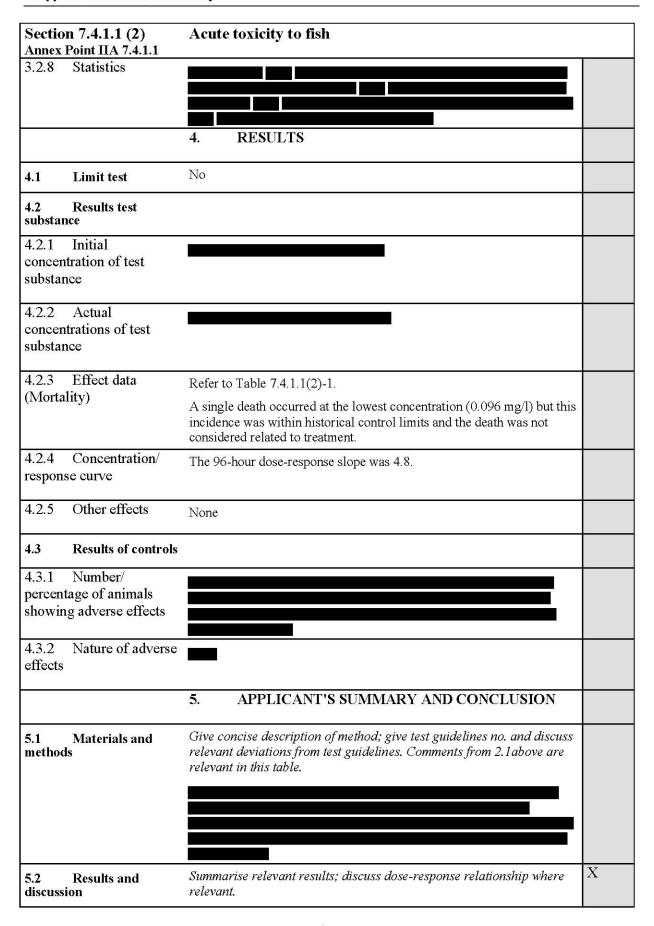
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Alkyl (C_{12-16}) dimethylbenzyl ammonium chloride

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on 7.4.1.1 (2)	Acute toxicity to fish	
Point IIA 7.4.1.1	Treate to Mercy to Hear	
LC0	Not stated; a single death at the lowest concentration was not considered treatment-related and was not used in the LC50 calculation	X
LC50	LC_{50} (96hr) = 0.28 mg/l (95% confidence limit = 0.23 and 0.34 mg/l)	
	Dose response slope = 4.8	
	Refer to Table 7.4.1.1(2)-2	
LC100	Not stated but 100% mortality observed at 0.57 mg/l (measured).	
Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	
	Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.096 mg/l.	X
Reliability	Based on the assessment of materials and methods include appropriate reliability indicator $0,1,2,3$ or 4	
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 comm views submitted	ents and
	EVALUATION BY RAPPORTEUR MEMBER STATE	
ials and Methods		
	Point IIA 7.4.1.1 LC0 LC50 LC100 Conclusion Reliability Deficiencies	Not stated; a single death at the lowest concentration was not considered treatment-related and was not used in the LC50 calculation LC50

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Rapporteur Member State: Italy

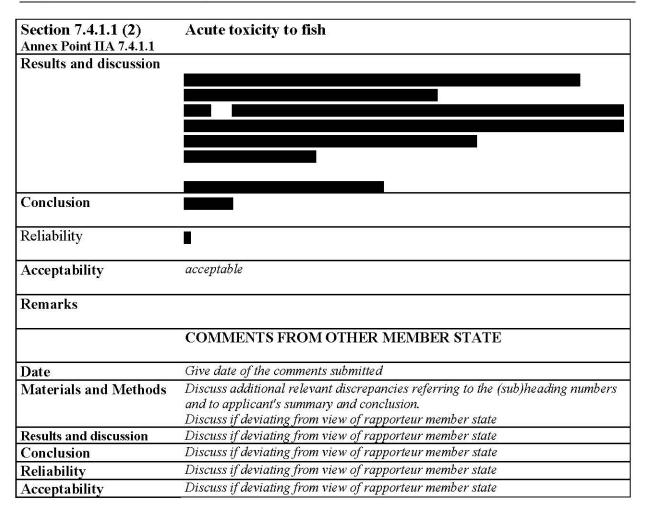


Table 7.4.1.1(3)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0.096	0/20	0/20	1/20	1/20
0.18	0/20	1/20	4/20	4/20
0.31	2/20	5/20	6/20	6/20
0.57	20/20	20/20	20/20	20/20
1.00	20/20	20/20	20/20	20/20

Table 7.4.1.1(3)-2

LC50

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	0.39	0.34	0.28	0.28
95% confidence	(0.31-0.57)	(0.30-0.40)	(0.23-0.34)	(0.23-0.34)
limits	No. 100	200		200

