Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride

September 2012

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Section 7.5.3.1.2(1) Annex Point III-A 7.5.3.1.2	Short-term toxicity	
methods	relevant deviations from test guidelines. Comments from 2.1above are relevant in this table.	
5.2 Results and discussion	Summarise relevant results; discuss dose-response relationship where relevant.	
	There were no treatment-related mortalities. There were no clinical observations or differences in body weight or feed consumption at 0, 562 or 1000 ppm a.s. test concentrations. At the 1780 ppm a.s. test concentration and higher, signs of toxicity observed included ruffled appearance, wing droop, lethargy, loss of coordination, reduced reaction to external stimuli (sound and movement) and lower limb weakness. At the 1780, 3160 and 5620 ppm a.s. test concentrations, there were concentration-responsive decreases in body weight gain over the exposure period. In the 5620 ppm a.s. dose group, there was a reduction in feed consumption the last day of treatment and the last two days of post-exposure.	
5.3 Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	X
	The dietary LC_{50} value for northern bobwhite exposed to ADBAC was determined to be greater than 5620 ppm a.s., the highest concentration tested. The no mortality concentration was 5620 ppm a.s. Based on a reduction in body weight gain and signs of toxicity at the 1780 ppm a.i test concentration, the no-observed effect concentration was 1000 ppm a.s.	
5.3.1 Reliability	Based on the assessment of materials and methods include appropriate reliability indicator $0,\ 1,\ 2,\ 3$ or 4	
5.3.2 Deficiencies		
5.5.2 Deficiencies	(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 comme views submitted	ents and
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Give date of action	
Materials and Methods		

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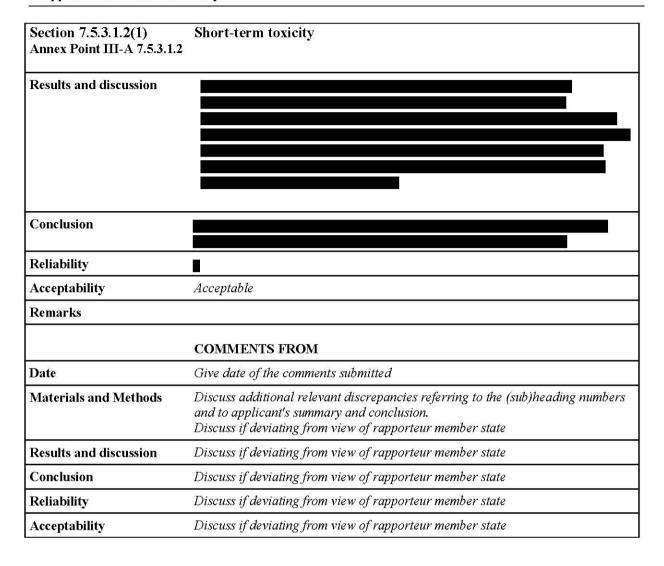


Table 7.5.3.1.2(1)-1. Mean feed consumption of control and test birds.

Experimental				Me	an Fee	ed Con	sumptio	n (g/bird/day)	
Group			Expo	osure !	Period	1		Post-Exposure	
(ppm a.i)		0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8
Control	Mean	11	7	7	7	8	22	12	13
0	SD	3	1	2	2	2	11	5	3
	N = 6								
Treatment									
562	Mean	10	5	5	5	5	15	11	13
	N = 2								
1000	Mean	10	6	6	6	5	12	10	15
	N = 2								
1780	Mean	11	5	8	8	6	14	12	10
	N = 2								

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	3160	Mean	9	6	6	5	6	15	9	10	

5 5

11

9

Mean N = 2 7

6

SD = Standard deviation N = Sample size

5620

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Sec Ann	tion 7.5.3.1.2(2) ex 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 Mallard. Report No. 350-102. Wildlife International Ltd., Easton, MD, USA (unpublished).	,
		[Ref. No. A118 (LON 3999)]	
1.2	Data protection	Yes	
WE 1990 N	0 1400001 AF	(indicate if data protection is claimed)	
1.2.1	l Data owner	Give name of company	
		ADBAC Issues Steering Committee	
1.2.2	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	2.1 Guideline study	Yes U.S. Environmental Protection Agency Series 850-Ecological Effects Test Guidelines OPPTS Number 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	Yes	
	required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3	Deviations	Yes	Х
	The mean daily relative humidity in the study room ranged from 66 to 80% during the course of the test, with an overall mean of 75% for the test period. The protocol indicated that the relative humidity would range from approximately 50-70%. Due to the constant replacement of air within the laboratory with outside air, relative humidity was influenced by the outdoor relative humidity. While slightly higher than the range specified in the protocol, the relative humidity in the study room was not considered detrimental to the test birds.		
		(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.	

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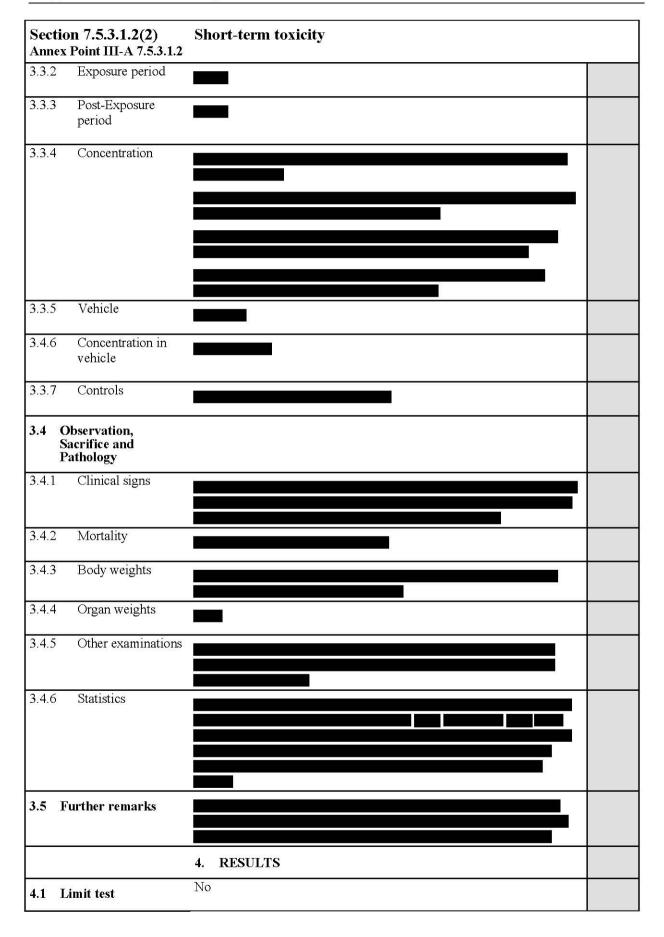
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Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2		Short-term toxicity	
3.1	Test material		
		Active substance (a.s.), Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC; 40% $\rm C_{12}$, 50% $\rm C_{14}$, 10% $\rm C_{16}$; CAS RN 68424-85-1), in aqueous/ethanol solution	
3.1.1	Lot/Batch number	List lot/batch number where relevant	
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.	
		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)	
3.1.4	Dramiter	Cina quality in a Ara a 1 Olymphy and of who active on hatomas	
3.1.4	Purity	Give purity in g/kg, g/l, %w/w or% v/v active substance	
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, <i>e.g.</i> at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.2	Test animals		
3.2.1	Species	Mallard (Anas platyrhynchos)	
3.2.2	Source		
3.2.3	Sex	Birds were immature and could not be differentiated by sex.	
3.2.4	Age/weight at study initiation		
3.2.5	Number of animals per test group		
3.2.6	Control animals		
3.3	Administration/ exposure		
3.3.1	Dose route	Oral feed ad libitum	

