Section 7.4.3.5.1 **Annex Point IIIA.7.4.3.5.1**	**Second and third study on effects on sediment dwelling organisms**
Evaluation of applicant's justification	[redacted]
Conclusion	*A "second and third study on effects on sediment dwelling organisms" is not required.*
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 7.4.3.5.2(1) **Annex Point IIIA.7.4.3.5.2**	**Aquatic plant toxicity**	
	1. REFERENCE	Official use only
1.1 Reference	Desjardins, D., J.A. McGregor and H.O. Krueger. (2005) A 7-Day Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC; 40% C_{12}, 50% C_{14}, 10% C_{16}; CAS RN 68424-85-1) with Duckweed (*Lemna gibba* G3). Study Number 650A-105. Wildlife International, Ltd., Easton, MD, USA. (Unpublished) [Ref. No. A120 (LON 4001)]	
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 **U.S. ENVIRONMENTAL PROTECTION AGENCY SERIES 850 – ECOLOGICAL EFFECTS TEST GUIDELINES OPPTS NUMBER 850.4400** **ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD) REVISED PROPOSAL FOR A NEW GUIDELINE 221 (JULY 2002)** *(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 7.4.3.5.2(1) Annex Point IIIA.7.4.3.5.2		Aquatic plant toxicity	
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 2.7 and 2.8 of Annex IIA 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	**Testing procedure**		
3.2.1	Test Medium	[redacted] algal medium	
3.2.2	Test organisms	Duckweed, *Lemna gibba* G3, [redacted]	
3.2.3	Test system	[redacted]	X
3.2.4	Test conditions	The test was carried out at 25 ± 2°C, 5000 ± 750 lux (continuous). [redacted]	
3.2.5	Duration of the test	7 days	
3.2.6	Test parameter	Frond number, biomass and growth rate (frond number and biomass)	
3.2.7	Nominal Concentrations of Test Substance	[redacted]	
3.2.8	Monitoring of test	[redacted]	

Section 7.4.3.5.2(1) Annex Point IIIA.7.4.3.5.2		Aquatic plant toxicity	
	substance		
3.2.9	Analysis	[redacted]	
3.2.7	Statistics	[redacted]	
		4. RESULTS	
4.1	**Limit test**	No	
4.2	**Results of test substance**		
4.2.1	Day 0 concentrations of test substance	<LOQ (Negative Control), 0.019, 0.043, 0.090, 0.21, 0.41 and 1.0 mg a.s./l	
4.2.2	Day 4 concentrations of test substance	<LOQ (Negative Control), <LOQ, <LOQ, <LOQ, 0.0085, 0.074 and 0.44 mg a.s./l	X
4.2.3	Remarks	Effect values were reported on the basis of Day 0 measured concentrations due to the decline in test concentration over the 96-hour exposure period.	X
4.3	**Environmental Conditions**	[redacted]	
4.3	**Effect data**		
4.3.1	Growth (Frond Number)	EC_{50} (95% Confidence Interval) = 0.12 mg a.s./l (0.045 – 0.17 mg a.s./l) NOAEC = 0.019 mg a.s./l	
4.3.2	Biomass	E_bC_{50} (95% Confidence Interval) = 0.13 mg a.s./l (0.030 – 0.18 mg a.s./l) NOAEC = 0.043 mg a.s./l	
4.3.3	Growth rate	Frond Number: E_rC_{50} (95% Confidence Interval) = 0.25 mg a.s./l (0.16 – 0.33 mg a.s./l) NOAEC = 0.043 mg a.s./l Biomass:	

Section 7.4.3.5.2(1) Annex Point IIIA.7.4.3.5.2	Aquatic plant toxicity	
	E_rC_{50} (95% Confidence Interval) = 0.37 mg a.s./l (0.31 – 0.45 mg a.s./l) NOAEC = 0.043 mg a.s./l	
4.3.3 Other effects	See Table 7.4.3.5.2-1.	
4.3 Results of controls	[redacted]	X
	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* [redacted]	X

Section 7.4.3.5.2(1) Annex Point IIIA.7.4.3.5.2	Aquatic plant toxicity	
	[redacted]	
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	*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*	

Section 7.4.3.5.2(1) **Annex Point IIIA.7.4.3.5.2**	**Aquatic plant toxicity**
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 7.4.3.5.2-1

