Section 6.6.4(1) **Annex Point IIA 6.6.4**	**In-vivo mutagenicity 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).* Kallesen, T. (1985) Assessment of the mutagenic activity of Hyamine 3500 in the mouse micronucleus test. Lab No. LZA 10753. The Scantox Laboratories Ltd. (Unpublished) [Ref No: A24 (LON 1029)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Joint Venture	
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 OECD Test Guideline No. 474, EEC Directive 79/831 Method No. 431 1985 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	No (GLP not compulsory at the time the study was performed) *(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]	

Section 6.6.4(1) Annex Point IIA 6.6.4		In-vivo mutagenicity study	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* 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 ethanol 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	*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., 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 species**		
3.2.1	Species	Mouse	
3.2.2	Strain	Bom:NMRI, GI.Bomholtgard Ltd, DK-8680 Ry	
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	Duration of test/exposure	Animals sacrificed 24, 48 and 72 hours after dosing	
3.3.3	Concentration	[redacted]	

Section 6.6.4(1) **Annex Point IIA 6.6.4**	**In-vivo mutagenicity study**	
3.3.4 Vehicle	[redacted]	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	
3.4 Test Methods		
3.4.1 Pre-sacrifice treatment	[redacted]	
3.4.2 Cell type	[redacted]	
	4. RESULTS	
4.1 Animal observations		
4.1.1 Clinical signs	[redacted]	
4.1.2 Mortality	[redacted]	
4.2 Cell observations		
4.2.1 Test substance	There was no significant increase in the number of micronuclei per thousand polychromatic erythrocytes: Control = 1.0 24-Hour Test = 0.8 48-Hour Test = 1.1 72-Hour Test = 1.0	
4.2.2 Positive control	There were significant increases in the number of micronuclei per thousand polychromatic erythrocytes (44.1)	
4.3 Remarks	The test substance is not designated as mutagenic in this test system.	
	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 6.6.4(1) **Annex Point IIA 6.6.4**	**In-vivo mutagenicity study**	
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* Alkyldimethylbenzylammonium Chloride did not cause any increases in the number of micronuclei and is not considered mutagenic in this assay.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2 Deficiencies	[redacted] *(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	The study is 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*	

Section 6.6.4(1) Annex Point IIA 6.6.4	In-vivo mutagenicity study
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]	
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 6.6.5 Annex Point IIA.6.6.5	Second *in vivo* mutagenicity test
	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)*
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]	
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)*	
Date	*Give date of comments submitted*	

Section 6.6.6 Annex Point IIA.6.6.6	Germ cell effects
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 6.7.7 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		

Section 6.6.7 Annex Point IIA.6.6.7	Further genetic toxicity tests on metabolites of concern
	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 6.7(1) Annex Point IIA 6.7	Carcinogenicity study in mice	
	1. REFERENCE	Official use only
1.1 Reference	Gill, M.W., Hermansky, S.J. and Wagner, C.L. (1991) Chronic dietary oncogenicity study with Alkyldimethylbenzylammonium Chloride in mice. Report No: 53-515. Union Carbide, Bushy Run Research Center, Export, PA, U.S.A. (Unpublished) [Ref No. A83 (LON 1886)]	
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	Yes U.S. EPA FIFRA 83-2 1991	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	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.	X
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	Stable	X
3.2 Test animals		
3.2.1 Species	Mouse	

Section 6.7(1) Annex Point IIA 6.7		Carcinogenicity study in mice	
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	
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 1500 ppm had depressed body weights and weight gains for the entire study.	

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**		X
4.4	**NOAEL**	NOAEL = 500 ppm equivalent to 73 and 92 mg/kg/day for males and females respectively.	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	X
5.2	**Results and discussion**	[redacted]	

Section 6.7(1) **Annex Point IIA 6.7**	**Carcinogenicity study in mice**	
5.3 Conclusion	NOEL = 500 ppm equivalent to 73 and 92 mg/kg/day for males and females respectively. The test substance is not considered to be carcinogenic in this strain of 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	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	

Section 6.7(1) **Annex Point IIA 6.7**	**Carcinogenicity study in mice**
Conclusion	[redacted]
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*

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats	
	1. REFERENCE	Official use only
1.1 Reference	Gill, M.W., Hermansky, S. J. and Wagner, C.L. (1991) Chronic dietary toxicity/oncogenicity study with alkyl dimethyl benzyl ammonium Chloride (ADBAC) in rats. Report No. 53-543. Bushy Run Research Center, Export, PA, U.S. (Unpublished) [Ref No. A21 (LON 1882)]	
1.2 Data protection	Yes	
Data owner	ADBAC Joint Venture	
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 1991	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material	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.	X
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
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).	

