Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

		LC50 = 68 mg/L
		NOEC = 22 mg/L
5.3.1	Other Conclusions	None
5.3.2	Reliability	1
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	-

Table A7_4_1_1-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	-
Vehicle control performed	-
Other procedures	Semi-static test; pretest for adequate solubility

Table A7_4_1_1-2: Dilution water

Criteria	Details
Source	Reconstituted water: Analytical grade salts were dissolved in deionized water
Alkalinity	0.4 mmol/L
Hardness	1.25 mmol/L (=125 mg/L as $CaCO_3$)
pH	6.5 at start
Oxygen content	8.1-9.1 mg/L
Conductance	Not reported
Holding water different from dilution water	No

Table A7_4_1_1-3: Test organisms

Criteria	Details
Species/strain	zebra fish (*Brachydanio rerio*)
Source	RCC laboratories
Wild caught	No
Age/size	Not reported / 3.1 $\pm$ 0.2 cm
Kind of food	Tetra Min Hauptfutter, supplied by TETRA-Werke, D-49304 Melle, Germany
Amount of food	Day 7 to Day1 before start
Feeding frequency	Not reported
Pretreatment	Acclimation period: One week
Feeding of animals during test	No

Table A7_4_1_1-4: Test system

Criteria	Details
Test type	Semi-static
Renewal of test solution	Semi-static system (renewal after 24 hours)
Volume of test vessels	5000 mL
Volume/animal	5000 mL/7 fish = 714 mL/fish
Number of animals/vessel	7
Number of vessels/ concentration	1/concentration (control=0; 4.6, 10, 22, 16, 100 mg/L)
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-5: Test conditions

Criteria	Details
Test temperature	Table 3: Temperatures (°C) in the freshly prepared and old test media and in the control Nominal test item concentration (mg/L) / Exposure time: 0 h (new); 24 h (old, new); 48 h (old, new); 72 h (old, new); 96 h (old) Control 22 22 22 21 22 22 22 22 4.6 22 22 22 21 22 22 22 22 10 22 22 22 21 22 22 22 22 22 22 22 22 21 22 22 22 22 46 22 22 22 21 22 22 22 22 100 22 22 22 21 -- -- -- -- --: not measured since all fish were dead
Dissolved oxygen	Table 4: Oxygen concentrations (mg/L) in the freshly prepared and old test media and in the control Nominal test item concentration (mg/L) / Exposure time: 0 h (new); 24 h (old, new); 48 h (old, new); 72 h (old, new); 96 h (old) Control 9.0 8.1 8.9 8.3 9.1 8.2 9.0 8.2 4.6 9.0 8.1 9.0 8.3 9.1 8.2 9.0 8.2 10 9.0 8.2 8.9 8.2 9.0 8.2 8.9 8.2 22 9.0 8.2 8.9 8.3 9.0 8.1 9.1 8.2 46 9.0 8.1 9.0 8.2 9.1 8.1 9.0 8.0 100 9.1 8.0 9.0 7.4 -- -- -- -- --: not measured since all fish were dead

pH	Table 3: pH values in the freshly prepared and old test media and in the control Nominal test item concentration (mg/L) / Exposure time: 0 h (new *), 24 h (old, new *), 48 h (old, new *), 72 h (old, new *), 96 h (old) Control 6.5 7.2 6.5 7.2 6.5 7.1 6.5 7.1 4.6 6.5 7.2 6.5 7.2 6.5 7.1 6.5 7.1 10 6.5 7.2 6.5 7.2 6.5 7.1 6.5 7.1 22 6.5 7.2 6.5 7.2 6.5 7.1 6.5 7.1 46 6.5 7.2 6.5 7.2 6.5 7.1 6.5 7.1 100 6.5 7.1 6.5 7.0 – – – – –: not measured since all fish were dead *: after adjustment of pH, see Section 2.5.2
Adjustment of pH	Yes pH = 6.5
Aeration of dilution water	Yes slightly
Intensity of irradiation	60-350 lux
Photoperiod	A 16-hour light to 8-hour dark photoperiod, with a 30-minute transition period.

Table A7_4_1_1-6: Mortality data

Test-Substance Concentration (21.1+19.6+21.3+/3 (nominal(n)/measured (m))[1] [mg/l]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
0 (n)	0/0	0/0	0/0	0/0	0	0	0	0
4.6 (n)	0/0	0/0	0/0	0/0	0	0	0	0
10 (n)	0/0	0/0	0/0	0/0	0	0	0	0
20.7 (m)	0/0	0/0	0/0	0/0	0	0	0	0
42.6 (m)	0/0	7/0	7/0	7/0	0	0	0	0
94.4 (m)	7/0	7/7	7/7	7/7	100	100	100	100
Temperature [°C]	22	22	22	22				
PH[2]	7.2/6.5	7.2/6.5	7.2/6.5	7.2/6.5				
Oxygen [mg/l][3]	8.2/8.9	8.3/9.0	8.2/9.0	8.2				

[1] specify, if TS concentrations were nominal or measured; [2] old/new after replacement;
[3] typical-old/new after replacement

Table A7_4_1_1-7: Effect data

	48 h [mg/l][1]	**95 % c.l.**	**96 h [mg/l][1]**	**95 % c.l.**
LC_0	22	-	22	-
LC_{50}	68	46-100	68	46-100
LC_{100}	100	-	100	-

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
Mortality of control animals <10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥80% of initial concentration during test	X	
Criteria for poorly soluble test substances	X	

