Section 6.6.4(1) **Annex Point IIA 6.6.4**	**In-vivo mutagenicity study**	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	Adopt applicant's version with the following correction: [redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	The study is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE (SPECIFY)	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 6.6.5 Annex Point IIA.6.6.5	Second in vivo mutagenicity test	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements.* *The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The applicant's justification is acceptable	

Section 6.6.5 Annex Point IIA.6.6.5	Second in vivo mutagenicity test
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 6.6.6 Annex Point IIA.6.6.6	Germ cell effects	
	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]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The applicant's justification is acceptable	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 6.6.6 Annex Point IIA.6.6.6	Germ cell effects
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 6.6.7 Annex Point IIA.6.6.7	Further genetic toxicity tests on metabolites of concern	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	The applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 6.6.7 Annex Point IIA.6.6.7	Further genetic toxicity tests on metabolites of concern
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 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
	1. REFERENCE	Official use only
1.1 Reference	Gill, M.W., S.J. Hermansky, and C.L. Wagner. (1991). Chronic dietary oncogenicity study with Didecyldimethylammonium Chloride in mice. Report No: 53-528. Union Carbide, Bushy Run Research Center, Export, PA, U.S.A. (Unpublished) Ref No. D21 (LON 1776)	
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 USEPA OPP 83-2 1988	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	X
	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 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
3.2.1 Species	Mouse	
3.2.2 Strain	CD-1	
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 Satellite group(s)	[redacted]	
3.2.8 Control Animals	[redacted]	
3.3 Administration/ Exposure		
3.3.1 Dose route	Oral by diet	
3.3.2 Duration of test/exposure	78 weeks	
3.3.3 Frequency of exposure	7 days/week	
3.3.4 Post exposure period	[redacted]	
3.3.5 Concentration	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.8 Actual dose received	[redacted]	
3.3.9 Controls	[redacted]	
3.4 Examinations		
3.4.1 Observations		
3.4.2 Clinical signs	[redacted]	
3.4.3 Mortality	[redacted]	

Section 6.7(1) Annex Point IIA 6.7		Carcinogenicity study in mice	
3.4.4	Bodyweight	[redacted]	
3.4.5	Food consumption	[redacted]	
3.4.6	Water consumption	[redacted]	
3.4.7	Ophthalmoscopic examination	[redacted]	
3.4.8	Haematology	[redacted]	
3.4.9	Clinical Chemistry	[redacted]	
3.4.10	Urinalysis	[redacted]	
3.5	**Sacrifice and Pathology**		
3.5.1	Organ weights	[redacted]	
3.5.2	Gross and histopathology	[redacted]	
3.5.3	Statistical analysis	[redacted]	
		4. RESULTS	
4.1	**Examinations**		
4.1.1	Observations		
4.1.2	Clinical signs	No treatment-related findings were observed at any treatment level.	
4.1.3	Mortality	No treatment-related findings were observed at any treatment level.	
4.1.4	Bodyweight	Male and female mice treated with 1000 ppm had depressed body weights and weight gains for the entire study.	X

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
4.1.5 Food consumption	No treatment-related findings were observed at any treatment level.	
4.1.6 Water consumption		
4.1.7 Ophthalmoscopic examination		
4.1.8 Haematology	No treatment-related findings were observed at any treatment level.	
4.1.9 Clinical Chemistry		
4.1.10 Urinalysis		
4.2 Sacrifice and Pathology		
4.2.1 Organ weights	No treatment-related findings were observed at any treatment level.	
4.2.2 Gross and Histopathology	No treatment-related findings were observed at any treatment level.	
4.2.3 Statistical analysis	As described above.	
4.3 LOAEL		
4.4 NOAEL	NOAEL = 500 ppm (equivalent to 32 and 41 mg/kg/d for males and females, respectively)	X
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOEL = 500 ppm (equivalent to 76.3 and 93.1 mg/kg/d for males and females, respectively) The test substance is not considered to be carcinogenic in this strain of	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
	mice under the conditions of this study.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*08.05.06*	
Guidelines and Quality Assurance	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	

