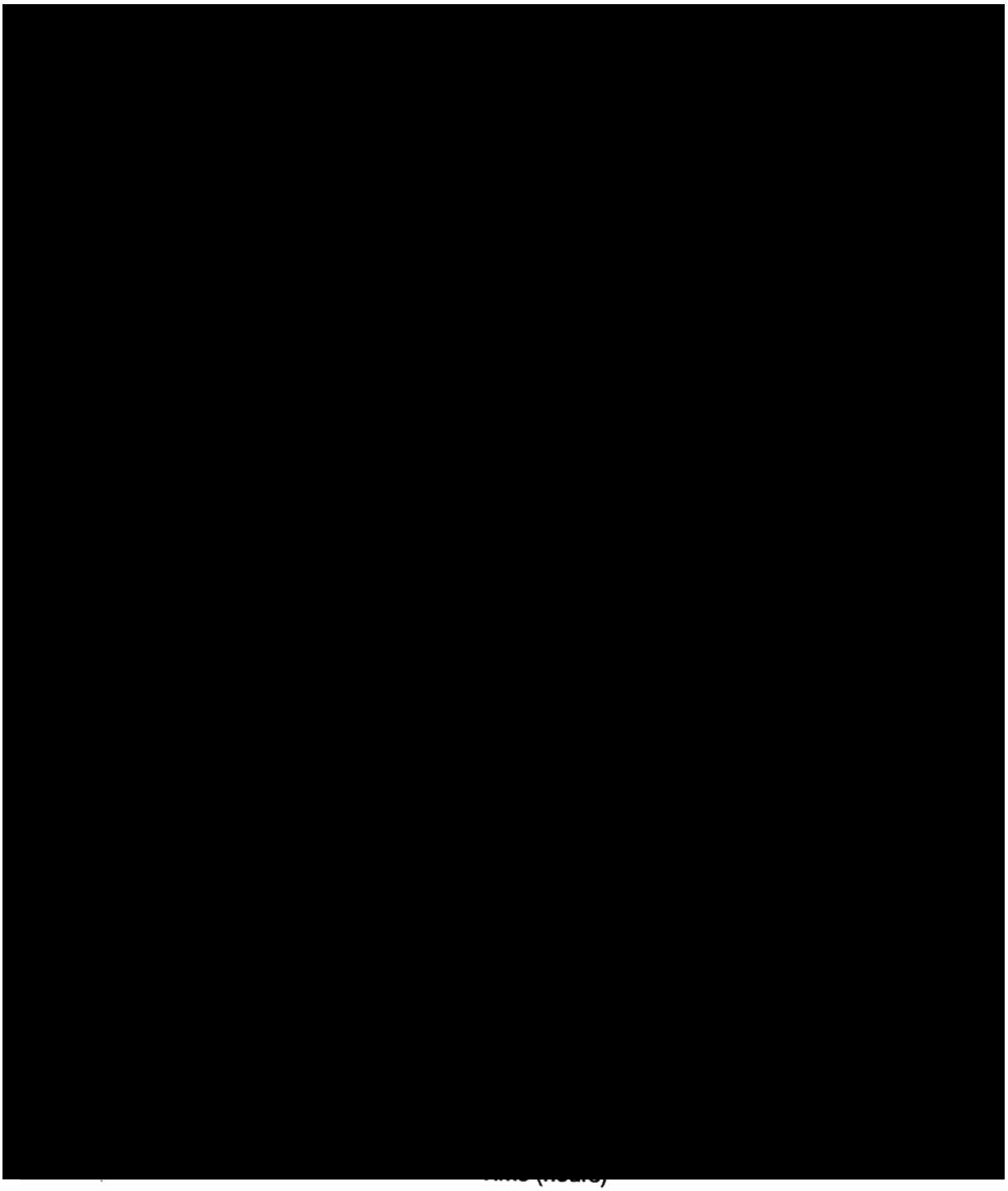


Fig 7.4.1.3 (1)-2 – [redacted]

Section 7.4.1.3 **Annex Point IIIA.7.4.1.3**	**Growth inhibition test on algae (marine)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section 7.4.1.4 (1) **Annex Point IIA 7.4.1.4**	**Inhibition on microbiological activity**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001). Bardap 26 (LZ1524.1): Assessment of the inhibitory effect on the respiration of activated sewage sludge. [redacted]. Project No. 102/382 (unpublished). Lonza Report No. 3388	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted 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 Directive 87/302/EEC, Part C and OECD Guideline No 209 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
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: Bardap 26 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	

Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
	[redacted]	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.1.6 Method of analysis	[redacted]	
3.1.7 Reference substance	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	X
3.2.2 Test organisms	[redacted]	X
3.2.3 Test system	[redacted]	X
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	*
3.2.9 Statistics	[redacted]	X
	4. RESULTS	
4.1 Limit test	[redacted]	X
4.1.1 Concentration	[redacted]	
4.1.2 Number/percentage of animals showing adverse effects	[redacted]	
4.1.3 Nature of adverse effects	[redacted]	
4.2 Results test substance		
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual	[redacted]	

Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
concentrations of test substance		
4.2.3 Effect data (Mortality)	[redacted]	
4.2.5 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals/species showing adverse effects	[redacted]	
4.4 Results test substance		
4.4.1 Number/percentage of animals/species showing adverse effects	[redacted]	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* The study was conducted according to the Directive 87/302/EEC, Part C and the OECD Guideline No. 209. The test system was activated sludge of a synthetic sewage.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The effect of the test material on the respiration of activated sewage sludge micro-organisms gave a 3-hour EC_{50} of 16.8 mg a.s./l .	
5.2.1 EC50	30 minutes EC_{50} = 30.8 mg a.s./l 3 hours EC_{50} = 16.8 mg a.s./l	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect-concentration (NOEC) was found to be 2.24 mg a.s./l.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	*(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.4.1.4 (1) **Annex Point IIA 7.4.1.4**	**Inhibition on microbiological activity**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Table 7.4.1.4(1)-1 [redacted]

Nominal Concentration (mg a.s./l)	Measurement Period (min)	O_2 Consumption Rates (mg O_2/l/min)	% Inhibition
[redacted]			

[redacted]

Section 7.4.1.4 (2) **Annex Point IIA 7.4.1.4**	**Inhibition on microbiological activity**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1996). Untersuchung auf Bakterienschädlichkeit Sauerstoff – Zehrungs – Hemmtest. [redacted] Report No. V89-0273-B unpublished). LONZA Report No. 2888	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Noechst AG and Lonza AG	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data on existing a.s. submitted for the first time for entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 209 and Directive 88/302/EEC, part C 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)	No *(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	X
	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	N,N-Didecyl-N-methylpoly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	[redacted]	X
3.1.2 Specification	As given in section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein: HOE S3519 tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	

Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	[redacted]	
3.2.3 Test system	[redacted]	
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Sampling	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	
3.2.9 Statistics	[redacted]	
	4. RESULTS	X
4.1 Limit test	[redacted]	
4.1.1 Concentration	[redacted]	
4.1.2 Number/percentage of animals showing adverse effects	[redacted]	
4.1.3 Nature of adverse effects	[redacted]	
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)	[redacted]	
4.2.4 Concentration/ response curve	[redacted]	
4.2.5 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals showing adverse effects	[redacted]	
4.3.2 Nature of adverse	[redacted]	

Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity	
effects		
4.4 Test with reference substance		
4.4.1 Concentrations	[redacted]	
4.4.2 Results	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	X
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.* The study was conducted according to the OECD Guideline No. 209 and the Directive 88/302/EEC, part C. The test system was activated sludge.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 EC_0	EC_0 = 3.9 mg a.s./l	
5.2.2 EC_{50}	EC_{50} = 11.8 mg a.s./l	
5.2.3 EC_{100}	EC_{100} = 46.1 mg a.s./l	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration effect relationship observed, the no-observed-effect-concentration (NOEC) was found to be 3.9 mg a.s./l.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	*(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]	

Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity
Acceptability	not acceptable. The original documentation provided is just a statement of results issued by the laboratory. The summary and the test itself cannot therefore be checked.
Remarks	
	COMMENTS FROM
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.4.2 Annex IIA Point 7.4.2	Bioconcentration	
	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]	X
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.4.2 Annex IIA Point 7.4.2	Bioconcentration
Conclusion	[redacted]
Remarks	

Section 7.4.2(1) Annex Point IIA 7.4.2	Bioconcentration	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (1990) Bioconcentration and Elimination of ^{14}C-residues by Bluegill (Lepomis machrochirus) Exposed to Didecyldimethylammonium Chloride (DDAC). Report no. 89-7-3043. [redacted] (unpublished). Ref No. D43 (LON 1790)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA Guideline 165-4 Year: 1989 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	[redacted] *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.4.2(1) **Annex Point IIA 7.4.2**		**Bioconcentration**	
		[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. Bardac 22 was tested *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	X
3.1.5	Stability	*Describe stability of test material* Stable	X
3.1.6	Method of analysis	[redacted]	
3.2	**Testing procedure**		
3.2.1	Dilution water	[redacted]	
3.2.2	Test organisms	Bluegill (*Lepomis macrochirus*) from SLI cultures.	
3.2.3	Test system	[redacted]	
3.2.4	Test conditions	[redacted]	
3.4.5	Duration of the test	[redacted]	
3.2.6	Test parameter	[redacted]	X
3.2.7	Sampling	[redacted]	

Section 7.4.2(1) Annex Point IIA 7.4.2	Bioconcentration	
	[redacted]	
3.2.8 Monitoring of test substance concentration	[redacted]	X
3.2.9 Statistics		
	4. RESULTS	
4.1 Limit test	[redacted]	
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)	[redacted]	X
4.2.4 Other effects	[redacted]	
4.3 Results of controls		
4.3.1 Number/percentage of animals showing adverse effects	[redacted]	
4.3.2 Nature of adverse effects	[redacted]	
	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.* The test was conducted according to the U.S. EPA Guideline 165-4. The test system was dynamic and bluegill fish was used as test organism.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.2.1 Edible tissue	BCF = 38 (predicted 52) Elimination after 14 Days 57% Elimination after 18 Days 38%	X
5.2.2 Non-edible tissue	BCF = 140 (predicted 160)	X

