Section 4.2c(1) Annex Point IIA 4.2	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water**	
	1. REFERENCE	Official use only
1.1 Reference	*Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).* Brewin, S. (2003) Didecyldimethylammonium Chloride (DDAC: CAS RN 7173-51-5) Validation of Methodology for the Determination of Residues in Drinking, Ground and Surface Water. Report No. ADB015/033168. Huntingdon Life Sciences, Ltd. (Unpublished) Ref No.: D90 (LON 3702)	
1.1 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 exiting a.s. for the purpose of its entry into Annex I.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 2003 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	[redacted]	
3.1.1 Lot/Batch	*List lot/batch number where relevant* [redacted]	

Section 4.2c(1) Annex Point IIA 4.2		Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water	
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. [redacted] 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]	
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 procedure**	Water samples were partitioned with 0.1 m heptanesulfonic acid and dichloromethane, then concentrated by rotary evaporation and redissolved in 0.1% formic acid in methanol. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
3.2.1	Water types	Drinking, ground and surface water	
3.2.2	Calibration standards	0.2-20 ng/ml	x
3.2.3	Validation range	0.1-1.0 µg/L	
		4. RESULTS	
4.1	**Accuracy data**	See table 4.2c(1)-1	
4.2	**Limit of quantitation (LOQ)**	0.1 µg/L	
4.3	**Limit of detection (LOD)**	1.0 ng/ml (equivalent to 0.01µg/L in drinking, ground and surface water)	
4.4	**Remarks**	Didecyldimethylammonium Chloride can be accurately determined in water at a limit of quantitation of 0.1 µg/L. The limit of detection of Didecyldimethylammonium Chloride in water was 1.0 ng/ml for this	

Section 4.2c(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) Water**	
	method.	
	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 91/414/EEC as amended by 96/46/EC, SANCO/3029/99 rev.4 guidelines to validate analytical methods in drinking, ground and surface water samples. Quantitation was by liquid chromatography with mass spectrometric detection (LC-MS).	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The mean recovery of Didecyldimethylammonium Chloride in drinking water was 91% (cv 8.1%), surface water was 80% (cv 10.8%) and ground water was 84% (cv 8.4%). The limit of quantitation was 0.1µg/L and the limit of detection was 1.0 ng/ml.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* 0.1 µg/L of the test substance can be accurately detected in water.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		

Section 4.2c(1) Annex Point IIA 4.2	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following: (c) Water**
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 4.2c(1) **Annex Point IIA 4.2**	**Analytical methods including recovery rates and the limits of determination for the active substance, and for residues thereof, and where relevant in/on the following:** **(c) Water**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	acceptable
Remarks	3.2.2.Calibration was actually performed in the range 1-50 ng/ml
	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*

Table 4.2c(1)-1. Recovery data

Drinking water			Surface water			Ground water		
Recovery range (%)	Mean recovery (%)	CV (%)	Recovery range (%)	Mean recovery (%)	CV (%)	Recovery range (%)	Mean recovery (%)	CV (%)
83-103	91	8.1	70-94	80	10.8	74-94	84	8.4

Section 4.2d Annex Point IIA.4.2d	Analytical methods for environmental media (human body fluids and tissues)	
	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	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 4.2d Annex Point IIA.4.2d	Analytical methods for environmental media (human body fluids and tissues)
Evaluation of applicant's justification	[redacted]
Conclusion	The Applicant justification is acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 4.3 Annex Point III-A.4.3	Analysis in foodstuffs	
	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		

Section 4.3 Annex Point III-A.4.3	Analysis in foodstuffs
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	The Applicant justification is acceptable.
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