Day 0 Measured Concentration (mg a.s./L)	Day 3 Percentage [1]				Day 5 Percentage [1]				Day 7 Percentage[1]			
	F [2]	D	C	N	F [2]	D	C	N	F [2]	D	C	N
Negative Control	44	0.0	0.0	0.0	93	0.0	0.0	0.0	228	0.0	0.69	0.58
0.019	44	0.0	0.0	0.0	95	0.0	0.0	0.0	221	0.0	0.0	1.4
0.043	43	0.0	0.0	0.74	87	0.0	0.0	1.2	198	0.0	0.16	2.2
0.090	38	0.0	0.0	1.8	62	0.0	0.0	0.48	134	0.0	0.0	5.4
0.21	31	0.0	1.1	0.0	46	0.0	0.69	0.0	63	0.56	64	12
0.41	30	0.0	3.3	6.6	39	0.0	2.7	5.3	43	4.8	45	29
1.0	26	0.0	3.7	6.6	27	0.0	0.0	40	29	10	44	36

D = Dead; C = Chlorotic; N = Necrotic
[1] Values represent the average percentage of dead, chlorotic or necrotic fronds for the three replicates per treatment.
[2] F = mean number of fronds per treatment or control group on each observation day. Number of fronds per treatment and control group on Day 0 = 15.

Section 7.5 Effects on terrestrial organisms
Annex Point IIA 7.5- headline only

Section 7.5.1 Terrestrial toxicity, initial tests
Annex Point IIA 7.5.1-headline only

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition on microbial activity**	
	1. REFERENCE	Official use only
1.1 Reference	De Vette, H.Q.M., R. Hanstveit and J. A. Schoonmade (2001). The Assessment of the Ecological Effects of Alkyldimethylbenzyl-ammonium Chloride (Guidelines OPPTS 850.5100 Soil Microbial Community Test, OECD 216 and OECD 217 and CTB section H.4.1). TNO Chemistry, Delft, The Netherlands. Report No. IMW-99-9072-02 (unpublished). [Ref No: A87 (LON 3382)]	
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 Guideline 216 and 217 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")*	X
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	

Section 7.5.1.1(1) Annex Point IIA 7.5.1.1		Inhibition on microbial activity	
3.1.1	Lot/Batch number	*List lot/batch number where relevant* [redacted]	X
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 conditions**		
3.2.1	Soil	Sandy loam and low humic content sand	X
3.2.2	Source	[redacted]	
3.2.3	Soil additive	[redacted]	
3.3.	Test procedure		
3.3.1	Duration of test	28 days	
3.3.2	Test parameters	Nitrite, nitrate, ammonium and carbon dioxide formation	
3.3.3	Control	[redacted]	
3.3.4	Test method	[redacted]	
3.3.5	Sampling	[redacted]	
3.3.6	Statistics		X

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition on microbial activity**	
	4. RESULTS	
4.1 Nitrogen metabolism	No	
4.1.1 Nitrate formation	Significant reduction in nitrate formation was observed in the low humic content sand soil at 10 and 1,000 ug/g after 5 days incubation; however no relevant reduction in nitrate formation was observed in treated soils relative to untreated soils after 28 days of incubation.	X
4.1.2 Nitrite formation	Significant reduction in nitrite formation was observed in the low humic content sand soil at 10 and 1,000 ug/g after 5 days incubation; however no relevant reduction in nitrate formation was observed in treated soils relative to untreated soils after 28 days of incubation.	X
4.1.3 Ammonium formation	No significant reduction in ammonium formation was observed.	
4.2 Carbon metabolism		
4.2.1 Microbial biomass	Values were considered to be characteristic for the soil types.	
4.2.2 Carbon content	Values were considered to be characteristic for the soil types.	
4.2.3 Carbon dioxide formation	No significant reduction in carbon dioxide formation was observed.	X
4.3 Remarks	The test substance can be considered as having a low potential for adversely affect the microbial functions in sandy loam and low humic content sand soils.	
	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.* The test substance can be characterised as having no long-term influence on nitrogen or carbon transformations in soils.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The test substance has low potential for adversely affecting the microbial functions in sandy loam and low humic content sand soils.	
5.3.1 Reliability	*Based on the assessment of materials and methods include appropriate*	

