

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	Dykes, J. and M. Fennessey. (1989) Determination of the Photolysis Rate of Didecyldimethylammonium Chloride (DDAC) in pH 7 Buffered Solution at 25 °C. Report No. 37005. ABC Laboratories Inc., Columbia, MO, USA (Unpublished).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	Yes U.S. EPA-FIFRA N-161-2 1988		
2.2 GLP (only where required)	Yes		
2.3 Deviations	No		
		3. MATERIALS AND METHODS	
3.1 Test material	Didecyldimethylammonium Chloride		
3.1.1 Lot/Batch number	██████████		
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.		
3.1.3 Description	██████████		
3.1.4 Purity	██████████		
3.1.5 Stability	Stable under the conditions of this study.		
3.2 Testing procedure	██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████ ██████████		

Section 7.1.1.1.2(1)		Phototransformation in water including identity of the products of transformation	
Annex Point IIA 7.1.1.1.2			
3.2.1	Light source	██████████	
3.2.2	Light spectrum	██████████	
3.2.3	Light intensity	████████████████████	
3.2.4	Sensitiser	██████████	
4. RESULTS			
4.1 Results of test substance			
4.1.1	Initial concentration of test substance	██████████	
4.2 Direct Photolysis			
4.2.1	Half Life	Not determined since no significant degradation of the test substance was detected during the 30-day evaluation period.	
4.2.2	Degradation %	No detectable degradation occurred during the 30-day test period.	
4.3 Indirect Photolysis			
4.3.1	Half Life	227 days (light, exposed) 432 days (dark, exposed)	
4.3.2	Degradation %	Approximately 7% over a period of 30 days when exposed to light. Little or no degradation occurred in the presence of acetone without exposure to the light source.	
4.3.3	Rate constant	0.00304 days ⁻¹ (light, exposed)/ 0.00160 days ⁻¹ (dark, exposed)	
4.3.4	Breakdown Products	Yes, only in the presence of a photosensitiser when exposed to light. Essentially all of the ¹⁴ C-moiety not present as parent compound was found in a single degradate.	
4.4	Remarks	Based on the data generated during this study, Didecyldimethylammonium Chloride 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. The overall mean ¹⁴ C-activity accountability for this study was 98.5%.	
5. APPLICANT'S SUMMARY AND CONCLUSION			

Section 7.1.1.1.2(1)		Phototransformation in water including identity of the products of transformation	
Annex Point IIA 7.1.1.1.2			
5.1	Materials and methods	[REDACTED]	
5.2	Results and discussion	[REDACTED]	
5.2.1	Direct photolysis	Degradation = 0% after 30 days	
5.2.2	Indirect photolysis	Degradation = 7% after 30 days Rate constants = 0.00304 days ⁻¹ (light, exposed), 0.00160 days ⁻¹ (dark, exposed)	
5.2.3	Half life	227 days (light, exposed), 432 days (dark, exposed)	
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	[REDACTED]	
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Materials and Methods			
Results and discussion			
Conclusion	[REDACTED]		
Reliability	[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
Acceptability	acceptable
Remarks	
COMMENTS FROM OTHER MEMBER STATE (<i>specify</i>)	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Section 7.1.1.2 Biotic

Annex Point IIA 7.1.1.2

Section 7.1.1.2.1 (1) Ready biodegradability		Official use only
Annex Point IIA 7.1.1.2.1		
1. REFERENCE		
1.1 Reference	Downing. (1993) Aerobic Aquatic Biodegradation of Didecyldimethylammonium Chloride Using a Shake Flask Test System. Report No. 40687. ABC Labs, Columbia, MO, USA (Unpublished). Ref No.: D52 (LON 2305)	
1.2 Data protection	Yes	
1.2.1 Data owner	<i>The Dialkyl Project</i>	
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 OTS 796.3100 1993	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
3. MATERIALS AND METHODS		
3.1 Test material	██████████	
3.1.1 Lot/Batch number	██████████	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. ██████████ Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	████████████████████	
3.1.4 Purity	████████████████████	
3.1.5 Stability	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	

Section 7.1.1.2.1 (1) Ready biodegradability Annex Point IIA 7.1.1.2.1		
	seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	Test procedure	
3.2.1	Test system	Loam, activated sludge and raw influent sewage
3.2.2	Control substance	██████████████████
3.2.3	Acclimation period	14 days
3.2.4	Contact time	28 days
3.2.5	Test condition	██ ██
4. RESULTS		
4.1	Results of test substance	
4.1.1	Initial concentration of test substance	██ ██
4.2	Kinetics	
4.2.1	Degradation %	See table 7.1.1.2.1(1)-1 78.1 – 85.6% degradation after 28 days, 10 day window criteria met.
4.2.3	ThDOC	DOC = 83.0 - 85.3%, mean = 84.5% ThDOC after 28 days
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	██ ██ ██ ██
5.2	Results and discussion	The observed rate of degradation was 78.1 - 85.6% after 28 days. The dissolved oxygen content was 83.0 – 85.3%.The mean dissolved oxygen content was 84.5% ThDOC after 28 days
5.3	Conclusion	The test substance is readily biodegradable.
5.3.1	Reliability	██
5.3.2	Deficiencies	█████