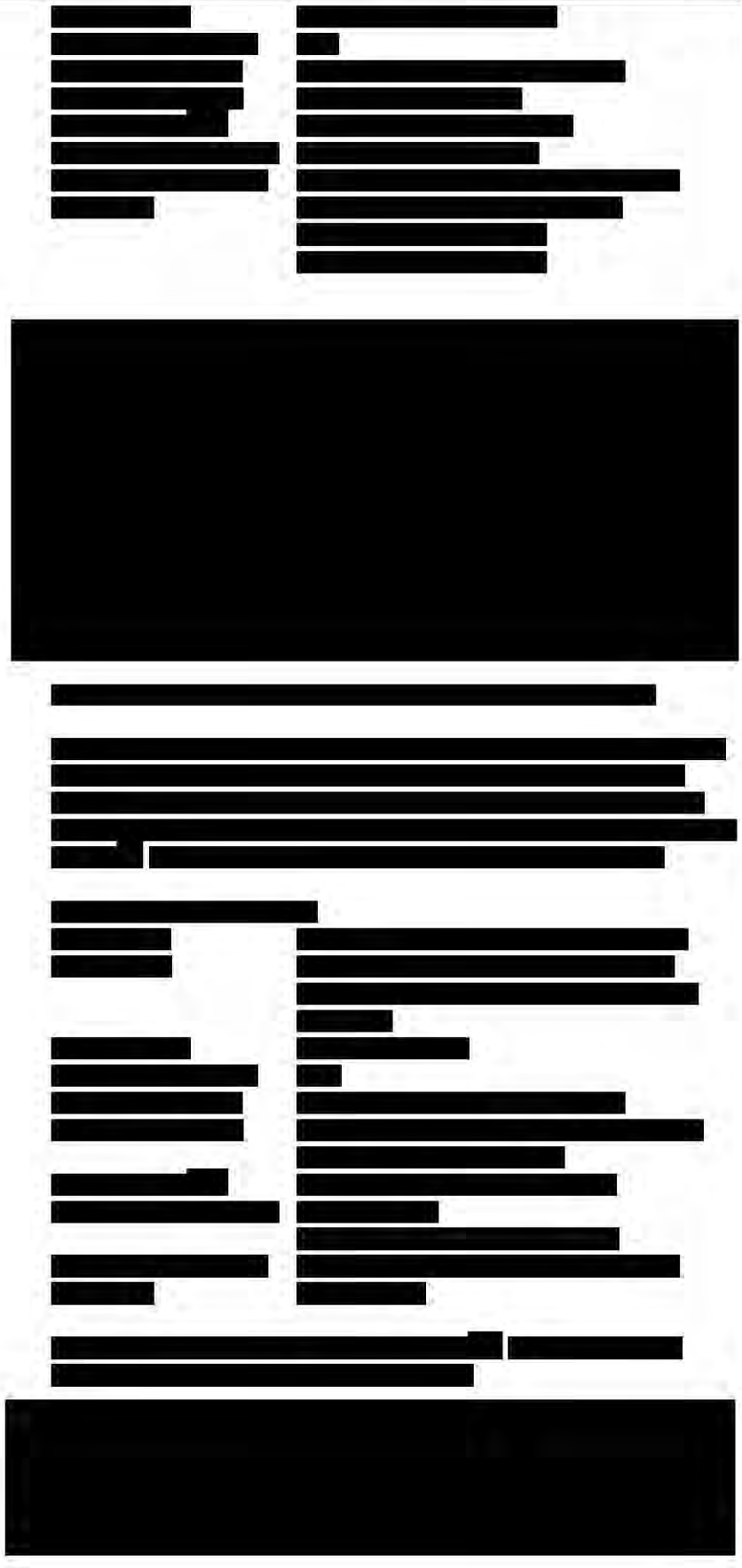
Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
5.1 Function	[redacted]	
5.2 Organism(s) to be controlled and products, organisms or objects to be protected	*Headline only*	
5.2.1 Organism(s) to be controlled	[redacted]	X
5.2.2 Products, objects	[redacted]	
5.3 Effects on target organisms and likely concentration at which the active substance will be used	*Headline only*	

Section 5 Annex Point IIA. 5		Effectiveness against target organisms and intended uses	Official use only
5.3.1	Effects on target organisms	[redacted]	X

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
5.3.1.1 Efficacy tests with single active substance formulation (DDAC) against fungi	[redacted]	

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only



Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

[redacted]

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
	[redacted]	
5.3.1.2 Efficacy tests with single active substance formulation (DDAC) against insects	[redacted]	

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

[redacted]

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

[redacted]

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only

[redacted]

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
	[redacted]	
5.3.2 Likely concentrations at which the active substance will be used	[redacted]	
5.4 Mode of action (including time delay)	*Headline only*	
5.4.1 Mode of action	[redacted]	

Section 5 **Annex Point IIA. 5**	**Effectiveness against target organisms and intended uses**	Official use only
	[redacted]	
5.4.2 Time delay	[redacted]	
5.5 Field of use envisaged	[redacted]	
5.6 User: industrial, professional, general public	[redacted]	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	*Headline only*	
5.7.1 Development of resistance	[redacted]	
5.7.2 Management strategies	[redacted]	
5.8 Likely tonnage to be placed on the market per year	[redacted]	

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
	EVALUATION BY RAPPORTEUR MEMBER STATE *AS REGARDS TERMITES STUDIES:*	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	

Section 5 Annex Point IIA. 5	Effectiveness against target organisms and intended uses	Official use only
Acceptability	[redacted]	

Section 6.1 – Acute toxicity
Annex Point IIA 6.1 – headline only

Section 6.1.1(1) Annex Point IIA 6.1.1	Acute oral toxicity test with rodent (rat)	
	1. REFERENCE	Official use only
1.1 Reference	Morris, T.D. (1992) Acute oral toxicity in rats—median lethal dosage determination with Didecyldimethylammonium Chloride (DDAC). Study No. 91-8114-21 (A). Hill Top Biolabs, Inc., Mill and Main streets, Miamiville, Ohio 45147 USA. (Unpublished) Ref No. D9 (LON 3746)	
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 FIFRA 40 CFR, TSCA 40 CFR, and OECD Guidelines (OECD Guideline used was not specified) 1991	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), 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 a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous,	