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition on microbial activity**	
	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	*Acceptable*	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE	

Section 7.5.1.1(1) **Annex Point IIA 7.5.1.1**	**Inhibition on microbial activity**
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 7.5.1.1(1)-1. Nitrate formation

Dose concentration (µg/g)	Mean nitrate formation rate (mg/kg dry weight/day)				% Reduction			
	Low humic content sand		Sandy loam		Low humic content sand		Sandy loam	
Day	5	28	5	28	5	28	5	28
0	2.71	2.19	4.86	1.09	---	---	---	---
10	1.41	2.16	8.21	0.97	47.9[a]	1.2	-68.9	11.5
100	2.12	1.99	6.09	1.18	21.7	9.2	-25.3	-8.3
1000	1.99	1.97	4.44	1.33	26.7[a]	9.8	8.7	-21.9

[a] Significant relevant reduction effect.

Table 7.5.1.1(1)-2. Nitrite formation

Dose concentration (µg/g)	Mean nitrite formation rate (mg/kg dry weight/day)				% Reduction			
	Low humic content sand		Sandy loam		Low humic content sand		Sandy loam	
Day	5	28	5	28	5	28	5	28
0	0.35	0.02	0.80	0.02	---	---	---	---
10	0.18	0.02	0.14[a]	0.01	48.7[a]	-1.5	82.5[a]	14.4
100	0.20	0.02	0.16	0.01	42.3[a]	13.6	79.7[a]	7.9
1,000	0.21	0.04	0.35[a]	0.01	42.3[a]	-51.1	56.4[a]	11.3

[a] Significant relevant reduction effect.

Table 7.5.1.1(1)-3. Ammonium formation

Dose concentration (µg/g)	Mean ammonium formation rate (mg/kg dry weight/day)				% Reduction			
	Low humic content sand		Sandy loam		Low humic content sand		Sandy loam	
Day	5	28	5	28	5	28	5	28
0	2.36	0.29	1.66	0.10	---	---	---	-
1,000	4.26	0.26	1.96	0.10	-80.6	11.0	-18.4	-5.6

Table 7.5.1.1(1)-4. Biomass and carbon content

Parameter	Low humic content sand	Sandy loam
Microbial biomass (µgC/g)	142	14
Carbon content (mgC/g)	5	9
Carbon content assumed to be in the biomass (%)	0.3	1.6

Table 7.5.1.1(1)-5. Carbon dioxide production

Dose concentration (µg/g)	Mean carbon dioxide formation rate (mg/kg dry weight/day)				% Reduction			
	Low humic content sand		Sandy loam		Low humic content sand		Sandy loam	
Day	5-8	25-28	5-8	25-28	5-8	25-28	5-8	25-28
0	284.0	28.6	237.9	25.7	---	---	---	---
10	323.4*	30.3*	243.8*	34.2	-13.9*	-6.0[b]	-2.5*	-33.1
100	323.6	32.8*	273.0	30.4	-14.0	-14.7*	-14.8	-18.5
1,000	191.4	88.7	183.5	38.9	32.6[a]	-210.3	22.9	-51.4

[a] Significant relevant reduction effect.

* deviation between replicates was > 15%. Percentage reduction < 50% (Criteria OPPTS for relevant reduction)

[b] deviation between replicates was > 15%. Range of percentage reduction (-37.4-52.8), i.e. the maximum reduction is slightly higher than 50% (Criteria OPPTS for relevant reduction).

Section 7.5.1.2(1) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	1. REFERENCE	Official use only
1.1 Reference	Rodgers, M. H. (2004). N-Alkyl (C12-16)-N,N-Dimethyl –N-Benzylammonium Chloride (ADBAC) Acute Toxicity (LC_{50}) to the Earthworm. HLS. Report No.: ADB023/033976 (unpublished). [Ref No: A95 (LON 3799)]	
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 Guideline No. 207 for Testing Chemicals "Earthworm, acute toxicity tests" Directive 88/302/EEC, Part C, Methods for determination of ecotoxicity, "Toxicity for earthworms: Artificial soil test" 1988 *(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]	