Section 6.7(2) Annex Point IIA 6.7		Carcinogenicity study in rats	
3.2	**Test animals**		
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]	
3.2.7	Satellite group(s)	[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]	

Section 6.7(2) Annex Point IIA 6.7		Carcinogenicity study in rats	
		[redacted]	
3.4.3	Mortality	[redacted]	
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]	
3.4.11	**Remarks**	[redacted]	
3.5	**Sacrifice and pathology**		
3.5.1	Organ weights	[redacted]	
3.5.2	Gross and histopathology	[redacted]	
3.5.3	Other examinations		
3.5.4	Statistics	[redacted]	
		4 RESULTS	
4.1	**Examinations**		
4.1.1	Observations		

Section 6.7(2) Annex Point IIA 6.7		Carcinogenicity study in rats	
4.1.2	Clinical signs	An increased incidence of loose faeces was noted in the male rats in all groups treated with the test substance. Based upon previous 14-day and 90-day dietary studies with the test substance, the increased incidence of loose faeces in this study was considered potentially treatment-related, but was not considered biologically significant due to the lack of a dose response relationship in incidence, the infrequent nature of the observation throughout all dose groups, and the lack of histological changes in the digestive tract. There were no other clinical signs observed in male rats considered to be treatment-related. No clinical signs observed in the female rats were considered to be related to treatment with test substance.	X
4.1.3	Mortality	No treatment-related findings were observed at any treatment level.	
4.1.4	Body weight gain	The mean absolute body weights of the 2000 ppm group male and female rats were statistically significantly decreased at most measurement periods from Week 1 to Week 26 (male) and Week 1 to 60 (female) and, while not consistently statistically significant, remained decreased throughout the study. On a percentage basis, the differences from the control ranged between 4 -5 % in males and 6 - 9% in females from Weeks 13 - 104.	X
4.1.5	Food consumption	There appeared to be a depression in food consumption in the male rats in the 1000 ppm treatment group during the first few months of the study. However, because of the small and transient nature of this finding, no toxicological significance was attributed to it.	X
4.1.6	Water consumption	Not applicable	
4.1.7	Ophthalmoscopic examination	No treatment-related effects	
4.1.8	Haematology	No treatment-related effects	
4.1.9	Clinical chemistry	No treatment-related effects	
4.1.10	Urinalysis	No treatment-related effects	
4.2	**Sacrifice and pathology**		
4.2.1	Organ weights	No treatment-related effects	
4.2.2	Gross and histopathology	No treatment-related effects	
4.2.3	Other examinations		
4.2.4	**Statistical analysis**	As noted above	
4.3	**LO(A)EL**	2000 ppm (approximately 102 mg/kg/day)	X
4.4	**NO(A)EL**	NOAEL=1000 ppm (approximately 50 mg/kg/day) for toxicity	X

Section 6.7(2) **Annex Point IIA 6.7**	**Carcinogenicity study in rats**	
	The NOAEL for carcinogenicity is >2000 ppm (approximately 102 mg/kg/day)	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 1000 ppm (approximately 50 mg/kg/day) for toxicity Alkyldimethylbenzylammonium Chloride was not carcinogenic 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]	

Section 6.7(2) Annex Point IIA 6.7	Carcinogenicity study in rats
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable

Section 6.7(2) Annex Point IIA 6.7	**Carcinogenicity study in rats**
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*

Section 6.8 Reproductive toxicity
Annex point IIA – headline only

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. (1992) Developmental toxicity evaluation II of Alkyldimethylbenzylammonium Chloride (ADBAC) administered by gavage to CD® rats. Project No: 91N0031. Union Carbide, Bushy Run Research Center, Mellon Road, Export, PA 15632, USA. (Unpublished). [Ref Nos A26 and A26a (LON 3241)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Joint Venture	
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 1992 *(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**	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	*List lot/batch number where relevant*	

Section 6.8.1(1) **Annex Point IIA 6.8.1**	**Teratogenicity test in rats**	
	[redacted]	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* 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	*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., 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	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	

