Section 7.5.1.2(2) Annex Point IIA 7.5.1.2	Acute toxicity test to earthworms or other soil non-target organisms	
	4. RESULTS	
4.1 Limit test	No	
4.2 Results of test substance		
4.2.1 Initial concentration of test substance	[redacted]	
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	
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 NOEL was 953 ppm a.s. A treatment related reduction in body weight was observed.	
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.	

Section 7.5.1.2(2) **Annex Point IIA 7.5.1.2**	**Acute toxicity test to earthworms or other soil non-target organisms**	
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		
Results and discussion		
Conclusion		
Reliability	[redacted]	
Acceptability	*Not acceptable:* [redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of the comments submitted*	
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*	
Results and discussion	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	1. REFERENCE	
1.1. **Reference**	Gray, J. (2004) N,N-Didecyl-N,N-Dimethylammonium Chloride (DDAC) – Acute Toxicity to Terrestrial Plants. Huntingdon Life Sciences Report No. DKG/014 (unpublished). Ref. No.: D114 (LON 3811)	
1.2 **Data protection**	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.2 Criteria for data protection	*Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:* Data submitted to the MS 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. 208 2004 *(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**	Didecyldimethylammonium Chloride	
3.1.1 Lot/Batch number	*List lot/batch number where relevan* [redacted]	X
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. [redacted] *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)*	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3		Acute toxicity to plants	
		[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* Stable	
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]	X
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	19-20 days	
3.3.2	Control	[redacted]	
3.3.3	Test method	[redacted]	X
3.3.4	Sampling	[redacted]	
3.3.5	Statistics	[redacted]	

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	Acute toxicity to plants	
	[redacted]	
	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 5.50, 7.75 and 8.50 at 400, 800 and 1600 mg a.s./kg respectively and 4.62 and 6.12 for wheat at 800 and 1600 mg a.s./kg. For mung bean the mean visual assessment was 5.63 at 1280 mg a.s./kg. (Scoring: 0 = no abnormal effects, to 10 = all plants within a replicate were dead.)	
4.1.2 Wet weight	For mustard, [redacted] 200 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in wet weight, which was reduced by 56, 67, 83 and 88% at 200, 400, 800 and 1600 mg a.s./kg respectively. Wet weight was reduced by 34% ($p<0.01$) at 100 mg a.s./kg. For wheat, [redacted] 800 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in wet weight, which was reduced by 74 and 79% at 800 and 1600 mg a.s./kg respectively. Wet weight was reduced by 48% at 400 mg a.s./kg For mung bean, [redacted] 320 mg a.s./kg and higher gave a significant reduction in wet weight, which was reduced by 20, and 44% at 1250 and 2500 mg a.s./kg respectively. See Table 7.5.1.3(1)-1	
4.1.3 Dry weight	For mustard, [redacted] 200 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in dry weight, which was reduced by 45, 54, 76 and 80% at 200, 400, 800 and 1600 mg a.s./kg respectively. Dry weight was reduced by 24% ($p<0.05$) at 100 mg a.s./kg. For wheat, [redacted] 800 mg a.s./kg and higher gave a significant reduction ($p<0.001$) in dry weight, which was reduced by 59 and 64% at 800 and 1600 mg a.s./kg respectively. Wet weight was reduced by 33% at 400 mg a.s./kg For mung bean, [redacted] 1280 mg a.s./kg gave a significant reduction in dry weight, which was reduced by 38%. Dry weight was reduced by 14% at 320 mg a.s./kg. See Table 7.5.1.3(1)-2	X
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: 3 and 11% at 800 and 1600 mg a.s./kg respectively. Wheat: 3% at 1600 mg a.s./kg Mung bean: None See Table 7.5.1.3(1)-3	
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]	

Section 7.5.1.3 (1) **Annex Point IIA 7.5.1.3**	**Acute toxicity to plants**
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.* The test substance had no significant effect on the number of germinated plants for any species. For mustard, all concentrations of the test substance significantly reduced both wet and dry weight. For wheat, the test substance at 400 mg a.s./kg and higher gave a significant reduction for both dry weight and wet weight. For mung bean, at 320 mg a.s./kg and higher gave a significant reduction for both wet and dry weight. Mustard: LC_{50} = 283 mg/kg (dry weight) Wheat: LC_{50} = 857 mg/kg (dry weight) Mung: LC_{50} = 1670 mg/kg (dry weight)
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* The results of the study indicate that Didecyldimethylammonium Chloride is slightly toxic to terrestrial plants.
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]

Section 7.5.1.3 (1) Annex Point IIA 7.5.1.3	**Acute toxicity to plants**
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	The study is acceptable.
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.5.1.3(1)-1 Wet weight results