Mason Europe Limited

Rapporteur Member State: Italy

Table 7.1.1.2.1(1)-1. % Degradation

Day	% Degradation	
	Didecyldimethylammonium Chloride	Control
3	4.1 - 5.5	██████████
7	27.9 - 30.7	██████████
14	62.5 - 65.1	██████████
21	72.2 - 75.7	██████████
28	78.1 - 85.6	██████████

n/d no data

Section 7.1.1.2.1(2) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
1. REFERENCE		Official use only
1.1 Reference	Schaefer, E.C. (1996) Aerobic Aquatic Biodegradation Test with Didecyldimethylammonium Chloride (DDAC) and a Bentonite Clay:DDAC Complex Conducted with Natural Sediment and Site Water. [Calgon-Sponsored Study - DDAC Molluscicide program] (Unpublished) Ref No.: D61a (LON 2923)	
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 EPA OTS 796.3260, also based on OECD Method 301B 1993	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
3. MATERIALS AND METHODS		
3.1 Test material	██████████	
3.1.1 Lot/Batch number	██████████	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. ██████████ Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	██████████	
3.1.4 Purity	██████████	

Section 7.1.1.2.1(2) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
3.1.5 Stability	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 procedure		
3.2.1 Test system	river water and sediment	
3.2.2 Sediment/water amounts	██████████ ██████████	
3.2.3 Sediment treatment	██ ██████	
3.2.4 Contact time	58 days	
3.2.5 Test condition	██ ██ ██████████	
3.2.6 CFU concentration	██████████	
4. RESULTS		
4.1 Results of test substance		
4.1.1 Initial concentration of test substance	██	
4.2 Degradation%	> 72.1 % after 28 days	
4.3 Half life	Didecyldimethylammonium Chloride $t_{1/2}$ = 11.2 days	
4.4 CO₂ parameters		
4.4.1 ThCO ₂	Didecyldimethylammonium Chloride: 90.2%	
4.4.2 Mean CO ₂ production	Average of 89.5% CO ₂ produced over 58 days, comparable to reference substance, sodium benzoate.	
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1 Materials and methods	██ ██ ██	
5.2 Results and discussion	<i>Summarise relevant results; discuss dose-response relationship where relevant.</i>	

Mason Europe Limited

Rapporteur Member State: Italy

Table 7.1.1.2.1(2)-1. % Th CO₂

Day	% Degradation	
	Didecyldimethylammonium Chloride	Control ()
2	-0.5 - 1.2	
6	21.3 - 31.2	
10	45.4 - 47.4	
14	58.9 - 62.9	
20	70.3 - 73.2	
24	71.5 - 78.6	
28	71.7 - 80.5	

Section 7.1.1.2.1 (3) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
1. REFERENCE		Official use only
1.1 Reference	Hirschen, D.M., M. Ziemer, D. Seifert. (1998) Bardac 22: DOC Die-Away Test OECD 301 A with pre-adapted inoculum. Report No. D0094-1 from Clariant. (Unpublished) Ref No.: D110 (LON 2970)	
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 OECD Guideline 301 A "Ready Biodegradability: DOC Die Away Test" 1998	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
3. MATERIALS AND METHODS		
.		
3.1 Test material	██████████	
3.1.1 Lot/Batch number	██████████	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. ████████████████████ Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	██	
3.1.4 Purity	██ ██ ██ ██ ██	

Section 7.1.1.2.1 (3) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
3.1.5	Stability	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 procedure	
3.2.1	Test system	Activated sludge, adapted (Biodegradation test preceded by Zahn-Wellens Test (OECD302B) to pre-adapt sludge.)
3.2.2	Control substance	██████████
3.2.3	Contact time	28 days
4. RESULTS		
4.1	Results of test substance	
4.1.1	Initial concentration of test substance	████████████████████
4.2	Kinetics	
4.2.1	% Degradation	See table 7.1.1.2.1(3)-1 90% degradation after 28 days, 10 day window criterion met.
4.2.2	DOC	See table 7.1.1.2.1(3)-1
4.3	Remarks	The test substance was readily biodegradable.
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	████████████████████ ████████████████████ ████████████████████ ████████████████████
5.2	Results and discussion	Biodegradation of the test substance measured 90% after 28 days. The DOC was 2.0 mg/l.
5.3	Conclusion	The test substance supports the evidence that Didecyldimethylammonium Chloride is readily biodegradable.
5.3.1	Reliability	████████████████████
5.3.2	Deficiencies	████████████████████ ████████████████████
Evaluation by Competent Authorities		

Mason Europe Limited

Rapporteur Member State: Italy

Table 7.1.1.2.1(3)-1

Time (days)	Control			Test substance (10 mg/l)	
	DOC (mg/l)	DOC (mg/l)	Degradation (%)	DOC (mg/l)	Degradation (%)
0				11.2	-
1				9.9	10
3				9.6	12
6				9.1	17
9				3.4	73
14				2.7	80
21				2.3	83
28				2.0	90

Section 7.1.1.2.1(4) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
1. REFERENCE		Official use only
1.1 Reference	Bazzon, M and Deschamps, F. (2002) Biotic degradation: biodegradability evaluation in aqueous medium: ultimate aerobía of the referenced compounds, CATIGENE T 50. for Stepan Europe, by INERIS; INERIS Study 506223 (Unpublished). Ref No.: D134 (LON 3796)	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	Data submitted to the MS after 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 EEC Guideline 84/449 -Method C5 2002	
2.2 GLP (only where required)	No (study conducted under the principles of GLP but not in full compliance – well documented study)	
2.3 Deviations	No	
3. MATERIALS AND METHODS		
3.1 Test material	████████████████████	
3.1.1 Lot/Batch number	██████████	
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.), alkyl(C ₁₂ -C ₁₈)dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3 Description	██████████	
3.1.4 Purity	██████████ Refer to Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein, for specifications of percent active substance, purity and typical impurities.	