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4.3 UD50 including confidence limits 4.3 Observation, Sacrifice and Pathology 4.3.1 Clinical signs No treatment-related signs of toxicity were noted at the 316, 562, 1000 or 1780 ppm a.s. test concentrations. At the 316 ppm a.s. test concentration, one bird was noted with its leg caught in the cage floor on the merring of Day 2 of the test and as a result was noted as lame through the afternoon of Day 4, but was normal for the remainder of the test. At the 3160 ppm a.s. test concentration, signs of toxicity were first observed on the afternoon of Day 4 of the test, when all birds were noted as slightly ruffled appearance and lethargio. All birds continued to exhibit a slightly ruffled appearance and slight lethargy on the morning of Day 3 through the afternoon of Day 6. All birds had recovered by the morning of Day 7 and were normal in appearance from the afternoon of Day 6. The birds had recovered by the morning of Day 7 and were normal in appearance and behavior for the remainder of the test. At the 5620 ppm a.s. test concentration, signs of toxicity included slightly ruffled appearance and lethargy, which was observed in all birds beginning on the afternoon of Day 4. All birds continued to exhibit a slightly ruffled appearance and slight lethargy from the morning of Day 5 through the afternoon of Day 6. In addition, one bird from this test concentration also exhibited slight wing droop and slight loss of coordination and slight ruffled appearance persisting through the morning of Day 7. All birds at this concentration also exhibited slight wing droop and slight loss of coordination and slight ruffled appearance and behavior for the remainder of the test. 4.3.2 Mortality There were no mortalities in the control groups or at any of the concentrations tested. 4.3.3 Bodyweight When compared to the control group, there was a concentration responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm as. test concentrations and a loss in mean body weight gain of the exposure peri		cion 7.5.3.1.2(2) ex Point III-A 7.5.3.1.2	Short-term toxicity	
Sacrifice and Pathology	4.2	LD50 including confidence limits	$LC_{50} > 5620 \text{ ppm a.s.}$	X
or 1780 ppm a.s. test concentrations. At the 316 ppm a.s. test concentration, one bird was noted with its leg caught in the cage floor on the morning of Day 2 of the test and as a result was noted as lame through the afternoon of Day 2, but was normal for the remainder of the test. At the 3160 ppm a.s. test concentration, signs of toxicity were first observed on the afternoon of Day 4 of the test, when all birds were noted as slightly ruffled appearance and lethargic. All birds continued to exhibit a slightly ruffled appearance and slight lethargy on the morning of Day 5, and a slight ruffled appearance from the afternoon of Day 5 through the afternoon of Day 6. All birds had recovered by the morning of Day 7 and were normal in appearance and behavior for the remainder of the test. At the 5620 ppm a.s. test concentration, signs of toxicity included slightly ruffled appearance and lethargy, which was observed in all birds beginning on the afternoon of Day 4. All birds continued to exhibit a slightly ruffled appearance and slight lethargy from the morning of Day 5 through the afternoon of Day 6. In addition, one bird from this test concentration also exhibited slight wing droop and slight loss of coordination throughout Day 6 with slight loss of coordination and slight ruffled appearance persisting through the morning of Day 7. All birds at this concentration recovered by the afternoon of Day 7 and were normal in appearance and behavior for the remainder of the test. 4.3.2 Mortality There were no mortalities in the control groups or at any of the concentrations tested. When compared to the control group, there was a concentration responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentrations during the exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562, 1000, 1780, 3160 and 5620 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 pp	4.3	Sacrifice and		
observed on the afternoon of Day 4 of the test, when all birds were noted as slightly ruffled appearance and lethargic. All birds continued to exhibit a slightly ruffled appearance and slight lethargy on the morning of Day 5, and a slight ruffled appearance from the afternoon of Day 5 through the afternoon of Day 6. All birds had recovered by the morning of Day 7 and were normal in appearance and behavior for the remainder of the test. At the 5620 ppm a.s. test concentration, signs of toxicity included slightly ruffled appearance and lethargy, which was observed in all birds beginning on the afternoon of Day 4. All birds continued to exhibit a slightly ruffled appearance and slight lethargy from the morning of Day 5 through the afternoon of Day 6. In addition, one bird from this test concentration also exhibited slight wing droop and slight loss of coordination throughout Day 6 with slight loss of coordination and slight ruffled appearance persisting through the morning of Day 7. All birds at this concentration recovered by the afternoon of Day 7 and were normal in appearance and behavior for the remainder of the test. 4.3.2 Mortality There were no mortalities in the control groups or at any of the concentrations tested. 4.3.3 Bodyweight When compared to the control group, there was a concentration responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentrations and a loss in mean body weight at the 5620 ppm a.s. test concentration during the exposure period. During the post-exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562, 1000, 1780, 3160 and 5620 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 316 and 5620 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable t	4.3.1	Clinical signs	or 1780 ppm a.s. test concentrations. At the 316 ppm a.s. test concentration, one bird was noted with its leg caught in the cage floor on the morning of Day 2 of the test and as a result was noted as lame through the afternoon of Day 2, but was normal for the remainder of the	
slightly ruffled appearance and lethargy, which was observed in all birds beginning on the afternoon of Day 4. All birds continued to exhibit a slightly ruffled appearance and slight lethargy from the morning of Day 5 through the afternoon of Day 6. In addition, one bird from this test concentration also exhibited slight wing droop and slight loss of coordination throughout Day 6 with slight loss of coordination and slight ruffed appearance persisting through the morning of Day 7. All birds at this concentration recovered by the afternoon of Day 7 and were normal in appearance and behavior for the remainder of the test. 4.3.2 Mortality There were no mortalities in the control groups or at any of the concentrations tested. 4.3.3 Bodyweight When compared to the control group, there was a concentration responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentration during the exposure period. During the post-exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562, 1000, 1780, 3160 and 5620 ppm a.s. treatment groups. 4.3.4 Organ weights Not applicable 4.3.5 Other examinations There were no clear treatment-related effects on feed consumption at the 316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period. 4.3.6 Statistics Not applicable			observed on the afternoon of Day 4 of the test, when all birds were noted as slightly ruffled appearance and lethargic. All birds continued to exhibit a slightly ruffled appearance and slight lethargy on the morning of Day 5, and a slight ruffled appearance from the afternoon of Day 5 through the afternoon of Day 6. All birds had recovered by the morning of Day 7 and were normal in appearance and behavior for the	
4.3.3 Bodyweight When compared to the control group, there was a concentration responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentrations and a loss in mean body weight at the 5620 ppm a.s. test concentration during the exposure period. During the post-exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562, 1000, 1780, 3160 and 5620 ppm a.s. treatment groups. 4.3.4 Organ weights Not applicable There were no clear treatment-related effects on feed consumption at the 316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period. 4.3.6 Statistics Not applicable			slightly ruffled appearance and lethargy, which was observed in all birds beginning on the afternoon of Day 4. All birds continued to exhibit a slightly ruffled appearance and slight lethargy from the morning of Day 5 through the afternoon of Day 6. In addition, one bird from this test concentration also exhibited slight wing droop and slight loss of coordination throughout Day 6 with slight loss of coordination and slight ruffed appearance persisting through the morning of Day 7. All birds at this concentration recovered by the afternoon of Day 7 and	
responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentrations and a loss in mean body weight at the 5620 ppm a.s. test concentration during the exposure period. During the post-exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562, 1000, 1780, 3160 and 5620 ppm a.s. treatment groups. 4.3.4 Organ weights Not applicable There were no clear treatment-related effects on feed consumption at the 316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period. Not applicable Not applicable	4.3.2	Mortality		
4.3.5 Other examinations There were no clear treatment-related effects on feed consumption at the 316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period. 4.3.6 Statistics Not applicable	4.3.3	Bodyweight	responsive reduction in mean body weight gain at the 316, 562, 1000, 1780 and 3160 ppm a.s. test concentrations and a loss in mean body weight at the 5620 ppm a.s. test concentration during the exposure period. During the post-exposure period, when compared to the control group, there was an increase in mean body weight gain by the 562,	
316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period. 4.3.6 Statistics Not applicable	4.3.4	Organ weights	Not applicable	
1vot applicable	5394.53000	16 Collection of the control of the	316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control	
4.4 Further remarks	4.3.6	Statistics	Not applicable	
	4.4	Further remarks		