Section 7.5.1.2(1) **Annex Point IIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
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.	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).	
3.1.6 Method of analysis		
3.2 Test procedure	[redacted]	
3.2.1 Test organisms	Earthworms *Eisenia foetida foetida* [redacted]	
3.2.2 Test system	Artificial OECD 207 soil, [redacted]	
3.2.3 Test conditions	[redacted]	
3.2.4 Duration of the test	14 days	
3.2.5 Test parameter	Mortality, behavioural and pathological signs.	
3.2.6 Sampling	[redacted]	
3.2.7 Monitoring of the test substance		

Section 7.5.1.2(1) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
concentration		
3.2.8 Statistics	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results of test substance		
4.2.1 Initial concentration of test substance	[redacted]	X
4.2.2 Actual concentration of test substance	[redacted]	
4.2.3 Effect data (Mortality)	See Table 7.5.1.2(1)-1	
4.2.4 Concentration/ response curve	Day 7 LC50 = 7160 ppm (95% confidence limits 5560-7590 ppm) slope = 53.6 Day 14 LC50 = 7070 ppm (95% confidence limits 5560-7400 ppm) slope = 52.9	X
4.2.5 Other effects	A treatment-related decrease in body weight was observed, see Table 7.5.1.2(1)-2	
4.3 Results of controls	[redacted]	
	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.* LC_{50} values for day 7 and day 14 were 7160 and 7070 ppm a.s., respectively. The NOEC was 953 ppm a.s. A treatment-related reduction in body weight was observed.	X

Section 7.5.1.2(1) **Annex Point IIA 7.5.1.2**		**Acute toxicity test to earthworms or other soil non-target organisms**	
5.3	**Conclusion**	*Subsections for NOAEL, LOAEL etc. if appropriate* The 14-day LC_{50} was 7070 ppm. The NOEC was 953 ppm a.s.	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]	
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*	

Section 7.5.1.2(1) **Annex Point IIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**
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 7.5.1.2(1)1 Cumulative mortality data

Group No.	Treatment (ppm a.s.)	Initial No. worms	Mortality		Total worms as %
			Day 7	Day 14	
1	0	40	0	0	0
2	953	40	0	0	0
3	1715	40	0	0	0
4	3086	40	0	0	0
5	5556	40	2	3	7.5
6	10000	40	40	40	100

Table 7.5.1.2(1)-2 Mean bodyweights (mg)

Group	Treatment (ppm a.s.)	Day 0	Day 14	% decrease
1	0	388	334	14
2	953	389	340	13
3	1715	390	323	17
4	3086	386	304	21
5	5556	389	250	36
6	10000	392	n/d	n/d

n/d no data (as all worms in this group had died)

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	1. REFERENCE	Official use only
1.1 Reference	Gray, J. (2004) N-Alkyl (C12-C16)-N,N-Dimethyl-N-Benzylammonium Chloride (ADBAC) – Acute Toxicity to Terrestrial Plants. Huntingdon Life Sciences (Study no. ADB/024) (unpublished). [Ref No: A94 (LON 3800)]	
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 Guideline 208 *(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")*	X
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):* 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.	X