Section 7.1.1.2.1(4) Ready biodegradability		
Annex Point IIA 7.1.1.2.1		
3.1.5	Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, e.g. at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).
3.2	Test procedure	
3.2.1	Test system	Activated sludge, non-adapted
3.2.2	Contact time	28 days
3.2.3	Control substance	██████████
3.2.4	Type	Aerobic
		4. RESULTS
4.1	Results of test substance	
4.1.1	Initial concentration of test substance	██
4.2	Kinetics	
4.2.1	Test substance	See table 7.1.1.2.1(1)-1
4.2.2	Control	See table 7.1.1.2.1(1)-1
4.2.3	Remarks	The test substance is readily biodegradable.
		5. APPLICANT'S SUMMARY AND CONCLUSION
5.1	Materials and methods	██ ██ ██ ██
5.2	Results and discussion	██ ██ ██ ██ ██ ██ ██ ██ ██ ██

Mason Europe Limited

Rapporteur Member State: Italy

0	0	0
5	9.5	0.65
15	55.3	4.65
28	71.6	5.0



Section 7.1.1.2.1 (5)		Ready biodegradability
Annex Point IIA 7.1.1.2.1		
1. REFERENCE		
1.1 Reference	Fiebig, S. (2006) Dodigen 1881: Ready Biodegradability: Modified Sturm Test. Dr. U. Noack-Laboratorien, Germany. Study No. AST97952 (unpublished). Ref No.: D159 (LON 4031)	
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 OECD Guideline 301B 1992	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
3. MATERIALS AND METHODS		
3.1 Test material	[REDACTED] DDAC as active substance, a.s. [REDACTED] [REDACTED]	
3.1.1 Lot/Batch number	[REDACTED]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [REDACTED] [REDACTED] Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5).	
3.1.3 Description	[REDACTED] [REDACTED]	
3.1.4 Purity	[REDACTED]	
3.1.5 Stability	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 procedure		
3.2.1 Test system	Mineral nutrient solution prepared according to OECD 301B.	

Mason Europe Limited

Rapporteur Member State: Italy

3.2.2 Inoculum	Non-adapted activated sludge from municipal sewage treatment plant
3.2.3 Control (reference) substance	[REDACTED]
3.2.4 Acclimation period	
3.2.5 Contact time	28 days
3.2.6 Test condition	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
4. RESULTS	
4.1 Results of test substance	
4.1.1 Initial concentration of test substance	[REDACTED]
4.2 Kinetics	
4.2.1 Degradation %	<p>Degradation of the test substance was 67 and 72% in the two test replicates after 28 days, respectively. The mean percent degradation as ThCO₂ was 69.5% in 28 days. See table 7.1.1.2.1(1)-1.</p> <p>The 10- day window criterion was met, with 10% degradation observed in both replicates after 5 days and degradation reaching 60% by Day 15 and 16 in the respective replicates.</p> <p>[REDACTED] [REDACTED] [REDACTED] [REDACTED]</p>
5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
5.2 Results and discussion	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]

5.3 Conclusion	The test substance is readily biodegradable.
5.3.1 Reliability	██
5.3.2 Deficiencies	█
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	██████████
Materials and Methods	
Results and discussion	
Conclusion	██
Reliability	█
Acceptability	Acceptable
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Mason Europe Limited

Rapporteur Member State: Italy

Table 7.1.1.2.1(1)-1. % Degradation

Day	% Degradation (as % ThCO ₂)		
	Toxicity Control (Test + Reference Substances)	Test Substance [REDACTED] DDAC as a.s.) [N=2] ^a	Control/Reference Substance [REDACTED] ^a
1	0	0, 0	[REDACTED]
3	7	0, 0	[REDACTED]
7	29	26, 26	[REDACTED]
10	51	44, 43	[REDACTED]
13	57	46, 51	[REDACTED]
15	61	56, 61	[REDACTED]
17	63	63, 64	[REDACTED]
21	63	60, 62	[REDACTED]
24	66	64, 63	[REDACTED]
28	70	71, 67	[REDACTED]
29 ^b	76	72, 67	[REDACTED]

^a Percent (%) degradation represents gross CO₂ evolution less the CO₂ evolution observed in the control

^b Results of acidified gas wash bottles following test termination.

Section 7.1.1.2.2 (1)		Inherent biodegradability	
Annex Point IIA 7.1.1.2.2			
		1. REFERENCE	Official use only
1.1 Reference	Hirschen, D.M., M. Ziemer, D. Seifert. (1998) Bardac 22: DOC Die-Away Test OECD 301 A with pre-adapted inoculum. Report No. D0094-1 from Clariant. (Unpublished)		
	Ref No.: D110 (LON 2970)		
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		
	OECD Guideline 302 B "Inherent biodegradability: Modified Zahn-Wellens Test"		
	1998		
2.2 GLP (only where required)	Yes		
2.3 Deviations	No		
		3. MATERIALS AND METHODS	
3.1 Test material	██████████		
3.1.1 Lot/Batch number	██████████		
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.		
	██		
	Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.		
3.1.3 Description	See comment regarding composition below.		

Section 7.1.1.2.2 (1)		Inherent biodegradability
Annex Point IIA 7.1.1.2.2		
3.1.4	Purity	[REDACTED]
3.1.5	Stability	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 procedure	
3.2.1	Test system	activated sludge, domestic, non-adapted
3.2.2	Control substance	[REDACTED]
3.2.3	Contact period	28 days
3.2	Remarks	The test was carried out twice
4. RESULTS		
4.1	Results of test substance	
4.1.1	Initial concentration of test substance	[REDACTED]
4.2	Kinetics	
4.2.1	% Degradation	See table 7.1.1.2.2(1)-1 87 – 94% degradation after 28 days, 10 day window criterion met.
4.2.1	DOC	See table 7.1.1.2.2(1)-1
4.3	Remarks	The test substance was inherently biodegradable.
5. APPLICANT'S SUMMARY AND CONCLUSION		
5.1	Materials and methods	[REDACTED]
5.2	Results and discussion	Degradation of the test substance was 87 - 94% after 28 days.
5.3	Conclusion	The test substance is inherently biodegradable.
5.3.1	Reliability	[REDACTED]

