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**
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 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 (%)**
83-104	92	8.1	77-95	82	6.8	78-99	88	8.0

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 accepted
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 IIIA.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.)*	

Section 4.3 Annex Point IIIA.4.3	Analysis in foodstuffs
	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	The Applicant justification is accepted.
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 Effectiveness against target organisms and intended uses

Section 5 Annex Point IIA. 5		Official use only
5.1 Function	[redacted]	X
5.2 Organism(s) to be controlled and products, organisms or objects to be protected	[redacted]	
5.2.1 Organism(s) to be controlled	[redacted]	
5.2.2 Products, objects	[redacted]	

Section 5 Annex Point IIA. 5		Official use only
5.3 Effects on target organisms and likely concentration at which the active substance will be used	[redacted]	
5.3.1 Effects on target organisms	[redacted]	
5.1.3.1 Efficacy tests with single active substance formulation (ADBAC) against fungi	[redacted]	X

Section 5 Annex Point IIA. 5	Official use only
[redacted]	

Section 5 Annex Point IIA. 5	Official use only

Section 5 Annex Point IIA. 5	Official use only

[redacted]

Section 5 Annex Point IIA. 5	Official use only

[redacted]

Section 5 Annex Point IIA. 5		Official use only
	[redacted]	
5.1.3.2 Efficacy tests with single active substance formulation (ADBAC) against insects	[redacted]	

Section 5 Annex Point IIA. 5		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)	[redacted]	
5.4.1 Mode of action	[redacted]	
5.4.2 Time delay	[redacted]	
5.5 Field of use envisaged	[redacted]	
5.6 User: industrial,	[redacted]	

Section 5 Annex Point IIA. 5		Official use only
professional, general public	[redacted]	
5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	[redacted]	
5.7.1 Development of resistance	[redacted]	X
5.7.2 Management strategies	[redacted]	
5.8 Likely tonnage to be placed on the market per year	[redacted]	
Evaluation by Competent Authorities		
	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	

Section 5 Annex Point IIA. 5	Official use only
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
ABDAC	[redacted]

Section 5 Annex Point IIA. 5	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		Official use only
Acceptability	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 6.1 Acute toxicity
Annex Point IIA 6.1 – headline only

Section 6.1.1(1) **Annex Point IIA6.1.1**	**Acute oral toxicity test with rodent (rat)**	
	1. REFERENCE	Official use only
1.1 Reference	Wallace, J.M. (1975). Acute oral LD_{50} toxicity study. Bio-Toxicology Laboratories, Inc., Moorestown, NJ, U.S. (published). [Ref No. A14 (LON1002)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Joint Venture	
1.2.3 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 None stated	
2.2 GLP (only where required)	No GLP was not compulsory at the time the study was performed.	
2.3 Deviations	No guidelines were in force when the study was undertaken.	
	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 II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	X
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	

Section 6.1.1(1) Annex Point IIA6.1.1		Acute oral toxicity test with rodent (rat)	
		five 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	No information	
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]	X
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]	
3.5 Further remarks		[redacted]	

Section 6.1.1(1) Annex Point IIA6.1.1	Acute oral toxicity test with rodent (rat)	
	4. RESULTS	
4.1 Limit Test	No	
4.2 LD_{50} including confidence limits	LD_{50} = 0.43 ml/kg 95% confidence limits 0.39 ml/kg to 0.47 ml/kg LD_{50} = ca. 344 mg/kg (corrected for a.s. purity)	
4.3 Observations, Sacrifice and Pathology		
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	See Table A6.1.1(1)-1 [redacted]	
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		
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	LD_{50} = 0.43 ml/kg 95% confidence limits of 0.39 ml/kg to 0.47 ml/kg. LD_{50} = ca. 344 mg/kg. Values corrected for 100% active substance (a.s.). [redacted]	X
5.3 Conclusion	Alkyldimethylbenzylammonium Chloride is classified as harmful if swallowed on the basis of this study and is assigned the symbol Xn and risk phrase R22	

Section 6.1.1(1) **Annex Point IIA6.1.1**	**Acute oral toxicity test with rodent (rat)**
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]

Section 6.1.1(1) Annex Point IIA6.1.1	Acute oral toxicity test with rodent (rat)
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table A6.1.1 (1)-1