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	tion 7.5.3.1.2(2) nex Point III-A 7.5.3.1.2	Short-term toxicity	
		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 2.1 above are relevant in this table.	
5.2	Results and discussion	Summarise relevant results; discuss dose-response relationship where relevant.	
		No treatment-related signs of toxicity were noted at the 316, 562, 1000 or 1780 ppm a.s. test concentrations. At the 3160 and 5620 ppm a.s. test concentrations, signs of toxicity included varying degrees of ruffled in appearance and lethargy that began on Day 4 but were resolved by Day 6 or Day 7. In addition, one bird from the 5620 ppm a.s. test concentration was observed with slight wing droop and slight loss of coordination but was recovered by Day 7. The increased weight gain during the post-exposure period appeared to be compensatory for earlier reductions in weight gain or losses of body weight during the exposure period. However, despite compensatory increases in mean weight gain, there were reductions in mean body weight gain for the entire test period at all concentrations tested. There were no clear treatment-related effects on feed consumption at the 316 and 562 ppm a.s. test concentrations. There were treatment-related reductions in feed consumption at the 1000, 1780, 3160 and 5620 ppm a.s. test concentrations during the exposure period, while mean feed consumption by all treatment groups was comparable to the control group during the post-exposure period.	
5.3	Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	X
		The dietary LC_{50} value for mallards exposed to ADBAC was determined to be greater than 5620 ppm a.s., the highest concentration tested. A NOEC could not be determined based on reduced mean body weight gain at the lowest concentration tested. The no mortality concentration was 5620 ppm a.s.	
5.3.	l Reliability	Based on the assessment of materials and methods include appropriate reliability indicator $0,\ 1,\ 2,\ 3$ or 4	
5.3.2	2 Deficiencies		
		(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)	
		Evaluation by Competent Authorities	

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Section 7.5.3.1.2(2) Annex Point III-A 7.5.3.1.2	Short-term toxicity
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	I
Acceptability	Acceptable
Remarks	
	COMMENTS FROM
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state
Results and discussion	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state

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

Experimental	Mean Feed Consumption (g/bird/day)								
Group			Exp	osure	Perio	d		Post-Exposure	
(ppm a.i.)		0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8
Control	Mean	63	87	84	105	109	107	138	175
0	SD	7	10	12	17	18	19	9	21
	N = 6								
Treatment									
316	Mean	57	64	75	88	98	118	130	162
	N = 2								
562	Mean	58	76	78	93	95	132	140	160
	N = 2								
1000	Mean	47	65	66	75	79	129	137	165
	N = 2								
1780	Mean	32	62	49	54	49	121	151	152
	N = 2								
3160	Mean	33	57	59	70	84	148	153	152
	N = 2								
5620	Mean	26	38	36	53	44	116	154	156
	N = 2								

SD = Standard deviation

N = Sample size

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Section 7.5.3.1.3 Annex Point IIIA.7.5.3.1.3	Avian reproduction study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	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	
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:		
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		
Evaluation of applicant's justification	Accepted	
Conclusion		