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.1.1.2.2 (1)		Inherent biodegradability	
Annex Point IIA 7.1.1.2.2			
5.3.2	Deficiencies	■	
Evaluation by Competent Authorities			
EVALUATION BY RAPporteur MEMBER STATE			
Date		■	
Materials and Methods			
Results and discussion			
Conclusion			
		■	
Reliability			
Acceptability			
		Acceptable	
Remarks			
		■	
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	Give date of the comments submitted		
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state		
Results and discussion	Discuss if deviating from view of rapporteur member state		
Conclusion	Discuss if deviating from view of rapporteur member state		
Reliability	Discuss if deviating from view of rapporteur member state		
Acceptability	Discuss if deviating from view of rapporteur member state		

Mason Europe Limited

Rapporteur Member State: Italy

Table 7.1.1.2.2(1)-1. % Degradation

Time (days)	Control DOC (mg/l)	██████████		Test substance (10 mg/l)			
		DOC (mg/l)	Degradation (%)	DOC (mg/l)		Degradation (%)	
				Test 1	Test 2	Test 1	Test 2
0				10.1	9.5	-	-
2				7.2	8.4	32	35
5				6.6	8.2	45	41
8				5.7	6.8	62	60
12				4.8	5.7	79	74
14				5.3	5.4	79	83
21				4.8	5.4	88	84
28				5.0	5.7	94	87

This page has been
left blank intentionally.

Section 7.1.1.2.3 Biodegradation in seawater Annex Point III-A.7.1.1.2.3		
JUSTIFICATION FOR NON-SUBMISSION OF DATA		
	Official use only	
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification <input type="checkbox"/>	
Detailed justification:	[REDACTED]	
Undertaking of intended data submission <input type="checkbox"/>		
Evaluation by Competent Authorities		
EVALUATION BY RAPPORTEUR MEMBER STATE		
Date	[REDACTED]	
Evaluation of applicant's justification		
Conclusion	<i>Agreed with applicant justification</i>	
Remarks		
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>		
Date	<i>Give date of comments submitted</i>	
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>	
Remarks		

Mason Europe Limited

Rapporteur Member State: Italy

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****Section 7.1.2.1 Biological sewage treatment****Annex Point IIA 7.1.2.1**

Section 7.1.2.1.1(1)		Aerobic biodegradation	
Annex Point IIA 7.1.2.1.1			
1. REFERENCE			Official use only
1.1 Reference	Schaefer, E.C. (2001) Didecyldimethylammonium Chloride (DDAC): Dieaway in Activated Sludge. Project No. 289E-112. Wildlife International, Inc., Easton, MA, USA (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	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			
3.1 Test material			
3.1.1 Lot/Batch number			
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.		

Section 7.1.2.1.1(1)		Aerobic biodegradation	
Annex Point IIA 7.1.2.1.1			
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	Biotic activated sludge [REDACTED]	
3.2.2	Control	[REDACTED]	
3.2.3	Source	[REDACTED]	
3.3 Test procedure			
3.3.1	Acclimation period	21 days	
3.3.2	Test period	28 days	
3.3.3	Test condition	Two 1 gallon jugs, with gas trapping systems, containing 2 litres of either biotic or abiotic activated sludge were dosed with [REDACTED] radiolabelled test substance.	
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	See table 7.1.2.1.1(1)-1 The amount of ¹⁴ CO ₂ increased over time reaching 93.3% after 28 days. No ¹⁴ CO ₂ evolved in the abiotic sample.	
4.2.2	Extracts	See table 7.1.2.1.1(1)-1	

Section 7.1.2.1.1(1)		Aerobic biodegradation	
Annex Point IIA 7.1.2.1.1			
	The amount of parent and metabolite decreased over time reaching 1.32% of metabolite and 0% of metabolite after 28 days. In the abiotic sample radioactivity was found as an average 92.2% parent and 0% metabolite.		X
4.2.3	Solids	See table 7.1.2.1.1(1)-1 The amount of radioactivity in the solid varied from 1.71 – 5.32% with 3.28% found after 28 days. 1.5% of the radioactivity was present as solid in the abiotic sample.	
4.3	Statistics		
4.3.1	2 compartment function kinetic analysis	See table 7.1.2.1.1(1)-2	
5. APPLICANT'S SUMMARY AND CONCLUSION			
5.1	Materials and methods	[REDACTED]	
5.2	Results and discussion	[REDACTED]	
5.3	Conclusion	Didecyldimethylammonium Chloride biodegrades in aerobic conditions	
5.3.1	Reliability	[REDACTED]	X
5.3.2	Deficiencies	■	
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Materials and Methods	[REDACTED]		
Results and discussion	[REDACTED]		
Conclusion	[REDACTED]		
Reliability	[REDACTED]		

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.1.2.1.1(1) Annex Point IIA 7.1.2.1.1	Aerobic biodegradation
Acceptability	acceptable
Remarks	<div style="background-color: black; width: 100px; height: 15px; display: inline-block;"></div> <div style="background-color: black; width: 100px; height: 15px; display: inline-block;"></div> <div style="background-color: black; width: 600px; height: 15px; display: inline-block;"></div>
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member stat</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>