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

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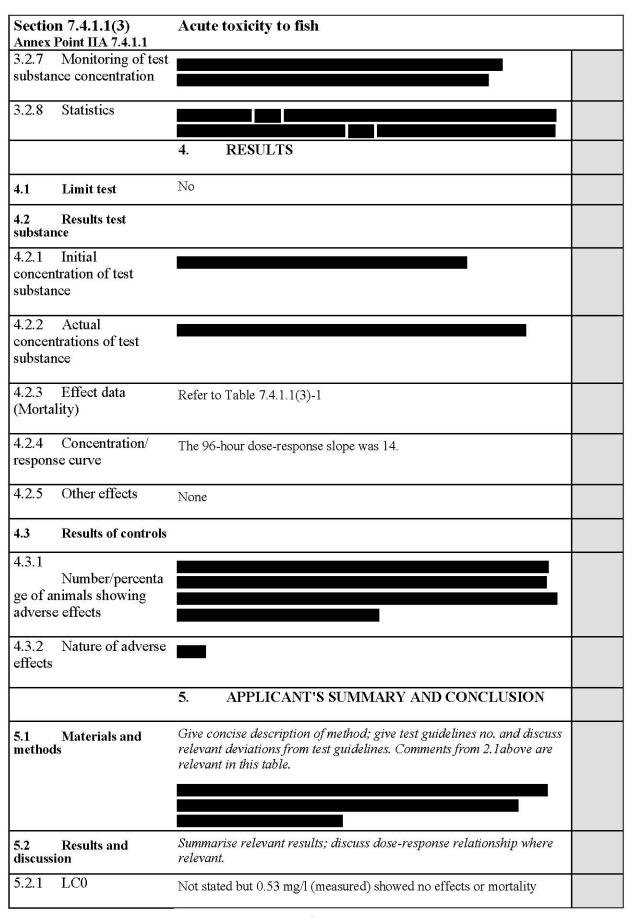
Section 7 Annex Poi	7.4.1.1(3) nt IIA 7.4.1.1	Acute toxicity to fish	
		1. REFERENCE	Official use only
1.1 Re	eference	Sword, M. C. and Stuerman, L. (1994) Static-Renewal Acute Toxicity of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow (<i>Pimephales promelas</i>) in Dilution Water Amended with 10 mg/l Humic Acid BC Laboratories, Columbia, MO, U. S. Report No. 41236 (unpublished).	X
		[Ref No: A7 (LON 3477)]	
1.2 Da	ata protection	Yes	
		(indicate if data protection is claimed)	
1.2.1 Da	ata owner	Give name of company	
		ADBAC Joint Venture	S.
1.2.2 Ci protection	riteria for data	Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:	
		Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of $$ its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1 G	uideline study	Yes	
		U.S. EPA TSCA 797.1400	
		Year: 1993	
		(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")	
	LP	Yes	
(only wher	e required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3 De	eviations	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 Te	est material	Alkyldimethylbenzylammonium Chloride	
3.1.1 Lo	ot/Batch number	List lot/batch number where relevant	

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	on 7.4.1.1(3) Point IIA 7.4.1.1	Acute toxicity to fish	
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. (describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):	X
3.1.3	Description	If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)	
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 Stable	
3.1.6 analys:	Method of is		
3.2	Testing procedure		ti.
3.2.1	Dilution water		
3.2.2	Test organisms	Fathead minnow (Pimephales promelas)	
3.2.3	Test system		e.
3.2.4	Test conditions	Static, daily renewal	
3.2.5 test	Duration of the	96 hours	
3.2.6	Test parameter	Mortality	

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Section 7.4.1.1(3) Annex Point IIA 7.4.1.1	Acute toxicity to fish
5.2.2 LC50	LC_{50} (96hr) = 0.77 mg/l (95% confidence limit = 0.53 and 0.98 mg/l)
	Dose response slope = 14
	Refer to Table 7.4.1.1(3)-2
5.2.3 LC100	Not stated but 100% mortality observed at 1.8 mg/l (measured).
5.3 Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate
	Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.53 mg/l.
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 comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion Reliability	•
Acceptability	Not acceptable:
Remarks	
Anne and the territorial Comment and	COMMENTS FROM OTHER MEMBER STATE

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

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Rapporteur Member State: Italy

Section 7.4.1.1(3) Annex Point IIA 7.4.1.1	Acute toxicity to fish
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 A7.4.1.1(3)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0.30	0/20	0/20	0/20	0/20
0.53	0/20	0/20	0/20	0/20
0.98	16/20	16/20	17/20	18/20
1.80	20/20	20/20	20/20	20/20
3.20	20/20	20/20	20/20	20/20