Section A 7.4.1.2 **Annex Point IIA7.2**	**Acute toxicity to invertebrates *Daphnia magna***	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	[redacted]	

Section A 7.4.1.2 **Acute toxicity to invertebrates *Daphnia magna***
Annex Point IIA7.2

[redacted]

Section A 7.4.1.2 Annex Point IIA7.2	Acute toxicity to invertebrates *Daphnia magna*
	[redacted]
Undertaking of intended data submission [ ]	
Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2 [redacted]

			Official use only
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2			
1.2.3	Criteria for data protection		
2.1	**Guideline study**		
2.2	**GLP**		
2.3	**Deviations**		
3.1	**Test material**		
3.1.1	Lot/Batch number		
3.1.2	Specification		
3.1.3	Purity		
3.1.4	Composition of Product		
3.1.5	Further relevant properties		x
3.1.6	Method of analysis		

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2

[redacted]

[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2 [redacted]

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]	x
3.3	**Reference substance**		
3.3.1	Method of analysis for reference substance		
3.4	**Testing procedure**		
3.4.1	Dilution water		
3.4.2	Test organisms		
3.4.3	Test system		
3.4.4	Test conditions		

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2

[redacted]

3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	
3.4.7	Sampling	
3.4.8	Monitoring of TS concentration	
3.4.9	Statistics	

Limit Test

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2 [redacted]

4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	
Results test substance		
4.1.4	Initial concentrations of test substance	
4.1.5	Actual concentrations of test substance	
4.1.6	Effect data (Immobilisation)	
4.1.7	Concentration / response curve	
4.1.8	Other effects	
Results of controls		
Test with reference substance		
4.1.9	Concentrations	
4.1.10	Results	
5.1	**Materials and methods**	

Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2 [redacted]

5.2	**Results and discussion**	[redacted]	
5.2.1	EC_0		x
5.2.2	EC_{50}		x
5.2.3	EC_{100}		x
5.3	**Conclusion**		
5.3.1	Other conclusions		
5.3.2	Reliability		
5.3.3	Deficiencies		