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Remarks

Rapporteur Member State: Italy

Section 7.5.3.1.3 Avian reproduction study

Annex Point IIIA.7.5.3.1.3

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

Discuss if deviating from view of rapporteur member state

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Section 7.5.4.1 Annex Point IIIA.7.5.4.1	Acute toxicity to honey bees	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	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	
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:		
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		
Evaluation of applicant's justification	Accepted	
Conclusion		

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Section 7.5.4.1 Annex Point IIIA.7.5.4.1	Acute toxicity to honey bees
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	

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride

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Rapporteur Member State: Italy

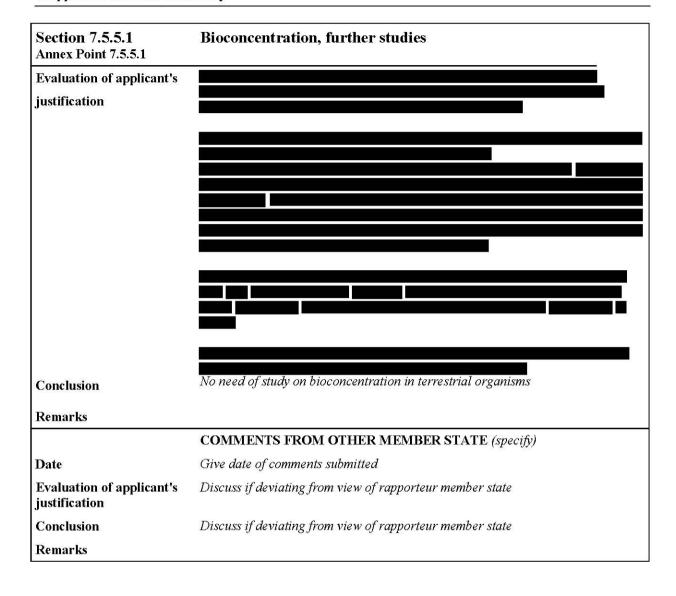
Section 7.5.5 Bioconcentration, terrestrial Annex Point IIA 7.5.5- headline only

Section 7.5.5.1 Annex Point 7.5.5.1	Bioconcentration, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	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	
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:		
		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		

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Section 7.5.6 Annex Point IIIA.7.5.6	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	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	
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:		
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		
Evaluation of applicant's justification	Accepted	
Conclusion		

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Remarks

Rapporteur Member State: Italy

Section 7.5.6 Effects on other terrestrial non-target organisms Annex Point IIIA.7.5.6 Remarks COMMENTS FROM OTHER MEMBER STATE (specify) Give date of comments submitted Date **Evaluation of applicant's** Discuss if deviating from view of rapporteur member state justification Conclusion Discuss if deviating from view of rapporteur member state

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium September 2012 chloride

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Rapporteur Member State: Italy

Lonza GmbH; Stepan Europe;

Section 7.5.7 Effects on mammals Annex Point IIA 7.5.7- headline only

Section 7.5.7.1 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 - 3- headline only

Section 7.5.7 Annex Point IIIA.7.5.7.	Effects on mammals (direct and/or indirect exposure)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	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	
Other existing data []	Technically not feasible [] Scientifically unjustified []	
Limited exposure [X]	Other justification []	
Detailed justification:		
Undertaking of intended	Give date on which the data will be handed in later (Only acceptable if	
data submission []	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		

Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride

September 2012

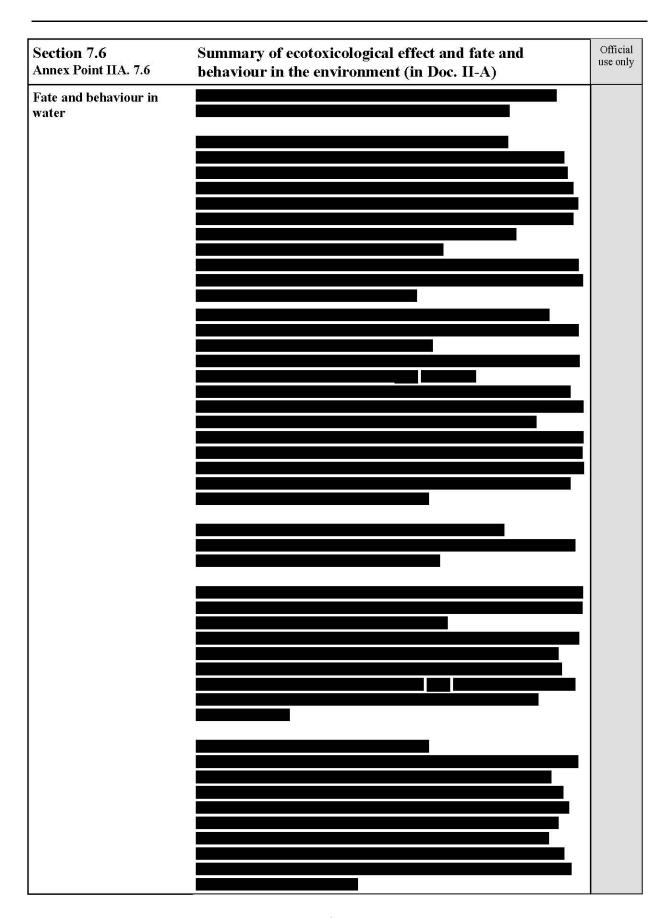
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Section 7.5.7 Annex Point IIIA.7.5.7.	Effects on mammals (direct and/or indirect exposure)
Evaluation of applicant's justification	Accepted
Conclusion	·
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	Give date of comments submitted
Evaluation of applicant's justification	Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Remarks	

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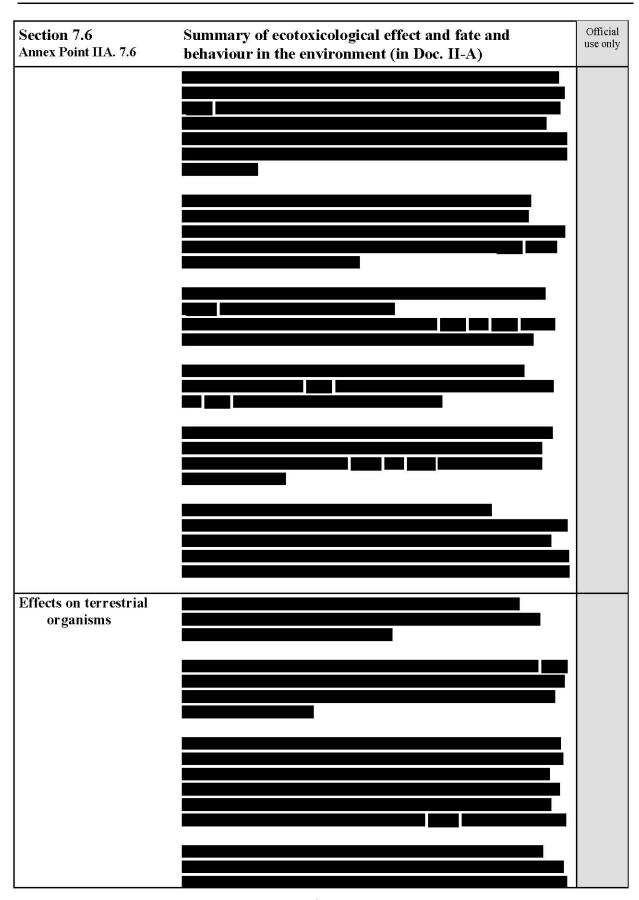
Rapporteur Member State: Italy