Section 7.4.2(1) **Annex Point IIA 7.4.2**		**Bioconcentration**	
		Elimination after 14 Days 71% Elimination after 18 Days 66%	
5.2.3	Whole-body	BCF = 81 (predicted 95) Elimination after 14 Days 67% Elimination after 18 Days 56%	X
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* Skin tissue showed ^{14}C-residues 2 to 6 times higher than edible tissue portions. The test substance may bind significantly to skin and scales of exposed fish. Of the accumulated ^{14}C-residue in the edible tissue of bluegill exposed 28 days to the test substance, 65.5% was extractable with a polar solvent (methanol), 8.1% was extractable with a nonpolar solvent (hexane) and 25.9% was not extractable with either solvent.	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	

Section 7.4.2(1) **Annex Point IIA 7.4.2**	**Bioconcentration**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable*
Remarks	*2.1 Guideline study: The US EPA guideline, subdivision N, referred to in the* [redacted]

Section 7.4.2(1) **Annex Point IIA 7.4.2**	**Bioconcentration**
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

[redacted]

[redacted]

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	Official use only
	[redacted]	
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.4.3.1 Annex Point IIIA.7.4.3.1	Prolonged toxicity to fish
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.4.3.2 (1) Annex Point IIIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	X
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.4.3.2 (1) Annex Point IIIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.4.3.2 (1) **Annex Point IIA 7.4.3.2**	**Effects on reproduction and growth rate on an appropriate species of fish**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001). Early Life Stage Test under intermittent flow-thorugh conditions with Didecyldimethylammonium Chloride and the fish species, *Brachydanio rerio* (OECD Guideline No. 210). Report No. 99-9048-03. [redacted] Ref No. D118 (LON 3373)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline No. 210 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	[redacted] *(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	
	[redacted]	
3.1 Test material	Bardac 22 with Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	[redacted]	

Section 7.4.3.2 (1) **Annex Point IIA 7.4.3.2**		**Effects on reproduction and growth rate on an appropriate species of fish**	
3.1.2	Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(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* The non-radiolabelled a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	X
3.2	**Test procedure**		
3.2.1	Dilution water	[redacted]	
3.2.2	Test organism	[redacted]	
3.2.3	Test system	[redacted]	
3.2.4	Test conditions	[redacted]	
3.2.5	Exposure period	[redacted]	
3.2.6	Test parameter	[redacted]	
3.2.7	Monitoring of test substance concentration	[redacted]	
3.2.8	Statistics	[redacted]	
3.3.	**Environmental**		

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
parameters		
3.3.1 pH	[redacted]	
3.3.2 Lowest oxygen concentration	[redacted]	
3.3.3 Temperature	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 Results of test substance		
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual concentration of test substance	See table 7.4.3.2(1)-1. [redacted].	
4.2.3 Hatching	[redacted]	
4.2.4. Mortality	[redacted]	
4.2.5 Behavioural observations	[redacted]	
4.2.6 Morphological observations	[redacted]	
4.2.7 Body lengths	[redacted]	
4.2.8 Body weights	[redacted]	
4.3 Statistics		
4.3.1 LC_{50}	[redacted]	X
4.3.2 NOEC	[redacted]	X
4.3.3 LOEC	[redacted]	X
4.4 Remarks		
	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.* The test was carried out in accordance with OECD Guideline No. 210. 4 replicates of 20 *Brachydanio rerio* eggs were treated with ^{14}C-Didecyldimethylammonium Chloride in an intermittent flow-through system.	
5.2 Results and	*Summarise relevant results; discuss dose-response relationship where*	

Section 7.4.3.2 (1) Annex Point IIA 7.4.3.2	Effects on reproduction and growth rate on an appropriate species of fish	
discussion	*relevant.* All fish died at a test substance concentration of 320 µg/l. At 100 µg/l fish were observed swimming on the surface. No morphological observations were made. The test substance did not affect body length, but body weight increased at 100 µg/l.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* LC_{50} = 81 µg/l NOEC = 32 µg/l LOEC = 100 µg/l	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	*Acceptable*	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE **(specify)**	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion		
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

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) Bio-accumulation in fish **Annex Point IIIA 7.4.3.3.1**		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	X
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 7.4.3.3.1 (1) **Annex Point IIIA 7.4.3.3.1**	**Bio-accumulation in fish**
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.4.3.3.2 Annex Point IIIA.7.4.3.3.2	Bioaccumulation in an appropriate invertebrate	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.4.3.3.2 Annex Point IIIA.7.4.3.3.2	Bioaccumulation in an appropriate invertebrate
Conclusion	[redacted]
Remarks	

Section 7.4.3.4(1) Annex Point IIIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	X
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 7.4.3.4(1) Annex Point IIIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
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	[redacted] (2001) Intermittent Flow Through Reproduction Test with Didecyldimethylammonium Chloride and *Daphnia magna*. [redacted] Report V99.1171. [redacted] Ref No. D7 (LON 3323)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 211 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	[redacted] *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Bardac 22 with radiolabelled Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	