Evaluation by Competent Authorities

Date

Materials and Methods

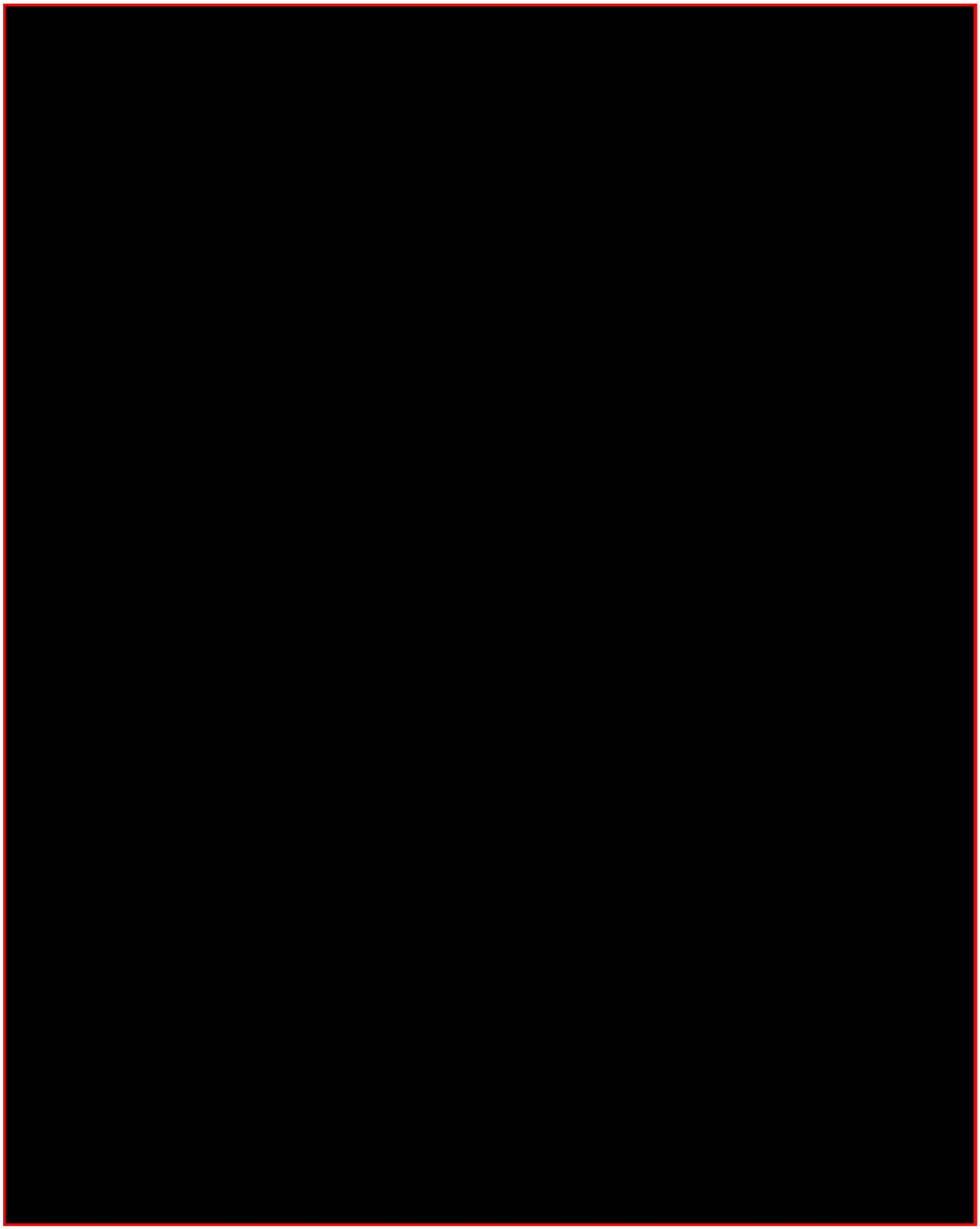
Results and discussion

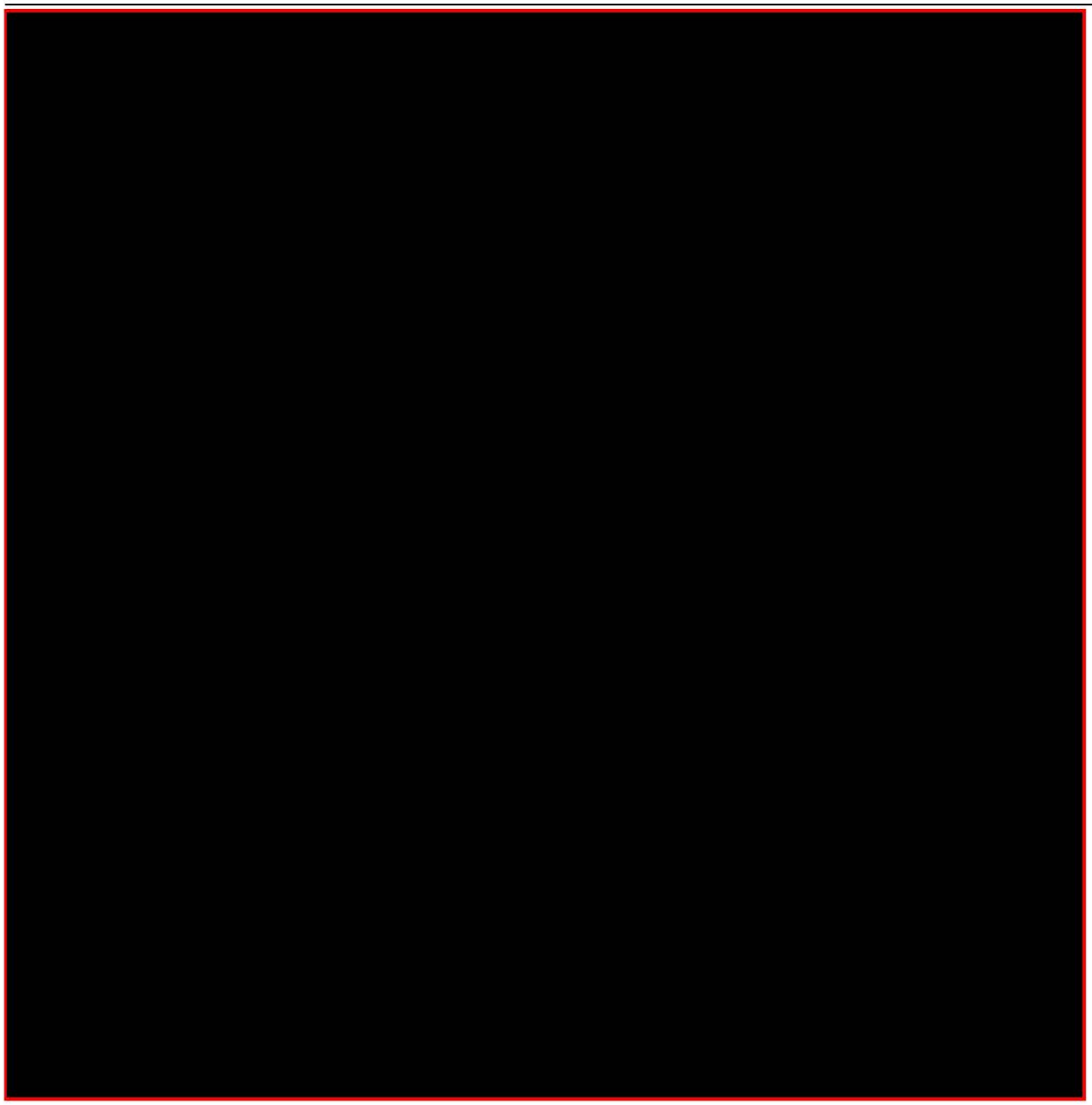
[redacted]