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 soil		-
		-
Effect on aquatic organisms		•
		-

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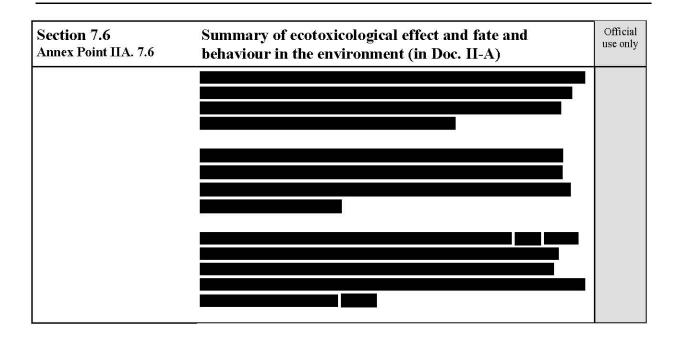
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Section 8 Measures necessary to protect man, animals and the environment

	tion 8 nex Point IIA. 8		Official use only
8.1	Recommended	Handling:	
	methods and precautions concerning handling, use, storage,	Avoid contact with skin and eyes. Provide sufficient air exchange and/or exhaust in work rooms. Wash hands before breaks and immediately after handling the product.	
	transport or fire	Use respirator when performing operations involving potential exposure to vapour of the product.	
		Wear suitable protective clothing, rubber or plastic gloves and eye/face protection.	
		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 (Class 8, Packaging group II, UN 3265)	
		Fire:	
		Use dry powder or water spray 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.	Products of combustion are toxic. Anticipated to contain oxides of carbon and nitrogen.	
8.3	Emergency measures	Personal precautions:	
	in case of an accident	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:	
		Absorb spill with inert material (sand, earth, chemical absorbent). Do not allow to get into drains, water courses etc. Neutralize with soda or sodium bicarbonate.	
8.4	Possibility of destruction or decontamination following release in or on the following:	Headline only	
	a. air	Alkyldimethylbenzylammonium Chloride is not volatile. The vapour pressure of the AS is <1E-05 hPa (<1E-03 Pa) at 50°C¹. As a wood preservative, this material is not intentionally aerosolized. Therefore, destruction in air is not a concern.	
		1 Document IIIA Section 3.2	

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Sec Ann		n 8 Point IIA. 8		Official use only
	b.	water, including drinking water	Alkyldimethylbenzylammonium 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	ma act	ocedures for waste anagement of the tive substance for dustry or ofessional users	Headline only	
8.5.1	L _s	Possibility of re-use or recycling	Where possible recycling is preferred to disposal or incineration.	
8.5.2	2	Possibility of neutralisation of effects	Incineration is recommended.	
8.5.3	3	Conditions for controlled discharge including leachate qualities on disposal	None	
8.5.4	1	Conditions for controlled incineration	Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.	
8.6	un un eff be	bservations on desirable or intended side- fects, e.g. on neficial and other n-target organisms	None	
8.7	sul wi Li: Ar	entification of any bstances falling thin the scope of st I or List II of the mex to Directive /68/EEC	None	

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Section 9 Classification and labelling

Sectio Annex	on 9 Point IIA. 9		Official use only
9.1 C	lassification		
9.1.1	Classified	as in Directive 67/548/EEC	
9.1.2	Class of danger	Corrosive; Dangerous for the environment	
9.1.3	R-Phrases	R21/22 Harmful in contact with skin and if swallowed	
		R34 Causes burns	
		R50 Very toxic to aquatic organisms	
9.1.4	Specific limits	No	
9.2 L	abelling		
9.2.1	Labelling	as in Directive 67/548/EEC	
9.2.2	Symbols	C, N	
9.2.3	R-Phrases	R21/22 Harmful in contact with skin and if swallowed	
		R34 Causes burns	
		R50 Very toxic to aquatic organisms	
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)	
		S61 Avoid release to the environment. Refer to special instructions/Safety data sheets	
9.2.5	Specific limits	No	

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	

Labelling

Labelling	Provisionally by manufacturer/importer	
Symbols	C, N	
R-Phrases	R22 Harmful if swallowed R34 Causes burns R50 Very toxic to aquatic organisms SCL: Cn ≥ 0.25%: N; R 50	X
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	

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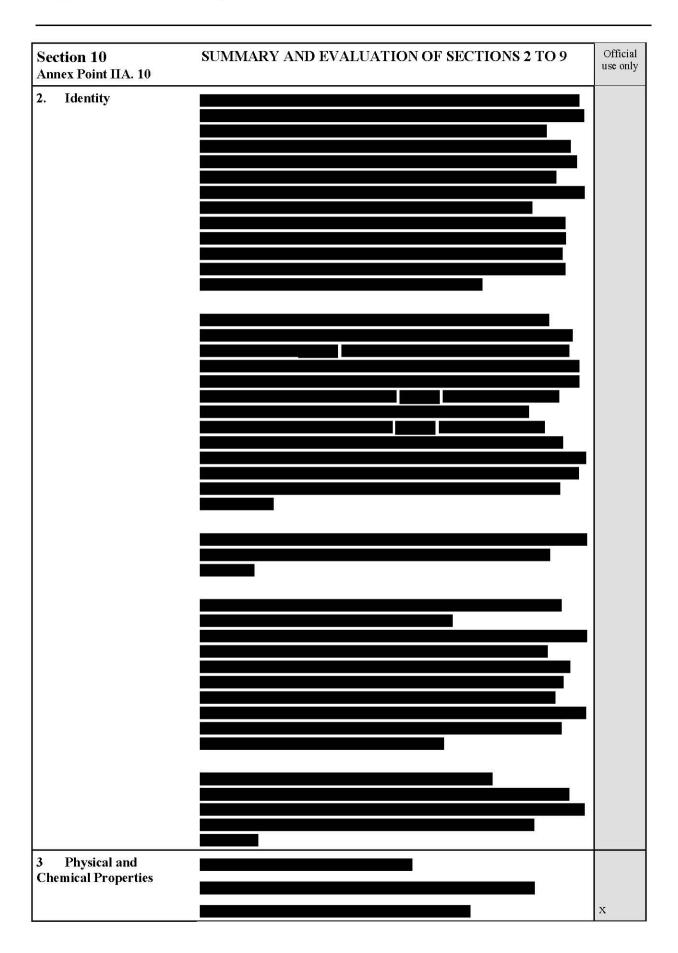
protection
S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S60 This material and its container must be disposed of as hazardous wasteS61 Avoid release to the environment. Refer to special instructions/Safety data sheets