Section 6.1.1(1) Annex Point IIA 6.1.1	Acute oral toxicity test with rodent (rat)	
	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	Rat	
3.2.2 Strain	Sprague Dawley	
3.2.3 Source	[redacted]	
3.2.4 Sex	Male and female	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Oral gavage	
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]	
3.4.5 Other examinations	[redacted]	
3.4.6 Statistics	[redacted]	

Section 6.1.1(1) Annex Point IIA 6.1.1	Acute oral toxicity test with rodent (rat)	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Limit Test	No	
4.2 LD_{50} including confidence limits	LD_{50} = 238 mg/kg with 95% confidence limits of 198 mg/kg to 287 mg/kg	
4.3 Observations, Sacrifice and Pathology	[redacted]	
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	See Table A6.1.1(1)-1	
4.3.3 Bodyweight	[redacted]	
4.3.4 Organ weights	[redacted]	
4.3.5 Other examinations	[redacted]	
4.3.6 Statistics	[redacted]	
4.4 Further remarks	[redacted]	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	*LD_{50} = 238 mg/kg with 95% confidence limits of 198-287 mg/kg* There were no treatment-related effects at the 10.0 mg/kg dose level and only minimal toxic effects at 20.0 and 30.0 mg/kg dose levels.	X
5.3 Conclusion	Didecyldimethylammonium Chloride is classified as harmful if swallowed on the basis of this study and is assigned the symbol Xn and	

Section 6.1.1(1) Annex Point IIA 6.1.1	Acute oral toxicity test with rodent (rat)	
	risk phrase R22.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
Remarks	[redacted]	
	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*	

Section 6.1.1(1) Annex Point IIA 6.1.1	Acute oral toxicity test with rodent (rat)
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table A6.1.1(1) -1

Dose levels (mg/kg)	Mortality	Group size
Phase I		
4000	10	10
1000	9	10
400	10	10
160	7	10
63.2	3	10
Phase II		
500	10	10
300	7	10
200	4	10
100	0	10
Phase III		
30.0	0	4
20.0	0	4
10.0	1	10

Section 6.1.2(1) Annex Point IIA 6.1.2	Acute dermal toxicity test	
	1. REFERENCE	Official use only
1.1 Reference	Siglin, J.C. (1987). Acute Dermal Toxicity Study in Rabbits LD50 Test (EPA), Test article DMD10AC. Study No. 3165.1.2C, Springborn Institute for Bioresearch, Inc., Spencerville, OH, USA. (Unpublished) Ref No. D85 (LON 3805)	
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 Equivalent to Pesticide Assessment Guideline 81-2, Acute Dermal Toxicity Study 1987	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), 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 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		

Section 6.1.2(1) Annex Point IIA 6.1.2	Acute dermal toxicity test	
3.2.1 Species	Rabbit	
3.2.2 Strain	New Zealand white	
3.2.3 Source	[redacted]	
3.2.4 Sex	Male and female	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Dermal	
3.3.2 Post exposure period	[redacted]	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Concentration in vehicle		
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 Bodyweight	[redacted]	
3.4.4 Gross necropsy	[redacted]	
3.4.5 Other examinations		
3.4.6 Statistics	[redacted]	
3.5 Further remarks		

Section 6.1.2(1) Annex Point IIA 6.1.2	Acute dermal toxicity test	
	4. RESULTS	
4.1 Limit Test	No	
4.2 LD_{50} including confidence limits	LD_{50} = 3342 mg/kg. Confidence Limits = 0-4292 mg/kg	
4.3 Observations, Sacrifice and Pathology		
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	See table 6.1.2(1)-2 No mortalities occurred at concentrations below 3328 mg/kg. 5 rabbits died at a concentration of 3328 mg/kg and 8 rabbits died at a concentration of 4448 mg/kg.	
4.3.3 Body weight	[redacted]	
4.3.4 Gross necropsy	[redacted]	
4.3.5 Other examinations	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The LD_{50} of Didecyldimethylammonium Chloride was calculated as 3342 mg/kg.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	

Section 6.1.2(1) **Annex Point IIA 6.1.2**	**Acute dermal toxicity test**
	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	[redacted]
	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*

Table 6.1.2(1)-1. Clinical Signs

[redacted]

Table 6.1.2(1)-2. Mortality data

Sex	Test substance concentration (mg/kg)	No. Animals	Study day															Total
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Male	552	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1104	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3328	5	0	0	0	0	0	2	0	0	0	0	0	1	0	0	0	3
	4448	5	0	0	0	1	3	1	-	-	-	-	-	-	-	-	-	5
Female	552	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	1104	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	3328	5	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	2
	4448	5	0	0	0	0	1	0	1	1	0	0	0	0	0	0	0	3

Table 6.1.2(1)-3. Mean body weight data (kg)

[redacted]