Section 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (SPECIFY)
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
	1. REFERENCE	Official use only
1.1 Reference	Gill, M.W., J.S. Chun, and C.L. Wagner. (1991). Chronic dietary toxicity/oncogenicity study with Didecyldimethylammonium Chloride in rats. Report No. 53-566. Union Carbide, Bushy Run Research Center, Export, PA, U.S.A. (Unpublished) Ref No. D30 (LON 1755)	
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 USEPA Guideline 83-5; OECD Guideline 453 1988	
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 6.7(2) Annex Point IIA 6.7		Carcinogenicity study in rats	
3.2.1	Species	Rat	
3.2.2	Strain	Sprague-Dawley CD	
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]	
3.2.8	Control animals	[redacted]	
3.3	**Administration/ exposure**		
3.3.1	Route of exposure	Oral by diet	
3.3.2	Duration of treatment	24 months (104 weeks)	
3.3.3	Frequency of exposure	7 days/week	
3.3.4	Post exposure period	[redacted]	
3.3.5	Concentration	[redacted]	
3.3.6	Vehicle	[redacted]	
3.3.7	Total volume applied	[redacted]	
3.3.8	Controls	[redacted]	
3.4	**Examinations**		
3.4.1	Observations		
3.4.2	Clinical signs	[redacted]	
3.4.3	Mortality	[redacted]	

Section 6.7(2) Annex Point IIA 6.7		Carcinogenicity study in rats	
3.4.4	Bodyweight	[redacted]	
3.4.5	Food consumption	[redacted]	
3.4.6	Water consumption	[redacted]	
3.4.7	Ophthalmoscopic examination	[redacted]	
3.4.8	Haematology	[redacted]	
3.4.9	Clinical Chemistry	[redacted]	
3.4.10	Urinalysis	[redacted]	
3..5	**Sacrifice and Pathology**		
3.5.1	Organ weights	[redacted]	
3.5.2	Gross and histopathology	[redacted]	
3.5.3	Other examinations	[redacted]	
3.5.4	Statistics	[redacted]	
		4. RESULTS	
4.1	**Examinations**		
4.1.1	Observations		
4.1.2	Clinical signs	No treatment-related findings were observed at any treatment level.	
4.1.3	Mortality	No treatment-related findings were observed at any treatment level.	
4.1.4	Body weight gain	Male and female rats treated with 1500 ppm had statistically significantly depressed body weights and weight gains for the entire study. No other treatment-related changes were observed.	

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
4.1.5 Food consumption	Male and female rats treated with 1500 ppm had statistically significantly decreased food consumption for the entire study. No other treatment-related changes were observed.	
4.1.6 Water consumption		
4.1.7 Opthalmoscopic examination	No treatment-related findings were observed at any treatment level.	
4.1.8 Haematology	No treatment-related findings were observed at any treatment level.	
4.1.9 Clinical chemistry	No treatment-related findings were observed at any treatment level.	
4.1.10 Urinalysis	No treatment-related findings were observed at any treatment level.	
4.2 Sacrifice and pathology		
4.2.1 Organ weights	No treatment-related findings were observed at any treatment level.	
4.2.2 Gross and histopathology	No gross necropsy changes were observed. At 1500 ppm, hyperplasia of the bile ducts in females and changes in the mesenteric lymph nodes of males and females related to blood in the sinuses were the only microscopic changes of potential but undetermined toxicologic significance. No treatment-related differences in tumour incidence or time to development of tumours were observed.	
4.2.3 Other examinations		
4.2.4 Statistical analysis	As noted above.	
4.3 LO(A)EL		
4.4 NO(A)EL	NOEL = 750 ppm (equivalent to 32 and 41 mg/kg/d for males and females, respectively)	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	