Mason Europe Limited

Rapporteur Member State: Italy

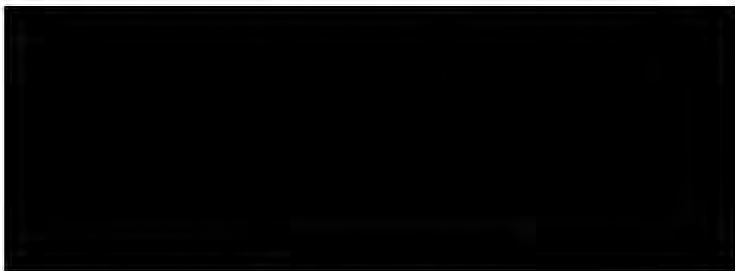

Table 7.1.2.1.1(1)-1. Radioactivity distribution (% total radioactivity)

DDAC	Biotic				Abiotic mean
	1 hr	12 hrs	Day 7	Day 28	
CO ₂	12.36	65.83	88.36	93.30	N/A
Extracts – parent	65.21	9.72	1.56	1.32	92.22
Extracts – metabolite	20.10	13.37	1.02	0.00	0.00
Solid	1.71	3.58	5.32	3.28	1.50
Total	99.38	92.50	96.26	97.90	93.72

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

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

Section 7.1.2.1.2 Anaerobic biodegradation	
Annex Point III-A.7.1.2.1.2	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data <input type="checkbox"/> Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/> Limited exposure <input checked="" type="checkbox"/> Other justification <input type="checkbox"/>	
Detailed justification: <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div> <div style="background-color: black; width: 100%; height: 15px; margin: 2px 0;"></div>	
Undertaking of intended data submission <input type="checkbox"/>	
Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date 	
Evaluation of applicant's justification	
Conclusion <i>Agreed with applicant justification</i>	
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date <i>Give date of comments submitted</i>	
Evaluation of applicant's justification <i>Discuss if deviating from view of rapporteur member state</i>	
Conclusion <i>Discuss if deviating from view of rapporteur member state</i>	
Remarks	

Section A7.1.2.2.2 (1) A Water/sediment degradation study Annex Point IIIA XII.2.1		Official use only
REFERENCE		
Reference	de Vette, H.Q.M., van Asten, J.G. and A.O. Hanstveit (2000) A water/sediment study of didecyldimethylammonium chloride (DDAC) using [¹⁴ C]-DDAC. TNO Nutrition and Food Research, Delft, The Netherlands. Study No. IMW-99-9048-01 (unpublished). Ref. No. D65 (LON 3255)	
Data protection	Yes	
iii) Data owner	The Dialkyl Project	
iv) Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
GUIDELINES AND QUALITY ASSURANCE		
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.	
GLP	Yes	
Deviations	No	
MATERIALS AND METHODS		
Test material	[¹⁴ C]-Didecyldimethylammonium Chloride (DDAC)  Non-radiolabelled – DDAC (provided as  a trade name for DDAC).	

Section A7.1.2.2.2 (1) A Water/sediment degradation study	
Annex Point IIIA	
XII.2.1	
i) Lot/Batch number	[REDACTED]
ii) 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. Specific activity: 23.39 mCi/mmol.
Purity	[REDACTED]
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).
Further relevant properties	[REDACTED]
Composition of Product	[REDACTED]
Specific chemical analysis	[REDACTED]
Reference substance	[REDACTED]
Initial concentration of reference substance	[REDACTED]
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.
Test media	[REDACTED]

Section A7.1.2.2.2 (1) A Water/sediment degradation study Annex Point IIIA XII.2.1	
	[REDACTED]
Test system	[REDACTED]
Test conditions	[REDACTED]
Method of preparation of test solution	[REDACTED]
Initial TS concentration	[REDACTED]
Duration of test	120 days

Section A7.1.2.2.2 (1) A Water/sediment degradation study
Annex Point IIIA
XII.2.1

Sampling

[Redacted text block containing multiple paragraphs of information, likely describing sampling procedures and results for the water/sediment degradation study.]

[Redacted text block at the bottom of the page.]

<p>Section A7.1.2.2.2 (1) A Water/sediment degradation study Annex Point IIIA XII.2.1</p>	
<p>Liquid scintillation counting</p>	<p>[REDACTED]</p>
<p>Chromatographic analysis</p>	<p>[REDACTED]</p>
<p>Controls</p>	<p>[REDACTED]</p>
<p>Statistics</p>	<p>[REDACTED]</p>
<p>RESULTS</p>	
<p>Recovery and distribution</p>	<p>The recovery and distribution of the applied radioactivity from the water/sediment systems is summarised in Table A7.1.2.2.2 (1)-2 and is presented graphically for the TNO and Kromme Rijn systems in Figures A7.1.2.2.2 (1)-2 and A7.1.2.2.2 (1)-3, respectively.</p> <p>The overall recovery of the applied radioactivity ranged from 75.7 to 96.3% and 69.1 to 91.7% for the TNO and Kromme Rijn systems, respectively. The recovery at 0 days was below 80% for both systems. The total recovery in these two systems improved to a generally acceptable level over the 7 to 14 day periods but then subsequently declined and comprised 79.0% and 69.7%, respectively, by the end of the study (120 days).</p> <p>Levels of applied radioactivity recovered from the water phase of the TNO and Kromme Rijn systems declined from 41.7% and 54.4%, respectively, at 0 days to < 5% in both systems by 14 days. Levels recovered in the sediment phase (extractable) increased to a maximum of 80.1% in the TNO system after 7 days and a maximum of 79.1% in the Kromme Rijn system after 1 day. Unextractable levels in the sediment phase increased to a maximum of 20.5% in the TNO system after 28 days and a maximum of 23.5% in the Kromme Rijn system after 56 days, before declining in both systems to approximately 16% after 120 days. The levels of total carbon dioxide evolved steadily</p>