Dose levels (ml/kg)	Mortality	Group size (male & female)
16.0	5	5
8.0	5	5
4.0	5	5
2.0	5	5
1.0	5	5
0.5	5	5
0.4	1	5
0.32	0	5
0.25	0	5

Section 6.1.2(1) Annex Point IIA6.1.2		Acute dermal toxicity test with rodent (rabbit)	
		1. REFERENCE	Official use only
1.1	**Reference**	Levenstein, I. (1977). Dermal LD_{50} Report number 73130, Leberco Laboratories, Roselle Park, NJ USA. (published). [Ref No: A15 (LON 3895)]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	U.S. EPA 16 CFR 1500.40 Year: 1977	
2.2	**GLP (only where required)**	No GLP was not compulsory at the time study was performed	
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 II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	X
3.1.5	Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	Test Animals		
3.2.1	Species	Rabbit	

Section 6.1.2(1) Annex Point IIA6.1.2		Acute dermal toxicity test with rodent (rabbit)	
3.2.2	Strain	Not specified	
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	Topical occluded: 2 animals/sex abraded skin; 2 animals/sex unabraded skin	
3.3.2	Post exposure period	[redacted]	
3.3.3	Concentration	[redacted]	X
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]s	
3.4.3	Bodyweight	[redacted]	
3.4.4	Organ weights	[redacted]	
3.4.5	Other examinations	[redacted]	
3.4.6	Statistics	[redacted]	
3.5	**Further remarks**	[redacted]	
		4. RESULTS	
4.1	**Limit Test**	No	

Section 6.1.2(1) **Annex Point IIA6.1.2**	**Acute dermal toxicity test with rodent (rabbit)**	
4.2 LD_{50} including confidence limits	LD_{50} = 3.56 ml/kg 95% Confidence limits 3.01 - 4.20 ml/kg	X
4.3 Observations, Sacrifice and Pathology	[redacted]	
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	See Table 6.1.2(1)-1	
4.3.3 Body weight	[redacted]	
4.3.4 Organ weights	[redacted]	
4.3.5 Other examinations	[redacted]	
4.3.6 Statistics	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	LD_{50} = 3.56 ml/kg. No differentiation was made between braded and unbraded skin in deriving LD_{50}. Lethal and non-lethal doses were severely irritating and resulted in skin damage in surviving animals. See also Table A6.1.2(1)-1	X
5.3 Conclusion	Not classified	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	

Section 6.1.2(1) Annex Point IIA6.1.2	Acute dermal toxicity test with rodent (rabbit)
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*

Section 6.1.2(1) **Annex Point IIA6.1.2**	**Acute dermal toxicity test with rodent (rabbit)**
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

Dose levels (ml/kg)	Mortality	Time to mortality
5 0	7/8	1, 2, 7 & 12 days
4.0	6/8	2, 3, 4 & 6 days
3.0	1/8	9 days

Table 6.1.2(1)-2

Dose levels (ml/kg)	Animal #	Bodyweight (kg)	
		Initial	Final
5	[redacted]		
4			
3			

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

Section 6.1.3 Annex Point IIA.6.1.3	Acute toxicity (inhalation)
Conclusion	*Discuss if deviating from view of rapporteur member state*

Section 6.1.4(1) Annex Point IIA6.1.4		Skin irritation study in rabbits	
		1. REFERENCE	Official use only
1.1	**Reference**	Wallace, J. M. (1975) Toxicity Studies: Primary Irritation Study, Federal Hazardous Substances Labeling Act – Barquat MB-80. Bio-Toxicology Laboratories, Inc., Moorestown, NJ, USA (published). [Ref No: A53 (LON 1003)]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No None stated, but conducted to Federal Hazardous Substances Labeling Act 1975	
2.2	**GLP (only where required)**	No GLP was not compulsory at the time the study was performed.	
2.3	**Deviations**	No guidelines were in force when the study was undertaken.	
		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 II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	X
3.1.5	Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Test Animals**		