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3		Acute toxicity to plants	
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	**Testing conditions**		
3.2.1	Test species	Mustard *(Brassica alba),* Mung bean (*Phaseolus aureus*) and Wheat (*Triticum aestivum*)	
3.2.2	Source	[redacted]	
3.2.3	Humidity	[redacted]	
3.2.4	Temperature	[redacted]	
3.2.5	Light intensity	[redacted]	
3.3	**Test procedure**		
3.3.1	Duration of test	18-20 days	
3.3.2	Control	[redacted]	X
3.3.3	Test method	[redacted]	X
3.3.4	Sampling	[redacted]	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	weight.	
3.3.5 Statistics		X
	4. RESULTS	
4.1 Observations		
4.1.1 Herbicidal symptoms	For all plant species there was significant growth inhibition at the higher rates of application. The mean visual assessment scores for mustard were 7.25 and 8.88 at 375 and 1200 mg a.s./kg respectively and 6.37 for wheat at 1200 mg a.s./kg. For mung bean the mean scores were 4.25 and 6.26 at 1250 and 2500 mg a.s./kg respectively. (Scoring: 0 = no abnormal effects, to 10 = all plants within a replicate were dead.)	X
4.1.2 Wet weight	For mustard, 117 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in wet weight, which was reduced by 37, 74 and 86% at 117, 375 and 1200 mg a.s./kg respectively. For wheat, 375 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in wet weight, which was reduced by 51 and 87% at 375 and 1200 mg a.s./kg respectively. For mung bean, 625 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in wet weight, which was reduced by 26, 44 and 56% at 625, 1250 and 2500 mg a.s./kg respectively.	
4.1.3. Dry weight	For mustard, 117 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in dry weight, which was reduced by 25, 64 and 74% at 117, 375 and 1200 mg a.s./kg respectively. For wheat, 375 mg a.s./kg and higher gave a significant reduction in dry weight, which was reduced by 35 and 80% at 375 and 1200 mg a.s./kg, $p<0.05$ and <0.001, respectively. For mung bean, 625 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in dry weight, which was reduced by 29, 43 and 54% at 625, 1250 and 2500 mg a.s./kg respectively.	
4.1.4 Growth	For all plant species there was significant growth inhibition at the higher rates of application.	
4.1.5 Bulk	Reductions in wet and dry weight at harvest are indicative of a reduction in bulk.	
4.1.6 Mortality	Mustard: 10 and 17% at 375 and 1200 mg a.s./kg respectively. Wheat: 9% at 1200 mg a.s./kg Mung bean: 2.5% at 1250 mg a.s./kg (not treatment-related)	X

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
4.2 Remarks		
	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.* Mustard: LC_{50} = 277 mg/kg (dry weight) Wheat: LC_{50} = 659 mg/kg (dry weight) Mung: LC_{50} = 1900 mg/kg (dry weight)	X
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The results of the study indicate that Alkyldimethylbenzylammonium Chloride is slightly toxic to terrestrial plants.	
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 7.5.1.3 (1) Annex Point IIA 7.5.1.3	**Acute toxicity to plants**
	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

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants
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 7.5.1.3 (1)-1 Geometric Mean Dry weight results

Species	Treatment	Soil concentration (mg a.i./Kg dry soil	Mean dry weight (mg)	Mean % reduction compared to control
Mustard (*Brassica alba*)	Water control	--	21.1	0
	ADBAC	12	21.1	0
		37	19.7	6
		117	15.8	25**
		375	7.5	64**
		1200	5.5	74**
Wheat (*Triticum aestivum*)	Water control	--	36.7	0
	ADBAC	12	29.1	21
		37	34.5	6
		117	28.3	23
		375	24.4	33*
		1200	7.5	80**
Mung bean (*Phaseolus aureus*)	Water control	--	77.6	0
	ADBAC	156	68.5	12
		313	70.6	9
		625	55.0	29**
		1250	44.3	43**
		2500	35.8	54**

* $p < 0.05$
** $p < 0.001$

Table 7.5.1.3 (1)-2 EC_{50} (inhibition of dry weight) and 95% confidence intervals

Species	EC_{50} (mg a.i./Kg dry soil)	95% Confidence iInterval
Mustard (*Brassica alba*)	277	222 - 347
Wheat (*Triticum aestivum*)	670	442 - 972
Mung bean (*Phaseolus aureus*)	1900	1480 - 2520

Section 7.5.2 Terrestrial tests, long-term tests
Annex Point IIA 7.5.2- headline only

Section 7.5.2.1 **Annex IIIA Point 7.5.2.1**	**Reproduction study with other soil non-target macro-organisms**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	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 7.5.2.1 Annex IIIA Point 7.5.2.1	**Reproduction study with other soil non-target macro-organisms**
Evaluation of applicant's justification	[redacted]
Conclusion	*No need to submit a further study on soil non target macro-organisms.*
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 7.5.2.2 Annex IIIA Point 7.5.2.2	Long-term test with terrestrial 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 [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	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	*Accepted*	
Conclusion	[redacted]	

Section 7.5.2.2 **Annex IIIA Point 7.5.2.2**	**Long-term test with terrestrial plants**
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 7.5.3 Effects on birds
Annex Point IIA 7.5.3- headline only

Section 7.5.3.1.1(1) **Annex Point IIA 7.5.3.1.1**	**Acute oral toxicity**	
	1. REFERENCE	Official use only
1.1 Reference	Campbell, S.M. and Jaber, M. (1993) An Acute Oral Toxicity Study with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) in the Northern Bobwhite Quail. Report No. 289-109. Wildlife International Ltd., Easton, MD, USA. (Unpublished) [Ref No.: A59 (LON 3801)]	
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 71-1 1993 *(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]	
3.1.2 Specification	*(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	X