Section 6.7(2) **Annex Point IIA 6.7**	**Carcinogenicity study in rats**	
5.3 Conclusion	NOEL = 750 ppm (equivalent to 32 and 41 mg/kg/d for males and females respectively) The test substance is not carcinogenic in this strain of rats under the conditions of this study.	
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 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*	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
	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).* Neeper-Bradley, T.L. (1991). Developmental toxicity evaluation of Didecyldimethylammonium Chloride administered by gavage to CD® (Sprague-Dawley) rats. Project No: 53-534. Union Carbide, Bushy Run Research Center, Mellon Road, Export, PA 15632, USA. (Unpublished) Ref No. D23 (LON 1781)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA Guideline 83-3; OECD Guideline 414 1991 *(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 number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
	[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]	X
3.1.5 Stability	*Describe stability of test material* The a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Test Animals		
3.2.1 Species	Rat	
3.2.2 Strain	Sprague Dawley	
3.2.3 Source	[redacted]	
3.2.4 Sex	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 Route of exposure	Oral gavage	
3.3.2 Duration of treatment	Days 6-15 of gestation	
3.3.3 Frequency of exposure	Once daily during exposure period	
3.3.4 Vehicle	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
3.3.5 Dose levels	[redacted]	X
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	X
3.3.8 Post exposure period	[redacted]	
3.4 Adult Examinations		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and examinations		
3.5.1 Maternal findings		
3.5.2 Gross necropsy findings	[redacted]	
3.5.3 Organ weights	[redacted]	
3.5.4 Other	[redacted]	
3.5.5 Foetal findings		
3.5.6 Bodyweight	[redacted]	
3.5.7 Gross necropsy findings	[redacted]	
3.5.8 Skeletal examinations	[redacted]	
3.5.9 Visceral examinations	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
4.6 Statistics	[redacted]	
4.7 Further remarks		
	4. RESULTS	
4.1 Maternal observations		
4.1.1 Clinical signs	Audible respiration and gasping at 20 mg/kg/d Audible respiration at 10 mg/kg/d	
4.1.2 Mortality	No mortalities	
4.1.3 Body weight gain	Reduced body weight gain at 20 mg/kg/d	
4.1.4 Food consumption	Reduced food consumption at 20 mg/kg/d	
4.1.5 Gross findings at necropsy	Ulceration of stomach and gas filled intestines at 20 mg/kg/d Gravid uterine and liver unaffected	
4.1.6 Other	No abortions or early births	
4.2 Foetal observations		
4.2.1 Bodyweight	No treatment-related effects	
4.2.2 Gross findings at necropsy	No malformations	
4.2.3 Skeletal findings	No treatment-related variations or malformations	
4.2.4 Visceral findings	No treatment-related variations or malformations	
4.3 Remarks	No developmental toxicity including teratogenicity was observed at any dosage employed	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 6.8.1(1) **Annex Point IIA 6.8.1**	**Teratogenicity test in rats**	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* No developmental toxicity including teratogenicity was observed at any dosage employed. The "no observable effect level" (NOEL) for maternal toxicity was 1 mg/kg/day; the NOEL for developmental toxicity was at least 20 mg/kg/day	X
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	X
	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, with the required adjustment of the dose level	
Remarks	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats
	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*

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
	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).* Tyl, R.W. (1989). Developmental toxicity study of Didecyldimethylammonium Chloride administered by gavage to New Zealand white rabbits. Project No: 51-590. Union Carbide, Bushy Run Research Center, Mellon Road, Export, PA 15632, USA. (Unpublished) Ref No. D26 (LON 1770)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA OPP 83-3 1989 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	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 number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	

Section 6.8.1(2) Annex Point IIA 6.8.1		Teratogenicity test in rabbits	
		[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 Animals**		
3.2.1	Species	Rabbit	
3.2.2	Strain	New Zealand White	
3.2.3	Source	[redacted]	
3.2.4	Sex	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	Route of exposure	Oral gavage	
3.3.2	Duration of treatment	Days 6-18 of gestation	
3.3.3	Frequency of exposure	Daily	
3.3.4	Vehicle	[redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
3.3.5 Dose levels	[redacted]	X
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	X
3.3.8 Post exposure period	[redacted]	
3.4 Adult Examinations		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and examinations		
3.5.1 Maternal findings		
3.5.2 Gross necropsy findings	[redacted]	
3.5.3 Organ weights	[redacted]	
3.5.4 Other		
3.5.5 Foetal findings		
3.5.6 Bodyweight	[redacted]	
3.5.7 Gross necropsy findings	[redacted]	
3.5.8 Skeletal examinations	[redacted]	
3.5.9 Visceral examinations	[redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
3.5.10 Statistics	[redacted]	
3.5.10 Further remarks		
	4. RESULTS	
4.1 Maternal observations		
4.1.1 Clinical signs	Treatment-related clinical signs were observed at 3.0 and 10 mg/kg/d primarily related to audible breathing and hypoactivity.	
4.1.2 Mortality	Four of 16 does died at 10 mg/kg/d prior to gd 13. All were pregnant.	
4.1.3 Body weight gain	Statistically significant reduced body weight gain for gd 6-13 was observed at the high dose. Reduced weight gain was also observed for gd 13-19. At 3.0 mg/kg/d, maternal weight gain was significantly reduced for gd 13-19 and for gd 6-19.	
4.1.4 Food consumption	Not determined	
4.1.5 Gross findings at necropsy	None	
4.1.6 Other	None	
4.2 Foetal observations		
4.2.1 Bodyweight	Reduced foetal weight at 10 mg/kg body weight	
4.2.2 Gross findings at necropsy	No malformations	
4.2.3 Skeletal findings	No treatment-related variations or malformations	
4.2.4 Visceral findings	No treatment-related variations or malformations	
4.3 Remarks	No developmental toxicity, including teratogenicity, was observed at any dosage employed.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits	
	[redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Not teratogenic; increased incidence of dead foetuses and reduced fatal weight at the maternal lethal dose of 10 mg/kg b.w. The "no observable effect level" (NOEL) for maternal toxicity was 1 mg/kg/day; the NOEL for developmental toxicity was at least 10 mg/kg/day.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	X
	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, with the required adjustment of the dose level	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE (SPECIFY)	