Section 7.4.3.4(1) **Annex Point IIA 7.4.3.4**	**Effects on reproduction and growth rate with *Daphnia magna***	
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., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Dilution water	[redacted]	
3.2.2 Test organisms	[redacted]	
3.2.3 Test system		
3.2.4 Test conditions	[redacted]	
3.2.5 Duration of the test	[redacted]	
3.2.6 Test parameter	[redacted]	
3.2.7 Monitoring of test substance concentration	[redacted]	
3.2.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 Results test substance		X
4.2.1 Initial concentration of test substance	[redacted]	
4.2.2 Actual	[redacted]	X

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*	
concentrations of test substance		
4.2.3 Effect data (Mortality)	[redacted]	
4.2.4 Other effects	[redacted].	X
4.3 Results of controls	**None**	
	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.* The study was conducted according to OECD Guideline 211. The test system was intermittent flow-though exposure at intervals of 51 minutes and *Daphnia magna* was used as test organism. Test substance concentration was measured by radioactivity determination and lack of degradation of the test substance was confirmed by HPLC. The NOEC and LOEC values were calculated based on measured concentrations.	X
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	X
5.2.1 NOEC/LOEC	Reproductive effect: NOEC = 0.018 mg/l LOEC = 0.032 mg/l Survival effect: NOEC = 0.010 mg/l LOEC = 0.018 mg/l Condition effect: NOEC = 0.018 mg/l LOEC = 0.032 mg/	X
5.2.2 EC50 reproduction LC50	0.018mg/l < EC_{50} for reproduction < 0.056 mg/l LC_{50} = 0.023 mg/l (95% confidence limit 0.0034 - 0.0057 mg/l)	X
5.3 Conclusion		
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	X
5.3.2 Deficiencies	No *(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]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	*Acceptable*
Remarks	[redacted]

Section 7.4.3.4(1) Annex Point IIA 7.4.3.4	Effects on reproduction and growth rate with *Daphnia magna*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

[redacted]

[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 IIIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	X
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	

Section 7.4.3.5.1(1) Annex Point IIIA 7.4.3.5.1	Effects on sediment dwelling organisms
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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	[redacted] (1995). Chronic Toxicity of Sediment-Incorporated Didecyldimethylammonium Chloride (DDAC)to Chironomus tentans. Final report No. 41005. [redacted] Ref No. D63 (LON 2941)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes American Society for Testing Materials (1992) ASTM Document No E 1383-93 U.S. EPA-600/3-75-009 American Society for Testing Materials (1992) ASTM Document No E 729-88a Standard Methods for the Examination of Water and Wastewater, American Public Health Association, Washington DC, 17th edition 1995 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	[redacted] *(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	Bardac 2280 with radiolabelled Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially	X

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**		**Effects on sediment dwelling organisms**	
		Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(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* The non-radiolabelled a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	X
3.2	**Testing procedure**		
3.2.1	Test organism	[redacted]	
3.2.2	Source	[redacted]	
3.2.3	Worm weights	[redacted]	
3.2.4	Soil	[redacted]	
3.2.5	Soil pH	[redacted]	
3.2.6	Dilution water	[redacted]	
3.2.7	Temperature	[redacted]	
3.2.8	Light	[redacted]	
3.3.	**Test procedure**		
3.3.1	Duration of test	[redacted]	
3.3.2	Test parameters	[redacted]	
3.3.3	Control	[redacted]	
3.3.4	Test method	[redacted]	X

Section 7.4.3.5.1(1) **Annex Point IIA 7.4.3.5.1**	**Effects on sediment dwelling organisms**	
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	
	4. RESULTS	
4.1 Observations		
4.1.1 Mortality	[redacted]	
4.1.2. Other effects	[redacted]	X
4.2 Result test substance	[redacted]	
4.2.1 Initial test substance concentration	[redacted]	X
4.2.2 Actual substance concentration	[redacted]	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* The study was conducted according to the ASTM Document No E 1383-93. American Society for Testing Materials (1992) Methods for Acute Toxicity Test with Fish, Macroinvertebrates and Amphibians U.S. EPA-600/3-75-009 Standard Methods for Conducting Basic Acute Toxicity Test with Fish , Macroinvertebrates and Amphibians ASTM Document No E 729-88a American Society for Testing Materials (1992) Standard Methods for the Examination of Water and Wastewater, American Public Health Association, Washington DC, 17th edition	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The 14-day and 28-day NOEC was found to be 530 mg/kg, based on the growth and emergence success. The 28-day LC_{50} was 2085 mg/kg.	X
5.2.1 LC50	See table 7.4.3.5.1.(1)-1	
5.2.2 NOEC/LOEC/ MATC	See table 7.4.3.5.1.(1)-1	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on the results of this study, the test substance was found to have adverse effects on the test organisms.	

