Section 6.4.1(3) **Annex Point IIA 6.4.1**	**Subchronic oral toxicity test**	
4.1.1 Observations		
4.1.2 Clinical signs	Clinical findings were restricted to the animals from the 4000 and 8000 ppm groups that died. The observations were, general cachexia (e.g. emaciation, unkempt appearance, hunched posture, etc.).	
4.1.3 Mortality	No males in the 4000 ppm group and no animals in the 8000 ppm group survived beyond Day-11. A single female in the 4000 ppm group survived to terminal sacrifice. Death was attributed to ileus and shock.	
4.1.4 Bodyweight	Minor decreases in bodyweight in female mice treated with 1000 ppm.	X
4.1.5 Food consumption	Decreased consumption was observed in the animal of the 4000 ppm group that survived the first week after the start of the treatment. The decrease was approximately 35% lower than the control.	
4.1.6 Water consumption	Not applicable	
4.1.7 Ophthalmoscopic examination	Not applicable	
4.1.8 Haematology	Not applicable	
4.1.9 Clinical Chemistry	Not applicable	
4.1.10 Urinalysis	Not applicable	
4.2 Sacrifice and Pathology		
4.2.1 Organ weights	No treatment-related effects.	
4.2.2 Gross and Histopathology	General cachexia and increased levels of liquid or semisolid material in the gastrointestinal tract	
4.2.3 Other examinations		
4.2.4 Statistical analysis	As noted above	
4.3 LO(A)EL	1000 ppm (174 mg/kg/day for males; 210 mg/kg/day for females)	
4.4 NO(A)EL	NOEL: 500 ppm (85 mg/kg/day for males; 102 mg/kg/day for females)	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	

Section 6.4.1(3) Annex Point IIA 6.4.1	Subchronic oral toxicity test	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 1000 ppm (approximately 192 mg/kg/day)	X
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 6.4.1(3) **Annex Point IIA 6.4.1**	**Subchronic oral toxicity test**
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 6.4.2(1) **Annex Point IIA 6.4.2**	**Subchronic dermal toxicity test**	
	1. REFERENCE	Official use only
1.1 Reference	Gill, M.W. and Wagner, C.L. (1990). Ninety-day subchronic dermal toxicity study with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) in rats. Bushy Run Research Center, Export, PA USA, Report No.: 52-623 (unpublished) Reference No.: A18a (LON 1876)	
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 82-3 1990	
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 6.4.2(1) Annex Point IIA 6.4.2		Subchronic dermal toxicity test	
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	1[redacted]	
3.2.7	Control Animals	[redacted]	
3.3	**Administration/ Exposure**		
3.3.1	Dose route	Dermal – occluded	
3.3.2	Duration of test/ exposure	90 days	
3.3.3	Frequency of exposure	6 hours/day for 5 days/week – Monday through Friday	
3.3.4	Post exposure period	[redacted]	
3.3.5	Concentration	[redacted]	
3.3.6	Vehicle	[redacted]	X
3.3.7	Concentration in vehicle	[redacted]	
3.3.8	Actual dose received	[redacted]	X
3.3.9	Controls	[redacted]	
3.4	**Examinations**		
3.4.1	Observations		
3.4.2	Clinical signs	[redacted]	

Section 6.4.2(1) Annex Point IIA 6.4.2		Subchronic dermal toxicity test	
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]	
3.5	**Sacrifice and Pathology**		
3.5.1	Organ weights	[redacted]	
3.5.2	Gross and histopathology	[redacted]	
3.5.3	Other examinations		
3.5.4	Statistical analysis	[redacted]	
		4. RESULTS	
4.1	**Examinations**		
4.1.1	Observations	Slight local irritation (hyperkeratosis) at the site of treatment was observed for males in all treatment groups including controls and for females in all treatment groups.	
4.1.2	Clinical signs	No treatment-related effects in any dose group	
4.1.3	Mortality	One female died from the high dose group on the first day of treatment. The death was attributed to stress from the dosing/wrapping procedure. The animal was replaced. No other deaths occurred.	
4.1.4	Bodyweight	No treatment-related effects in any dose group	