<p>Section A7.1.2.2.2 (1) Annex Point IIIA XII.2.1</p>	<p>A Water/sediment degradation study</p>	
<p>Degradation of test substance</p>	<p>increased to 7.8% and 15.4% in the respective systems after 120 days. Formation of organic volatiles was negligible.</p>	
	<p>Analysis of the water and sediment layers indicated that no significant (i.e. > 2%) metabolites were formed. Procedural losses, however, during sample work up were significant (up to 77%), especially for the water layer, and unacceptable. Such procedural losses call into question any results presented; these procedural losses are, therefore, not detailed further in this summary.</p> <p>Loss of the active substance from the aqueous phase of these systems is summarized in terms of DT50 and DT90 (see Table A7.1.2.2.2 (1)-3), which were determined using 'best fit' models.</p> <p>First order half-lives determined for the dissipation of the active substance from the water layer to the sediment layer were 1.7 and 0.4 days for the TNO and Kromme Rijn systems, respectively (see Table A7.1.2.2.2 (1)-4).</p> <p>The metabolite profile was not confirmed in a secondary analytical system.</p>	
<p>APPLICANT'S SUMMARY AND CONCLUSION</p>		
<p>Materials and methods</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	
<p>Results and discussion</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	

Section A7.1.2.2.2 (1) A Water/sediment degradation study	
Annex Point IIIA	
XII.2.1	
	[REDACTED]
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.
Reliability	[REDACTED]
Deficiencies	[REDACTED]
	<ul style="list-style-type: none"> ■ [REDACTED] ■ [REDACTED]
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	■
Acceptability	acceptable
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>

Section A7.1.2.2.2 (1)	A Water/sediment degradation study
Annex Point IIIA	
XII.2.1	
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