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1		Effects on sediment dwelling organisms	
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	X
5.3.2	Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
		Evaluation by Competent Authorities	
		Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
		EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		[redacted]	
Materials and Methods		[redacted]	
Results and discussion		[redacted]	
Conclusion		[redacted]	
Reliability		[redacted]	
Acceptability		Not acceptable because the read across to DDAC has not been accepted.	
Remarks		[redacted]	

Section 7.4.3.5.1(1) Annex Point IIA 7.4.3.5.1	Effects on sediment dwelling organisms
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

[redacted]

Section 7.4.3.5.1 **Annex Point III-A.7.4.3.5.1**	**Second and third study on effects on sediment dwelling organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[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]	

Section 7.4.3.5.1 Annex Point III-A.7.4.3.5.1	Second and third study on effects on sediment dwelling organisms
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.4.3.5.2 **Annex IIIA Point 7.4.3.5.2**	**Aquatic plant toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X

Section 7.4.3.5.2 Annex IIIA Point 7.4.3.5.2	Aquatic plant toxicity
Undertaking of intended data submission [ ]	[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]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

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

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

Section 7.5.1.1 (1) **Annex Point IIIA 7.5.1.1**	**Inhibition to microbial activity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always* [redacted]	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	X
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.1.1 (1) Inhibition to microbial activity

Annex Point IIIA 7.5.1.1

Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) The assessment of the ecological effects of Didecyldimethylammonium Chloride (Guidelines OPPTS 850.5100 Soil Microbial Community Test, OECD 216 and OECD 217 and CTB section H.4.1). Study No.: IMW-99-9048-05. [redacted] Ref No. 119 (LON 3378)	
1.2. Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guidelines 216 and 217 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	[redacted] *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	X
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Bardac 22	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Bardac 22 (Dodigen 1881) was tested. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	

Section 7.5.1.1(1) Annex Point IIA 7.5.1.1	Inhibition to microbial activity	
	(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* The a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	X
3.2 Test conditions		
3.2.1 Soil	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Soil additive	[redacted]	
3.3 Test procedure		
3.3.1 Duration of test	[redacted]	
3.3.2 Test parameters	[redacted]	
3.3.3 Control	[redacted]	
3.3.4 Test method	[redacted]	X
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	X
	4. RESULTS	
4.1 Nitrogen metabolism		
4.1.1 Nitrate formation	[redacted]	X
4.1.2 Nitrite formation	[redacted]	X
4.1.3 Ammonium formation	[redacted]	
4.2 Carbon metabolism		

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**	
4.2.1 Microbial biomass	[redacted]	
4.2.2 Carbon content	[redacted]	
4.2.3 Carbon dioxide formation	[redacted]	
4.3 Remarks	[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.* The study was carried out in accordance with OECD Guidelines 216 and 217. 50 g samples of low humic content sand and sandy loam were treated with Didecyldimethylammonium Chloride at concentrations of 0, 10, 100 and 1000 µg a.s./dry weight soil and incubated in the dark at 20°C for 28 days. Nitrogen and carbon transformations were determined.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The test substance had no effect on the production of nitrates, nitrites and carbon dioxide. The rate of ammonium production increased.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Didecyldimethylammonium Chloride can be characterised as having no long-term influence on nitrogen or carbon transformations in soils.	X
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition to microbial activity**
Materials and Methods	3.1.4 – Bardac 22 contained 50% DDAC, 20% isopropanol and 30% water (under [redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Not acceptablebecause the read across to DDAC has not been accepted.
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Section 7.5.1.2 (1) **Annex Point IIIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
	1. REFERENCE	Official use only
1.1. Reference	[redacted] (2004) Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26) Acute Toxicity to the Earthworm. [redacted] Report No. LZA 251/033986. [redacted] (unpublished) Report No. 3836	X
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1Data owner	*Give name of company* Lonza AG	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data on existing a.s. submitted for the first time for entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 207 and Directive 88/302/EEC, Part C 2004 *(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)	[redacted]	
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	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [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: Bardap 26 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]	

Section 7.5.1.2 (1) **Annex Point IIIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v* [redacted]	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.2 Testing procedure		
3.2.1 Test organism	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Worm weights	[redacted]	
3.2.4 Soil	[redacted]	
3.2.5 Soil pH	[redacted]	
3.2.6 Soil water content	[redacted]	
3.2.7 Temperature	[redacted]	
3.2.8 Light	[redacted]	
3.3. Test procedure		
3.3.1Duration of test	[redacted]	
3.3.2 Test parameters	[redacted]	
3.3.3 Control	[redacted]	
3.3.4 Test method	[redacted]	

Section 7.5.1.2 (1) Annex Point IIIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	[redacted]	
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	X
	4. RESULTS	
4.1 Observations		
4.1.1 Mortality	[redacted]	
4.1.2. Body weight	[redacted]	
4.1.3 Morphological observations	[redacted]	
4.1.4 Behavioural observations	[redacted]	
4.2 Remarks	[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.* The study was carried out in accordance with the OECD Guideline 207 and Directive 88/302/EEC, Part C.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* Since the bodyweights were reduced substantially compared with control at 2000 mg a.s. /kg, the overall no-observed effect concentration (NOEC) was not determined.	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The test substance had an effect on mortality and body weights.	
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	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.1.2 (1) Annex Point IIIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	[redacted]
	Comments from
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