Section 6.1.3 Annex Point IIA.6.1.3	Acute toxicity (inhalation)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's justification is acceptable.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section 6.1.4(1) Annex Point IIA 6.1.4		Skin irritation study in rabbits	
		1. REFERENCE	Official use only
1.1	**Reference**	Jones, J.R. and T.A. Collier. (1986) . P0151: OECD 404 Acute Dermal Irritation/Corrosion Test in the Rabbit. Project No: 102/1. Safepharm Laboratories Limited, Derbyshire, UK. (Unpublished) Ref No.: D103 (LON 1241)	
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 404, Acute Dermal Irritation/Corrosion 1986	
2.2	**GLP (only where required)**	Yes	
2.3	**Deviations**	No	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	X
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	X
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 Animals**		
3.2.1	Species	Rabbit	

Section 6.1.4(1) Annex Point IIA 6.1.4	Skin irritation study in rabbits	
3.2.2 Strain	New Zealand White	
3.2.3 Source	[redacted]	
3.2.4 Sex	Not stated	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Preparation of test substance	[redacted]	
3.3.2 Area of exposure	[redacted]	
3.3.3 Dose route	Dermal Application (Occlusive)	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Duration of treatment	1st test: 3 minutes 2nd test: 4 hours	
3.3.7 Vehicle	[redacted]	
3.3.8 Concentration in vehicle	[redacted]	
3.3.9 Total volume applied	[redacted]	
3.3.10 Removal of test substance	[redacted]	
3.4 Observations, Sacrifice and Pathology		
3.4.1 Scoring system	[redacted]	
3.4.2 Examination Time points	[redacted]	

Section 6.1.4(1) **Annex Point IIA 6.1.4**	**Skin irritation study in rabbits**	
3.4.5 Other examinations	[redacted]	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and Pathology		
4.1.1 Scores	3 minute exposure: PDII = 0.3 4 hour exposure: PDII =7 Average Score – Erythema = 4 Average Score – Oedema = 2.7	
4.1.2 Sacrifice	N/A	
4.2 Reversibility	No	
4.3 Other effects	None	
4.4 Further remarks		
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	3 minute exposure: PDII = 0.3 Slightly irritating 4 hour exposure: PDII =7 Corrosive	
5.3 Conclusion	Classified as Corrosive (causes burns)	
5.3.3 Reliability	[redacted]	
5.3.4 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 6.1.4(1) Annex Point IIA 6.1.4	Skin irritation study in rabbits
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 6.1.4(2) Annex Point IIA 6.1.4		Primary eye irritation study in rabbits.	
		1. REFERENCE	Official use only
1.1	**Reference**	Morris, T.D. (1991). Primary eye irritation study in rabbits with Didecyldimethylammonium Chloride (DDAC). Study No. 91-8114-21. Hill Top Biolabs, Inc., Cincinnati, Ohio, USA. (Unpublished) Ref No.: D10 (LON 3806)	
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 FIFRA 40 CFR, TSCA 40 CFR, and OECD Guidelines (OECD Guideline used Not advised) 1991	
2.2	**GLP (only where required)**	Yes	
2.3	Deviations	Due to the short duration of this experiment the Quality Assurance audit was missed	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	X
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), 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 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).	

Section 6.1.4(2) Annex Point IIA 6.1.4		Primary eye irritation study in rabbits.	
3.2	**Test Animals**		
3.2.1	Species	Rabbit	
3.2.2	Strain	New Zealand White	
3.2.3	Source	[redacted]	
3.2.4	Sex	Male	
3.2.5	Age/weight at study initiation	[redacted]	
3.2.6	Number of animals per group	[redacted]	
3.2.7	Control animals	[redacted]	
3.3	**Administration/ exposure**		
3.3.1	Preparation of test substance	[redacted]	
3.3.2	Dose route	Intraocular	
3.3.3	Post exposure period	[redacted]	
3.3.4	Concentration	[redacted]	
3.3.5	Duration of treatment	1 hour	
3.3.6	Vehicle	[redacted]	
3.3.7	Concentration in vehicle	[redacted]	
3.3.8	Amount of substance instilled	[redacted]	
3.4	**Observations, Sacrifice and Pathology**		
3.4.1	Ophthalmoscopic examination	[redacted]	
3.4.2	Scoring system	[redacted]	

Section 6.1.4(2) Annex Point IIA 6.1.4		Primary eye irritation study in rabbits.	
3.4.3	Observation period	[redacted]	
3.4.4	Tool used to assess score	[redacted]	
3.5	**Further remarks**	[redacted]	
		4. RESULTS	
4.1	**Observations, Sacrifice and Pathology**		
4.1.1	Score		
4.1.1.1	Cornea	4	
4.1.1.2	Iris	Could not be determined due to corrosion	
4.1.1.3	Conjunctivae (Redness)	4	
4.1.1.4	Conjunctivae (Chemosis)	4	
4.1.1.5	Overall Irritation Score	96	
4.2	**Description of lesions**	The test material produced extreme corneal opacity, iritis, and conjunctival irritation at 1 hour. In addition, the eye of the animal appeared misshapen (corrosion).	
4.3.	**Reversibility**	No	
4.4	**Other effects**		
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	Classified as Corrosive.	