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

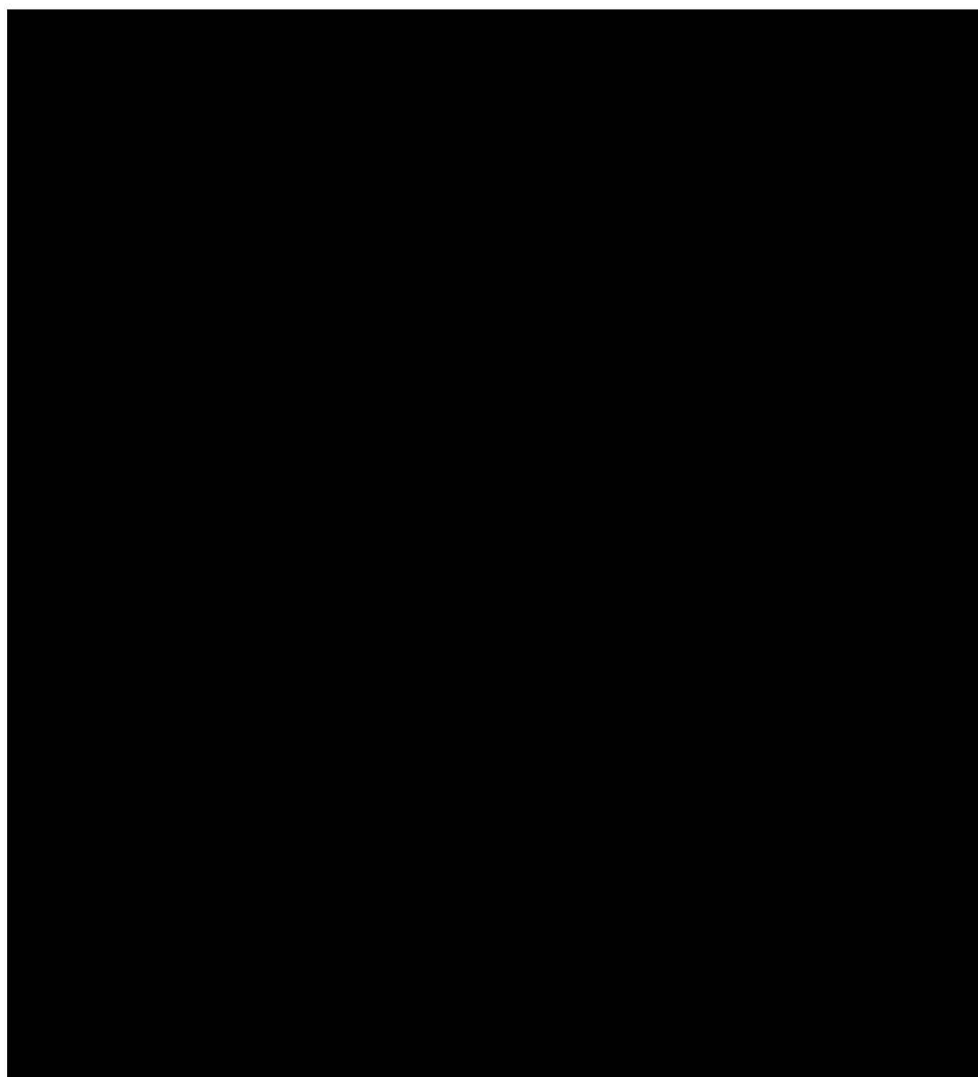


Figure A7.1.2.2.2 (1)-1: Test system incubation vessels



Mason Europe Limited

Rapporteur Member State: Italy

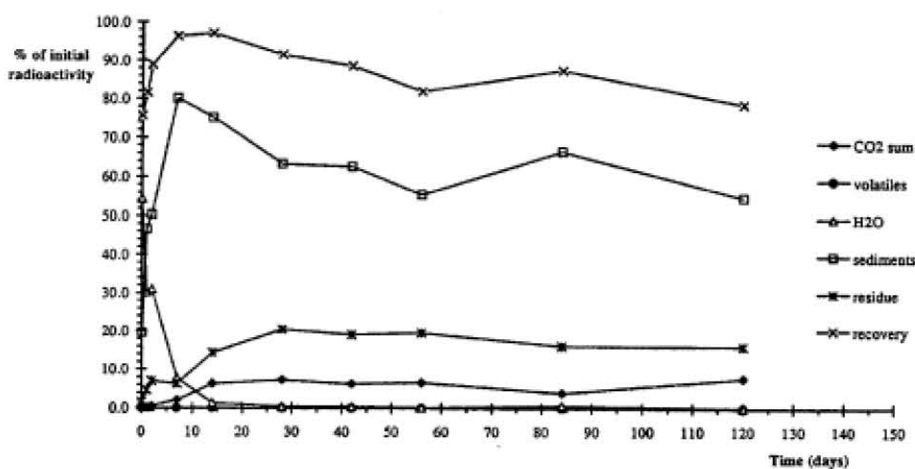
Table A7.1.2.2.2 (1)-2: Recovery and distribution of applied radioactivity from the water/sediment systems

Days	TNO water/sediment system									
	0	1	2	7	14	28	42	56	84	120
CO ₂ trap	n.d.	0.0	0.0	0.1	0.6	1.2	2.8	4.2	3.8	7.6
CO ₂ in H ₂ O	n.d.	0.2	0.4	2.0	5.8	6.1	3.5	2.5	0.2	0.2
CO ₂ sum	n.d.	0.2	0.4	2.1	6.3	7.3	6.3	6.7	4.0	7.8
Volatiles	n.d.	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
H ₂ O	54.4	30.2	31.0	7.8	1.3	0.4	0.4	0.2	0.7	0.1
Sediments	19.6	46.5	50.4	80.1	75.2	63.4	62.8	55.6	66.8	55.0
Residue	1.6	4.7	7.0	6.3	14.3	20.5	19.2	19.7	16.2	16.1
Recovery	75.7	81.6	88.9	96.3	97.1	91.6	88.8	82.2	87.8	79.0
Days	Kromme Rijn water/sediment system									
	0	1	2	7	14	28	42	56	84	120
CO ₂ trap	n.d.	0.0	0.0	1.1	5.6	13.5	16.8	11.2	11.9	14.9
CO ₂ in H ₂ O	n.d.	0.4	0.6	5.3	9.0	2.5	0.8	0.8	0.7	0.5
CO ₂ sum	n.d.	0.5	0.7	6.4	14.6	16.1	17.6	11.9	12.5	15.4
Volatiles	n.d.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
H ₂ O	41.7	5.9	7.7	10.1	0.0	3.9	0.2	0.4	-0.4	0.0
Sediments	25.3	79.1	75.8	69.7	61.4	46.9	49.7	42.5	53.2	38.0
Residue	2.1	4.5	4.2	5.5	13.1	19.4	18.4	23.5	16.5	16.4
Recovery	69.1	90.0	88.4	91.7	89.1	86.2	85.9	78.3	82.2	69.7

Legend:

CO₂ trap Results of carbon dioxide measurements in the traps.
CO₂ in H₂O Carbon dioxide remaining in the aqueous phase.
CO₂ sum Sum of the carbon dioxide measurements
volatiles Radioactivity in the oil-covered quartz wool
H₂O Radioactivity in the aqueous phase (excluding CO₂)
sediments Extractable radioactivity in the sediments and particles collected on cotton wool filter
residue Unextractable radioactivity in the sediments
recovery Overall recovery
nd Not determined

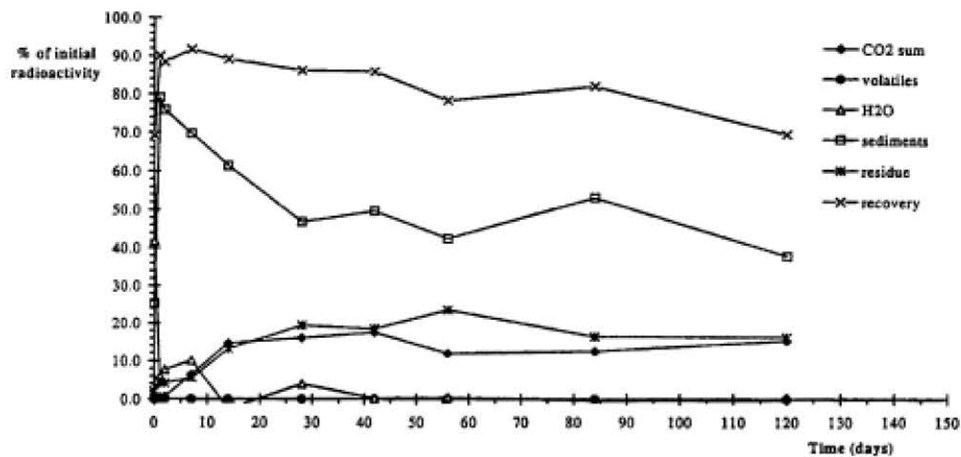
Figure A7.1.2.2.2 (1)-2: Recovery and distribution of applied radioactivity from the TNO water/sediment system



Mason Europe Limited

Rapporteur Member State: Italy

Figure A7.1.2.2.2 (1)-3: Recovery and distribution of applied radioactivity from the Kromme Rijn water/sediment system

Table A7.1.2.2.2 (1)-3: Loss of ^{14}C -DDAC (DT50 and DT90) from aqueous phase of water/sediment systems using “best fit” model