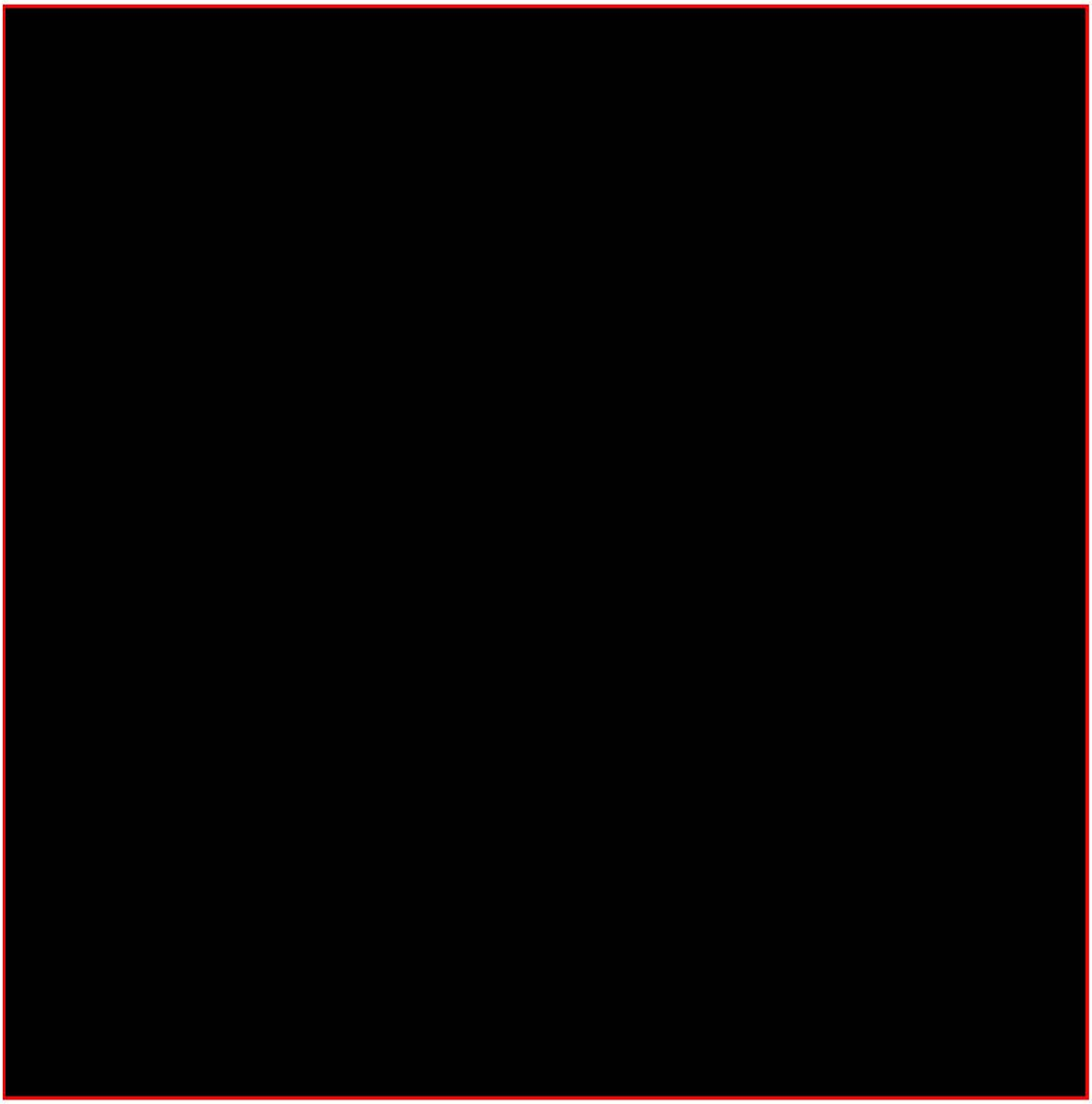
Section A7.4.1.2 Acute toxicity to invertebrates Daphnia magna

Annex Point IIA7.2 [redacted]

Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	







Section A7.4.1.3 Annex Point IIA7.3	Growth inhibition test on algae	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X]	Technically not feasible [ ] Scientifically unjustified [ ]	
Limited exposure [ ]	Other justification [ ]	
Detailed justification:	[redacted]	

Section A7.4.1.3 Annex Point IIA7.3	Growth inhibition test on algae
	[redacted]

x

Section A7.4.1.3 Annex Point IIA7.3	Growth inhibition test on algae
	[redacted]
Undertaking of intended data submission [ ]	
Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion	[redacted]

Section A7.4.1.3 Annex Point IIA7.3	Growth inhibition test on algae
Remarks	-

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

			Official use only
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2			
1.2.3	Criteria for data protection		
2.1	**Guideline study**		
2.2	**GLP**		
2.3	**Deviations**		
3.1	**Test material**		
3.1.1	Lot/Batch number		
3.1.2	Specification		
3.1.3	Purity		
3.1.4	Composition of Product		
3.1.5	Further relevant properties		x
3.1.6	Method of analysis		

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

[redacted]

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	x
3.3	**Reference substance**	
3.3.1	Method of analysis for reference substance	
3.4	**Testing procedure**	
3.4.1	Culture medium	

Section A7.4.1.3 **Growth inhibition test on algae**

Annex Point IIA7.3 [redacted]

[redacted]

3.4.2 Test organisms

3.4.3 Test system

3.4.4 Test conditions

3.4.5 Duration of the test

3.4.6 Test parameter

3.4.7 Sampling

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

[redacted]

[redacted]

3.4.8 Monitoring of TS concentration

3.4.9 Statistics

Limit Test

4.1.1 Concentration

4.1.2 Number/ percentage of animals showing adverse effects

Results test substance

4.1.3 Initial concentrations of test substance

4.1.4 Actual concentrations of test substance

4.1.5 Growth curves

4.1.6 Concentration / response curve

4.1.7 Cell concentration data

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

4.1.8	Effect data (cell multiplication inhibition)	[redacted]
4.1.9	Other observed effects	
Results of controls		

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

Test with reference substance

4.1.10 Concentrations

4.1.11 Results

5.1 Materials and methods

[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

5.2 Results and discussion

[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3

[redacted]