Section 6.8.1(2) Annex Point IIA 6.8.1	Teratogenicity test in rabbits
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 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	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).* Neeper-Bradley, T. L. (1991). Two-generation reproduction study in Sprague-Dawley (CD®) rats with Didecyldimethylammonium Chloride administered in the diet. Report No. 52-648. Union Carbide, Bushy Run Research Center, Export, PA, U.S.A. (Unpublished) Ref No. D29 (LON 1777)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA OPP 83-4 1991 *(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 number	*List lot/batch number where relevant* [redacted]	
3.1.2 Specification	As given in Section 2 of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	[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]	X
3.1.5 Stability	*Describe stability of test material* The a.s., DDAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least seven years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
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 Route of exposure	Oral feed	
3.3.2 Duration of treatment	F0: 27 weeks (from 1st prebreed dose to last F0 sacrifice) F1: 32 weeks (from 1st F1B wean to last F1B sacrifice) F2B: to weaning	
3.3.3 Frequency of exposure	Ad libitum	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
3.3.4 Vehicle	[redacted]	
3.3.5 Dose levels	[redacted]	
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Actual dose administered	[redacted]	X
3.3.8 Post exposure period	[redacted]	
3.4 Examinations		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Bodyweight	[redacted]	
3.4.4 Food consumption	[redacted]	
3.4.5 Water consumption	[redacted]	
3.5 Sacrifice and Pathology		
3.5.1 Organ weights	[redacted]	
3.5.2 Gross and histopathology	[redacted]	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	[redacted]	
3.5.3 Other examinations		
3.6 Statistics	[redacted]	
3.7 Further remarks	[redacted]	
	4. RESULTS	
4.1 Observations (Parental data)		
4.1.1 Clinical signs	No significant signs of toxicity during the prebreed, mating, gestation or lactation periods at any dose for either generation.	
4.1.2 Mortality	None	
4.1.3 Body weight	F0 and F1 10-Week Premating Exposure: No treatment-related effects on body weights were observed at 300 or 750 ppm. Males and females at 1500 ppm had reductions in body weight beginning one week after treatment. Body weight gain was also reduced. F0 and F1 Gestation/Lactation: No treatment-related effects on body weights were observed at 300 or 750 ppm. Females in the 1500ppm group showed significant reductions in body weights but no body weight gain reductions during the first (producing the F1A and F2A litters) breeding period. Body weight but not weight gain was also reduced throughout lactation. During the second breeding (producing the F1B and F2B litters), gestational body weights and weight gains appeared to be lower than control and lactational body weights but not weight gains were reduced.	
4.1.4 Gestation period	Reproductive parameters were unaffected by treatment for all groups during the first and second breeding of both the F0 and F1 animals.	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
4.1.5 Food consumption	F0 and F1 10-Week Premating Exposure: No treatment-related effects on food consumption were observed at 300 or 750 ppm. Food consumption in males and females was reduced throughout the prebreed periods for the 1500 ppm group. F0 and F1 Gestation/Lactation: Food consumption during gestation and lactation for both breeding periods was unaffected by test substance treatment at any dose.	
4.1.6 Other	No treatment-related effects on any reproductive parameters were observed at any dose level. NOAEL (parental) = 750 ppm.	
4.2 Observations (Foetal data)		
4.2.1 Clinical signs	There were no signs of toxicity in the F1A, F1B, F2A or F2B animals.	
4.2.2 Mortality	There was no increased incidence of mortality compared to control in any of the offspring at any dose.	
4.2.3 Body weight	No treatment-related effects on body weights were observed at 300 or 750 ppm. F1A litters exhibited reduced body weights and weight gains from pnd 14 through 28 at 1500 ppm. A similar effect was observed for F1B, F2A and F2B pups.	
4.2.4 Other	NOAEL (F1 offspring) = 750 ppm NOAEL (F2 offspring) = 750 ppm	
4.3 Sacrifice and pathology		
4.3.1 Gross and histopathology	There were no treatment-related observations or histopathological findings in either the F0 or F1 adult animals at any dose. There were no treatment-related findings in the F1A, F1B, F2A or F2B weanling animals at necropsy.	
4.4 Other		
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	*Give concise description of method; give test guidelines no. and discuss relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.* [redacted]	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study	
	[redacted]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Didecyldimethylammonium Chloride was not toxic to reproduction in this study. NOAEL (parental) = 750 ppm NOAEL (F1 offspring) = 750 ppm NOAEL (F2 offspring) = 750 ppm	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	X
	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, with the required adjustment of the dose level	
Remarks	NO	