Section 6.1.4(2) **Annex Point IIA 6.1.4**	**Primary eye irritation study in rabbits.**
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 6.1.5(1) Annex Point IIA 6.1.5		Skin sensitisation	
		1. REFERENCE	Official use only
1.1	**Reference**	Clement, C. (1992). BARDAC-22: Test to Evaluate the Sensitising Potential by Topical Applications in the Guinea Pig. Report No. 704323 RE. Hazleton-Institute Français de Toxicologie, Neuilly sur Seine, France. (Unpublished) Ref No. D105 (LON 1243)	
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**	No guideline followed 1992	
2.2	**GLP (only where required)**	Yes	X
2.3	**Deviations**	The induction procedure was a single injection of Freund's adjuvant followed by seven cutaneous applications of the test substance occluded for 48 or 72 hours.	
		3. MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	X
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), 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 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**		

Section 6.1.5(1) Annex Point IIA 6.1.5		Skin sensitisation	
3.2.1	Species	Guinea pig	
3.2.2	Strain	Duncan-Hartley	
3.2.3	Source	[redacted]	
3.2.4	Sex	Males and females	
3.2.5	Age/weight at study initiation	[redacted]	
3.2.6	Number of animals per group	[redacted]	
3.2.7	Control animals	[redacted]	
3.3	**Administration/ exposure**		
3.3.1	Application	Occlusive epicutaneous	
3.3.2	Induction Schedule	[redacted]	
3.3.3	Route of Induction	Occlusive epicutaneous	
3.3.4	Concentrations used for induction	[redacted]	
3.3.5	Challenge schedule	[redacted]	
3.3.6	Concentrations used for challenge	[redacted]	
3.3.7	Rechallenge	[redacted]	
3.3.8	Removal of the test substance	[redacted]	

Section 6.1.5(1) Annex Point IIA 6.1.5	Skin sensitisation	
3.3.9 Scoring schedule	[redacted]	
3.3.10 Positive control substance	[redacted]	
3.4 Examinations		
3.4.1 Results of primary irritation studies	[redacted]	
3.4.2 Induction phase	[redacted]	
3.4.3 Challenge phase	[redacted]	
3.4.4 Further remarks	[redacted]	
	4. RESULTS	
4.1 Results		
4.1.1 Results of primary irritation study	N/A	
4.1.2 Induction phase	None reported	
4.1.3 Challenge phase	Two males and one female exhibited Grade 1 erythema at the challenge site. There were no responses in the initial 48-hour exposure so these findings were considered to be 'doubtful'. Histopathologic examination showed only a focus of parakeratosis in the skin sample from the female and no findings in the males. No other responses were observed in any animals. The test was considered to be negative for skin sensitisation.	
4.1.4 Further remarks		
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section 6.1.5(1) Annex Point IIA 6.1.5	Skin sensitisation	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Not Sensitising	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Guidelines and Quality Assurance	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	[redacted] the study can be considered acceptable as supporting to the results coming from a second study presented for the same end-point.	
Remarks	[redacted]	
	COMMENTS FROM	

Section 6.1.5(1) Annex Point IIA 6.1.5	Skin sensitisation
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 6.1.5(2) Annex Point IIA 6.1.5	Skin sensitisation	
	1. REFERENCE	Official use only
1.1 Reference	Kukulinksi, M. (2003) Skin Sensitization Study of Maquat 4480-E, Batch #30717J5, OPPTS 870.2600. Project ID. 03-092-5. Tox Monitor Laboratories, Inc., Oak Park, IL, USA. (unpublished) [Ref. No. D155 (LON 4003)]	
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	U.S. EPA Health Effects Test Guidelines, TSCA No. 789.4100; U.S. EPA Pesticide Assessment Guideline No. 81-6; and *OECD Guideline for the Testing of Chemicals No. 406.*	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), Didecyldimethylammonium Chloride (DDAC; CAS RN 7173-51-5), in aqueous/alcohol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted] Refer to Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein, for specifications of percent active substance, purity and typical impurities.	
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 Animals		
3.2.1 Species	Guinea pig	
3.2.2 Strain	Hartley	

Section 6.1.5(2) Annex Point IIA 6.1.5	Skin sensitisation	
3.2.3 Source	[redacted]	
3.2.4 Sex	Males and females	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Irritation Screening for HNIC		
3.3.1 Preparation of Animals	[redacted]	
3.3.2 Test Article Concentration	[redacted]	
3.3.3 Vehicle	[redacted]	
3.3.4 Dose Volume	[redacted]	
3.3.5 Route of Administration	Occlusive dermal exposure using a 25-mm Hill Top Chamber	
3.3.6 Exposure Duration	6 hours	
3.3.7 Dermal Evaluations	[redacted]	
3.4 Main Sensitisation Test		
3.4.1 Preparation of Animals	[redacted]	
3.4.2 Induction Phase		
3.4.2.1 Test Article Concentration	[redacted]	
3.4.2.2 Vehicle	[redacted]	
3.4.2.3 Dose Volume	[redacted]	
3.4.2.4 Route of Administration	Occlusive dermal exposure using a 25 mm Hill Top Chamber	
3.4.2.5 Dosing Schedule	[redacted]	
3.4.2.6 Exposure Duration	6 hours	
3.4.2.7 Dermal Evaluations	[redacted]	
3.4.3 Challenge Phase		