[redacted]

5.2.1	NOE_rC	x
5.2.2	$\mathbf{E_{r50}}$	x
5.2.3	$\mathbf{E_{\mu}X_{50}}$	x
5.3	**Conclusion**	x

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

[redacted]

5.3.1 Reliability

5.3.2 Deficiencies

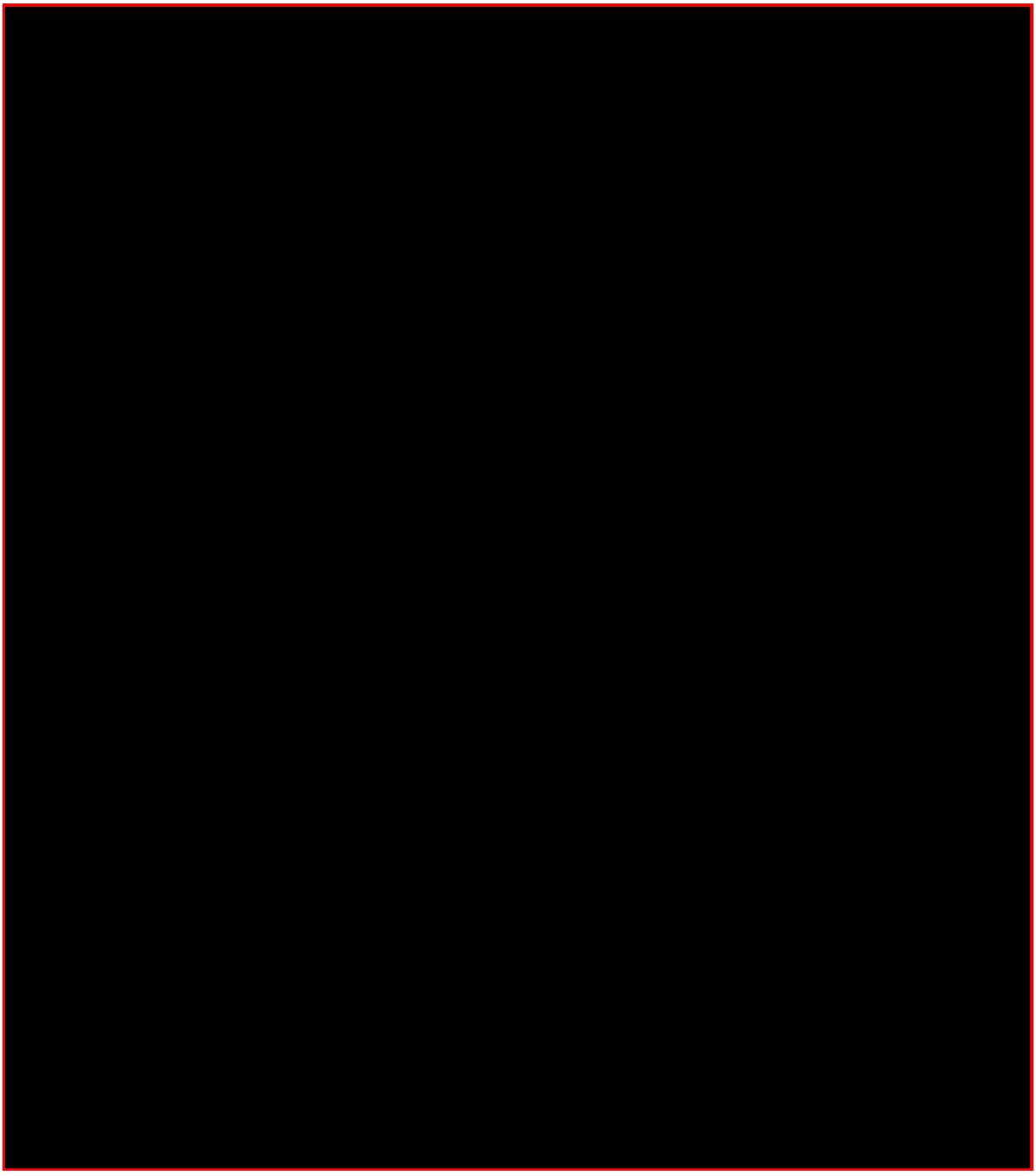
Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	