Section 6.4.2(1) Annex Point IIA 6.4.2		Subchronic dermal toxicity test	
4.1.5	Food consumption	No treatment-related effects in any dose group.	
4.1.6	Water consumption	Not applicable.	
4.1.7	Ophthalmoscopic examination	No treatment-related effects in any dose group.	
4.1.8	Haematology	No treatment-related effects in any dose group.	
4.1.9	Clinical Chemistry	No treatment-related effects in any dose group.	
4.1.10	Urinalysis	Not applicable	
4.2	**Sacrifice and Pathology**		
4.2.1	Organ weights	No treatment-related effects in any dose group	
4.2.2	Gross and Histopathology	Hyperkeratosis was observed for males in all treatment groups including controls and for females in the test substance treatment groups. These results were questionable due to the high incidence in the control male group.	
4.2.3	Other examinations		
4.2.4	Statistical analysis	As noted above	
4.3	**LOAEL**	>20 mg/kg/day.	
4.4	**NOAEL**	NOAEL: 20 mg/kg/day	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	

Section 6.4.2(1) Annex Point IIA 6.4.2	Subchronic dermal toxicity test	
5.3 Conclusion	NOAEL 20 mg/kg bw	X
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		

Section 6.4.2(1) **Annex Point IIA 6.4.2**	**Subchronic dermal toxicity test**
	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 6.4.3 Annex Point IIIA.6.4.3	Subchronic toxicity test (inhalation)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 6.4.3 **Annex Point IIIA.6.4.3**	**Subchronic toxicity test (inhalation)**
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 6.5(1) **Annex Point IIA 6.5**	**Chronic toxicity in dogs**	
	1. REFERENCE	Official use only
1.1 Reference	Goldenthal, E.I. (1994). Evaluation of ADBAC in a one-year chronic dietary toxicity study in dogs. International Research and Development Corp, Mattawan, MI, USA. Report No.: 638-004 (unpublished) Reference No.: A20 (LON 3443)	
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 US. EPA OPP 83-1 1994	
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).	X
3.2 Test animals		

Section 6.5(1) Annex Point IIA 6.5		Chronic toxicity in dogs	
3.2.1	Species	Dog	
3.2.2	Strain	Beagle	
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	Dietary	
3.3.2	Duration of test/exposure	52 weeks	
3.3.3	Frequency of exposure	Free access to diet for three hours every day	
3.3.4	Post exposure period	[redacted]	
3.3.5	Concentration	[redacted]	
3.3.6	Vehicle	Diet	
3.3.7	Concentration in vehicle	[redacted]	
3.3.8	Actual dose received	[redacted]	X
3.3.9	Controls	[redacted]	
3.4	**Examinations**		
3.4.1	Observations	[redacted]	
3.4.2	Clinical signs	[redacted]	

Section 6.5(1) Annex Point IIA 6.5		Chronic toxicity in dogs	
		[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]	
3.5	**Sacrifice and Pathology**		
3.5.1	Organ weights	[redacted]	
3.5.2	Gross and histopathology	[redacted]	
3.5.3	Other examinations		
3.5.4	Statistical analysis	[redacted]	
		4. RESULTS	
4.1	**Examinations**		
4.1.1	Observations		
4.1.2	Clinical signs	No treatment-related effects	
4.1.3	Mortality	None.	
4.1.4	Bodyweight	Decreased bodyweight and bodyweight gain were observed for all animals in the 1200 ppm group.	

Section 6.5(1) Annex Point IIA 6.5		Chronic toxicity in dogs	
4.1.5	Food consumption	Decreased food consumption were observed for all animals in the 1200 ppm group. However, the treatment related decreased for the females group was questionable, because of the inconsistant nature of the changes.	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	Decreases in the cholesterol levels were observed for males and females of the 1200 ppm groups.	
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		
4.3	**LOAEL**	1200 ppm	X
4.4	**NOAEL**	400 ppm	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]	
5.2	**Results and discussion**	[redacted]	
5.3	**Conclusion**	NOAEL = 400 ppm (13.1 mg/kg/day for males; 14.6 mg/kg/day for females) LOAEL = 1200 ppm (33.8 mg/kg/day for males; 38.6 mg/kg/day for	

Section 6.5(1) Annex Point IIA 6.5	Chronic toxicity in dogs	
	females	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	

Section 6.5(1) **Annex Point IIA 6.5**	**Chronic toxicity in dogs**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
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 6.5(2) **Annex IIA Point 6.5**	**Chronic toxicity 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	
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 EPA Guideline 83-5 OECD Guideline No. 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 6.5(2) Annex IIA Point 6.5		Chronic toxicity 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	Control Animals	[redacted]	
3.3	**Administration/ Exposure**		
3.3.1	Dose route	Oral feed	
3.3.2	Duration of test/exposure	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	Animal diet	
3.3.7	Actual dose received	[redacted]	
3.3.8	Controls	[redacted]	
3.4	**Examinations**		
3.4.1	Observations		
3.4.2	Clinical signs	[redacted]	