Section 6.1.5(2) Annex Point IIA 6.1.5	Skin sensitisation	
3.4.3.1 Test Article Concentration (HNIC)	[redacted]	
3.4.3.2 Vehicle	[redacted]	
3.4.3.3 Dose Volume	[redacted]	
3.4.3.4 Route of Administration	Occlusive dermal exposure using a 25 mm Hill Top Chamber	
3.4.3.5 Dosing Procedures: Test Animals	[redacted]	
3.4.3.6 Dosing Procedures: Naive Control Animals	[redacted]	
3.4.3.7 Exposure Duration	6 hours	
3.4.3.8 Dermal Evaluations	[redacted]	
3.4.4 Body Weights	[redacted]	
3.5 Evaluations		
3.5.1 Incidence Index	[redacted]	
3.5.2. Severity Index	[redacted]	
3.5.3 Further Remarks		
3.6 Positive Control		
3.6.1 Historical Positive Control Data	[redacted]	
	4. RESULTS	
4.1 Results		
4.1.1 Challenge Phase		
4.1.1.1 Test Animals	None of the test animals exhibited a positive sensitisation response (score greater than or equal to 1.0) at 24 or 48 hours after challenge. Very faint erythema (±) was noted for two of 20 test animals at 24 hours after challenge but was cleared by 48 hours.	
4.1.1.2 Naive Control Animals	[redacted]	
4.1.2 Historical Positive Control Study	[redacted]	
4.1.3 Incidence Index	See Table 6.1.5(2)-2.	

Section 6.1.5(2) Annex Point IIA 6.1.5	Skin sensitisation	
4.1.4 Severity Index	See Table 6.1.5(2)-2.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	Based on these findings and under the conditions of this study, [redacted] is not considered to be a contact sensitiser.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	

Section 6.1.5(2) Annex Point IIA 6.1.5	Skin sensitisation
Acceptability	The study is acceptable, although it has to be highlighted that results refers to a product (*). However, being the product a simple dilution of the active substance in alcohol:water, without addition of any other component, it can be considered acceptable.
Remarks	[redacted]
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.1.5(2)-1

Scoring System

0	No perceptible reaction
±	Slight, diffuse or ill-defined erythema
1	Slight but confluent, or moderate patchy erythema
2	Moderate erythema
3	Severe erythema with or without edema

Grades of ± are equal to 0.5 for the purpose of calculating severity indices.

Table 6.1.5(2)-2

	Sensitisation Response Indices			
	Incidence of Positive Response[1]		Severity [2]	
	Hours		Hours	
	24	48	24	48
Test Animals	0/20	0/20	0.05	0
Naïve Control Animals	[redacted]	[redacted]	[redacted]	[redacted]

[1] Animals with scores greater than 0.5.
[2] Sum of the erythema scores divided by the number of animals evaluated.

Section 6.1.5(3) Annex Point IIA 6.1.5	Skin sensitisation	
	1. REFERENCE	Official use only
1.1 Reference	Merkel, D.J. (2004). Bardac 2280: Dermal Sensitization Study in Guinea Pigs (Buehler Method). Study No. 15512. Product Safety Laboratories, Dayton, NJ, USA. (Unpublished) [Ref. No. D154 (LON 4005)]	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialky 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	*U.S. EPA Health Effects Test Guidelines, OPPTS 870.2600 (2003)*	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	X
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted] Active substance (a.s.), didecyldimethylammonium chloride (DDAC; CAS RN 7173-51-5), in aqueous/ethanol solution.	X
3.1.1 Lot/Batch number	D4223025	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), 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 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	Guinea pig	
3.2.2 Strain	Hartley albino	
3.2.3 Source	[redacted]	
3.2.4 Sex	Males and females	

Section 6.1.5(3) Annex Point IIA 6.1.5	Skin sensitisation	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Preliminary Irritation Testing for HNIC		
3.3.1 Preparation of Animals	[redacted]	
3.3.2 Test Article Concentration	[redacted]	
3.3.3 Vehicle	[redacted]	
3.3.4 Dose Volume	[redacted]	
3.3.5 Route of Administration	Occlusive dermal exposure using a 25-mm Hill Top Chamber	
3.3.6 Exposure Duration	6 hours	
3.3.7 Dermal Evaluations	[redacted]	
3.4 Main Sensitisation Test		
3.4.1 Preparation of Animals	[redacted]	
3.4.2 Induction Phase		
3.4.2.1 Test Article Concentration	[redacted]	
3.4.2.2 Vehicle	[redacted]	
3.4.2.3 Dose Volume	[redacted]	
3.4.2.4 Route of Administration	Occlusive dermal exposure using a 25-mm Hill Top Chamber	
3.4.2.5 Dosing Schedule	[redacted]	
3.4.2.6 Exposure Duration	6 hours	
3.4.2.7 Dermal Evaluations	[redacted]	