Section 6.1.4(1) Annex Point IIA6.1.4		Skin irritation study in rabbits	
3.2.1	Species	Rabbit	
3.2.2	Strain	Not specified	
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	Preparation of test substance	[redacted]	
3.3.2	Area of exposure	[redacted]	
3.3.3	Dose route	Dermal application (occlusive) to abraded and unabraded areas	
3.3.4	Post exposure period	[redacted]	
3.3.5	Concentration	[redacted]	
3.3.6	Duration of treatment	24 hours	
3.3.7	Vehicle	[redacted]	
3.3.8	Concentration in vehicle	[redacted]	
3.3.9	Total volume applied	[redacted]	
3.4	**Observations, Sacrifice and Pathology**		
3.4.1	Scoring system	[redacted]	
3.4.2	Examination Time points	[redacted]	
3.4.5	Other examinations	[redacted]	

Section 6.1.4(1) **Annex Point IIA6.1.4**	**Skin irritation study in rabbits**	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and pathology		
4.1.1 Scores	Refer to Table 6.1.4 (1)-1 Primary Irritation Index: 6.29	
4.2 Reversibility	No	
4.3 Other effects	Not applicable	
4.4 Further remarks	Not applicable	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	X
5.3 Conclusion	Alkyldimethylbenzylammonium Chloride is classified as corrosive on the basis of this study and is assigned the symbol C and risk phrase R34.	
5.3.1 Reliability	[redacted]	X
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	

Section 6.1.4(1) **Annex Point IIA6.1.4**	**Skin irritation study in rabbits**
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.1.4(1)-1 Skin Irritation table (intact)

3 Animals	Mean score*	Maximum value	Maximum duration of any effect	Maximum value at the end of the observation period
erythema/eschar	3.33	4	-	4
oedema	2.66	3	-	3
*Calculated on the basis of the scores at 24 and 72 hours for all animals				

Skin Irritation table (abraded)

3 Animals	Mean score*	Maximum value	Maximum duration of any effect	Maximum value at the end of the observation period
erythema/eschar	3.5	4	-	4
oedema	3	3	-	3
*Calculated on the basis of the scores at 24 and 72 hours for all animals				

Section 6.1.4(2) Annex Point IIA6.1.4		Primary eye irritation study in rabbits	
		1. REFERENCE	Official use only
1.1	**Reference**	Wallace, J. M. (1975) Toxicity Studies: Primary irritation study, Federal Hazardous Substances Labeling Act – Barquat MB-80. Bio-Toxicology Laboratories, Inc., Moorestown, NJ, USA (published). [Ref No: A54 (LON 1001)]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	ADBAC Issues Steering Committee	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No None stated, but conducted to Federal Hazardous Substances Labeling Act 1975	
2.2	**GLP (only where required)**	No GLP was not compulsory at the time the study was performed.	
2.3	**Deviations**	No guidelines were in force when the study was undertaken.	
		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 II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted] Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	X
3.1.5	Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	**Test Animals**		

Section 6.1.4(2) Annex Point IIA6.1.4		Primary eye irritation study in rabbits	
3.2.1	Species	Rabbit	
3.2.2	Strain	Not specified	
3.2.3	Source	[redacted]	
3.2.4	Sex	Not specified	
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	Eyes were unwashed and evaluated at 24, 48 and 72 hours after dosing	
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]	
3.4.3	Observation period	[redacted]	
3.4.4	Tool used to assess score	[redacted]	

Section 6.1.4(2) **Annex Point IIA6.1.4**	**Primary eye irritation study in rabbits**	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations, Sacrifice and Pathology		
4.1.1 Score		
4.1.1.1 Cornea	See Table 6.1.4(2)-1	X
4.1.1.2 Iris	Not advised	X
4.1.1.3 Conjunctivae (Redness)	Not advised	X
4.1.1.4 Conjunctivae (Chemosis)	Not advised	X
4.1.1.5 Overall Irritation Score	Not advised	X
4.2 Description of lesions		
4.3. Reversibility	No	
4.4 Other effects	Not advised	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	X
5.3 Conclusion	Classified as Corrosive.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	X
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

Section 6.1.4(2) Annex Point IIA6.1.4	Primary eye irritation study in rabbits
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable [redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*

Section 6.1.4(2) **Annex Point IIA6.1.4**	**Primary eye irritation study in rabbits**
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 6.1.4(4)-1 Eye irritation