Section 6.8.1(1) **Annex Point IIA 6.8.1**	**Teratogenicity test in rats**	
3.3.3 Frequency of exposure	Once daily during exposure period	
3.3.4 Vehicle	[redacted]	
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		
3.5.1.1 Gross necropsy findings	[redacted]	
Organ weights	[redacted]	
Other	[redacted]	
3.5.2 Foetal findings		
3.5.2.1 Bodyweight	[redacted]	
3.5.2.2 Gross necropsy findings	[redacted]	

Section 6.8.1(1) Annex Point IIA 6.8.1	Teratogenicity test in rats	
3.5.2.3 Skeletal examinations	[redacted]	
3.5.2.4 Visceral examinations	[redacted]	
3.6 Statistics	[redacted]	
3.7 Further remarks		
	4 RESULTS	
4.1 Maternal observations		
4.1.1 Clinical signs	Perioral wetness in 67% of dams and audible respiration in 3 dams at 100 mg/kg/day. One dam in this group exhibited dehydration, unkempt appearance, loose feces, urine stains, and perioral wetness Audible respiration in 2 dams at 30 mg/kg/day. One of these dams also exhibited urine stains, gasping, perinasal encrustation, loose feces and perioral wetness.	
4.1.2 Mortality	No mortalities	
4.1.3 Body weight gain	There were no effects of treatment on gestational body weight and body weight gain, and gravid uterine weight in any dose group.	
4.1.4 Food consumption	Food consumption was reduced for Days 6 to 9 in the 30 and 100 mg/kg/day treatment groups.	
4.1.5 Gross findings at necropsy	Ulceration of stomach and gas filled intestines, color changes in liver and lymph nodes and small spleen in one dam at 100 mg/kg/day Swollen liver in one dam at 30 mg/kg/day	
4.1.6 Other	One female in the mid-dose group delivered early and was removed from the study. At scheduled sacrifice, one female in the control group had no viable foetuses. There were no treatment-related differences in the number of ovarian corpora lutea and in gestational parameters including total number of implantations, number of viable and nonviable implants.	
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	

Section 6.8.1(1) **Annex Point IIA 6.8.1**		**Teratogenicity test in rats**	
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]	X
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	X
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 10 mg/kg/day; the NOEL for developmental toxicity was at least 100 mg/kg/day.	X
5.3.1	Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4* [redacted]	
5.3.2	Deficiencies	[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]	

Section 6.8.1(1) **Annex Point IIA 6.8.1**	**Teratogenicity test in rats**
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[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*

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).* Neeper-Bradley, T.L. and Kubena, M.F (1992). Developmental toxicity evaluation of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Administered by gavage to New Zealand White Rabbits. Project No: 91N0032. Union Carbide, Bushy Run Research Center, Mellon Road, Export, PA 15632, USA. (Unpublished) [Ref Nos A27 and A27a (LON 3242)	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Joint Venture	
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 1992 *(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**	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 6.8.1(2) Annex Point IIA 6.8.1		Teratogenicity test in rabbits	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* 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.	X
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* 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	
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	

Section 6.8.1(2) **Annex Point IIA 6.8.1**	**Teratogenicity test in rabbits**	
3.3.3 Frequency of exposure	Daily	
3.3.4 Vehicle	[redacted]	
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		
Gross necropsy findings	[redacted]	
Organ weights	[redacted]	
Other	[redacted]	
3.5.2 Foetal findings		
3.5.2.1 Bodyweight	[redacted]	
3.5.2.2 Gross necropsy findings	[redacted]	

Section 6.8.1(2) **Annex Point IIA 6.8.1**	**Teratogenicity test in rabbits**	
3.5.2.3 Skeletal examinations	[redacted]	
3.5.2.4 Visceral examinations	[redacted]	
3.6 Statistics	[redacted]	
3.7 Further remarks		
	4. RESULTS	
4.1 Maternal observations		
4.1.1 Clinical signs	Treatment-related clinical signs were observed at 9.0 mg/kg/day primarily related to laboured or audible breathing and hypoactivity.	
4.1.2 Mortality	No mortalities	
4.1.3 Body weight gain	No treatment related changes	
4.1.4 Food consumption	No treatment related changes	
4.1.5 Gross findings at necropsy	None	
4.1.6 Other	No abortions or early births. There were no treatment-related differences in the number of ovarian corpora lutea and in gestational parameters including total number of implantations, number of viable and nonviable implants.	
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	