Section 6.1.5(3) Annex Point IIA 6.1.5	Skin sensitisation	
3.4.3 Challenge Phase		
3.4.3.1 Test Article Concentration (HNIC)	[redacted]	
3.4.3.2 Vehicle	[redacted]	
3.4.3.3 Dose Volume	[redacted]	
3.4.3.4 Route of Administration	Occlusive dermal exposure using a 25-mm Hill Top Chamber	
3.4.3.5 Dosing Procedures: Test Animals	[redacted]	
3.4.3.6 Dosing Procedures: Naive Control Animals	[redacted]	
3.4.3.7 Exposure Duration	6 hours	
3.4.3.8 Dermal Evaluations	[redacted]	
3.4.4 Body Weights	[redacted]	
3.5 Evaluations		
3.5.1 Incidence Index	[redacted]	
3.5.2 Severity Index	[redacted]	
3.5.3 Further Remarks	[redacted]	
3.6 Positive Control		
3.6.1 Historical Positive Control Validation Study	[redacted]	
	4. RESULTS	
4.1 Results		
4.1.1 Induction Phase: Test Animals	Very faint to moderate erythema (0.5-2.0) was noted at all sites after the first induction application (0.75%) with desquamation and/or eschar noted prior to the second application. The dose concentration was reduced (0.5%) for the second induction application, however similar irritation was observed after the second application. Therefore, the	

Section 6.1.5(3) Annex Point IIA 6.1.5	Skin sensitisation	
	concentration was lowered to 0.25% for the third application. After the third induction application, there was a decrease in the severity of irritation. Additionally, the dose site was relocated to an adjacent naïve area after each induction application.	
4.1.2 Challenge Phase		
4.1.2.1 Test Animals	None of the test animals exhibited a positive sensitisation response (score greater than 0.5) at 24 or 48 hours after challenge. Very faint erythema (0.5) was noted for four of 20 test animals at 24 hours after challenge. Similar irritation persisted at two sites through 48 hours.	
4.1.2.2 Naive Control Animals	[redacted]	
4.1.3 Historical Positive Control Study	[redacted]	
4.1.4 Incidence Index	See Table 6.1.5(3)-2.	
4.1.5 Severity Index	See Table 6.1.5(3)-2.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	

Section 6.1.5(3) **Annex Point IIA 6.1.5**	**Skin sensitisation**	
	[redacted]	
5.3 Conclusion	Based on these findings and under the conditions of this study, [redacted] is not considered to be a contact sensitiser.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Guidelines and Quality Assurance	[redacted]	
Materials and Methods	*Include revised version.* **3.1 Test material** [redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	The study is acceptable, although it has to be highlighted that results refers to a product (*). However, being the product a simple dilution of the active substance in alcohol:water, without addition of any other component, it can be considered acceptable.	
Remarks	[redacted]	
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

Section 6.1.5(3) Annex Point IIA 6.1.5	Skin sensitisation
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.1.5(3)-1

Scoring System

0	No reaction
0.5	Very faint erythema, usually non-confluent*
1	Faint erythema, usually confluent
2	Moderate erythema
3	Severe erythema with or without edema

*Very faint erythema is not considered a positive reaction.

Table 6.1.5(3)-2

	Sensitisation Response Indices			
	Incidence of Positive Response[1]		Severity[2]	
	Hours		Hours	
	24	48	24	48
Test Animals	0/20	0/20	0.10	0.05
Naïve Control Animals	[redacted]	[redacted]	[redacted]	[redacted]

[1] Animals with scores greater than 0.5.
[2] Sum of the erythema scores divided by the number of animals evaluated.

Section 6.2(1) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	1. REFERENCE	Official use only
1.1 Reference	Roper, C. S. (2001). The In Vitro Percutaneous Absorption of [^{14}C]-Didecyldimethylammonium Chloride (DDAC) Through Human Skin. Report No. 19128. Inveresk Research. (Unpublished) Ref No. D45 (LON 3329)	
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 for the testing of chemicals. Skin absorption: *in vitro* method. 1999. (Draft) OECD guidance document for the conduct of skin absorption studies. 1999. (Draft) COLIPA. Cosmetic ingredients: guidelines for percutaneous absorption/penetration. 1995. 2001	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted] radiolabelled Didecyldimethylammonium Chloride	X
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.	
3.1.2.1 Non-radiolabelled	[redacted]	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	