Table 7.4.1.1(3)-2

T	C50
L	COU

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	0.81	0.81	0.79	0.77

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	on 7.4.1.1 (4) Point IIA 7.4.1.1	Acute toxicity to fish	
1 KIHIVA	10000111177711111	1. REFERENCE	Official use only
1.1	Reference	Sword, M. C. and Stuerman, L. (1994) Static-Renewal Acute Toxicity of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Fathead Minnow (<i>Pimephales promelas</i>) in Dilution Water Amended with 20 mg/l Humic Acid. ABC Laboratories, Columbia, MO, U. S. Report No. 41235 (unpublished).	X
		[Ref No: A8 (LON 3478)]	
1.2	Data protection	Yes	
		(indicate if data protection is claimed)	
1.2.1	Data owner	Give name of company	
		ADBAC Joint Venture	
1.2.2 protec	Criteria for data tion	Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:	
		Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1 Gu	Guideline study	Yes	
		U.S. EPA TSCA 797.1400	
		Year: 1993	
		(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")	
2.2	GLP	Yes	
(only v	vhere required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3	Deviations	No	
		(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	List lot/batch number where relevant	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.	X

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3.1.4 Purity Give purity in g/kg, g/l, 1/6w/w or 1/6 v/v active substance 3.1.5 Stability Describe stability of test material Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the 96 hours 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration		on 7.4.1.1 (4) Point IIA 7.4.1.1	Acute toxicity to fish	
3.1.4 Purity Give purity in g/kg, g/l, 1/6w/w or 1/6 v/v active substance 3.1.5 Stability Describe stability of test material Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the 96 hours 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration				
3.1.5 Stability Describe stability of test material Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.1.3	Description		
3.1.5 Stability Describe stability of test material Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration				
Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.1.4	Purity	Give purity in g/kg, g/l, %w/w or % v/v active substance	
Stable 3.1.6 Method of analysis 3.2 Testing procedure 3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	215	Q. 1.11.		
3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.1.5	Stability	· ·	
3.2.1 Dilution water 3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.1.6 analysi			
3.2.2 Test organisms Fathead minnow (Pimephales promelas) 3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.2	Testing procedure		
3.2.3 Test system 3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.2.1	Dilution water		
3.2.4 Test conditions Static, daily renewal 3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.2.2	Test organisms	Fathead minnow (Pimephales promelas)	
3.2.5 Duration of the test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.2.3	Test system		
test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	3.2.4	Test conditions	Static, daily renewal	
test 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration	2.2.5	D		
3.2.7 Monitoring of test substance concentration	3.2.5 test	Duration of the	96 hours	
substance concentration	3.2.6	Test parameter	Mortality	
3.2.8 Statistics	3.2.7 substar			
·	3.2.8	Statistics		

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Section 7.4.1.1 (4) Annex Point IIA 7.4.1.1		Acute toxicity to fish	
Ailica	1 OIII 11A 7.4.1.1		
		4. RESULTS	
4.1	Limit test	No	
4.2 substan	Results test		
4.2.1 concen substan	Initial tration of test ace		
4.2.2 concen substan	Actual trations of test		
4.2.3 (Morta	Effect data lity)	Refer to Table 7.4.1.1(4)-1	
4.2.4 respons	Concentration/ se curve	The 96-hour dose-response slope was 15.	
4.2.5	Other effects	None	
4.3	Results of controls		
	Number/percenta nimals showing e effects		
4.3.2 effects	Nature of adverse		
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 method	Materials and ls	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 discussi	Results and ion	Summarise relevant results; discuss dose-response relationship where relevant.	
5.2.1	LC0	Not stated but 0.99 mg/l (measured) showed no effects or mortality	
5.2.2	LC50	LC_{50} (96hr) = 1.4 mg/l (95% confidence limit = 0.99 and 1.8 mg/l) Dose response slope = 15	
		Refer to Table 7.4.1.1(4)-2	

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Section	on 7.4.1.1 (4)	Acute toxicity to fish
Annex	Point IIA 7.4.1.1	
5.2.3	LC100	Not stated but 100% mortality observed at 3.2 mg/l (measured).
5.3	Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate
		Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.99 mg/l.
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	
		(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		
Result	ts and discussion	
Concl	usion	
Reliab	ility	
Accep	tability	Not acceptable:
Rema	rks	
		COMMENTS FROM OTHER MEMBER STATE

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

September 2012

Mason Europe Limited

Rapporteur Member State: Italy

Section 7.4.1.1 (4) Annex Point IIA 7.4.1.1	Acute toxicity to fish
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 A7.4.1.1(4)-1

Cumulative Mortalities

Concentration (mg/l)	24 hours	48 hours	72 hours	96 hours
0/20	0/20	0/20	0/20	0/20
0/20	0/20	0/20	0/20	0/20
0/20	0/20	0/20	0/20	0/20
1.8	19/20	19/20	19/20	19/20
3.2	20/20	20/20	20/20	20/20