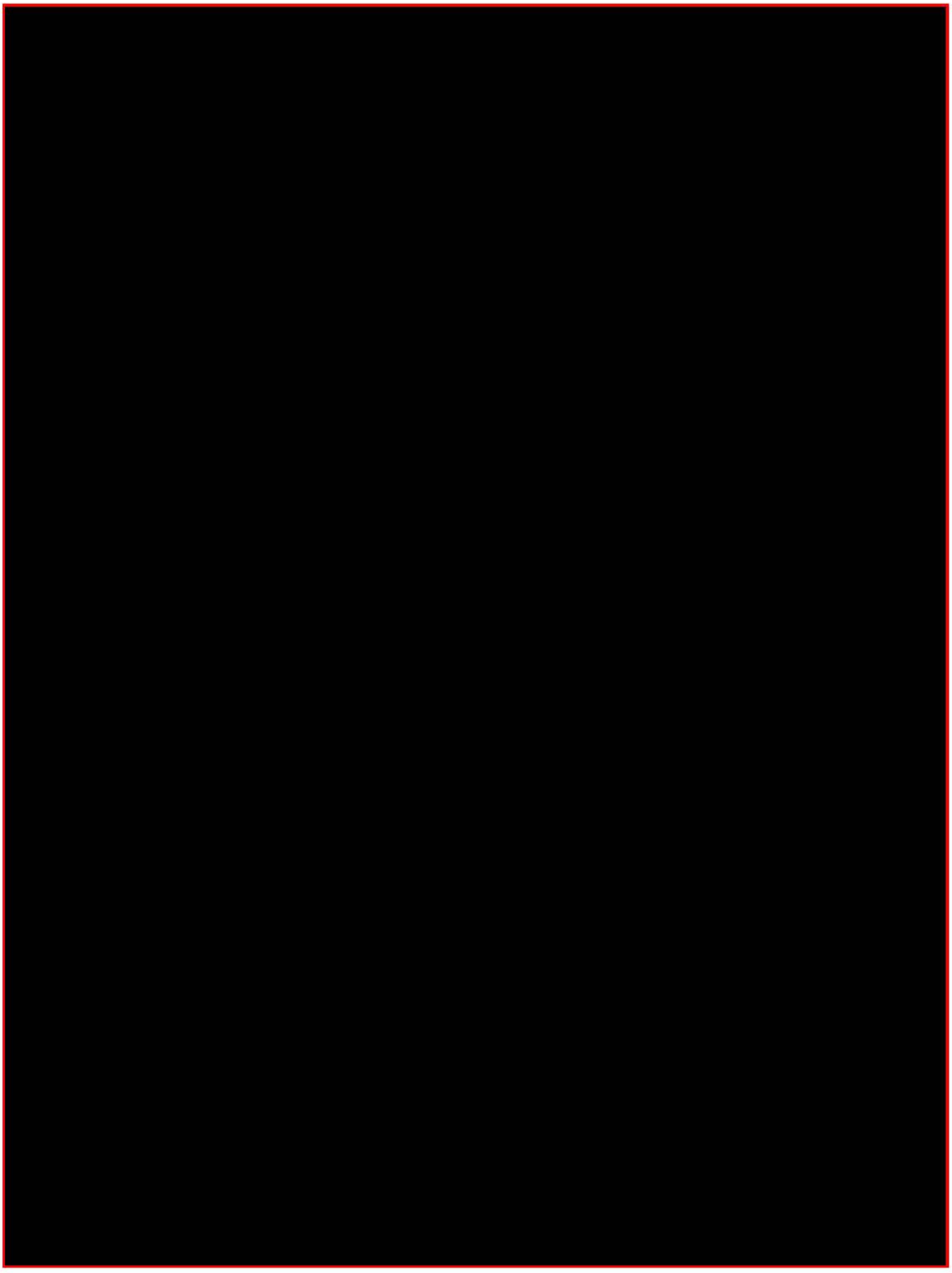
Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 [redacted]

Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	

[redacted]





Section A7.4.1.4 Annex Point IIA7.4	Inhibition to microbiological activity (aquatic)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [X]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4 [redacted]

			Official use only
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2			
1.2.3	Criteria for data protection		
2.1	**Guideline study**		
2.2	**GLP**		
2.3	**Deviations**		x
3.1	**Test material**		
3.1.1	Lot/Batch number		x
3.1.2	Specification		
3.1.3	Purity		x
3.1.4	Composition of Product		
3.1.5	Further relevant properties		
3.1.6	Method of analysis		
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**		
3.3	**Reference substance**		
3.3.1	Method of analysis for reference substance		

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4 [redacted]

3.4	**Testing procedure**	[redacted]	
3.4.1	Culture medium		x
3.4.2	Inoculum / test organism		
3.4.3	Test system		
3.4.4	Test conditions		x
3.4.5	Duration of the test		
3.4.6	Test parameter		

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA 7.4

[redacted]

[redacted]

3.4.7 Analytical parameter

3.4.8 Sampling

3.4.9 Monitoring of TS concentration

3.4.10 Controls

3.4.11 Statistics

Preliminary test

4.1.1 Concentration

4.1.2 Effect data

Results test substance

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4 [redacted]

4.1.3	Initial concentrations of test substance	[redacted]
4.1.4	Actual concentrations of test substance	
4.1.5	Growth curves	
4.1.6	Cell concentration data	

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4 [redacted]

4.1.7 Concentration/ response curve

[redacted]

4.1.8 Effect data

4.1.9 Other observed effects

Results of controls

Test with reference substance

4.1.10 Concentrations

4.1.11 Results

5.1 Materials and methods

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4

[redacted]

5.2 Results and discussion

[redacted]