Section 6.2(1) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
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).	
3.1.6 Method of analysis	[redacted]	
3.2 Test procedure		
3.2.1 Test system	Human dermatomed skin membranes in vitro	
3.2.2 Method of application	Flow through diffusion cell system	
3.2.3 Application media	[redacted]	X
3.2.4 Concentration	[redacted]	X
3.2.5 Receptor fluid	[redacted]	
3.2.6 Remarks	[redacted]	X
	4. RESULTS	
4.1 Application rate	[redacted]	
4.1.1 Target dose level	[redacted]	
4.2 Mean % recovery after 24 hours	See table 6.2(1)-1	
4.3 Cumulative flux	^{14}C-Didecyldimethylammonium Chloride (aqueous) = 0.11 µg equiv.cm^{-2}	
4.4 Remarks	Less than 0.1% of applied ^{14}C-Didecyldimethylammonium Chloride penetrated the human skin. 2.92% ^{14}C-Didecyldimethylammonium	X

Section 6.2(1) **Annex Point IIA 6.2**	**Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study**	
	Chloride was absorbed into the skin over 24 hours. 96.25% was not absorbed.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	X
5.3 Conclusion	Less than 0.1% of the ^{14}C-Didecyldimethylammonium Chloride penetrated human skin. Total absorption was 2.92%.	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 6.2(1) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 6.2(1) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.2(1)-1. Mean % recovery after 24 hours

Commodities analysed	**Mean recovery (% of applied dose)**
Skin wash	44.45
Cell wash	3.38
Swab	28.14
Cling film	0.05
Stratum corneum	13.75
Epidermis (dose site)	6.49
Dermis (dose site)	2.67
Non-dose site skin	0.18
Receptor fluid	0.06
Receptor rinse	0.00
Cumulative Results	
Total penetrated	0.06
Dermal delivery	2.85
Total unabsorbed	96.25
Total absorbed	2.92
Total recovery	99.16

Section 6.2(2) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	1. REFERENCE	Official use only
1.1 Reference	Selim, S. (1989). Absorption, Distribution, Metabolism and Excretion Studies of Didecyldimethylammonium Chloride (DDAC) in the Rat. Study No. P01421. Biological Test Center, Irvine, CA, USA. (Unpublished) Ref Nos D34 and D35 (LON 1779)	
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 Guideline 85-1 1989	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted] radiolabelled Didecyldimethylammonium Chloride	X
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.	
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 Procedure	In vivo	

Section 6.2(2) Annex Point IIA 6.2		Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
3.2.1	Method of analysis	[redacted]	
3.3	**Test Animals**		
3.3.1	Species	Rat	
3.3.2	Strain	Sprague Dawley	
3.3.3	Source	[redacted]	
3.3.4	Sex	Male and female	
3.3.5	Age/weight at study initiation	[redacted]	
3.3.6	Number of animals per group	[redacted]	
3.3.7	Control animals	[redacted]	
3.4	**Administration/ exposure**		
3.4.1	Dose route	Experiment 1: Oral gavage – single low dose Experiment 2: Oral gavage – single high dose Experiment 3: Dietary – repeated low oral dose	
3.4.2	Post exposure period	[redacted]	
3.4.3	Concentration	[redacted]	X
3.4.4	Vehicle	[redacted]	
3.4.5	Concentration in vehicle	[redacted]	X
3.4.6	Controls	[redacted]	
		4. RESULTS	
4.1	**Results**		
4.1.1	% Recovery	Experiment 1: Males: 1.65% urine; 89.11% faeces Female: 1.42% urine; 92.13% faeces Total Recovery: 90.82 ± 7.30% - males; 93.56 ± 6.96% females Experiment 2: Males: 1.19% urine; 93.88% faeces Female: 1.74% urine; 90.11% faeces Total Recovery: 95.09 ± 1.92% - males; 91.88 ± 4.98% females	X

Section 6.2(2) Annex Point IIA 6.2	Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study	
	Experiment 3: Males: 1.17 % urine; 99.46% faeces Female: 2.36% urine; 91.93% faeces Total Recovery: 100.94 ± 2.68% - males; 94.47 ± 4.62% females Less than 1% in tissues in all experiments.	
4.1.2 Metabolites	4 major metabolites were identified. The only metabolism which occurred involved oxidation of the two decyl side chains to hydroxy and hydroxyketo derivatives. All were more polar and presumed less toxic than the parent compound. It is predicted that there is no major metabolite greater than 10% of the dosed radioactivity.	X
4.2 Remarks	Most, if not all, the metabolism appears to be in the gut by intestinal microflora. Female rats metabolised the test substance more extensively. A dose dependent rate of metabolism was observed in female rats.	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.1 Results and discussion	[redacted]	
5.3 Conclusion	The majority of orally administered Didecyldimethylammonium Chloride is excreted via the faeces and appears to be metabolised in the gut of rats, apparently by microflora. Metabolism in females was greater than in males and lower doses were more extensively metabolised than higher doses in females. No tissue accumulation of the test substance was observed. Repeated dosing did not alter the uptake, distribution or metabolism of Didecyldimethylammonium Chloride.	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	