System	R ²	DT ₅₀ (d)	DT ₉₀ (d)
TNO	0.974	0.05	6.7
Kromme Rijn	0.990	0.01	0.13

Table A7.1.2.2.2 (1)-4: Loss of ^{14}C -DDAC (dissipation rates and half lives) from aqueous phase of water/sediment systems using 1st order model

System	R ²	A (%)	K _d (d ⁻¹)	t _{1/2} (d)
TNO	0.917	69.0 ± 5.2	0.41 ± 0.08	1.7
Kromme Rijn	0.904	60.4 ± 10.6	1.92 ± 0.62	0.4

Section 7.1.2.2.2 Water/sediment degradation study Annex Point III-A.7.1.2.2.2	
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Official use only	
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/>
Limited exposure <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Other justification <input type="checkbox"/>	
Detailed justification:	[Redacted text]
Undertaking of intended data submission <input type="checkbox"/>	
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)	

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.1.2.2.2 Annex Point III-A.7.1.2.2.2	Water/sediment degradation study
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.1.3		Adsorption/desorption screening test	
Annex Point II A.7.1.3			
		JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>		
Detailed justification:	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>		
Undertaking of intended data submission <input type="checkbox"/>			
Evaluation by Competent Authorities			
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted			
EVALUATION BY RAPporteur MEMBER STATE			
Date	[REDACTED]		
Evaluation of applicant's justification			
Conclusion	Agreed with applicant justification		
Remarks			
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	<i>Give date of comments submitted</i>		
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>		
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>		
Remarks			

Section 7.1.4 Annex Point III-A.7.1.4		Studies on adsorption and desorption in water/sediment systems	
JUSTIFICATION FOR NON-SUBMISSION OF DATA			Official use only
Other existing data <input type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input checked="" type="checkbox"/>	
Limited exposure <input type="checkbox"/>	Other justification <input type="checkbox"/>		
Detailed justification:	[REDACTED]		
Undertaking of intended data submission <input type="checkbox"/>	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			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Evaluation of applicant's justification	[REDACTED]		
Conclusion	Agreed with applicant justification.		
Remarks			
COMMENTS FROM OTHER MEMBER STATE (specify)			
Date	Give date of comments submitted		
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state		

Section 7.1.4 Annex Point III-A.7.1.4	Studies on adsorption and desorption in water/sediment systems
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.1.4.1	Field study on accumulation in the sediment
Annex Point III-A.7.1.4.1	

Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
-------------------	--

Remarks	
----------------	--

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.2.2.1 Annex Point III-A.7.2.2.1	Rate and route of degradation, including the identification of the processes involved and identification of any metabolites and degradation in at least three soil types under appropriate conditions
---	--

Remarks

Section 7.2.2.4(1) Annex Point IIA 7.2.2.4		Photolysis in Soil	
1. REFERENCE			Official use only
1.1 Reference	Schmidt, J. (1992) Determination of the Photolysis Rate of Didecyldimethylammonium Chloride on the Surface of Soil. Report No. 39505. ABC Laboratories, Columbia, MO, USA (Unpublished). Ref No.: D38 (LON 3069)		
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, 40 CFR 158.130, Guideline N-161-3 1992		
2.2 GLP (only where required)	Yes		
2.3 Deviations	No		
3. MATERIALS AND METHODS			
3.1 Test material	[REDACTED]		
3.1.1 Lot/Batch number	[REDACTED] [REDACTED]		
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.		
3.1.3 Description	[REDACTED] [REDACTED]		
3.1.4 Purity	[REDACTED] [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 7.2.2.4(1)		Photolysis in Soil
Annex Point IIA 7.2.2.4		
		Section 2.6.1 of Annex IIA).
3.2	Test system	Sandy loam
3.3	Test procedure	[REDACTED]
3.3.1	Light source	[REDACTED]
3.3.2	Light spectrum	[REDACTED]
4. RESULTS		
4.1	Results of test substance	
4.1.1	Initial concentration of test substance	[REDACTED]
4.2	Residues	
4.2.1	Extractable residues	Decreased from 90.5% to 80.8% (exposed) and 81.1% (non-exposed)
4.2.2	Soil bound residues	Increased from 9.48% to 25.2% (exposed) and 20.9% (non-exposed)
4.2.3	Extractable bound residues	73.8 to 74% recovered, no significant degradation products
4.3	Degradation%	No significant degradation, only parent compound obtained
4.4	Half life	An accurate estimate of the half-life for the photolysis could not be determined since no significant degradation of the test compound was detected during the 30 day evaluation period. Calculations of half-lives were: $t_{1/2} = 132$ days (exposed) $t_{1/2} = 169$ days (non-exposed)
4.5	Rate constants	5.26×10^{-3} days ⁻¹ (exposed) 4.11×10^{-3} days ⁻¹ (non-exposed)
4.6	Remarks	The mean ¹⁴ C-mass balance was 104% for exposed and non-

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.2.2.4(1)		Photolysis in Soil	
Annex Point IIA 7.2.2.4			
exposed test systems.			
5. APPLICANT'S SUMMARY AND CONCLUSION			
5.1 Materials and methods	[REDACTED]		
5.2 Results and discussion	[REDACTED]		
5.3 Conclusion	The test substance was stable and not subject to photodegradation on soil.		
5.3.1 Reliability	[REDACTED]		
5.3.2 Deficiencies	[REDACTED]		
Evaluation by Competent Authorities			
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>			
EVALUATION BY RAPPORTEUR MEMBER STATE			
Date	[REDACTED]		
Materials and Methods			
Results and discussion			
Conclusion	[REDACTED]		
Reliability	[REDACTED]		
Acceptability	acceptable		

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.2.2.4(1) Annex Point IIA 7.2.2.4	Photolysis in Soil
Remarks	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of the comments submitted</i>
Materials and Methods	<i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>