Table 7.4.1.1(4)-2

LC50

LC50 ppm (mg/l)	24hr	48hr	72hr	96hr
	1.4	1.4	1.4	1.4

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Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1		Acute toxicity to fish	
		1. REFERENCE	Official use only
1.1	Reference	Pate. H.O. and D.O. McIntyre (1991). Daily Static-Renewal Acute 96-hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to Rainbow Trout. Battelle Columbus Division, Columbus, OH, U. S. Report No. SC890051 (unpublished).	
		[Ref No: A8b (LON 1864)]	
1.2	Data protection	Yes	
		(indicate if data protection is claimed)	
1.2.1	Data owner	Give name of company	
		ADBAC Joint Venture	
1.2.2 protec	Criteria for data tion	Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:	
		Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Yes	
		U.S. EPA, FIFRA Subdivision E, Guideline 72-1, Hazard evaluation: Wildlife and aquatic organisms	
		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	Yes	
(only w	vhere required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3	Deviations	No	
		(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	List lot/batch number where relevant	

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	on 7.4.1.1 (5) Point IIA 7.4.1.1	Acute toxicity to fish	
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.	X
		Alkyldimethylbenzylammonium Chloride was tested.	
		(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)	
3.1.4	Purity	Give purity in g/kg, g/l, %w/w or % v/v active substance	X
3.1.5	Stability	Describe stability of test material	
		Stable	
3.1.6 analysi	Method of		
3.2	Testing procedure		
3.2.1	Dilution water		
3.2.2	Test organisms	Rainbow trout (Oncorhynchus mykiss) supplied	
3.2.3	Test system		
3.2.4	Test conditions	Static, daily renewal	
3.2.5	Duration of the	96 hours	

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride

September 2012

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Rapporteur Member State: Italy

Section 7.4.1.1 (5) Acute toxicity to fish Annex Point IIA 7.4.1.1 3.2.6 Test parameter Mortality 3.2.7 Monitoring of test substance concentration 3.2.8 Statistics RESULTS 4. No 4.1 Limit test 4.2 Results test substance 4.2.1 Initial concentration of test substance 4.2.2 Actual concentrations of test substance 4.2.3 Effect data Refer to Table 7.4.1.1(5)-1 (Mortality) 4.2.4 Other effects Three hours after test initiation, three fish in the 1.354 mg/l dose group were swimming erratically on the water surface. No mortality or nonlethal toxic symptoms occurred in test substance concentration of 0.619 mg/l during the 96-hour exposure. 4.3 Results of controls 4.3.1 Number/ percentage of animals showing adverse effects 4.3.2 Nature of adverse effects APPLICANT'S SUMMARY AND CONCLUSION 5. Give concise description of method; give test guidelines no. and discuss 5.1 Materials and relevant deviations from test guidelines. Comments from 2.1above are methods relevant in this table.

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

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Rapporteur Member State: Italy

Lonza GmbH; Stepan Europe;

Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
5.2 Results and discussion	Summarise relevant results; discuss dose-response relationship where relevant.	
5.2.1 LC0	$LC_0 (96hr) = 0.619 \text{ mg/l}$	
5.2.2 LC50	LC_{50} (96hr) = 0.930 mg/l (95% confidence limit = 0.866 to 0.984 mg/l) Refer to Table 7.4.1.1(5)-2	
5.2.3 LC100		
5.3 Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	
	Based on concentration effect relationship observed, the no-observed-effect concentration the 96 hr (NOEC) was found to be 0.619 mg/l.	
5.3.1 Reliability	Based on the assessment of materials and methods include appropriate reliability indicator θ , 1 , 2 , 3 or 4	
5.3.2 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 comments of views submitted	and
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Materials and Method	is	
Results and discussion		
Conclusion		
Reliability	Acceptable	
Acceptability Remarks	Hecephanie	
	COMMENTS FROM OTHER MEMBER STATE	
Date	Give date of the comments submitted	

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride

September 2012

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Rapporteur Member State: Italy

Section 7.4.1.1 (5) Annex Point IIA 7.4.1.1	Acute toxicity to fish	
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 7.4.1.1(5)-1

Mortality data

Concentration (mg/l)	Percent Mortality at:			
	24 hours	48 hours	72 hours	96 hours
1.354	10	95	100	100
1.204	0	60	100	100
1.029	0	5	30	60
0.864	0	0	25	40
0.619	0	0	0	0

Table 7.4.1.1(5)-2

LC50

LC50 (mg/l)	24 hr	48 hr	72 hr	96 hr
	>1.354	1.175	1.1066	0.930
95% confidence limits	not determined	(1.029-1.354)	(0.864-1.204)	(0.866-0.984)

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

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Mason Europe Limited

Section 7.4.1.1 Annex Point IIIA.7.4.1.1	Acute toxicity to fish (marine)	
	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		
Conclusion	The applicant's justification is acceptable	
Remarks	p v A	

Lonza GmbH; Stepan Europe; Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium September 2012 chloride