Section 6.5(2) Annex IIA Point 6.5		Chronic toxicity 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	Statistical analysis	[redacted]	
		4. RESULTS	
4.1	**Examinations**		
4.1.1	Observations		
4.1.2	Clinical signs	An increased incidence of loose faeces was noted in the male rats in all groups treated with test substance. Based upon previous 14-day and 90-	X

Section 6.5(2) Annex IIA Point 6.5		Chronic toxicity in rats	
		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	
4.1.3	Mortality	None observed	
4.1.4	Bodyweight	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 also 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	**LOAEL**	2000 ppm (approximately 102 mg/kg/day)	X
4.4	**NOAEL**	NOAEL = 1000 ppm (approximately 50 mg/kg/day) for toxicity	X
		5. APPLICANT'S SUMMARY AND CONCLUSION	

Section 6.5(2) Annex IIA Point 6.5	Chronic toxicity in rats	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	NOAEL = 1000 ppm (44 mg/kg/day for males; 57 mg/kg/day for females for toxicity. LOAEL = 2000 ppm (88 mg/kg/day for males; 116 mg/kg/day for females	
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]	

Section 6.5(2) **Annex IIA Point 6.5**	**Chronic toxicity in rats**
Results and discussion	[redacted]
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*

Section 6.5(2) Annex IIA Point 6.5	Chronic toxicity in rats
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 6.6 Genotoxicity studies
Annex Point IIA 6.6 – headline only

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**	
	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).* Thompson, P.W. (2001) LZ1392 (Alkyl(C10-C18) (Dimethylbenzylammonium Chloride): Reverse mutation assay "Ames Test" using *Salmonella typhimurium*. Project No. 102/367. Safepharm Laboratories Limited, Derby, UK. (Unpublished) [Ref No: A56 (LON 3342)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Directive 92/69/EEC, B.14, OPPTS Harmonised Guideline 2001 *(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]	

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [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 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 Cell type	*Salmonella typhimurium*	
3.2.2 Strain	TA1535, TA1537, TA102, TA98 and TA100	
3.3 Metabolic activation		
3.3.1 Metabolic activation system	S9-mix	
3.3.2 Control in presence of metabolic activation	[redacted]	
3.3.2 Control in absence of metabolic activation	[redacted]	
3.4 Test Methods		
3.4.2 Negative control	[redacted]	

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**	
3.4.2 Vehicle Control	[redacted]	
3.4.3 Cytotoxicity Concentrations	[redacted]	
3.4.4 Genotoxicity concentrations	[redacted]	
3.4.5 Statistical methods	[redacted]	
3.5 Remarks	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity		
4.1.1 With metabolic activation	See Table 6.6.1(1)-1	
4.1.2 Without Metabolic activation	See Table 6.6.1(1)-1	
4.1.3 Remarks	The test substance caused a visible reduction in the growth of the bacterial lawn to all of the tester strains both with and without S9-mix beginning at 15 µg/plate.	
4.2 Genotoxicity		
4.2.1 With metabolic activation	See Table 6.6.1(1)-2	
4.2.2 Without metabolic activation	See Table 6.6.1(1)-2	
4.2.3 Remarks	The test substance was considered to be non-mutagenic.	
	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 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**	
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* The test substance was considered to be non-mutagenic.	
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*	

Section 6.6.1(1) **Annex Point IIA 6.6.1**	***In vitro* gene mutation study in bacteria**
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.6.1(1)-1. Cytotoxicity (Number of revertant colonies)

		Test substance concentration (µg/plate)										
With/ Without S9-mix	**Strain**	**0**	**0.15**	**0.5**	**1.5**	**5**	**15**	**50**	**150**	**500**	**1500**	**5000**
Without	TA100	91	91	81	83	64	17S	0T	0T	0T	0T	0T
With	TA100	97	105	103	103	83	50S	0T	0T	0T	0T	0T

S=sparse bacterial background lawn

T= toxic, no bacterial lawn

Table 6.6.1(1)-2. Genotoxicity (Mean number of revertant colonies)