5.2.1 EC_{20}

5.2.2 EC_{50}

5.2.3 EC_{80}

5.3 Conclusion

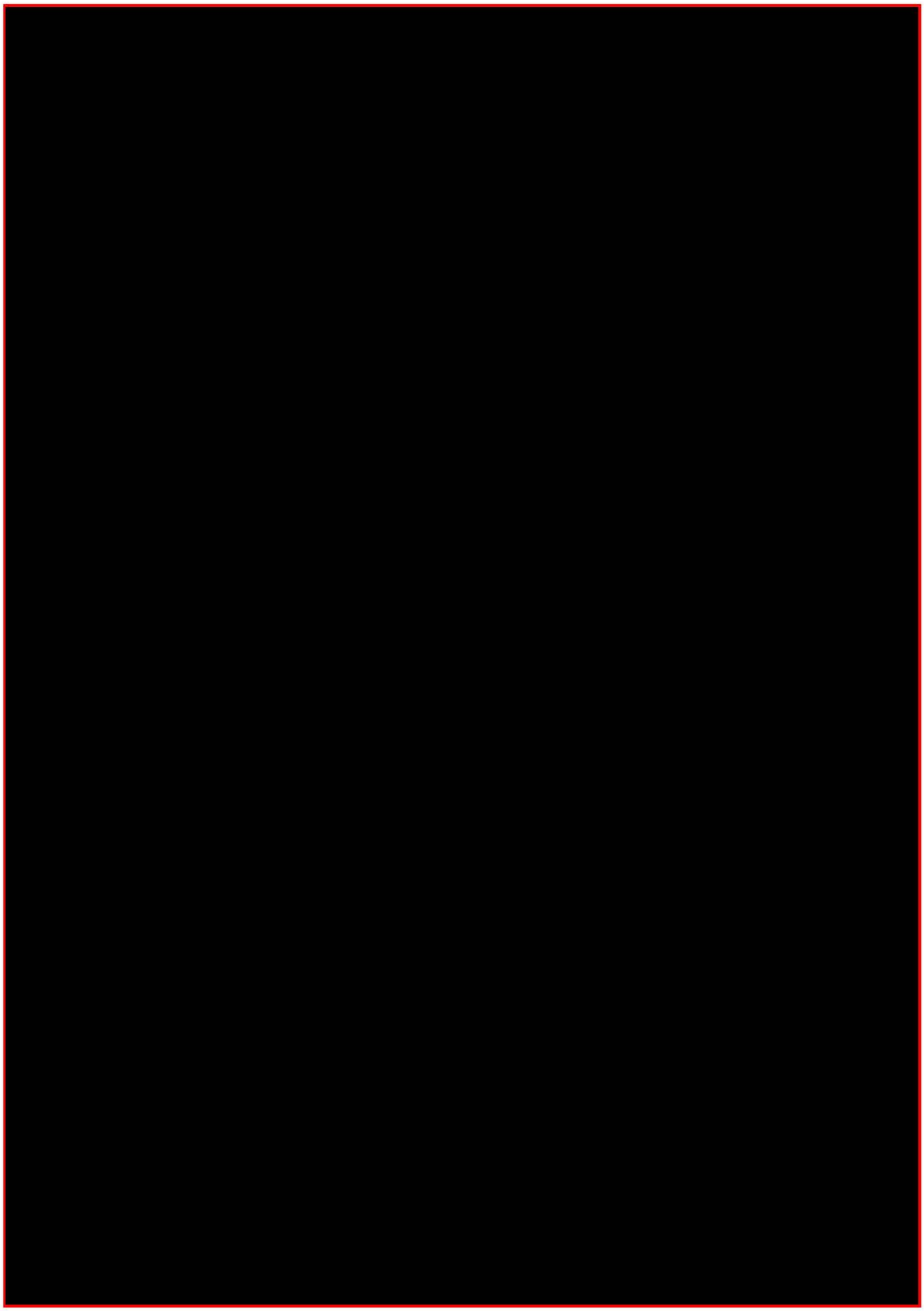
5.3.1 Reliability

5.3.2 Deficiencies

Section A7.4.1.4 Inhibition to microbiological activity (aquatic)

Annex Point IIA7.4 [redacted]

Evaluation by Competent Authorities	
Date **Materials and Methods** **Results and discussion** **Conclusion** **Reliability** **Acceptability** **Remarks**	[redacted]
	COMMENTS FROM ...
Date	*Give date of 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*
Remarks	



Section A7.4.2 Annex Point IIA7.5	Bioconcentration in aquatic organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [X]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion	[redacted]	

Section A7.4.2 Annex Point IIA7.5	Bioconcentration in aquatic organisms
Remarks	[redacted] -

Section A7.5.1.1 Annex Point IIA7.4	Inhibition to microbial activity (terrestrial)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [X]	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
Date Evaluation of applicant's justification Conclusion Remarks	[redacted] -	

Section A7.5.1.2 Annex Point IIIA XIII 3.2	Earthworm, acute toxicity test	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [X]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section 7.5.1.3 Annex Point IIIA XIII 3.4	Terrestrial plant toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [X]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]		
Evaluation by Competent Authorities		
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section A8 Measures necessary to protect man, animals and the environment

Subsection (Annex Point)			Official use only
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**	
8.1.0	**Methods and precautions concerning placing on the market**	On the basis of available information octanoic acid will not cause any significant health or environmental effects when used according to instructions provided by the supplier. However, because octanoic acid is classified as irritant to skin and eyes personal protection equipment (PPE) is strongly recommended when handling the substance.	x
8.1.1	**Methods and precautions concerning production, handling and use of the active substance**	Technical Measures: • Local exhaust and general ventilation must be adequate to meet exposure standards. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. • Wear suitable protecting clothing resistant to acids. Use neoprene or rubber gloves (EN 374). Taking into account the diversity of the types, it is necessary to respect the instructions of the manufacturers. • Chemical goggles or face shield with safety glasses. • Trained cleaning personnel properly equipped with eye protection should handle spills. • Prevent entry to sewers and public waters. • After spillage / leakage: Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill. Use suitable disposal containers.	
8.1.2	**Methods and precautions concerning storage of the active substance**	Storage conditions: • Store on a clean area allowing recuperation of leaks and effusion. • Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep container closed when not in use. • Handle in accordance with good industrial hygiene and safety procedures. Ensure prompt removal from eyes, skin and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking and when leaving work. Packaging material: Use containers made of polyethylene or polypropylene, certified for use with acid.	x
8.1.3	**Methods and precautions concerning transport of the**	Transport information: not hazardous for transport Proper shipping name: n.a. UN Nr.: n.a. H.I. Nr.: n.a.	x