Species	Treatment	Application rate (mg a.s./kg)	Geometric mean wet weight (mg)	Percent reduction	*p*
Mustard (*Brassica alba*)	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]
	DDAC	100	467	34	<0.001***[W]
	DDAC	200	310	56	<0.001***[W]
	DDAC	400	232	67	<0.001***[W]
	DDAC	800	119	83	<0.001***[W]
	DDAC	1600	85	88	<0.001***[W]
Wheat (*Triticum aestivum*)	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]
	DDAC	100	254	19	0.409[W]
	DDAC	200	268	14	0.409[W]
	DDAC	400	163	48	0.001**[W]
	DDAC	800	82	74	<0.001***[W]
	DDAC	1600	65	79	<0.001***[W]
Mung bean (*Phaseolus aureus*)	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]
	DDAC	5	853	0[a]	>0.999[W]
	DDAC	20	818	0[a]	>0.999[W]
	DDAC	80	787	0[a]	>0.999[W]
	DDAC	320	608	20	<0.001***[W]
	DDAC	1280	426	44	<0.001***[W]

p values are for the comparison with Water control using Williams' test (W) and the *t*-test (T)
** $p < 0.01$, *** $p < 0.001$
0[a] No reduction

Table 7.5.1.3 (1)-2 Dry weight results

Species	Treatment	Application rate (mg a.s./kg)	Geometric mean dry weight (mg)	Percent reduction	*p*
Mustard (*Brassica alba*)	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]
	DDAC	100	26.9	24	0.009**[W]
	DDAC	200	19.7	45	<0.001***[W]
	DDAC	400	16.2	55	<0.001***[W]
	DDAC	800	8.7	76	<0.001***[W]
	DDAC	1600	7.2	80	<0.001***[W]
Wheat (*Triticum aestivum*)	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]
	DDAC	100	24.1	15	0.725[W]
	DDAC	200	27.7	2	0.725[W]
	DDAC	400	19.0	33	0.035*[W]
	DDAC	800	11.6	59	<0.001***[W]
	DDAC	1600	10.6	63	<0.001***[W]
Mung bean (*Phaseolus*	Water control		[redacted]	[redacted]	
	Solvent control		[redacted]	[redacted]	[redacted]

aureus)	DDAC	5	62.7	0[a]	>0.999[W]
	DDAC	20	59.7	0[a]	>0.999[W]
	DDAC	80	56.6	0[a]	>0.999[W]
	DDAC	320	46.6	14	0.006**[W]
	DDAC	1280	33.7	38	<0.001***[W]

p values are for the comparison with Water control using Williams' test (W) and the *t*-test (T)
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$
0[a] No reduction

Table 7.5.1.3 (1)-3 EC_{50} (inhibition of dry weight) and 95% confidence intervals

Species	EC_{50} (mg a.s./kg)	95% Confidence interval
Mustard (*Brassica alba*)	283	213 - 375
Wheat (*Triticum aestivum*)	857	552 - 1410
Mung bean (*Phaseolus aureus*)	1670	1240 - 2530

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

Section 7.5.2.1 **Annex Point III-A.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 [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	

Section 7.5.2.1 Annex Point III-A.7.5.2.1	Reproduction study with other soil non-target macro-organisms
Conclusion	A reproduction study with other soil non-target macroorganisms is not necessary because risk reduction measures are proposed.
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 Point III-A.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]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	A long term test with terrestrial plants is not needed because risk reduction measures are proposed.	

Section 7.5.2.2 Annex Point III-A.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 III-A 7.5.3.1.1**	**Acute oral toxicity**	
	1. REFERENCE	Official use only
1.1 Reference	Campbell, S, K.A. Hoxter, and G.J. Smith. (1991) - Didecyldimethylammonium Chloride (DDAC): An Acute Oral Toxicity Study with the Northern Bobwhite. Project No. 289-103A. Wildlife International Ltd., Easton, MD, USA (unpublished) Ref No. D1 (LON 1784)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.3 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 authorisation.	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA Guideline 71-1 Year: 1990 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	X
3.1.1 Lot/Batch number	*List lot/batch number where relevant* [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. [redacted]	

Section 7.5.3.1.1 (1) Annex Point III-A 7.5.3.1.1	Acute oral toxicity	
	(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	
3.1.5 Stability	*Describe stability of test material* Stable	X
3.2 Test animals		
3.2.1 Species	Northern bobwhite *(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]	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Oral gavage	
3.3.2 Post exposure period	14 days	
3.3.3 Concentration	[redacted]	X
3.3.4 Vehicle	Distilled water	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	
3.4 Observations, Sacrifice and Pathology		

