Section 6.8.2(1) **Annex Point IIA 6.8.2**		**Two generations reproduction study**	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* Alkyldimethylbenzylammonium Chloride was not toxic to reproduction in this study. NOEL (parental) = 1000 ppm NOEL (F1 offspring) = 1000 ppm NOEL (F2 offspring) = 1000 ppm	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	No *(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]	
		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*	

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

Section 6.9 Annex Point IIIA.6.9	Neurotoxicity study
Conclusion	Applicant's proposal for not presenting data on neurotoxicity is acceptable, pending the justification amendements 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 6.10 Annex Point IIIA.6.10	Mechanistic 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 justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 6.10 **Annex Point IIIA.6.10**	**Mechanistic 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 6.11 **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]
[redacted]	[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 sites 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	No incidences of poisoning have been reported.	
6.12.3 Health records, both from industry and any other available sources	No incidences of contamination have been 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	
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 IIIA.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	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 6.14 Annex Point IIIA.6.14	Other test(s) related to the exposure of humans	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Applicant's justification is acceptable	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 6.15.1 Annex Point IIIA.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	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	

Section 6.15.1 **Annex Point IIIA.6.15.1**	**Residues in food/ feedstuffs**
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 IIIA.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*	

Section 6.15.2 Annex Point IIIA.6.15.2	Behaviour of residues in food/ feedstuffs
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 6.15.3 Annex Point IIIA.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 IIIA.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 IIIA.6.15.4	Proposed acceptable residues	
	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 6.15.4 **Annex Point IIIA.6.15.4**	**Proposed acceptable residues**
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	*Applicant's justification is*
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 6.15.5 Annex Point IIIA.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*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.15.6 Annex Point IIIA.6.15.6	Summary of 6.15	
	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	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion	*Applicant's justification is acceptable*	

Section 6.15.6 **Annex Point IIIA.6.15.6**	**Summary of 6.15**
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 6.16 **Annex Point IIIA.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	*The applicant's justification is acceptable*	
Conclusion		
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 IIIA.6.17**	**Assessment of toxic effects of metabolites from treated plants**	
	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 6.17 **Annex Point IIIA.6.17**	**Assessment of toxic effects of metabolites from treated plants**
	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]	X
Irritation and Sensitisation	[redacted]	X
Repeated dose toxicity, neurotoxicity and carcinogenicity	[redacted]	X X

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

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Date	[redacted]	
[redacted]	[redacted]	
Acute Toxicity	[redacted]	
Irritation and Sensitization	[redacted]	

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only
Repeated dose toxicity, neurotoxicity and carcinogenicity	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	[redacted]	
Remarks		

Section 6.18 Annex Point IIA. 6.18	Summary of mammalian toxicology and conclusions (in Doc. II-A)	Official use only

Section 7.1 Fate and behaviour in water
Annex Point IIA 7.1 – headline only

Section 7.1.1 Degradation, initial studies
Annex Point IIA 7.1.1 – headline only

Section 7.1.1.1 Abiotic
Annex Point IIA 7.1.1.1 – headline only

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	Carpenter, M. and FennesseyM. (1988) Hydrolysis of ADBAC as a Function of pH at 25 °C. Report number 35712. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, U. S. (Unpublished) [Ref No.: A2 (LON 1870)]	
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 Guideline subdivision N 161-1 1987	
2.2 GLP (only where required)	Yes	
2.3Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lot/Batch number	[redacted]	X
3.1.2 Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous solution.	

Section 7.1.1.1.1 (1) **Annex Point IIA 7.1.1.1**		**Hydrolysis as a function of pH and identification of breakdown products**	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	
3.1.5	Stability	The non-radiolabelled 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 procedure**	[redacted]	
3.3	**Method of analysis**	[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**	pH 5 = > 30 day(s) at 25 °C pH 7 = > 30 day(s) at 25 °C pH 9 = > 30 day(s) at 25 °C.	
4.4	**Remarks**	An accurate estimate of the half-life for hydrolysis could not be determined as no significant degradation could be detected over the 30 day evaluation period.	
		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.*	

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	
	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test substance was found to be hydrolytically stable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
Remarks		
	COMMENTS FROM	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	