Section 6.8.1(2) **Annex Point IIA 6.8.1**		**Teratogenicity test in rabbits**	
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]	X
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, were observed at any dosage employed. The "no observable effect level" (NOEL) for maternal effects was 3.0 mg/kg/day. The NOEL for developmental toxicity was at least 9.0 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.)*	
		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		[redacted]	
Remarks		[redacted]	

Section 6.8.1(2) **Annex Point IIA 6.8.1**	**Teratogenicity test in rabbits**
	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 6.8.2(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. (1990). Two-generation reproduction study in Sprague-Dawley (CD®) rats with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) administered in the diet. Report No. 52-524. Union Carbide, Bushy Run Research Center, Export, PA, U.S.A. (Unpublished) [Ref No: A25 (LON 1881)]	
1.2	**Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1	Data owner	*Give name of company* ADBAC Joint Venture	
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 1990 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2	**GLP (only where required)**	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**	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 6.8.2(1) Annex Point IIA 6.8.2		Two generations reproduction study	
3.1.2	Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):* 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.	X
3.1.3	Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4	Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5	Stability	*Describe stability of test material* 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	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	F_0: 19 weeks (from 1st prebreed dose to last F_0 sacrifice) F_1: 25 weeks (from 1st F_1 wean to last F_1 sacrifice)	

Section 6.8.2(1) **Annex Point IIA 6.8.2**	**Two generations reproduction study**	
	F_2: to weaning	
3.3.3 Frequency of exposure	Ad libitum	
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		
	4. RESULTS	
4.1 Observations (Parental data)		
4.1.1 Clinical signs	No significant signs of toxicity during the pre-breed, mating, gestation or lactation periods at any dose for either generation.	
4.1.2 Mortality	None	
4.1.3 Body weight	During the 10-week pre-breed exposure, F0 males exhibited no reduction in body weight. During the same period, F0 females at 2000 ppm exhibited reductions in body weight for weeks 5, 6, 9 and 10 of pre-breed treatment. Body weight gain was also reduced at 2000 ppm for one week (week 8-9) during the pre-breed period. On lactational day 21 mean body weight of F0 dams at 2000 ppm exhibited a significant increase. Increased lactational body weight gain was observed at 2000 ppm throughout lactation. During the 10-week pre-breed exposure, F1 males at 2000 ppm exhibited no reduction in body weights but weight gain was reduced at 2000 ppm for the second treatment week. There were no significant effects on the F1 females. F1 maternal body weights at 2000 ppm were unaffected during the gestational and lactational periods.	
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.	
4.1.5 Food consumption	Food consumption in the F0 females at 2000 ppm was reduced for the first four exposure weeks. Food consumption in F0 males was significantly reduced at 2000 ppm for the first week of treatment only. At F0 breed to produce F1 litters food consumption during gestation and lactation was unaltered by treatment. Food consumption for the Fl males exhibited significant reductions at 2000 ppm for weeks 3-4 and 6-7 of the pre-breed period and for week	

Section 6.8.2(1) Annex Point IIA 6.8.2		Two generations reproduction study	
		15-16. Treated Fl females exhibited no reductions in food consumption throughout the ten-week pre-breed period. At the F1 breed to produce F2 litters gestational food consumption was reduced for days 7-11 and 14-17 at 2000 ppm.	
4.1.6	Other	No treatment-related effects on any reproductive parameters were observed at any dose. NOEL (parental) = 1000 ppm	
4.2	**Observations (Foetal data)**		
4.2.1	Clinical signs	There were no signs of toxicity in the F1 or F2 animals.	
4.2.2	Mortality	There was no effects of treatment on postnatal deaths.	
4.2.3	Body weight	The F1 litters exhibited reduced body weights per litter on postnatal days 21 and 28 at 2000 ppm. F1 pup body weight gains were reduced for lactation days 14-21 and 21-28. F2 pup weights per litter were reduced at 2000 ppm on postnatal day 28. Pup weight gains were also reduced at 2000 ppm for lactational days 14-21 and for days 21-28.	
4.2.4	Other	NOEL (F1and F2 offspring) = 1000 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 F1 or F2 pups that died during lactation or randomly selected F1and F2 pups 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]	X
5.2	**Results and discussion**	*Summarise relevant results; discuss dose-response relationship where relevant.* [redacted]	