Section 7.5.3.1.1 (1) **Annex Point III-A 7.5.3.1.1**	**Acute oral toxicity**	
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		
	4. RESULTS	
4.1 Limit test	No	
4.2 LD50 including confidence limits	LD_{50} = 229 mg/kg (95% confidence interval of 164 – 331 mg/kg) NOEL<31 mg/kg	
4.3 Observations, Sacrifice and Pathology	There were no treatment-related effects at the 31 and 62 mg kg dose level. At the 125 and 250 mg/kg dose levels, signs of toxicity were first noted approximately 2.5 to 3 hours after dosing; at 500 mg/kg dose level, signs of toxicity were observed 5 hours after dosing.	
4.3.1 Clinical signs	[redacted]	
4.3.2 Mortality	See table 7.5.3.1.1(1)-1	
4.3.3 Bodyweight	[redacted]	
4.3.4 Organ weights	[redacted]	
4.3.5 Other examinations		
4.3.6 Statistics	The LD50 was calculated to be 229 mg/kg.	
4.4 Further remarks	[redacted]	
	5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and	*Give concise description of method; give test guidelines no. and discuss*	

Section 7.5.3.1.1 (1) Annex Point III-A 7.5.3.1.1	Acute oral toxicity	
methods	*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.* All birds died at 500 mg/kg and 30% mortality was observed at 125 and 250 mg/kg. The LD_{50} was calculated to be 229 mg/kg (95% confidence interval of 164 – 331 mg/kg). The NOELwas less than the lowest dose (31 mg/kg) due to the decrease observed in weight gain during the first 3 days following dosing.	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on the results of this study, the LD_{50} for Northern bobwhite was found to be 229 mg/kg and the no-observed-effect concentration (NOEL) was less than 31 mg/kg.	
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]	

Section 7.5.3.1.1 (1) Annex Point III-A 7.5.3.1.1	Acute oral toxicity
Reliability	[redacted]
Acceptability	The study is considered acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.5.3.1.1(1)-1 Mortality data

Mean measured concentration (mg/kg)	Percent Mortality
0	0
31	0
62	0
125	30
250	30
500	100

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	Long, R.D., K.A. Hoxter, and G.J. Smith. (1991) Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Northern Bobwhite. Report (No. 289-101). Wildlife International Ltd., Easton, MD, USA (unpublished). Ref No. D2 (LON 1785)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.3 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 authorisation	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA Guideline 71-2 Year: 1990 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	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	Didecyldimethylammonium Chloride	X
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	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA. [redacted] *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	
3.1.3 Description	*If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)* [redacted]	
3.1.4 Purity	*Give purity in g/kg, g/l, %w/w or % v/v active substance* [redacted]	X
3.1.5 Stability	*Describe stability of test material* Stable	X
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 group	[redacted]	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Oral feed	
3.3.2 Post exposure period	8 days: 5 days exposure, 3 days post-exposure observation period	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
3.3.5 Concentration in vehicle	[redacted]	
3.3.6 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 NOEL = 1780 ppm	X
4.3 Observations, Sacrifice and Pathology		
4.3.1 Clinical signs	Mortality, loss of coordination, lethargy, ruffled appearances and reduction in body weight gains.	
4.3.2 Mortality	No deaths occurred in the 4 control groups or at Didecyldimethylammonium Chloride concentrations below 5620 ppm. One mortality occurred on Day 5 at 5620 ppm and was considered to be treatment related.	
4.3.3 Bodyweight	There was reduction in bodyweight gains for the birds in the 3160 and 5620 ppm dose groups.	
4.3.4 Organ weights		
4.3.5 Other examinations	There was no apparent effect on feed consumption.	
4.3.6 Statistics		

Section 7.5.3.1.2(1) **Annex Point III-A 7.5.3.1.2**	**Short-term toxicity**	
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.*	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the LC_{50} was found to be greater than 5620 ppm and the no-observed-effect concentration (NOEC) was 1780 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	[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]	

Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2	Short-term toxicity
Acceptability	The study is considered acceptable
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.5.3.1.2(1)-1. Estimated feed consumption of control and test birds.