Section 7.5.1.2 (2) Annex Point IIIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	1. REFERENCE	Official use only
1.1. Reference	[redacted] (2004) Didecylmethylpoly(oxyethyl)ammonium Propionate (Bardap 26) Acute Toxicity (LC_{50}) to the Earthworm. [redacted]. LZA 247/033913. [redacted] Report No. 3837	X
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1Data owner	*Give name of company* Lonza AG	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data on existing a.s. submitted for the first time for entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 207 and Directive 88/302/EEC, Part C 2004 *(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)	[redacted] *(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	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [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: Bardap 26 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]	

Section 7.5.1.2 (2) **Annex Point IIIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v* [redacted]	
3.1.5 Stability	*Describe stability of test material* Stable at room temperature	
3.2 Testing procedure		
3.2.1 Test organism	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Worm weights	[redacted]	
3.2.4 Soil	[redacted]	
3.2.5 Soil pH	[redacted]	
3.2.6 Soil water content	[redacted]	
3.2.7 Temperature	[redacted]	
3.2.8 Light	[redacted]	
3.3. Test procedure		
3.3.1Duration of test	[redacted]	
3.3.2 Test parameters	[redacted]	
3.3.3 Control	[redacted]	
3.3.4 Test method	[redacted]	

Section 7.5.1.2 (2) Annex Point IIIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	[redacted]	
3.3.5 Sampling	[redacted]	
3.3.6 Statistics	[redacted]	
	4. RESULTS	
4.1 Observations		
4.1.1 Mortality	[redacted]	
4.1.2. Body weight	[redacted]	
4.1.3 Morphological observations	[redacted]	
4.1.4 Behavioural observations	[redacted]	
4.2 Remarks	[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.* The study was carried out in accordance with the OECD Guideline 207 and Directive 88/302/EEC, Part C.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* Under the conditions of the test, the LC50 value was determined to be greater than 1000 mg a. s./kg, the highest level tested.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The test substance had no effect on mortality and body weights.	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	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.1.2 (2) Annex Point IIIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	
	Comments from
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section 7.5.1.3(1) Annex IIA Point 7.5.1.3	Acute toxicity to plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [X] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.1.3(1) Annex IIA Point 7.5.1.3	Acute toxicity to plants
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.1.3 (1) **Annex Point IIA 7.5.1.3**	**Acute toxicity to plants**
	1. REFERENCE
1.1. Reference	[redacted] (2004) N,N-Didecyl-N,N-Dimethylammonium Chloride (DDAC) – Acute Toxicity to Terrestrial Plants. [redacted] DKG/014 (unpublished). Ref. No.: D114 (LON 3811)
1.2 Data protection	Yes *(indicate if data protection is claimed)*
1.2.1 Data owner	*Give name of company* The Dialkyl Project
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.
	2. GUIDELINES AND QUALITY ASSURANCE
2.1 Guideline study	Yes OECD Guideline No. 208 2004 *(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)	[redacted] *(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	Bardac 22
3.1.1 Lot/Batch number	[redacted] | [redacted]
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Bardac 22 [redacted] was tested. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(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*

Section 7.5.1.3 (1) Acute toxicity to plants

Annex Point IIA 7.5.1.3

		[redacted]
3.1.5	Stability	*Describe stability of test material* The a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).
3.2	**Testing conditions**	
3.2.1	Test species	[redacted]
3.2.2	Source	[redacted]
3.2.3	Humidity	[redacted]
3.2.4	Temperature	[redacted]
3.2.5	Light intensity	[redacted]
3.3.	**Test procedure**	
3.3.1	Duration of test	[redacted]
3.3.2	Control	[redacted]
3.3.3	Test method	[redacted]
3.3.4	Sampling	[redacted]
3.3.5	Statistics	[redacted]

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	[redacted]	
	4. RESULTS	
4.1 Observations		
4.1.1 Herbicidal symptoms	[redacted]	
4.1.2 Wet weight	[redacted]	
4.1.3 Dry weight	[redacted]	X
4.1.4 Growth	[redacted]	
4.1.5 Bulk	[redacted]	
4.1.6 Mortality	[redacted]	
4.2 Remarks		
	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.* The study was conducted according to OECD Guideline 208. Mustard *(Brassica*	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	alba), Mung bean (*Phaseolus aureus*) and Wheat (*Triticum aestivum*) were the test species.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The test substance had no significant effect on the number of germinated plants for any species. For mustard, all concentrations of the test substance significantly reduced both wet and dry weight. For wheat, the test substance at 400 mg a.s./kg and higher gave a significant reduction for both dry weight and wet weight. For mung bean, at 320 mg a.s./kg and higher gave a significant reduction for both wet and dry weight. Mustard: LC_{50} = 283 mg/kg (dry weight) Wheat: LC_{50} = 857 mg/kg (dry weight) Mung: LC_{50} = 1670 mg/kg (dry weight)	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The results of the study indicate that Didecyldimethylammonium Chloride is slightly toxic to terrestrial plants.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	The study is not acceptable because the read across to DDAC has not been accepted..
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