Section 6.8.2(1) Annex Point IIA 6.8.2	Two generations reproduction study
	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*

Section 6.9 Annex Point III-A.6.9	Neurotoxicity study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's proposal for not presenting data on neurotoxicity is acceptable, pending the justification amendement as suggested above.	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 6.9 Annex Point III-A.6.9	Neurotoxicity study
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 6.10 Annex Point III-A.6.10	Mechanistic study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X]	
Limited exposure [ ]	**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 6.10 Annex Point III-A.6.10	Mechanistic study
Remarks	

Section 6.11 Annex Point III-A 6.11	Studies on other routes of administration (parenteral)	
	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 proposal for not presenting data on other route of administration is acceptable, pending the justification is changed as suggested above.	
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 6.12 **Annex Point IIA. 6.12**	**Medical data in anonymous form**	Official use only
6.12.1 Medical surveillance data on manufacturing plant personnel if available	Personnel at the manufacturing site are examined on a regular basis for potential health effects by the company's Occupational Health Department. No substance-specific effects have been noted. The a.s. is not classified as a skin sensitiser.	
6.12.2 Direct observation, e.g. clinical cases, poisoning incidents if available	[redacted] No reported incidences of contamination have led to symptoms of poisoning. All cases were limited to reversible irritation of skin or mucous membranes. [redacted] No incidences of contamination have been reported.	
6.12.3 Health records, both from industry and any other available sources	20.012003: One worker was exposed to [redacted] on his back and chest when cleaning up a spillage. After having been decontaminated at the work place he consulted the physician. An observed redness on the respective areas of skin subsided on the third day after application of a cortisone ointment dressing. 15.03.2001: One worker was exposed to two drops of [redacted] on hisleft forearm. The site was decontaminated with Cetiol S + Praecutan, - redness of skin subsided on the second day, after application of a cortisone ointment dressing. 22.06.2001: One worker was exposed to splashes of [redacted] on his face when dismantling a pump. During washing some residual chemical was presumably washed into his eyes. He realised an irritation approximately 3 hours later. Redness of the lower eye section was observed. No symptoms were noticed on the face. The eyes were flushed and eye drops of a cortisone solution applied. The irritation subsided during the evening while the redness was still present. No symptoms were noted on the following morning. 05.08.1998: One worker was contaminated with [redacted] when cleaning a pump station. After decontamination a cortisone ointment dressing was applied. The patient did not revisit the physician. 18.08.2000: One worker was exposed to splashes of [redacted] on his shirt and trousers when trying to fill an already full drum. Cleaning with plenty ofwater immediately occurred. No visual or subjective symptoms were reported	
6.12.4 Epidemiological studies on the general population, if available	No epidemiological studies have been performed	
6.12.5 Diagnosis of poisoning including specific signs of poisoning and clinical tests, if available	No incidences of poisoning have been reported	
6.12.6 Sensitisation/ allergenicity observations, if available	No specific observations on sensitisation/ allergenicity have been reported	

Section 6.12 **Annex Point IIA. 6.12**	**Medical data in anonymous form**	Official use only
6.12.7 Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment, if known	Not applicable	
6.12.8 Prognosis following poisoning	Not applicable	

Section 6.13 Annex Point III-A.6.13	Toxic effects on livestock and pets	
	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*	
Remarks		

Section 6.14 **Annex Point III-A.6.14**	**Other test(s) related to the exposure of humans**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	*Applicant's justification is acceptable*	
Remarks		

Section 6.14 Annex Point III-A.6.14	Other test(s) related to the exposure of humans
	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 6.15.1 Annex Point III-A.6.15.1	Residues in food/feedstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
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	