Strain	**TA100**		**TA1535**		**TA102**		**TA98**		**TA1537**	
Test substance concentration (µg/plate)										
With S9										
+ve control type (concentration (µg/plate))	[redacted]		[redacted]		[redacted]		[redacted]		[redacted]	
Test number	1	2	1	2	1	2	1	2	1	2
+ve control	1772	2317	287	135	886	723	229	251	582	336
-ve control	143	137	17	17	349	308	36	25	12	22
0.15	129	137	13	13	357	315	26	24	13	18
0.5	134	11	10	14	346	313	33	25	15	14
1.5	129	127	15	14	373	307	32	26	16	14
5	142	143	10	13	369	341	32	23	17	16
15	132	0	12	2	363	151	37	11	17	6
50	28	0	10	0	276	0	22	0	10	0
Without S9										
+ve control type (concentration (µg/plate))	[redacted]		[redacted]		[redacted]		[redacted]		[redacted])	
Test number	1	2	1	2	1	2	1	2	1	2
+ve control	621	464	603	430	854	961	142	126	656	716
-ve control	153	134	12	18	316	336	38	22	16	17
0.15	150	123	13	15	340	308	29	18	18	19
0.5	132	114	11	21	331	339	30	18	17	18
1.5	154	111	19	16	339	232	25	14	15	11
5	145	111	9	10	326	325	28	19	12	18
15	84	0	11	0	320	0	23	0	0	0
50	0	0	0	0	0	0	0	0	0	0

Section 6.6.2(1) **Annex Point IIA 6.6.2**	**In-vitro Cytogenicity study in mammalian cells**	
	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).* Durward, R. (2001) LZ1392 (Alkyl (C10-C18) dimethylbenzylammonium Chloride): Chromosomal aberrations assay in human lymphocytes *in vitro*. Project No. 102/366. Safepharm Laboratories Limited, Derby, UK. (Unpublished) [Ref No: A57 (LON 3434)]	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS after 13 May 2000 on 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. 473, Directive 92/69/EEC B10 2001 *(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	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	

Section 6.6.2(1) **Annex Point IIA 6.6.2**	**In-vitro Cytogenicity study in mammalian cells**	
	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 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 Cell type	Human lymphocytes	
3.2.2 Strain	Not applicable	
3.3 Metabolic activation		
3.3.1 Metabolic activation system	S9	
3.3.2 Positive Control in presence of metabolic activation	[redacted]	
3.3.3 Positive Control in absence of metabolic activation	[redacted]	
3.4 Test Methods		
3.4.1 Negative control	[redacted]	
3.4.2 Vehicle Control	[redacted]	
3.4.3 Cytotoxicity Concentrations	[redacted]	

Section 6.6.2(1) Annex Point IIA 6.6.2	In-vitro Cytogenicity study in mammalian cells	
3.4.4 Genotoxicity concentrations	[redacted]	
3.4.5 Statistical methods	[redacted]	
3.4.6 Duplicate/Independent assay	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity		
4.1.1 With Metabolic activation	Slightly Toxic at 20 µg/ml with S9 activation in test 1.	
4.1.2 Without Metabolic activation	Toxic at 16 µg/ml without S9 activation in test 1 and toxic at 20 µg/ml without S9 activation in test 2	
4.2. Genotoxicity		
4.2.1 With Metabolic activation	Negative See Table 6.6.2(1) – 1 and -2	
4.2.1.1 Polyploidy incidence	None observed	
4.2.1.2 Frequency of effects	Acceptable range (0-3.5 for aberrations and 0-2 for polyploidy)	
4.2.2 Without Metabolic activation	Negative See Table 6.6.2(1) – 1 and -2	
4.2.1.1 Polyploidy incidence	None observed	
4.2.1.2 Frequency of	Acceptable range (0-3 for aberrations and 0-1.5 for polyploidy)	

Section 6.6.2(1) Annex Point IIA 6.6.2	In-vitro Cytogenicity study in mammalian cells	
effects		
4.3 Duplicate assay	Yes	
	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]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Cytotoxicity observed. No genotoxicity observed	
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	

Section 6.6.2(1) **Annex Point IIA 6.6.2**	**In-vitro Cytogenicity study in mammalian cells**
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*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 6.6.2(1) – 1: Summary of Test Results – Experiment 1

Treatment (µg/mL)	S9 Activation	Treatment Time	Mean Mitotic Index	Cells Scored	Total Number of Aberrations +Gaps - Gaps	Cells with Numerical Aberrations + Gaps(%)	Cells with Structural Aberrations - Gaps(%)
Vehicle	-	4	4.2	200	11 7	5.0	3.5
ADBAC							
4	-	4	3.2	200	6 1	3.0	0.5
8	-	4	2.7	200	2 1	1.0	0.5
16	-	4	1.5	200	7 5	3.0	2.0
Positive control [redacted] 0.4	-	4	2.2	200	83 64	32.0	26.0**
Vehicle	+	4	3.9	200	5 1	2.5	0.5
ADBAC							
8	+	4	2.3	200	4 1	2.0	0.5
16	+	4	2.1	200	7 4	2.5	1.0
20	+	4	1.6	200	7 3	3.5	1.5
Positive control [redacted] 12.5	+	4	1.4	300	76 45	20.0	12.0**

Treatment: Cells from the 4-hour treatment regimens were harvested 20 hours after the initiation of the treatments.