Table 7.5.1.3 (1)-2 Dry weight results

[redacted]

[redacted]

Section 7.5.2 Terrestrial tests, long-term tests
Annex Point IIA 7.5.2-headline only

Section 7.5.2.1 **Annex IIIA Point 7.5.2.1**	**Reproduction study with other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[redacted]	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.2.1 Annex IIIA Point 7.5.2.1	Reproduction study with other soil non-target macro-organisms
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.2.2 Annex IIIA Point 7.5.2.2	Long-term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[redacted]	
Evaluation by Competent Authorities		
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.2.2 Annex IIIA Point 7.5.2.2	Long-term test with terrestrial plants
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.3 Effects on birds
Annex Point IIA 7.5.3- headline only

Section 7.5.3.1.1 (1) **Annex Point IIIA 7.5.3.1.1**	**Acute oral toxicity**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] (2001) – Bardap 26: An Acute Oral Toxicity Study with the Northern Bobwhite. Project No. 289-115. [redacted] Easton, MD, USA (unpublished) Lonza Report No. 3440	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* Lonza AG	
1.2.3 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 authorisation	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes US EPA FIFRA Guideline 71-1 Year: 2001 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2 GLP (only where required)	[redacted] *(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	N,N-Didecyl-N-methyl-poly(oxyethyl)ammonium Propionate	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [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: Bardap 26 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)*	

Section 7.5.3.1.1 (1) Annex Point IIIA 7.5.3.1.1	Acute oral toxicity	
	[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 at room temperature	
3.2 Test animals		
3.2.1 Species	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Sex	[redacted]	
3.2.4 Age/weight at study initiation	[redacted]	
3.2.5 Number of animals per group	[redacted]	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	[redacted]	
3.3.2 Post exposure period	[redacted]	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Controls	[redacted]	
3.4 Observations, Sacrifice and Pathology		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Body weights	[redacted]	
3.4.4 Organ weights	[redacted]	
3.4.5 Other examinations	[redacted]	
3.4.6 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 LD50 including confidence limits	[redacted]	X
4.3 Observations,		

Section 7.5.3.1.1 (1) Acute oral toxicity **Annex Point IIIA 7.5.3.1.1**		
Sacrifice and Pathology		
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	[redacted]	
4.3.3 Bodyweight	[redacted]	
4.3.4 Feed consumption	[redacted] ls.	
4.3.5 Other examinations	[redacted]	
4.4 Further remarks	[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.* The test was conducted according to the US EPA FIFRA Guideline 71-1 and Northern bobwhite was the test organism.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The acute oral LD_{50} for Northern bobwhite was found to be 226 mg a.s./kg. Lesions observed at necropsy, primarily associated with necrosis in the esophagus and crop, would indicate a "point of entry" effect of the test substance.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on the results of this study, the LD_{50} for Northern bobwhite was found to be 226 mg a.s. /kg and the no mortality level was 78 mg a.s./kg.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate*	

Section 7.5.3.1.1 (1) Annex Point IIIA 7.5.3.1.1	Acute oral toxicity	
	reliability indicator 0, 1, 2, 3 or 4 [redacted]	
5.3.2 Deficiencies	No *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted]	

Section 7.5.3.1.2 (1) Annex Point IIIA 7.5.3.1.2	Short-term toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	X
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	

Section 7.5.3.1.2 (1) Short-term toxicity

Annex Point IIIA 7.5.3.1.2

Evaluation of applicant's justification

[redacted]

Conclusion

[redacted]

Remarks

COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date

[redacted]

Evaluation of applicant's justification

[redacted]

Conclusion

[redacted]

Remarks

Section 7.5.3.1.2(1) Short-term toxicity **Annex Point III-A 7.5.3.1.2**			
		1. REFERENCE	Official use only
1.1	**Reference**	[redacted] (1991) Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Northern Bobwhite. Report (No. 289-101). [redacted] (unpublished). Ref No. D2 (LON 1785)	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* The Dialkyl Project	
1.2.3	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 authorisation	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes U.S. EPA FIFRA Guideline 71-2 Year: 1990 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	X
2.2	**GLP (only where required)**	[redacted] *(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**	Bardac 2280	X
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2	Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Bardac 2280 was tested. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(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)*	

Section 7.5.3.1.2(1) Short-term toxicity **Annex Point III-A 7.5.3.1.2**		
	[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 a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	X
3.2 Test animals		
3.2.1 Species	[redacted]	
3.2.2 Source	[redacted]	
3.2.3 Sex	[redacted]	
3.2.4 Age/weight at study initiation	[redacted]	
3.2.5 Number of animals per group	[redacted]	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	[redacted]	
3.3.2 Post exposure period	[redacted]	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	
3.4 Observations, Sacrifice and Pathology		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Body weights	[redacted]	
3.4.4 Organ weights	[redacted]	