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Section 7.4.1.1 Annex Point IIIA.7.4.1.1	Acute toxicity to fish (marine)
	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

September 2012

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	on 7.4.1.2(1) Point IIA 7.4.1.2	Acute toxicity to invertebrates	
		1. REFERENCE	Official use only
1.1	Reference	Pate, H. O. and D. O. McIntyre (1991). Daily Static-Renewal Acute 48-Hour Toxicity Test of Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) to <i>Daphnia magna</i> . Report No. SC890052.Battelle Columbus Division, Columbus, OH, U. S (unpublished).	
		[Ref No: A68 (LON 0097)]	
1.2	Data protection	Yes	
		(indicate if data protection is claimed)	
1.2.1	Data owner	Give name of company	
		ADBAC Joint Venture	
1.2.2 protect	Criteria for data tion	Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:	
		Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA	
		2. GUIDELINES AND QUALITY ASSURANCE	
2.1	Guideline study	Yes	
		U.S. EPA FIFRA Subdivision E, Guideline 72-2 Hazard evaluation: Wildlife and aquatic organisms	
		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		Yes	
(only w	vhere required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)	
2.3	Deviations	No	
		(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")	
		3. MATERIALS AND METHODS	
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.	
3.1	Test material	Alkyldimethylbenzylammonium Chloride	
3.1.1	Lot/Batch number	List lot/batch number where relevant	

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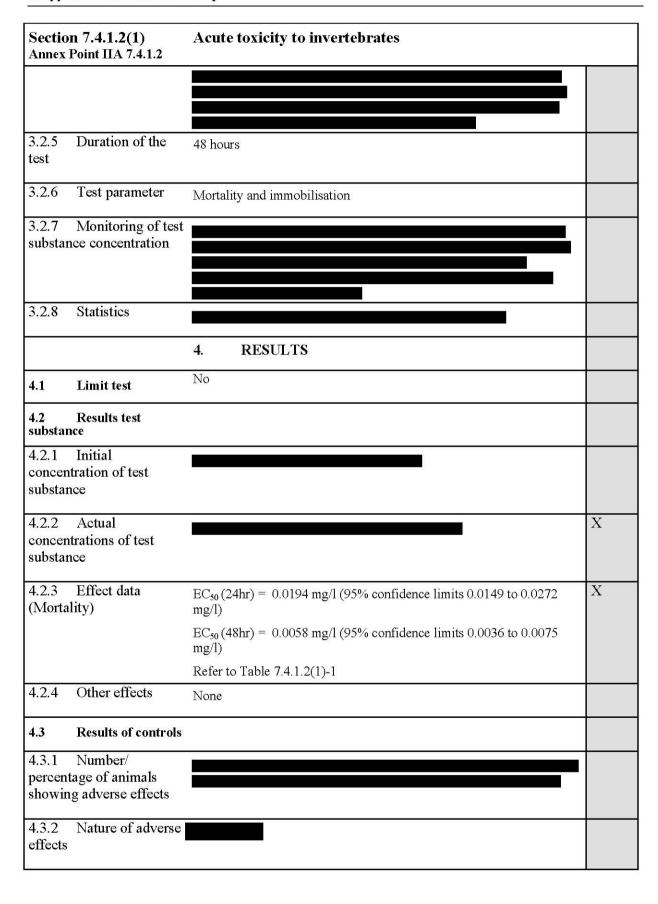
	on 7.4.1.2(1) Point IIA 7.4.1.2	Acute toxicity to invertebrates	
3.1.2	Specification	As given in section II of Annex IIA of Directive 98/8/EC, especially 2.7 and 2.8 of Annex IIA.	X
		Alkyldimethylbenzylammonium Chloride was tested.	
		(describe specification under separate subheadings, such as the following; 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)	
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	
		Stable	
3.1.6	Method of		
analys	is		
3.2	Testing procedure		
3.2.1	Dilution water		
3.2.2	Test organisms	D. J.	
3.4.4	Test organisms	Daphnia magna	
3.2.3	Test system		
3.2.4	Test conditions	Daphnia magna neonates were	
renuiroso dell' 2º		treated with the test substance	
		l for 48 hours under static-	
		renewal conditions.	