Concentration (mg a.s./kg food)	Grams per birds per day	
	Exposure days 0-5	Observation days 6-8
0	8	11
562	8	9
1000	10	11
1780	9	11
3160	10	10
5620	9	15

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
	1. REFERENCE	Official use only
1.1 Reference	Long, R.D., K.A. Hoxter, and G.J. Smith. 1991. Didecyldimethylammonium Chloride: A Dietary LC_{50} Study with the Mallard. Report (No. 289-102). Wildlife International Ltd., Easton, MD, USA (unpublished). Ref No. D3 (LON 1783)	
1.2 Data protection	Yes *(indicate if data protection is claimed)*	
1.2.1 Data owner	*Give name of company* The Dialkyl Project	
1.2.3 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 authorisation	
	2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes U.S. EPA FIFRA Guideline 71-2 Year: 1990 *(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")*	
2.2 GLP (only where required)	Yes *(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)*	
2.3 Deviations	No *(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")*	
	3. MATERIALS AND METHODS	
	In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1 Test material	Didecyldimethylammonium Chloride	X
3.1.1 Lot/Batch number	*List lot/batch number where relevant* B-1889	
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. [redacted] *(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):*	

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
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] Test substance also contained ethanol that was lost during diet preparation	
3.1.5 Stability	*Describe stability of test material* Stable	
3.2 Test animals		
3.2.1 Species	Mallard *(Anas platyrhynchos)*	
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 group	[redacted]	
3.2.6 Control animals	[redacted]	
3.3 Administration/ exposure		
3.3.1 Dose route	Oral feed	
3.3.2 Post exposure period	5 days exposure period and 3 days post exposure observation period	
3.3.3 Concentration	[redacted]	
3.3.4 Vehicle	[redacted]	
3.4.5 Concentration in vehicle	[redacted]	
3.3.6 Controls	[redacted]	
3.4 Observation, Sacrifice and Pathology		

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
3.4.1 Clinical signs	[redacted]	
3.4.2 Mortality	[redacted]	
3.4.2 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 NOEL = 562 ppm	X
4.3 Observation, Sacrifice and Pathology		
4.3.1 Clinical signs	Reduction in body weight gains and reduction in feed consumpton.	
4.3.2 Mortality	There were no mortalities and no overt signs of toxicity in the control groups or at any of the concentrations tested.	
4.3.4 Bodyweight	There was a reduction in bodyweight gains for the 1000 ppm and higher dose groups and loss in bodyweight occured at 3160 pppm and higher concentrations.	
4.3.5 Other examinations	A marked and progressive reduction in feed consumption during exposure was noted at 1780 ppm and higher dose groups.	
4.3.6 Statistics	[redacted]	
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]	

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
5.2 Results and discussion	*Summarise relevant results; discuss dose-response relationship where relevant.*	
5.3 Conclusion	*Subsections for NOAEL, LOAEL etc. if appropriate* Based on concentration-effect relationship observed, the LC_{50} was found to be greater than 5620 ppm and the no-observed-effect concentration (NOEC) was 562 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	[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 considered acceptable	

Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of the comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*

Table 7.5.3.1.2(2)-1. Estimated feed consumption of control and test birds.

Concentration (mg a.s./kg food)	Grams per birds per day	
	Exposure days 0-5	Observation days 6-8
0	79	111
562	68	101
1000	77	124
1780	39	116
3160	37	151
5620	23	92

Section 7.5.3.1.3 Annex Point III-A.7.5.3.1.3	Avian reproduction study	
	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	[redacted] *the applicant's justification is considered acceptable.*	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section 7.5.3.1.3 Annex Point III-A.7.5.3.1.3	Avian reproduction study
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 7.5.4 Effects on honeybees
Annex Point IIA 7.5.4- headline only

Section 7.5.4.1 **Annex Point III-A.7.5.4.1**	**Acute toxicity to honey bees**	
	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*	

Section 7.5.4.1 Annex Point III-A.7.5.4.1	Acute toxicity to honey bees
Conclusion	[redacted]
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 7.5.5 Bioconcentration, terrestrial
Annex Point IIA 7.5.5- headline only

Section 7.5.5.1 Bioconcentration, further studies
Annex Point IIA 7.5.5.1- headline only

Section 7.5.5.1 **Annex Point III-A.7.5.5.1**	**Bioconcentration (further studies)**	
	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]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.5.1 Annex Point III-A.7.5.5.1	Bioconcentration (further studies)
Evaluation of applicant's justification	[redacted]
Conclusion	No need of study on bioconcentration in terrestrial 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 7.5.6 Annex Point III-A.7.5.6	Effects on other terrestrial non-target 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 [ ]**	X
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	Further tests are not required.	
Remarks		

Section 7.5.6 Annex Point III-A.7.5.6	Effects on other terrestrial non-target organisms
	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 7.5.7 Effects on mammals
Annex Point IIA 7.5.7- headline only

Section 7.5.7 For some product types, direct and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment
Annex Point IIA 7.5.7.1- headline only