Frequency of Aberrant Cells: **, $p \leq 0.001$

Table 6.6.2(1) – 2: Summary of Test Results – Experiment 2

Treatment (µg/mL)	S9 Activation	Treatment Time	Mean Mitotic Index	Cells Scored	Total Number of Aberrations +Gaps - Gaps	Cells with Numerical Aberrations + Gaps(%)	Cells with Structural Aberrations - Gaps(%)
Vehicle	-	4	7.0	200	4 1	2.0	0.5
ADBAC							
4	-	24	4.9	200	6 4	2.0	1.0
8	-	24	2.7	200	6 6	2.5	2.5
12	-	24	2.6	200	12 2	6.0	1.0
Positive control [redacted] 0.2	-	24	2.3	200	115 86	37.0	30.0**
Vehicle	+	4	5.9	200	8 4	2.5	0.5
ADBAC							
8	+	4	5.2	200	7 3	3.5	1.5
16	+	4	3.3	200	0 0	0	0
24	+	4	3.4	200	1 1	0.5	0.5
Positive control [redacted] 12.5	+	4	1.4	200	108 79	33.5	27.0**

Treatment: Cells from both the 4-hour and 24 hour treatment regimens were harvested 20 hours after the initiation of the treatments.

Frequency of Aberrant Cells: **, $p \leq 0.001$

Section 6.6.3(1) Annex Point IIA 6.6.3	***In vitro* gene mutation assay in mammalian cells**	
	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).* Young, R. R. (1989) Mutagenicity test on Alkyl dimethyl benzyl ammonium Chloride (ADBAC) in the CHO/HGPRT forward mutation assay. Report No. 10238-0-435. Hazleton Laboratories America, Inc., Kensington, MD, U.S.A. (Unpublished) [Ref No: A58 (LON 1874)]	
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 FIFRA 84-4 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	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 6.6.3(1) **Annex Point IIA 6.6.3**	***In vitro* gene mutation assay in mammalian cells**	
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]	
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/strain		
3.2.1 Cell type	Female Chinese hamster ovary cells (CHO)	
3.2.2 Strain	CHO-K1-BH_4	
3.3 Metabolic activation		
3.3.1 Metabolic activation system	S9	
3.3.2 Control in presence of metabolic activation	[redacted]	
3.3.3 Control in absence of metabolic activation	[redacted]	
3.4 Test Methods		
3.4.1 Negative control	[redacted]	
3.4.2 Vehicle Control	[redacted]	
3.4.3 Cytotoxicity Concentrations	[redacted]	

Section 6.6.3(1) **Annex Point IIA 6.6.3**	***In vitro* gene mutation assay in mammalian cells**	
3.4.4 Genotoxicity concentrations	[redacted]	X
3.4.5 Statistical methods	[redacted]	
3.4.6 Duplicate/Independent assay	[redacted]	
	4. RESULTS	
4.1 Cytotoxicity		
4.1.1 With Metabolic activation	Completely toxic at 40 µg/ml and higher with activation.	
4.1.2 Without Metabolic activation	Completely toxic at 20 µg/ml and higher without activation	
4.2 Genotoxicity		
4.2.1 With Metabolic activation	Negative Mutation Frequency/10^6 cells Trial I: Control: 6.9, 0 Treated: 0.8 – 6.6 Positive Control (3-MCA): 235.3 Trial II: Control: 1.3, 2.9 Treated: 0.8 – 6.5 (all within historical control range) Positive Control (3-MCA): 131.7	
4.2.1.1 Mutant frequency	Within the acceptable range for background mutant frequencies (0 to 13.5 x 10^{-6} with S9 mix)	
4.2.2 Without Metabolic activation	Negative Mutation Frequency/10^6 cells Trial I:	

Section 6.6.3(1) Annex Point IIA 6.6.3	*In vitro* gene mutation assay in mammalian cells	
	Control: 0, 7.2 Treated: 0 – 4.0 Positive Control (BrdU): 133.3 Trial II: Control: 8.9, 2.9 Treated: 0.8 – 14.6 (all within historical control range) Positive Control (BrdU): 114.0	
4.2.2.1 Mutant Frequency	Acceptable range for background mutant frequencies (0 to 15 x 10^{-6} without S9 mix)	
4.3 Duplicate/ Independent assay	Negative	
	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]	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Not genotoxic.	
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.)*	

Section 6.6.3(1) Annex Point IIA 6.6.3	*In vitro* gene mutation assay in mammalian cells
	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	[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*