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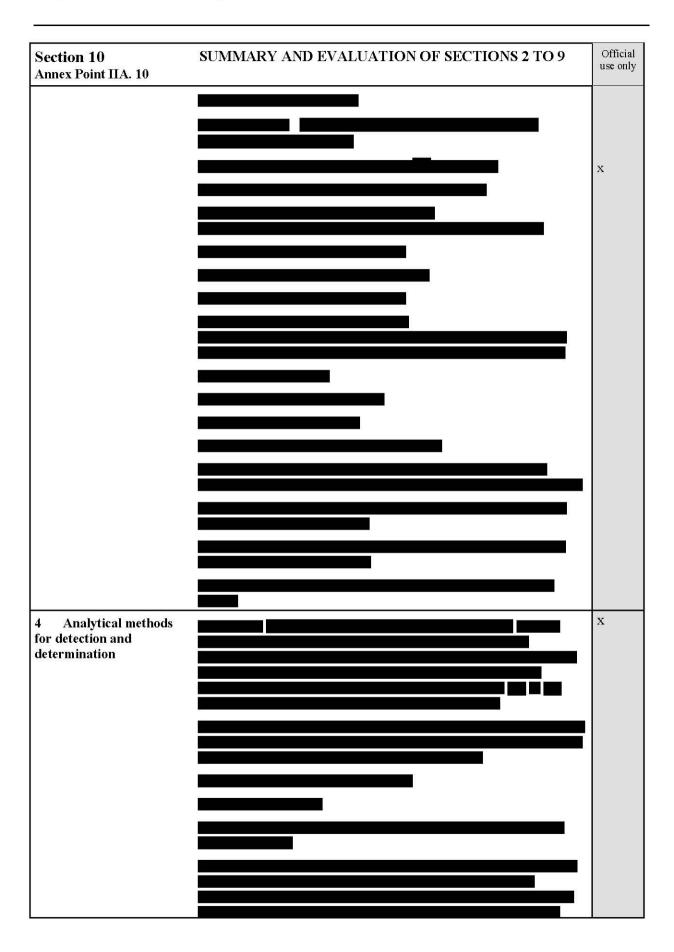
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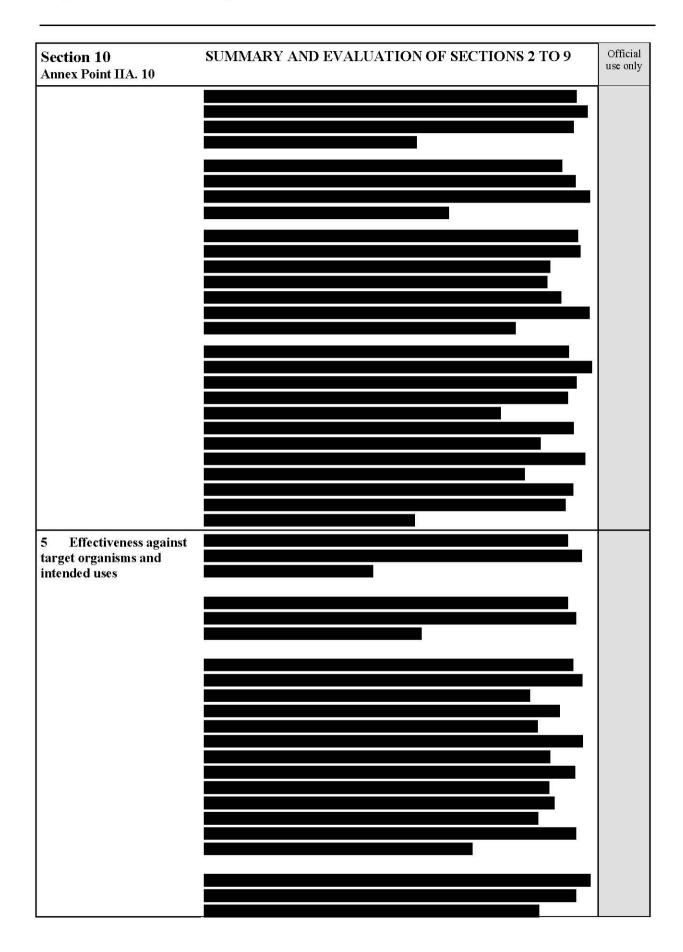
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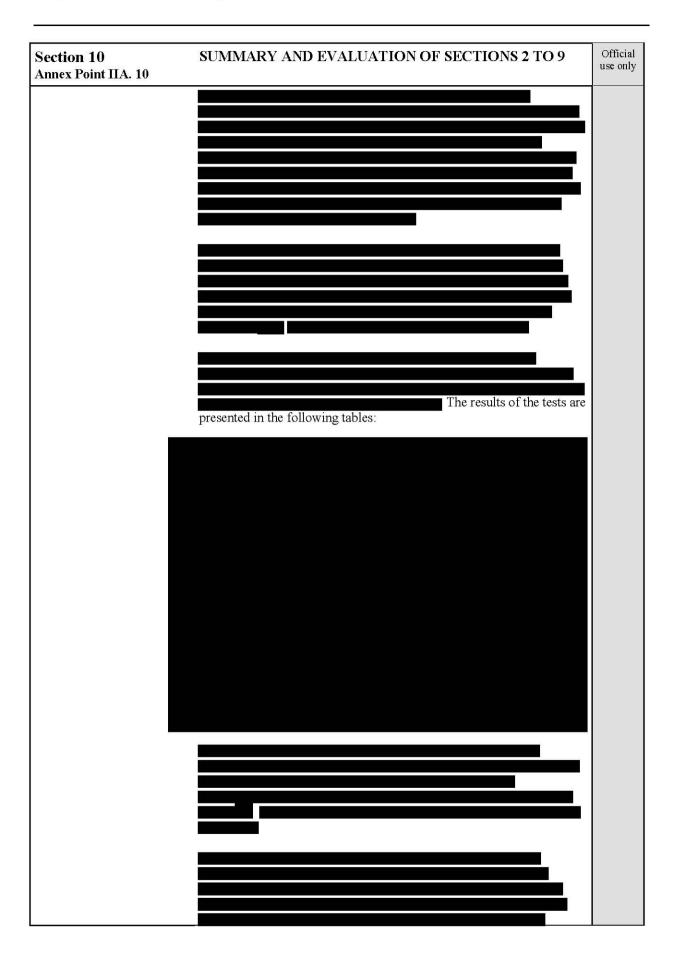