Section 7.5.7.1 **Annex Point III-A.7.5.7**	**Effects on mammals (direct and/or indirect exposure)**	
	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]	X
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Section 7.5.7.1 Annex Point III-A.7.5.7	Effects on mammals (direct and/or indirect exposure)
Evaluation of applicant's justification	[redacted]
Conclusion	No need to submit a study on effects on mammals.
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 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
Fate and behaviour in water	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	
Fate and behaviour in soil	[redacted]	
Effect on aquatic organisms	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	
Effects on terrestrial organisms	[redacted]	

Section 7.6 Annex Point IIA. 7.6	Summary of ecotoxicological effect and fate and behaviour in the environment (in Doc. II-A)	Official use only
	[redacted]	

Section 8 Measures necessary to protect man, animals and the environment

Section 8 Annex Point IIA. 8		Official use only
8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire	Handling: Avoid contact with skin and eyes. Provide sufficient air exchange and/or exhaust in work rooms. Wash hands before breaks and immediately after handling. Use respirator when performing operations involving potential exposure to vapour. Wear suitable protective clothing, rubber or plastic gloves and eye/face protection. Highly flammable. Keep away from sources of ignition – No smoking. Take precautionary measures against static discharges. Storage: Keep container tightly closed. To maintain product quality, do not store in heat or direct sunlight. Keep in a dry, cool and well-ventilated place. Transport: Classified as corrosive liquid, flammable (Class 8, Packaging group II, UN 2920) Fire: Use dry powder, water spray or foam as extinguishing media. Water mist may be used to cool closed containers. Wear self-contained breathing apparatus.	
8.2 In case of fire, nature of reaction products, combustion gases, etc.	Heating or fire can release toxic gases. Anticipated to contain oxides of carbon and nitrogen	
8.3 Emergency measures in case of an accident	Personal precautions: Use respirator when performing operations involving potential exposure to vapour of the product. Environmental precautions: Do not flush into surface water or sanitary sewer system. Methods for cleaning up: Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations.	
8.4 Possibility of destruction or decontamination following release in or on the following:	*Headline only*	
a. air	Didecyldimethylammonium Chloride is not volatile. The vapour pressure of the a.s. is 2.3E-04 Pa at 50°C[1]. As a wood preservative, this material is not intentionally aerosolized. Therefore, destruction in air is not a concern.	

Section 8 Annex Point IIA. 8			Official use only
		1 Document III-A Section 3.2	
	b. water, including drinking water	Didecyldimethylammonium Chloride is readily biodegradable and adsorbs to organic matter.	
	c. soil	Direct and/or intentional release to soil is not anticipated for the use of the product as a wood preservative. In the event of a significant accidental release, contaminated soil should be disposed according to local regulations.	
8.5	**Procedures for waste management of the active substance for industry or professional users**	*Headline only*	
8.5.1	Possibility of re-use or recycling	Where possible recycling is the preferred option	
8.5.2	Possibility of neutralisation of effects	Incineration is recommended	
8.5.3	Conditions for controlled discharge including leachate qualities on disposal	None	
8.5.4	Conditions for controlled incineration	Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.	
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms**	None	
8.7	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC**	None	

Section 9 Classification and labelling

Section 9 Annex Point IIA. 9			Official use only
9.1 Classification			
9.1.1	Classified	as in Directive 67/584/EEC	
9.1.2	Class of danger	Corrosive	
9.1.3	R-Phrases	R22 Harmful if swallowed R34 Causes burns	
9.1.4	Specific limits	No	
9.2 Labelling			
9.2.1	Labelling	as in Directive 67/584/EEC	
9.2.2	Symbols	C	
9.2.3	R-Phrases	R22 Harmful if swallowed R34 Causes burns	
9.2.4	S-Phrases	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28 After contact with skin, wash immediately with plenty of ... S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)	
9.2.5	Specific limits	No	

Classification

Classified	Provisionally by manufacturer/importer	
Class of danger	Corrosive; Dangerous to the environment	
R-Phrases	R22 Harmful if swallowed R34 Causes burns R50 Very toxic to aquatic organisms	
Specific limits	Yes Cn ≥2.5%: N; R 50	X

Labelling

Labelling	Provisionally by manufacturer/importer	
Symbols	C, N	
R-Phrases	R22 Harmful if swallowed R34 Causes burns R50 Very toxic to aquatic organisms	
S-Phrases	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28 After contact with skin, wash immediately with plenty of ...	