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
	active substance	Class: n.a. Packing group: n.a. EMS: n.a. MFAG-Nr: n.a. Hazard Label(s): n.a.	
8.1.4	**Methods and precautions concerning fire of the active substance**	Fire – fighting measures • Extinguishing media: Use extinguishing media appropriate for surrounding fire. • Special exposure hazards: May release heat and harmful fumes. • Protection against fire: Wear proper protective equipment. • Special procedures: Exercise caution when fighting any chemical fire.	
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)**	
		• Contains no organically bound halogen.	x
8.3		**Emergency measures in case of an accident (IIA8.3)**	
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	• Inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures. • Skin contact: Remove contaminated clothing and shoes. Flush with plenty of water. Obtain medical attention. Eye contact: Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand). Seek medical attention immediately. Ingestion: Rinse mouth. DO NOT INDUCE VOMITING Take to hospital.	x
8.3.2	**Emergency measures to protect the environment**	• Prevent entry into sewers and public waters. • Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill. Use suitable disposal containers.	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	Octanoic acid has a low vapour pressure; accidental release into air does not lead to hazardous vapour concentrations. Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Octanoic acid is readily biodegradable and has a low toxicity. Once diluted to non-irritating concentration no harmful effects are expected.	

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Dilution with water to neutralise the low pH is recommended.	x
8.5		**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	
8.5.1	**Possibility of re-use or recycling**	Reuse is not intended. Unused material may be returned to the manufacturer.	
8.5.2	**Possibility of neutralisation of effects**	Dilute with copious of water to lower the acidity.	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal**	Diluted solution can be released after neutralisation to a STP.	
8.5.4	**Conditions for controlled incineration**	Octanoic acid could be safely incinerated in a licensed facility.	
8.6		**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)**	
		Octanoic acid is a substance with low toxicity. Spraying of a solution of octanoic acid on plants is known to have harmful effects and is therefore mentioned in the use instruction.	x
8.7		**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7*)***	
		Octanoic acid falls under List II of the Annex to Directive 80/98/EEC	

Evaluation by Competent Authorities	
Date	[redacted]
Materials and methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A9	Proposals including Justification for the Proposals for the Classification and Labelling of the Active Substance according to Council Directive 67/548/EEC		
Classification and Labelling			Official use only
Hazard symbol	Xi		X
Indication of danger	irritant		X
Labelling symbol			
Risk phrases	R36/38	Irritating to eyes and skin.	X
Safety phrases	S2	Keep out of the reach of children.	
	S24/25	Avoid contact with skin and eyes.	
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.	X
Justification for the proposal			
Xi	Substances and preparations shall be classified as irritant and assigned the symbol 'Xi' and the indication of danger 'irritant' in accordance with the criteria given in ANNEX VI - GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS.		
R36	Substances and preparations which, when applied to the eye of the animal, cause significant ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours. Ocular lesions are significant if the mean scores of the eye irritation test cited in Annex V have any of the following values: - cornea opacity equal to or greater than 2 but less than 3, - iris lesion equal to or greater than 1 but not greater than 1,5, - redness of the conjunctivae equal to or greater than 2,5, - oedema of the conjunctivae (chemosis) equal to or greater than 2, in tests observations as listed above have been observed; their magnitude was not as such to indicate a higher danger.		
R38	Substances and preparations which cause significant inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours determined on the rabbit according to the cutaneous irritation test method cited in Annex V. For octanoic acid the score of skin reaction in the most relevant test		

Section A9	Proposals including Justification for the Proposals for the Classification and Labelling of the Active Substance according to Council Directive 67/548/EEC	
	results in the classification for R38.	
	No other risk phrases are applicable since the available data would not lead to classification (see also DOC IIA).	
S2	Required for all dangerous substances (S13 will not apply as the danger irritant does not apply for food contact)	
S24/25	Recommended for substances and preparation irritating to skin and eyes.	
S36/37/39	Recommended for substances and preparation irritating to skin and eyes.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	August 2010	
Materials and Methods	n.a.	
Results and discussion	Decanoic acid and Octanoic acid cause serious eye damage and skin irritation. Environmental hazard classification is added (see below).	
Conclusion	Please see the classification and labelling proposal presented in Doc II-A1.5.with regard to 67/548/-EEC and Reg. 1272/2008/EC. Environmental Classification: Decanoic acid is currently not classified according to Annex VI of Reg. 1272/2008/EC therefore the following classification is proposed: Directive 67/548/EEC The log kow of Octanoic acid is > 3 (3.03 see Doc. II-A 4) and the most sensitive species is Algae (E_rC_{50} = 1.76 mg/L see Doc. II-A 4). Although the substance is considered to be readily degradable this lead to the following classification: N; R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. S61 Avoid release to the environment. Refer to special instructions/safety data sheets. Reg. 1272/2008/EC The cut-off value considering the Bioaccumulation is for the log kow>4. Therefore Octanoic acid is not classified: Not classified.	
Reliability	n.a.	
Acceptability	n.a..	
Remarks	n.a..	