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**
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Section 7.1.1.1.2 (1) Annex Point IIA 7.1.1.1.2	Phototransformation in water including identity of the products of transformation	
	1. REFERENCE	Official use only
1.1 Reference	Carpenter, M. and Fennessey, M. (1988) Determination of the Photolysis rate of ADBAC in pH 7 Buffered Solution at 25 °C. Report number 35713. Analytical Bio-Chemistry Laboratories, Inc., Columbia, MO, U. S. (Unpublished) [Ref No.: A1 (LON 1871)]	
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 Guideline subdivision N 161-2 "Photodegradation studies in water" 1987	
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	
	3. MATERIALS AND METHODS	
3.1 Test material	Alkyldimethylbenzylammonium Chloride	
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 2.7 and 2.8 of Annex IIA.Sections 2.6-2.8 therein. Active substance (a.s.), alkyl(C_{12}-C_{16})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.4 Stability	The non-labelled 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,	

Section 7.1.1.1.2 (1) Annex Point IIA 7.1.1.1.2	Phototransformation in water including identity of the products of transformation	
	e.g. at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.5 Method of analysis	[redacted]	
3.2 Testing procedure		
3.2.1 Light source	[redacted]	
3.2.2 Light spectrum	[redacted]	
3.2.3 Light intensity	[redacted]	
3.2.4 Exposure period	[redacted]	
3.2.5 Sensitiser	[redacted]	
	4. RESULTS	
4.1 Results of test substance		
4.1.1 Initial concentration of test substance	[redacted]	
4.2 Direct Photolysis		
4.2.1 Half Life	> 30 days	
4.2.2 Degradation %	0% after 30 days	
4.3 Indirect Photolysis		
4.3.1 Half Life	10.9 days (exposed)	
4.3.2 Degradation %	83% after 30 days	
4.3.3 Rate Constant	0636 days (exposed)	
4.3.4 Breakdown products	Occurred only in the presence of a photosensitiser when exposed to light. Essentially all of the ^{14}C-moiety not present as parent compound was found in one degradate.	
4.4 Remarks	Based on the data generated during this study, ADBAC was found to be photolytically stable in the absence of a photosensitiser. An accurate estimate of the photolysis rate constants and the half-life for solutions containing no photosensitiser and all dark controls (both sensitised and nonsensitised) could not be determined since no significant degradation of the test substance was detected during the 30-day evaluation period. The overall mean ^{14}C-activity accountability for this study was 99.3% for the nonsensitised samples and 97.8% for the sensitised samples.	

Section 7.1.1.1.2 (1) **Annex Point IIA 7.1.1.1.2**	**Phototransformation in water including identity of the products of transformation**	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	ADBAC is photolytically stable in the absence of a photosensitising agent. In the presence of the energy from a xenon arc lamp and the photosensitising agent, acetone, it appears that ADBAC breaks down to form a single degradate.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
Remarks		

Section 7.1.1.1.2 (1) **Annex Point IIA 7.1.1.1.2**	**Phototransformation in water including identity of the products of transformation**
	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 7.1.1.2 Biotic
Annex Point IIA 7.1.1.2 – headline only

Section 7.1.1.2.1(1) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	Bazzon, M and Deschamps, F. (2002) Biotic degradation: biodegradability evaluation in aqueous medium: ultimate aerobia of the referenced compounds, CATIGENE T 50 for Stepan Europe, by INERIS; INERIS Study 506223 (Unpublished). [Ref No.: A88 (LON 3796)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	Data submitted to the MS 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 EEC Guideline 84/449 -Method C5 2002	
2.2 GLP (only where required)	No (study conducted under the principles of GLP but not in full compliance – well documented study)	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	
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_{18})dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous/ethanol solution.	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted] Refer to Section 2 of Annex IIA of Directive 98/8/EC, especially	

Section 7.1.1.2.1(1) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
	Sections 2.6-2.8 therein, for specifications of percent active substance, purity and typical impurities.	
3.1.5 Stability	The a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, *e.g.* at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2 Test procedure		
3.2.1 Test system	Activated sludge, non-adapted	
3.2.2 Contact time	28 days	
3.2.3 Control substance	[redacted]	
3.2.4 Type	Aerobic	
	4. RESULTS	
4.1 Results of test substance		
4.1.1 Initial concentration of test substance	[redacted]	
4.2 Kinetics		
4.2.1 Test substance	See Table 7.1.1.2.1(1)-1	
4.2.2 Control	See Table 7.1.1.2.1(1)-1	
4.2.3 Remarks	The test substance is readily biodegradable.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	

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	[redacted]	
5.3 Conclusion	The test substance is readily biodegradable.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Materials and Methods	[redacted]	
Results and discussion	[redacted]	
Conclusion	[redacted]	
Reliability	[redacted]	
Acceptability	Acceptable	
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 7.1.1.2.1(1)-1. % Degradation of Alkyldimethylbenzylammonium Chloride (ADBAC) and control.