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride

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

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Section 7.4.1.2(1) Annex Point IIA 7.4.1.2		Acute toxicity to invertebrates		
		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.		
	Manager Laborato Sano		v	
5.2 discuss	Results and sion	Summarise relevant results; discuss dose-response relationship where relevant.	X	
5.2.1	EC0	Not defined		
5.2.2	EC50	EC_{50} (24hr) = 0.0194 mg/l (95% confidence limits 0.0149 to 0.0272 mg/l) EC_{50} (48hr) = 0.0058 mg/l (95% confidence limits 0.0036 to 0.0075 mg/l)	X	
5.2.3	EC100	Not stated but 100% mortality observed at 0.0227 mg/l (measured).		
5.3	Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate Based on concentration effect relationship observed, the no-observed- effect concentration (NOEC) was found to be less than 0.006 mg/l.		
5.3.1	Reliability	200 Acc	X	
5.3.2	Deficiencies			
		(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)		
		Evaluation by Competent Authorities	an weeks white the	
		Use separate "evaluation boxes" to provide transparency as to the commerciews submitted	nts ana	
		EVALUATION BY RAPPORTEUR MEMBER STATE		
Date				
Mater	ials and Methods			
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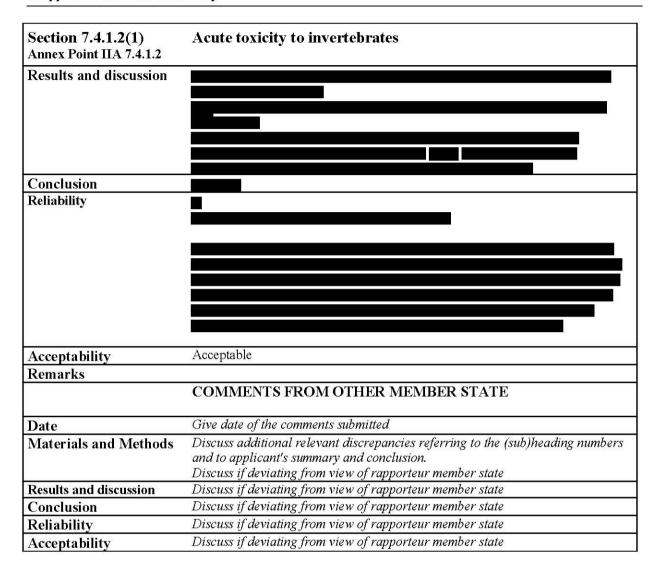


Table A7.4.1.2(1)-1

Mortality data

Mean measured	Percent	Mortality at:
concentration (mg/l)	24 hours	48 hours
0.0516	100	100
0.0272	100	100
0.0227	65	100
0.0149	25	95
0.0060	5	53
0.0	0	10

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

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Mason Europe Limited

Section 7.4.1.2 Annex Point IIIA.7.4.1.2	Acute toxicity to invertebrates (marine)	
	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:		
	<u> </u>	
Undertaking of intended		
data submission []		
	Evaluation by Competent Authorities Use separate "evaluation boxes" to provide transparency as to the	
	comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date		
Evaluation of applicant's		
justification		
Conclusion		
Remarks	The applicant's justification is acceptable	
IXCHIAI KS	COMMENTS FROM OTHER MEMBER STATE (specify)	
l	COMMITTED FROM OTHER MEMBER STATE (Specify)	

Lonza GmbH; Stepan Europe; Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium September 2012 chloride

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Section 7.4.1.2 Annex Point IIIA.7.4.1.2	Acute toxicity to invertebrates (marine)	
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

September 2012

Mason Europe Limited

Section 7.4.1.3(1) Annex Point IIA 7.4.1.3		Growth inhibition test on algae	
		1. REFERENCE	Official use only
1.1	Reference	Mayer, P, H. Oldersma and J. A. Schoonmade (2001). Determination of the effect of Alkyldimethylbenzylammonium Chloride (ADBAC) on the growth of fresh water green alga <i>Selenastrum capricornutum</i> (OECD Guideline No. 201 and EU C.3). TNO Chemistry, Delft, The Netherlands. Report no. 99-9072-03 (unpublished).	
		[Ref No: A48 (LON 3374)]	
1.2	Data protection	Yes	
ER 9/0/2002	0000	(indicate if data protection is claimed)	
1.2.1	Data owner	Give name of company	
		ADBAC Issues Steering Committee	
1.2.2 protecti	Criteria for data ion	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. 201 "Algal Growth Inhibition Test"	
		2001	
		(If yes, give references to the guidelines (for example test number in Annex V of Dir. 67/548/EEC); if no, give justification, e.g. "no guidelines available" or "methods used comparable to guidelines xy")	
2.2 GLP		Yes	
(only w	here required)	(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		
3.1.1	Lot/Batch number	List lot/batch number where relevant	
2.)			

Lonza GmbH; Stepan Europe;