	S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) S60 This material and its container must be disposed of as hazardous waste S61 Avoid release to the environment. Refer to special instructions/Safety data sheets	X
Specific limits	Yes Cn ≥2.5%: N; R 50	X

Section 10 Summary and Evaluation of Sections 2 to 9

Section 10 Annex Point IIA. 10		Official use only
2. Identity	[redacted]	
3. Physical and Chemcial Properties	[redacted]	

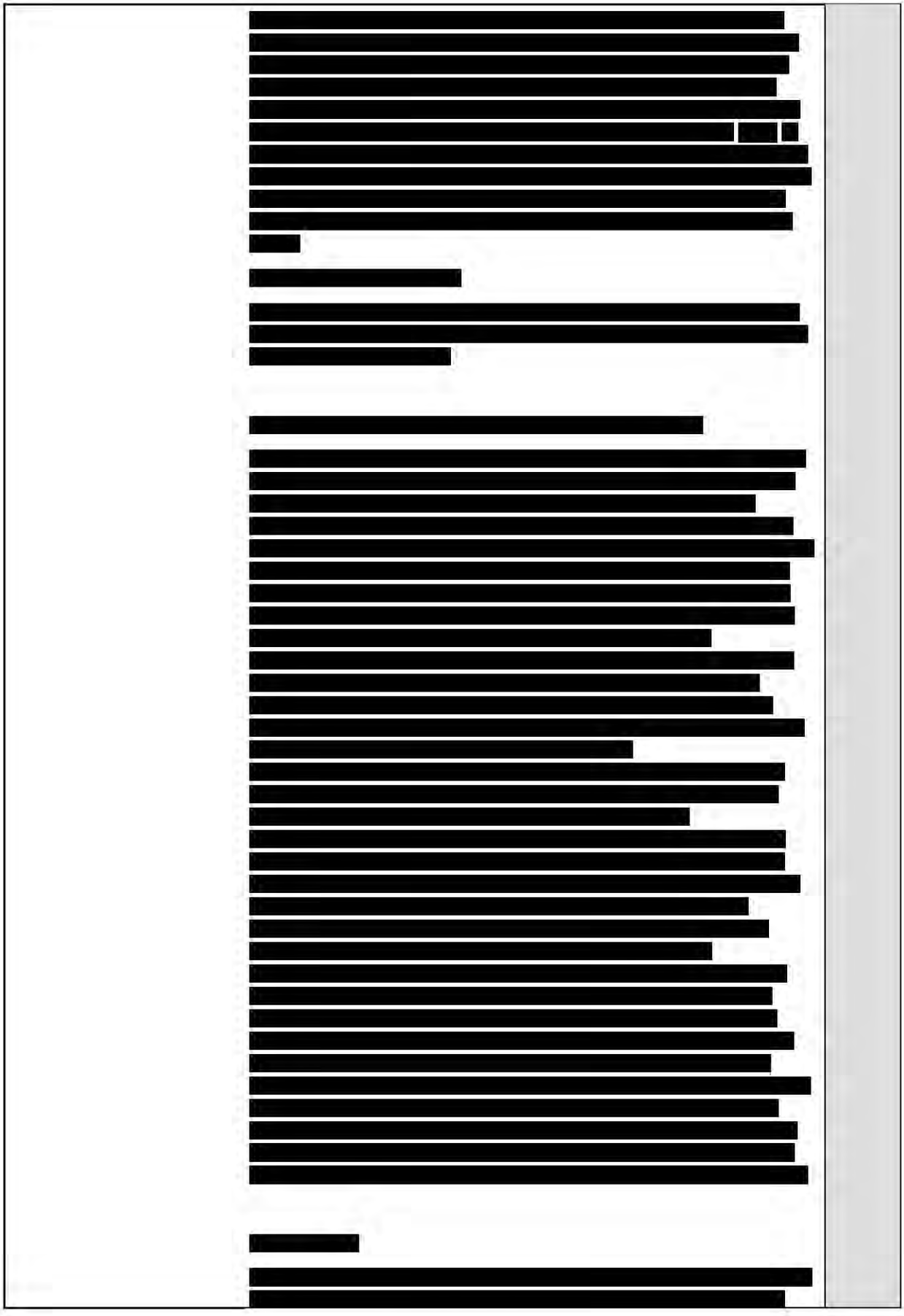
	[redacted]	
4. Analytical methods for detection and determination	[redacted]	x

	[redacted]	
5. Effectiveness against target organisms and intended uses	[redacted]	