Section 7.5.3.1.1(1) Annex Point IIA 7.5.3.1.1	Acute oral toxicity	
	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 Animals		
3.2.1 Species	Northern bobwhite quail *Colinus virginianus*	
3.2.2 Source	[redacted]	
3.2.3 Sex	Male and female	
3.2.4 Age/weight at study initiation	[redacted]	
3.2.5 Number of animals per group	[redacted]p	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Oral intubation	
3.3.2 Post exposure period	14 days	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	

Section 7.5.3.1.1(1) **Annex Point IIA 7.5.3.1.1**	**Acute oral toxicity**	
3.4 Observations, Sacrifice and Pathology		X
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Body weights	[redacted]	
3.4.6 Statistics	[redacted]	X
3.5 Further remarks		
	4. RESULTS	
4.1 Limit Test	No	
4.2 LD_{50} including confidence limits	164 mg/kg b.w. (confidence limits = 125 – 250 mg/kg b.w.)	
4.3 Observations, Sacrifice and Pathology		
4.3.1 Clinical signs	See Table 7.5.3.1.1(1)-1. No clinical signs were observed in control birds or birds dosed with 62.5 mg/kg b.w.	
4.3.2 Mortality	See Table 7.5.3.1.1(1)-2. No mortalities occurred in control birds or birds dosed with 62.5 mg/kg b.w.	
4.3.3 Bodyweight	See Table 7.5.3.1.1(1)-3. No weight loss was observed in control birds or birds dosed with 62.5 mg./kg b.w.	
4.3.4 Statistics	NOEL = 62.5 mg/kg b.w.	
4.4 Further remarks		
	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.* No clinical signs, mortalities or weight loss were observed in birds dosed with 62.5 mg./kg b.w. All birds died when dosed with a	

Section 7.5.3.1.1(1) Annex Point IIA 7.5.3.1.1	Acute oral toxicity	
	concentration of 250 mg/kg b.w. test substance and higher concentrations.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* NOEL = 62.5 mg/kg b.w. LD_{50} = 164 mg/kg b.w.	
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	*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*	

Section 7.5.3.1.1(1) **Annex Point IIA 7.5.3.1.1**	**Acute oral toxicity**
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 7.5.3.1.1(1)-1. Clinical signs

Dose concentration (mg/kg b.w.)	Time clinical signs were first observed	General symptoms
0	None observed	Ruffled appearance, wing droop, loss of co-ordination, lower limb rigidity, lower limb weakness, gasping, lethargy, salivation, prostate posture, reduced reaction to external stimuli (sound and movement), depression and coma
62.5	None observed	
125	Day 1	
250	4.5 hours after dosing	
500	3 hours after dosing	
1000	1.25 hours after dosing	
2000	2 hours after dosing	

Table 7.5.3.1.1(1)-2. Mortality (n=10/group)

Dose concentration (mg/kg b.w.)	Total No. deaths at study termination
0	0
62.5	0
125	4
250	10
500	10
1000	10
2000	10

Table 7.5.3.1.1(1)-3. Body weight data

Dose concentration (mg/kg b.w.)	Body weight (g) day 0		Body weight (g) day 14		Total change	
	male	female	male	female	male	female
0	191	183	202	196	11	13
62.5	186	181	192	191	6	10
125	181	193	173	147	-8	-46
250	182	174	n/d	n/d	n/d	n/d
500	193	186	n/d	n/d	n/d	n/d
1000	185	178	n/d	n/d	n/d	n/d
2000	186	179	n/d	n/d	n/d	n/d

n/d no data as all birds were dead

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
	1. REFERENCE	Official use only
1.1 Reference	Gallagher, S.P., K.H. Martin and J.B. Beavers. (2005) A Dietary LC_{50} Study with Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC; 40% C_{12}, 50% C_{14}, 10% C_{16}; CAS RN 68424-85-1) in the Northern Bobwhite. Report No. 350-101, Wildlife International Ltd., Easton, MD, USA (unpublished). [Ref. No. A117 (LON 3997)]	
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 U.S. Environmental Protection Agency Series 850-Ecological Effects Test Guidelines OPPTS 850.2200 OECD Guideline 205 *(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] Active substance (a.s.), Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC; 40% C_{12}, 50% C_{14}, 10% C_{16}; CAS RN 68424-85-1), in aqueous/ethanol solution	
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [redacted]	