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Section Annex	n 7.4.1.3(1) Point IIA 7.4.1.3	Growth inhibition test on algae	
3.1.2	Specification	(describe specification under separate subheadings, such as the following; additional subheadings may be appropriate):	X
		As given in section II of Annex IIA of Directive 98/8/EC, especially Sections 2.6-2.8 therein.	
		Active substance (a.s.), alkyl(C ₁₂ -C ₁₆)dimethylbenzylammonium chloride (ADBAC; CAS RN 68424-85-1), in aqueous solution.	
3.1.3	Description	If appropriate, give e.g. colour, physical form (e.g. powder, grain size, particle size/distribution)	
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	X
		The non-radiolabelled a.s., ADBAC, is hydrolytically and photolytically stable under the conditions of this study and has been shown to be stable in aqueous, alcohol and alcohol/aqueous solutions for extended periods, e.g. at least five years under standard laboratory conditions (see Section 2.6.1 of Annex IIA).	
3.1.6 analysi	Method of s		
3.2	Testing procedure		
3.2.1	Dilution water		
3.2.2	Test organisms	Selenastrum capricornutum	
3.2.3	Test system		X
3.2.4	Test conditions	The test was carried out at 22.3°C average, and a pH of 8.2. All other parameters were also within the guideline recommendations.	
3.2.5 test	Duration of the	72 hours	
3.2.6	Test parameter	Growth and growth rate	
3.2.7	Monitoring of test		

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	n 7.4.1.3(1) Point IIA 7.4.1.3	Growth inhibition test on algae		
substar	nce			
3.2.8	Analysis			
3.2.9	Statistics		X	
		4. RESULTS		
4.1	Limit test	No		
4.2 substar	Results test			
4.2.1 concen substan	Nominal trations of test nce			
4.2.2 concen substan	Actual tration of test nce		X	
4.2.3	Other effects	None		
4.3	Results of controls			
		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 discuss	Results and ion	Summarise relevant results; discuss dose-response relationship where relevant.		
5.2.1	EC10	$ErC_{10} = 9 \mu g/l$ $EbC_{10} < 1.2 \mu g/l$	X	
5.2.2	EC50	$ErC_{50} = 49 \mu g/l$ $EbC_{50} = 14 \mu g/l$	X	
5.2.3	EC90	$ErC_{90} = 270 \ \mu g/1 \ EbC_{90} = 57 \ \mu g/1$		
5.3	Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	X	
		Based on concentration effect relationship observed, the no-observed-effect concentration (NOEC) was found to be less than or equal to 0.0012 mg/l.		
5.3.1	Reliability	Based on the assessment of materials and methods include appropriate reliability indicator 0, 1, 2, 3 or 4		

Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium Lonza GmbH; Stepan Europe; chloride

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Rapporteur Member State: Italy

Section 7.4.1.3(1) Growth inhibition test on algae Annex Point IIA 7.4.1.3 5.3.2 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 comments and views submitted EVALUATION BY RAPPORTEUR MEMBER STATE Date Materials and Methods Results and discussion Conclusion Reliability Acceptability Acceptable Remarks COMMENTS FROM OTHER MEMBER STATE

Lonza GmbH; Stepan Europe;

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Section 7.4.1.3(1) Growth inhibition test on algae Annex Point IIA 7.4.1.3	
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 7.4.1.3(1)-1. 72-Hour Effect Concentrations for Growth Rate and Area Under the Growth Curve (AUC).

Parameter	EC ₁₀ (ug a.i./l)	EC ₅₀ (ug a.i./l)	EC ₉₀ (ug a.i./l)
Growth Rate (E _r C)	9.0	49	270
AUC (E _b C)	<1.2	14	57

Table 7.4.1.3(1)-2. Mean Values of cell algal densities (10⁴ cells/ml corrected for background)

8	Measured concentrations of ADBAC (ug a.i./l)E _b C ₁₀ (ug/l)								
Time	$\mathrm{E_{b}C_{50}(ug/l)}$								
(hours)	$\mathrm{E_{b}C_{90}(ug/l)}$								
	0	0	1.2	5.1	11	22	98	382	
0	1.0	1.0							
23	4.8	4.7	4.6	4.4	3.6	3.8	0.7	0.6	
47	24.3	24.0	21.9	19.6	16.0	7.1	0.7	0.1	
71	111.2	110.9	96.0	82.9	66.3	29.3	0.9	-3.0	

⁻⁻ Not determined

Table 7.4.1.3(1)-3. The area under the growth curve (A) and the percentage reduction in growth (I_A) after 72 hours of exposure to ADBAC

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

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	Measured concentrations of ADBAC (ug a.i./l)							
Parameter	0	0	1.2	5.1	11	22	98	382
A	1974	1956	1726	1511	1203	552	-14	-43
I_A	0	0	12	23	39	72	101	102

Lonza GmbH; Stepan Europe; Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride

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

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Section 7.4.1.3 Annex Point IIIA.7.4.1.3	Growth inhibition test on algae (marine)	
	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		
Conclusion	The applicant's justification is acceptable	
Remarks		

Lonza GmbH; Stepan Europe; Alkyl (C₁₂₋₁₆) dimethylbenzyl ammonium chloride

Mason Europe Limited September 2012

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Remarks

Rapporteur Member State: Italy

Section 7.4.1.3
Annex Point IIIA.7.4.1.3

COMMENTS FROM OTHER MEMBER STATE (specify)

Date

Evaluation of applicant's justification

Conclusion

Lonza GmbH; Stepan Europe;