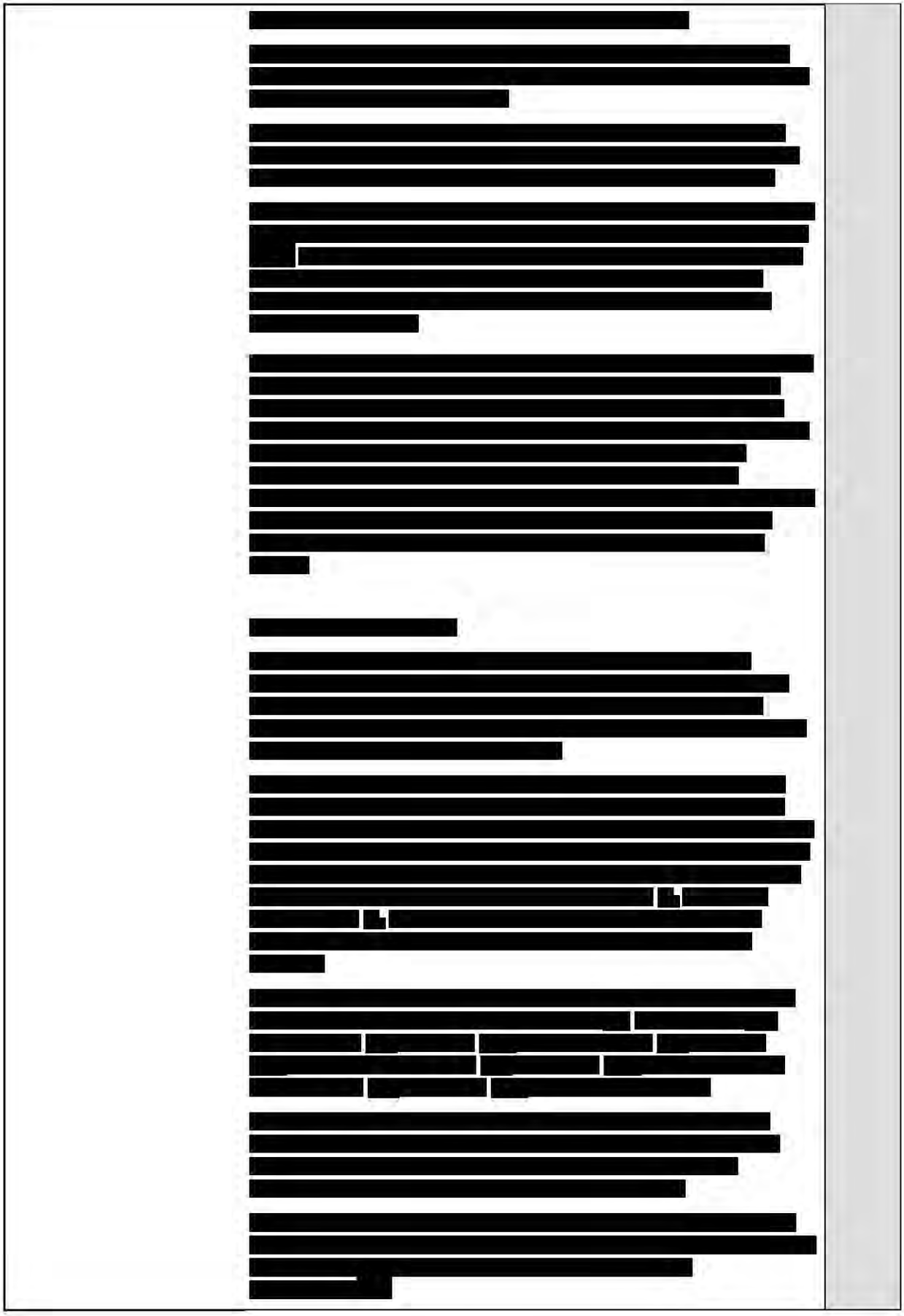
[redacted]