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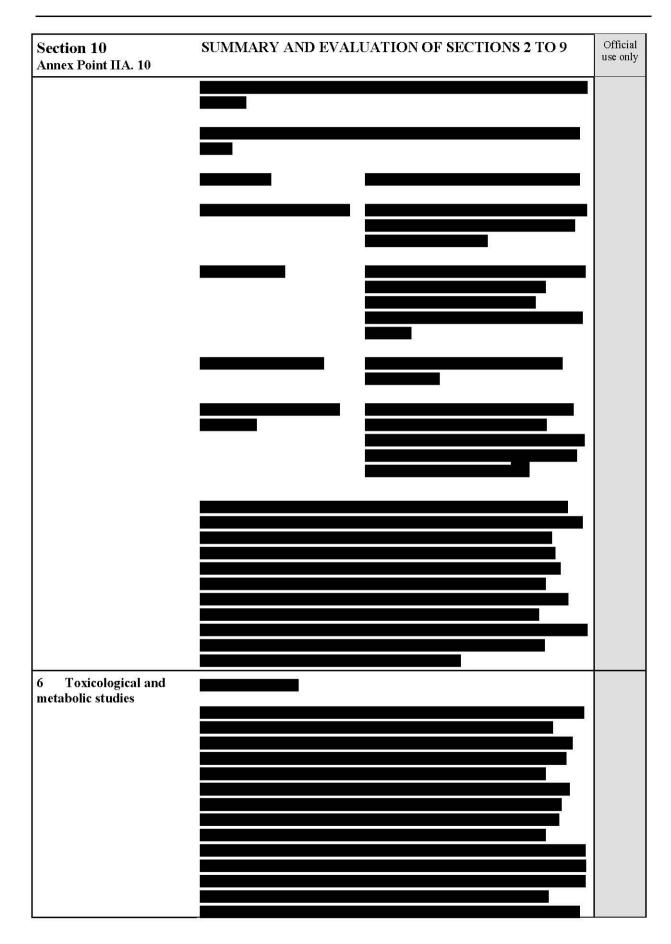
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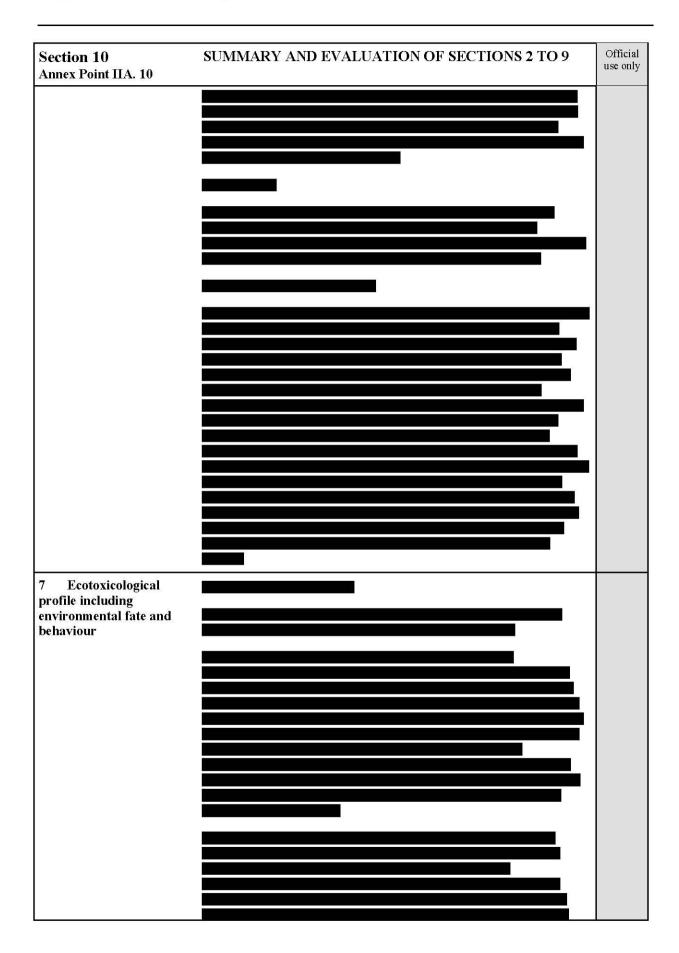
Lonza GmbH; Stepan Europe;