6 Animals	Mean score*	Maximum value	Maximum duration of any effect	Maximum value at the end of the observation period
conjunctiva/redness	3	3	-	3
conjunctiva/chemosis	4	4	-	4
cornea	4	4	-	4
iris	2	2	-	2
* Calculated on the basis of the scores at 24, 48, 72 hours for all animals				

Section 6.1.5(1) **Annex Point IIA6.1.5**	**Skin sensitisation**	
	1. REFERENCE	Official use only
1.1 Reference	Kreuzmann, J.J (1988) Photoallergy study in Guinea pigs with Alkyldimethylbenzylammonium Chloride (ADBAC). Hill Top Biolabs Inc., Miamiville, OH, USA. Report No. 88-3226-21. (Unpublished). [Ref No. A55 (LON 1880)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Joint Venture	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	No. Adaptation of the method of Buehler *et al.*, 1985. Fd. Chem. Toxic. 23: 689-694) 1988	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted] (Alkyldimethylbenzylammonium Chloride)	X
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. [redacted]. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted].	X
3.1.5 Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of	

Section 6.1.5(1) Annex Point IIA6.1.5		Skin sensitisation	
		Annex IIA).	
3.2 Test Animals			
3.2.1	Species	Guinea pig	
3.2.2	Strain	Hartley	
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		Topical	
3.3.1	Concentrations used for primary irritation screen	[redacted]	
3.3.2	Irritation screen schedule	[redacted]	
3.3.3	Route of Induction	Topical	
3.3.4	Concentrations 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]	
3.3.9	Scoring schedule	[redacted]	X
3.3.10	Positive control	[redacted]	

Section 6.1.5(1) Annex Point IIA6.1.5	Skin sensitisation	
[redacted]		
3.4 Examinations		
3.4.1 Primary irritation study	[redacted]	
3.4.2 Induction phase	[redacted]	
3.4.3 Challenge phase	[redacted]	
3.5 Further remarks		
	4. RESULTS	
4.1 Results		
4.1.1 Results of primary irritation study	In the group receiving 100, 50, 25 and 10% w/v two animals were found dead after the primary irritation screen. In addition, two animals in this group were sacrificed due to the condition of the sites. In the group receiving 5, 2.5, 0.5 and 0.25% w/v erythema and oedema, blanching, coriaceous, discoloration and scabbing were observed.	
4.1.2 Induction phase	The induction phase of the definitive study was imitated with a dose of 0.5% for the first 4 applications. Due to excessive irritation at induction sites, the concentration was lowered to 0.25% w/v for the final 5 induction doses.	
4.1.3 Challenge phase	See Table 6.1.5(1)-1 For the ADBAC initiated and challenge group, during challenge there were no incidences of Grade 1 responses and 7/10 incidence of Grade ± responses. The 24 and 48 hours severity indices were 0.3 and 0.1 respectively.	
4.1.4 Further remarks	None	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	

Section 6.1.5(1) **Annex Point IIA6.1.5**	**Skin sensitisation**	
5.3 Conclusion	Alkyldimethylbenzylammonium Chloride is not considered to be a photoallergen or 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]	
Acceptability	Acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	

Section 6.1.5(1) **Annex Point IIA6.1.5**	**Skin sensitisation**
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(1)-1

Group	Challenge Test Substance	Challenge Concentration	Incidence of Response (24-hr) 0 ± 1 2 3	Incidence of Response (48-hr) 0 ± 1 2 3	Mean Severity Score 24-hr	48-hr
Test	ADBAC	0.5%	4 6 0 0 0	8 2 0 0 0	0.3	0.1
Vehicle Control	ADBAC	0.5%	6 4 0 0 0	8 2 0 0 0	0.2	0.1
Naive Control	ADBAC	0.5%	5 5 0 0 0	5 5 0 0 0	0.3	0.3
Positve Control	Musk Ambrette	25%	1 7 2 0 0	1 7 2 0 0	0.6	0.6

Section 6.1.5(2) 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: A102 (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**	Yes	X
2.3	**Deviations**	The induction procedure was a single injection of Freund's adjuvant followed by 7 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 II 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	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [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).	

Section 6.1.5(2) **Annex Point IIA 6.1.5**	**Skin sensitisation**	
3.2 Test Animals		
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(2) 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]	