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Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4		Inhibition on microbiological activity				
		1. REFERENCE	Official use only			
1.1	Reference	Author(s), year, title, laboratory name, laboratory report number, report date (if published, list journal name, volume: pages) If necessary, copy field and enter other reference(s).				
		Mayer, P, H., J. A. Schoonmade and A. O. Hanstveit (2001). Screening of the Effect of Alkyldimethylbenzylammonium Chloride on the Respiration Rate of Activated Sludge (OECD Guideline No. 209). TNO Nutrition and Food Research, Delft, The Netherlands. Report no. 99-9072-04 (unpublished).				
		[Ref No: A49 (LON 3324)]				
1.2	Data protection	Yes				
		(indicate if data protection is claimed)				
1.2.1	Data owner	Give name of company				
		ADBAC Issues Steering Committee				
1.2.2 protec	Criteria for data tion	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 $\ensuremath{\mathrm{I/IA}}$				
		2. GUIDELINES AND QUALITY ASSURANCE				
2.1	Guideline study	Yes				
		OECD Guideline No. 209 "Activated Sludge, Respiration Inhibition Test"				
		2001	X			
		(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	Yes				
(only w	vhere required)	(If no, give justification, e.g. state that GLP was not compulsory at the time the study was performed)				
2.3	Deviations	No				
		(If yes, describe deviations from test guidelines or refer to respective field numbers where these are described, e.g. "see 3.x.y")				
		3. MATERIALS AND METHODS				
		In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.				
3.1	Test material	Alkyldimethylbenzylammonium Chloride	X			
3.1.1	Lot/Batch number	List lot/batch number where relevant				

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	n 7.4.1.4 (1) Point IIA 7.4.1.4	Inhibition on microbiological activity	
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.	X
		(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)	
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	
	2000 1110)	Stable	
3.1.6	Method of	Stable	
analysi			
3.2	Testing procedure		
3.2.1	Dilution water		
3.2.1	Test organisms	Activated sludge, domestic	
3.2.2	Test system		X
3.2.3	Test conditions		X
3.2.4 test	Duration of the	3 hours	
3.2.5	Test parameter	Inhibition on respiration rate	X
3.2.6 substar	Monitoring of test nee concentration		
3.2.7	Statistics		X
		4. RESULTS	
4.1	Limit test	No	
4.2 substar	Results test		
4.2.1 concen substar	Initial tration of test nce		

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

Mason Europe Limited

Rapporteur Member State: Italy

Lonza GmbH; Stepan Europe;

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	n 7.4.1.4 (1) Point IIA 7.4.1.4	Inhibition on microbiological activity	
4.2.2 concent substan	Actual rations of test ce		X
4.2.3 (Mortal	Effect data ity)	See section 5. 2	
4.2.4	Other effects	None	
4.3 controls	Results of		
percent	species showing		
4.3.2 effects	Nature of adverse		
		5. APPLICANT'S SUMMARY AND CONCLUSION	
5.1 methods	Materials and	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 discussi	Results and	Summarise relevant results; discuss dose-response relationship where relevant.	
5.2.1	EC20	$EC_{20} = 3.4 \text{ mg a.s./l}$	
5.2.2	EC50	$EC_{50} = 7.75 \text{ mg a.s.} / 1$	X
5.2.3	EC80	$EC_{80} = 17.8 \text{ mg a.s./l}$	
5.3	Conclusion	Subsections for NOAEL, LOAEL etc. if appropriate	X
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	(If yes, discuss the impact of deficiencies and implications on results. If relevant, justify acceptability of study.)	

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Section 7.4.1.4 (1) Annex Point IIA 7.4.1.4	Inhibition on microbiological activity
	Evaluation by Competent Authorities
	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 OTHER MEMBER STATE
Date	Give date of the comments submitted
Materials and Methods	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.
D14	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

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

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Mason Europe Limited

Section 7.4.1.4 (2) Annex Point IIA 7.4.1.4		Inhibition on microbiological activity		
		1. REFERENCE	Official use only	
1.1	Reference	Corby J.E. (1992) Determination of the Acute Toxicity of Chemicals and Wastewaters to Aquatic Microorganisms. Roy F. Weston, Inc., Lionville, PA, USA. Report No. 91-062 (unpublished).		
		[Ref No: A62]		
1.2	Data protection	Yes		
		(indicate if data protection is claimed)		
1.2.1	Data owner	Give name of company		
		ADBAC Joint Venture		
1.2.2 protect	Criteria for data tion	Choose one of the following criteria (see also TNsG on Product Evaluation) and delete the others:		
		Data submitted to the MS before 14 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.		
		2. GUIDELINES AND QUALITY ASSURANCE		
2.1	Guideline study	Yes	X	
		Modification to a five day biochemical oxygen demand analysis		
		1992		
		(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	Yes		
(only w	here required)	(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			
3.1.1	Lot/Batch number	List lot/batch number where relevant		
lo .				