Official use only Section 10 SUMMARY AND EVALUATION OF SECTIONS 2 TO 9 Annex Point IIA. 10

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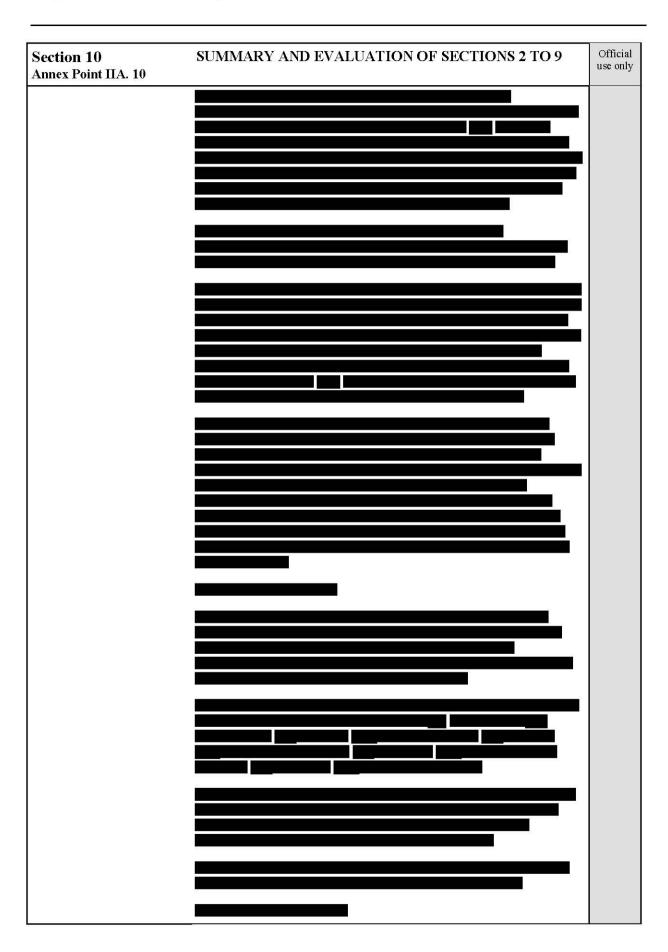
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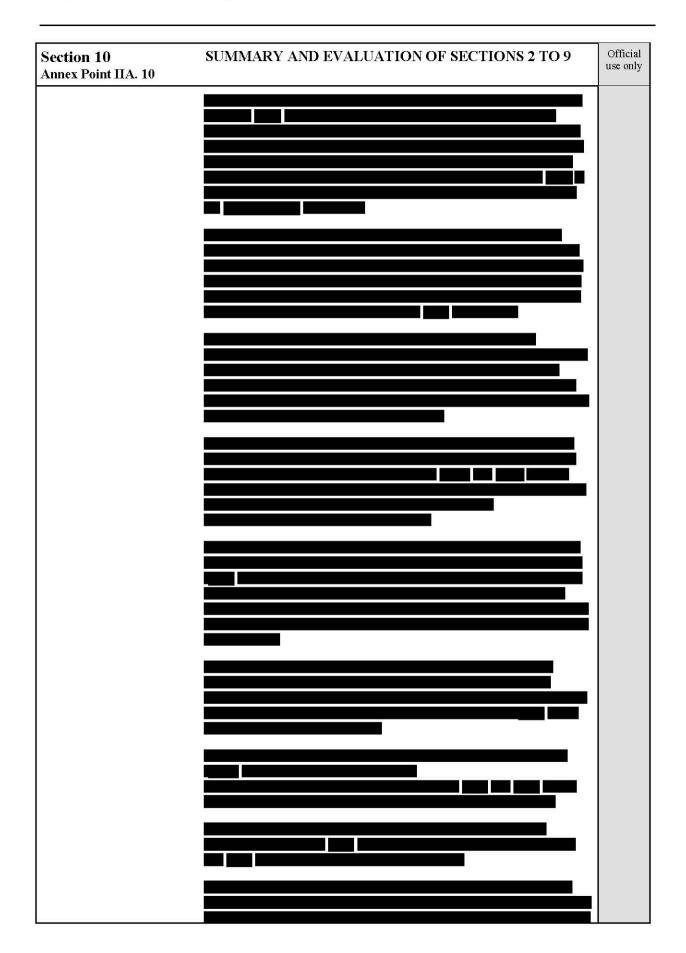
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September 2012

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Official Section 10 SUMMARY AND EVALUATION OF SECTIONS 2 TO 9 use only Annex Point IIA. 10 MAN: Measures necessary to protect man, animals Handling: and the environment Avoid contact with skin and eyes. Provide sufficient air exchange and/or exhaust in work rooms. Wash hands before breaks and immediately after handling the product. Use respirator when performing operations involving potential exposure to vapour of the product. Wear suitable protective clothing, rubber or plastic gloves and eye/face

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Section 10 Annex Point IIA. 10	SUMMARY A	AND EVALUATION OF SECTIONS 2 TO 9	Official use only		
with the control of the production of the control o	protection.				
	Take precaution	ary measures against static discharges.			
	Storage:				
		ightly closed. To maintain product quality, do not store sunlight. Keep in a dry, cool and well-ventilated place.			
	Transport:				
	Classified as cor	rosive liquid (Class 8, Packaging group II, UN 3265)			
	In case of fire:				
		water spray or foam as extinguishing media. Water d to cool closed containers.			
		ned breathing apparatus. Heating or fire can release icipated to contain oxides of carbon and nitrogen			
	Emergency mea	sures in case of accident:			
	Personal precaut	ions:			
		Personal precautions: Use respirator when performing operations involving potential exposure to vapour of the product.			
	Environmental p	precautions:			
	Do not flush into	surface water or sanitary sewer system.			
	Methods for cleaning up:				
		h inert material (sand, earth, chemical absorbent). Do into drains, water courses etc. Neutralize with soda or late			
	ANIMALS ANI	ANIMALS AND ENVIRONMENT:			
	Waste Alkyldim	ethylbenzylammonium Chloride:			
	Incineration is p	recycling is preferred to disposal or incineration. referred. Waste must be incinerated in a suitable at holding a permit delivered by the competent			
9 Classification and labelling	and a comman and a substitution and a community of the co	enzylammonium Chloride is classified and labelled, ective 67/548/EEC as follows:			
	Symbol:	C (Corrosive) N (Dangerous to the environment)			
	Risk phrases	R21/22 Harmful in contact with skin and if swallowed			
		R34 Causes burns			
		R50 Very toxic to aquatic organisms			
	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			
		S36/37/39 Wear suitable protective clothing, gloves			

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Section 10 Annex Point IIA. 10	SUMMARY A	AND EVALUATION OF SECTIONS 2 TO 9	Official use only
		and eye/face protection	
		S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)	
		S61 Avoid release to the environment. Refer to special instructions/Safety data sheets	
		to the manufacturer/ importer, Alkyldimethylbenzyl- oride should be classified and labelled as follows:	
	Symbol:	C (Corrosive)	
		N (Dangerous to the environment)	
	Risk phrases:	R22 Harmful if swallowed	
		R34 Causes burns	
		R50 Very toxic to aquatic organisms	
		SCL: Cn ≥0.25%: N; R50	X
		NOTE: Based on the results of an acute dermal study (LD $_{50}$ > 2000 mg/kg), R21/22 is changed to R22	
	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	
		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	X
		S61 Avoid release to the environment. Refer to special instructions/Safety data sheets	