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2		Short-term toxicity	
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 animals**		
3.2.1	Species	Northern bobwhite (*Colinus virginianus*)	
3.2.2	Source	[redacted]	
3.2.3	Sex	Birds were immature and could not be differentiated by sex.	
3.2.4	Age/weight at study initiation	[redacted]	
3.2.5	Number of animals per test group	[redacted]	
3.2.6	Control animals	[redacted]	
3.3	**Administration/ exposure**		
3.3.1	Dose route	Oral feed *ad libitum*	
3.3.2	Exposure period	[redacted]	
3.3.3	Post-Exposure period	[redacted]	
3.3.4	Concentration	[redacted]	

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
	[redacted]	
3.3.5 Vehicle	[redacted]	X
3.3.6 Concentration in vehicle	[redacted]	
3.3.7 Controls	[redacted]	
3.4 Observations, Sacrifice and Pathology		
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.3 Body weights	[redacted]	
3.4.4 Organ weights	[redacted]	
3.4.5 Other examinations	[redacted]	
3.4.6 Statistics	[redacted]	
3.5 Further remarks	[redacted]	
	4. RESULTS	
4.1 Limit test	No	
4.2 LD50 including confidence limits	LC_{50} > 5620 ppm a.s. NOEC = 1000 ppm a.s.	X
4.3 Observations, Sacrifice and Pathology		

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2		Short-term toxicity	
4.3.1	Clinical signs	At the 1780 ppm a.s. test concentration, signs of toxicity were first observed on the morning of Day 3 of the test, when all birds were noted with a slight ruffled appearance. Signs of toxicity, including slight wing droop and ruffled appearance, continued to be observed in all birds through the afternoon of Day 5. With the exception of one bird, all birds at this concentration recovered by the morning of Day 6 and were normal in appearance and behavior for the remainder of the test. One bird began to display clinical signs including reduced reaction to external stimuli (sound and movement), wing droop, loss of coordination, lower limb weakness and ruffled appearance on the morning of Day 6 and continued to display clinical signs until test termination. However, necropsy of this bird following study termination revealed evidence of sub-cranial bruising, possibly the result of a head injury. In the 3160 ppm a.s. treatment group, signs of toxicity were first observed on the afternoon of Day 2, when all birds were noted with a slight ruffled appearance and three birds were also noted with wing droop. Clinical signs of toxicity, including wing droop, ruffled appearance and/or lethargy, were exhibited by all ten birds in this group through the afternoon of Day 6 and by one bird on the morning of Day 7. All birds were normal in appearance and behavior from the afternoon of Day 7 until test termination At the 5620 ppm a.s. test concentration, signs of toxicity were first noted on the afternoon of Day 1, when all birds were exhibiting a ruffled appearance and two birds were also exhibiting some loss of coordination. Clinical signs of toxicity, including reduced reaction to external stimuli (sound and movement), wing droop, loss of coordination, lower limb weakness, ruffled appearance and/or lethargy, continued to be exhibited by all birds in this treatment group through the afternoon of Day 6. All birds at this concentration had recovered by the morning of Day 7 and were normal in appearance and behavior for the remainder of the test.	
4.3.2	Mortality	No treatment-related deaths occurred during the course of the study. At the 562 and 1000 ppm a.s. test concentrations, one animal in each group broke a leg and was euthanized.	
4.3.3	Bodyweight	When compared to the control group, there were no effects on body weight at the 562 and 1000 ppm a.s. test concentration. There were treatment-related, concentration-responsive reductions in bodyweight gains for the birds in the 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period.	
4.3.4	Organ weights	Not applicable	
4.3.5	Other examinations	When compared to the control group, there were no effects on feed consumption at test concentrations up to and including 3160 ppm a.s. There was a reduction in feed consumption in the high dose group on the last day of treatment (Day 5) and the last two days of post-exposure.	
4.3.7	Statistics	Not applicable	
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and		*Give concise description of method; give test guidelines no. and discuss*	