Section 6.15.1 Annex Point III-A.6.15.1	Residues in food/feedstuffs
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 6.15.2 Annex Point III-A.6.15.2	Behaviour of residues in food/feedstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
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*	

Section 6.15.2 Annex Point III-A.6.15.2	Behaviour of residues in food/feedstuffs
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.15.3 **Annex Point III-A.6.15.3**	**Exposure estimation**	
	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 [ ]** **Other justification [X]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	

Section 6.15.3 Annex Point III-A.6.15.3	Exposure estimation
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	*Applicant's justification is acceptable.*
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.15.4 Annex Point III-A.6.15.4	Proposed acceptable residues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
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		

Section 6.15.4 Annex Point III-A.6.15.4	Proposed acceptable residues
	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 6.15.5 Annex Point III-A.6.15.5	Other relevant information (ADI, MRL, etc.)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
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*	

Section 6.15.5 Annex Point III-A.6.15.5	Other relevant information (ADI, MRL, etc.)
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.15.6 Annex Point III-A.6.15.6	Summary of 6.15	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
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 6.15.6 Summary of 6.15 Annex Point III-A.6.15.6
Remarks

Section 6.16 **Annex Point III-A.6.16**	**Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary may be required.**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	*Applicant's justification is acceptable*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 6.17 Annex Point III-A.6.17	Assessment of toxic effects of metabolites from treated plants	
	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*	
Remarks		

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Pharmacokinetics	[redacted]	X
Acute Toxicity	[redacted]	
Irritation and Sensitisation	[redacted]	
Repeated dose toxicity, neurotoxicity and carcinogenicity	[redacted]	X X X

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
	[redacted]	
Mutagenicity	[redacted]	
Reproduction and Development	[redacted]	
Conclusion	[redacted]	X
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Pharmacokinetics	[redacted]	
Acute Toxicity	[redacted]	
Irritation and Sensitization	[redacted]	
Repeated dose toxicity, neurotoxicity and carcinogenicity	[redacted]	

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Conclusion	*Include revised version only for paragraphs tagged with X.*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Remarks		

Section 7.1 Fate and behaviour in water
Annex Point IIA 7.1

Section 7.1.1 Degradation, initial studies
Annex Point IIA 7.1.1

Section 7.1.1.1 Abiotic
Annex Point IIA 7.1.1.1

Section 7.1.1.1.1(1) **Annex Point IIA 7.1.1.1.1**	**Hydrolysis as a function of pH and identification of breakdown products**	
	1. REFERENCE	Official use only
1.1 Reference	Dykes, J. and M. Fennessey. (1989) Hydrolysis of Didecyldimethylammonium Chloride (DDAC) as a Function of pH at 25°C. Report No. 37004. ABC Laboratories, Inc., Columbia, MO, USA (Unpublished) Ref No.: D36 (LON 1791)	
1.2 Data protection	Yes	
1.2.1 Data owner	The Dialkyl Project	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA-FIFRA N-161-1 1989	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	[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.	
3.1.3 Description	[redacted]	

Section 7.1.1.1.1(1) Annex Point IIA 7.1.1.1.1	Hydrolysis as a function of pH and identification of breakdown products	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable under the conditions of this study.	
3.2 Testing Procedure	[redacted]	
	4. RESULTS	
4.1 Results of test substance		
4.1.1 Initial concentration of test substance	[redacted]	
4.1.2 Actual concentrations of test substance	[redacted]	
4.2 Degradation %	No degradation determined.	
4.3 Half life	An accurate estimate of the half-life for the hydrolysis could not be determined since no significant degradation of the test compound was detected during the 30-day evaluation period. Projected half-lives were: pH 5 = 368 days pH 7 (HEPES) = 175 days pH 7 (TRIS) = 194 days pH 9 = 506 days	
4.4 Remarks	The actual half-lives may vary since the reported values are based on thirty days of observation and the projected values are longer than this observation period. The mass balance ^{14}C accountability was 98.5% ± 3.95% over a pH range of 5 to 9 at 25°C.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and	[redacted]	

Section 7.1.1.1.1(1) Annex Point IIA 7.1.1.1.1	Hydrolysis as a function of pH and identification of breakdown products	
discussion	[redacted]	
5.3 Conclusion	The test substance was found to be hydrolytically stable in the pH range 5 to 9 at 25°C.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods		
Results and discussion		
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*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*	