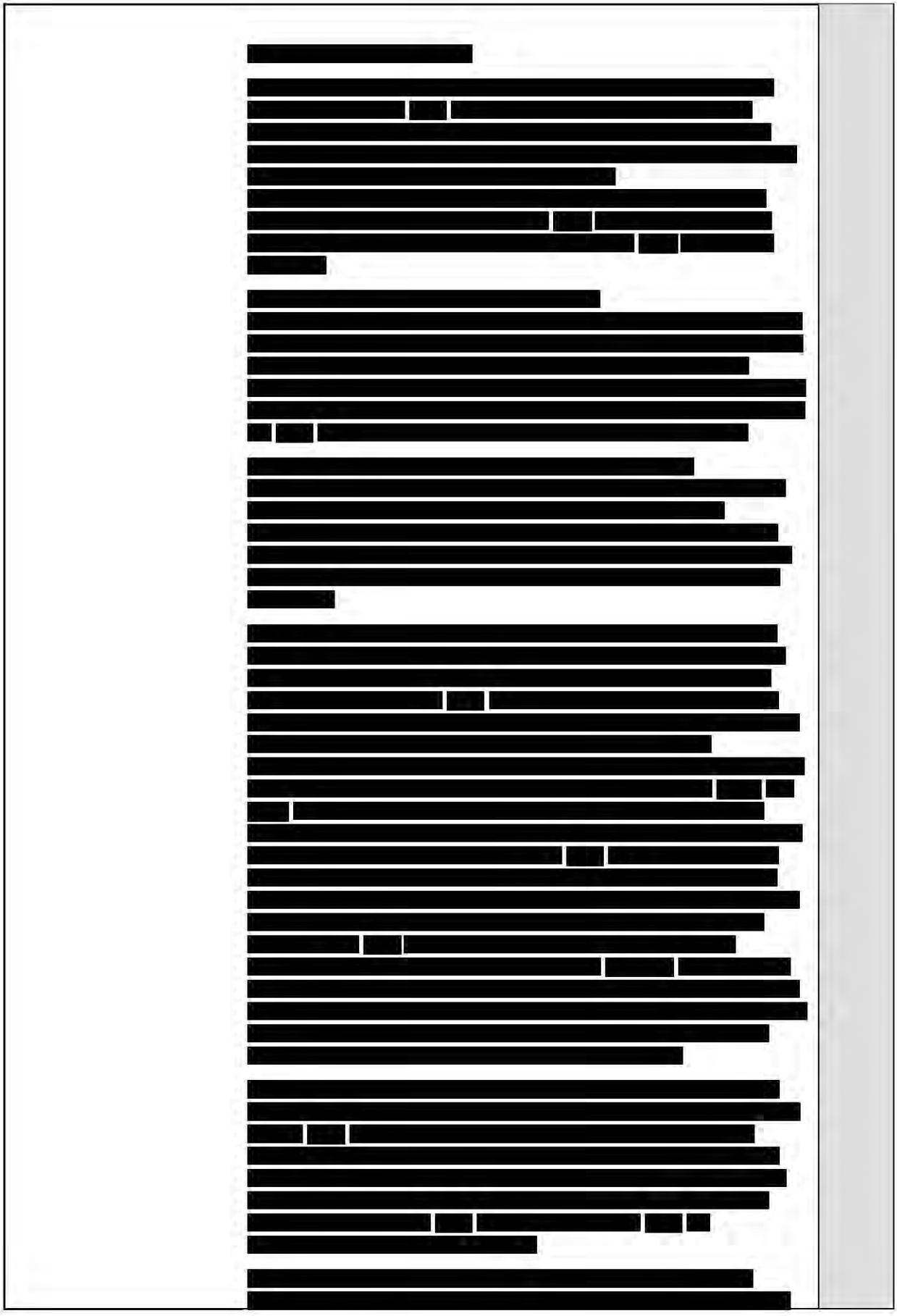
[redacted]

6. Toxicological and metabolic studies	[redacted]



	[redacted]	
7. Ecotoxicological profile including environmental fate and behaviour	[redacted]	





[redacted]

8. Measures necessary to protect man, animals and the environment	MAN: Handling: Avoid contact with skin and eyes. Provide sufficient air exchange

	and/or exhaust in work rooms. Wash hands before breaks and immediately after handling. Use respirator when performing operations involving potential exposure to vapour. Wear suitable protective clothing, rubber or plastic gloves and eye/face protection. Highly flammable. Keep away from sources of ignition – No smoking. Take precautionary measures against static discharges. Storage: Keep container tightly closed. To maintain product quality, do not store in heat or direct sunlight. Keep in a dry, cool and well-ventilated place. Transport: Classified as corrosive liquid, flammable (Class 8, Packaging group II, UN 2920) Fire: Use dry powder, water spray or foam as extinguishing media. Water mist may be used to cool closed containers. Wear self-contained breathing apparatus. Emergency measures in case of an accident. Personal precautions: Use respirator when performing operations involving potential exposure to vapour of the product. Environmental precautions: Do not flush into surface water or sanitary sewer system. Methods for cleaning up: Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations. ANIMALS AND ENVIRONMENT Where possible, recycling is the preferred option. Incineration is preferred. Waste must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.	
9. Classification and labelling	Didecyldimethylammonium Chloride is classified and labelled according to Directive 67/584/EEC as follows: Symbol: C Risk Phrases: R22 Harmful if swallowed R34 Causes burns	

Safety Phrases:	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28 After contact with skin, wash immediately with plenty of soap and water. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)	
As proposed by the manufacturer/importer, Didecyldimethylammonium Chloride should be classified and labelled as follows:		
Symbol:	C, N	
Risk Phrases:	R22 Harmful if swallowed R34 Causes burns R50 Very toxic to aquatic organisms	X
SCL for environmental Classification	Cn≥2.5%: N; R50	
Safety Phrases:	S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice S28 After contact with skin, wash immediately with plenty of soap and water. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)	X
	S60 This material and its container must be disposed of as hazardous waste S61 Avoid release to the environment. Refer to special instructions/Safety data sheets	