Day	% degradation ADBAC 5(mg/l)	% degradation ADBAC 10(mg/l)	% degradation control [redacted]
0	0	0	
5	9.5	0.65	
15	55.3	4.65	
28	71.6	5.0	

Section 7.1.1.2.1(2) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
	1. REFERENCE	Official use only
1.1 Reference	Hirschen, M., Ziemer, M and Seifert, D. (1997) Pürfung der biologischen Abbaubarkeit (ready biodegradability) gemäß OECD-Richtlinie 301A (DOC Die-Away Test). Report No. D0457. Clariant GmbH, Frankfurt, Germany. (Unpublished) [Ref No.: A44 (LON 3435)]	
1.2 Data protection	Yes	
1.2.1 Data owner	ADBAC Issues Steering Committee	
1.2.2 Criteria for data protection	Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD Guideline 301 A "Ready Biodegradability: DOC Die Away Test" 1997	
2.2 GLP (only where required)	No	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted] Cocodimethylbenzylammonium Chloride[redacted]	
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]	
3.1.3 Description	[redacted]	
3.1.4 Purity	[redacted]	
3.1.5 Stability	The a.s. is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable for extended periods (see Section 2.6.1 of Annex IIA).	
3.2 Test procedure		

Section 7.1.1.2.1(2) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**	
3.2.1 Test system	Activated sludge, non-adapted	
3.2.2 Contact time	28 days	
3.2.3 Control substance	[redacted]	
3.2.4 Type	Aerobic	
	4. RESULTS	
4.1 Results of test substance		
4.1.1 Initial concentration of test substance	[redacted]	
4.2 Kinetics		
4.2.1 Test substance	See Table 7.1.1.2.1(2)-1 85% degradation after 28 days	
4.2.2 Control	See Table 7.1.1.2.1(2)-1 99% degradation after 4 days	
4.2.3 Remarks	The test substance is readily biodegradable.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	The test substance is readily biodegradable.	
5.3.1 Reliability	[redacted]	

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5.3.2 Deficiencies	[redacted]
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE
	Give date of the comments submitted
Date	*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*
Materials and Methods	*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	

Table 7.1.1.2.1(2)-1. % Degradation of ADBAC and control.

Day	% degradation ADBAC	% degradation control
0	0	[redacted]
1	5	
4	8	
11	67	
14	85	
21	84	
28	85	

n/d no data

Section 7.1.1.2.1(3) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**	
	1. REFERENCE	Official use only
1.1 Reference	Corby, J. E. (1992) CO_2 Production Test – Hyamine 3500-80. Report No. 91-066. Roy F. Weston, Inc., Lionville, PA, U. S. (Unpublished) [Ref No.: A4 (LON 2301)]	
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 OECD Guideline 301B 1991	
2.2 GLP (only where required)	Yes	
2.3 Deviations	No	
	3. MATERIALS AND METHODS	
3.1 Test material	[redacted]	
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 ethanol solution.	
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 7.1.1.2.1(3) Annex Point IIA 7.1.1.2.1	Ready biodegradability	
3.2 Test procedure	[redacted]	
3.2.1 Test system	Acclimated activated sludge, [redacted]	
3.2.2 Contact time	28 days	
3.2.3 Temperature range	[redacted]	
	4. RESULTS	
4.1 Kinetics	See Table 7.1.1.2.1(3)-1	
4.2 Final results	See Table 7.1.1.2.1(3)-2 84.0% and 82.6% CO_2 was produced in vessels dosed with 5 mg/L and 10 mg/L Hyamine 3500-80 respectively.	
4.3 Remarks	The test substance was found to be biodegradable.	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	X
5.3 Conclusion	The test material was considered readily biodegradable.	
5.3.1 Reliability	[redacted]	X

Section 7.1.1.2.1(3) **Annex Point IIA 7.1.1.2.1**	**Ready biodegradability**
5.3.2 Deficiencies	[redacted]
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	Acceptable
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.1.1.2.1(3)-1. $\%TCO_2$ over time

Day	[redacted]	[redacted] 5 mg active/L	[redacted] 10 mg active/L
2	[redacted]	9.3	1.8
5	[redacted]	43.8	39.1
8	[redacted]	58.5	54.2
11	[redacted]	75.4	67.9
14	[redacted]	85.0	76.0
17	[redacted]	88.5	80.2
20	[redacted]	87.2	81.6
23	[redacted]	85.6	81.9
28	[redacted]	85.0	82.3
28	[redacted]	84.0	82.6

Table 7.1.1.2.1(3)-2. Final results

Test substance	Concentration (mg active/L)	Final %TCO2	Final SOC (ml/L)
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	5	84.0	0.7
[redacted]	10	82.6	0.6