Section 7.5.3.1.2(1) Short-term toxicity **Annex Point III-A 7.5.3.1.2**			
3.4.5	Other examinations	[redacted]	
3.4.6	Statistics	[redacted]	
3.5	**Further remarks**	[redacted]	
		4. RESULTS	
4.1	**Limit test**	[redacted]	
4.2	**LD50 including confidence limits**	[redacted]	X
4.3	**Observations, Sacrifice and Pathology**		
4.3.1	Clinical signs	[redacted]	
4.3.2	Mortality	[redacted]	
4.3.3	Bodyweight	[redacted]	
4.3.4	Organ weights		
4.3.5	Other examinations	[redacted]	
4.3.6	Statistics		
4.4	**Further remarks**		
		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.* The test was conducted according to the U.S. EPA FIFRA Guideline 71-2 and Northern bobwhite was used as test organism.	
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the LC_{50} was found to be greater than 5620 ppm and the no-observed-effect concentration (NOEC) was 1780 ppm.	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	No	

Section 7.5.3.1.2(1) Short-term toxicity Annex Point III-A 7.5.3.1.2	
	(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)
Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	The study is considered acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	**Short-term toxicity**	
	1. REFERENCE	Official use only
1.1 Reference	[redacted] 1991. Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Mallard. Report (No. 289-102). [redacted] unpublished). Ref No. D3 (LON 1783)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.3 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 authorisation	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA Guideline 71-2 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)	[redacted] *(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	Bardac 2280	X
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2A of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Bardac 2280 was tested. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution. *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	

Section 7.5.3.1.2(2) Short-term toxicity Annex Point III-A 7.5.3.1.2			
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., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Test animals**		
3.2.1	Species	[redacted]	
3.2.2	Source	[redacted]	
3.2.3	Sex	[redacted]	
3.2.4	Age/weight at study initiation	[redacted]	
3.2.5	Number of animals per group	[redacted]	
3.2.6	Control animals	[redacted]	
3.3	**Administration/ exposure**		
3.3.1	Dose route	[redacted]	
3.3.2	Post exposure period	[redacted]	
3.3.3	Concentration	[redacted]	
3.3.4	Vehicle	[redacted]	
3.4.5	Concentration in vehicle	[redacted]	
3.3.6	Controls	[redacted]	
3.4	**Observation, Sacrifice and Pathology**		
3.4.1	Clinical signs	[redacted]	
3.4.2	Mortality	[redacted]	
3.4.2	Body weights	[redacted]	

Section 7.5.3.1.2(2) Short-term toxicity Annex Point III-A 7.5.3.1.2		
3.4.4 Organ weights	[redacted]	
3.4.5 Other examinations	A[redacted]	
3.4.6 Statistics	[redacted]	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Limit test	[redacted]	
4.2 LD50 including confidence limits	[redacted]	X
4.3 Observation, Sacrifice and Pathology		
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	[redacted]	
4.3.4 Bodyweight	[redacted]	
4.3.5 Other examinations	[redacted]	
4.3.6 Statistics	[redacted]	
4.4 Further remarks		
	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.* The test was conducted according to the U.S. EPA FIFRA Guideline 71-2 and Mallard was used as test organism.	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the LC_{50} was found to be greater than 5620 ppm and the no-observed-effect concentration (NOEC) was 562 ppm.	X
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4*	

Section 7.5.3.1.2(2) Short-term toxicity Annex Point III-A 7.5.3.1.2		
	[redacted]	
5.3.2 Deficiencies	No *(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	The study is considered acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	

Section 7.5.3.1.2(2) Short-term toxicity **Annex Point III-A 7.5.3.1.2**	
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

[redacted]

Section 7.5.3.1.3 **Annex Point IIIA.7.5.3.1.3**	**Avian reproduction study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.3.1.3 Annex Point IIIA.7.5.3.1.3	Avian reproduction study
Conclusion	[redacted]
Remarks	

Section 7.5.4 Effects on honeybees
Annex Point IIA 7.5.4- headline only

Section 7.5.4.1 **Annex Point IIIA.7.5.4.1**	**Acute toxicity to honey bees**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	

Section 7.5.4.1 Annex Point IIIA.7.5.4.1	Acute toxicity to honey bees
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.5 Bioconcentration, terrestrial
Annex Point IIA 7.5.5- headline only

Section 7.5.5.1 **Annex Point 7.5.5.1**	**Bioconcentration, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA [redacted]	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[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]	

Section 7.5.5.1 **Annex Point 7.5.5.1**	**Bioconcentration, further studies**
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.6 Annex Point IIIA.7.5.6	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	

Section 7.5.6 Annex Point IIIA.7.5.6	Effects on other terrestrial non-target organisms
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.5.7 Effects on mammals
Annex Point IIA 7.5.7- headline only

Section 7.5.7.1-3 **Annex Point IIIA.7.5.7.1-3**	**Effects on mammals (direct and/or indirect exposure)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	[redacted]	
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	[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]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.7.1-3 **Annex Point IIIA.7.5.7.1-3**	**Effects on mammals (direct and/or indirect exposure)**
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	
Fate and behaviour in water	[redacted]	
Fate and behaviour in soil	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	
Effect on aquatic organisms	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	
Effects on terrestrial organisms	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	