

5.2 Results and discussion	The properties of the test substance give no indications to assume any relevant influences on the test result
5.2.1 LC ₀	Could not derived from the study
5.2.2 LC ₅₀	>93 mg/L
5.2.3 LC ₁₀₀	>93 mg/L
5.3 Conclusion	The validity criteria as given in table A7.4.1.1-24 can be considered as fulfilled. The result, LC ₅₀ of >93 mg/L, means that [REDACTED] can be classified as “slightly toxic” according to the EU classification
5.3.1 Other Conclusions	No other conclusions
5.3.2 Reliability	[REDACTED]
5.3.3 Deficiencies	[REDACTED]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
Comments from ...	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]							
	[REDACTED]				[REDACTED]			
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Section A7.4.1.1/04 Acute toxicity to fish

Annex Point IIA7.1

1 Reference

1.1 Reference

[REDACTED]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company, Ltd.

Official
 use only

1.2.3 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study OECD 203 (17 July 1992) - equivalent to EEC C.1

2.2 GLP [REDACTED]

2.3 Deviations [REDACTED]

3 Materials and Methods

3.1 Test material [REDACTED]

3.1.1 Lot/Batch number [REDACTED]

3.1.2 Specification [REDACTED]

3.1.3 Purity [REDACTED]

3.1.4 Composition of Product [REDACTED]

3.1.5 Further relevant properties [REDACTED]

3.1.6 Method of analysis [REDACTED]

3.2 Preparation of TS solution for poorly soluble or volatile test substances [REDACTED]

3.3 Reference substance [REDACTED]

3.3.1 Method of analysis for reference substance [REDACTED]

3.4 Testing procedure

3.4.1 Dilution water [REDACTED]

3.4.2 Test organisms Rainbow trout [REDACTED]

3.4.3 Test system [REDACTED]

3.4.4 Test conditions [REDACTED]

3.4.5 Duration of the test 96 hours

3.4.6 Test parameter Mortality

3.4.7 Sampling Sampling interval: start (0 hours) and end (96 hours) of exposure

3.4.8 Monitoring of TS Yes

concentration 0 and 96 hours

3.4.9 Statistics

[REDACTED]

4 Results

4.1 Limit Test

Performed [REDACTED]

4.1.1 Concentration

[REDACTED]

4.1.2 Number/ percentage of animals showing adverse effects

[REDACTED]

4.1.3 Nature of adverse effects

[REDACTED]

4.2 Results test substance

4.2.1 Initial concentrations of test substance

[REDACTED]

4.2.2 Actual concentrations of test substance

Mean measured concentrations were 0.061, 0.15, 0.22, 0.45 and 0.62 mg/L. [REDACTED]

4.2.3 Effect data (Mortality)

[REDACTED]

4.2.4 Concentration / response curve

[REDACTED]

4.2.5 Other effects

[REDACTED]

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects

[REDACTED]

4.3.2 Nature of adverse effects

[REDACTED]

4.4 Test with reference substance

4.4.1 Concentrations

[REDACTED]

4.4.2 Results

[REDACTED]

5 Applicant's Summary and conclusion

5.1 Materials and methods

The study was conducted according to OECD guideline 203. The test system was flow-through and rainbow trout were used as the test organisms

5.2 Results and discussion

Dimethyl formamide was used to prepare concentrated stock solutions to allow dosing using the proportional diluter. Measured concentrations

	confirmed that that the dose was performing correctly
5.2.1 LC ₀	0.15 mg/L
5.2.2 LC ₅₀	0.29 mg/L
5.2.3 LC ₁₀₀	0.45 mg/L
5.3 Conclusion	The validity criteria as given in table A 7.4.1.1-32 can be considered as fulfilled. The result, LC ₅₀ of 0.29 mg/L, indicates that [REDACTED] can be classified as “highly toxic” according to the EU classification
5.3.1 Other Conclusions	No other conclusions
5.3.2 Reliability	[REDACTED]
5.3.3 Deficiencies	[REDACTED]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
Comments from ...	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	

Remarks

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]						
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]							
	[REDACTED]				[REDACTED]			
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

7.4.1.2 Acute toxicity to invertebrates

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

1 Reference

1.1 Reference

[REDACTED] (1989); [REDACTED]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company, Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

[REDACTED]

U.S. EPA Methods for acute toxicity tests with fish macroinvertebrates and amphibians, Ecological Research Series, EPA-660/3-75-009 (April 1975)

2.2 GLP

[REDACTED]

2.3 Deviations

[REDACTED]

3 Materials and Methods

3.1 Test material

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.3 Purity

[REDACTED]

3.1.4 Composition of Product

[REDACTED]

3.1.5 Further relevant properties

Not applicable

3.1.6 Method of analysis

[REDACTED]

3.2 Preparation of TS solution for poorly soluble or volatile test substances

Not applicable

Official
use only

3.3 Reference substance Not applicable

3.3.1 Method of analysis for reference substance Not applicable

3.4 Testing procedure

3.4.1 Dilution water [REDACTED]

3.4.2 Test organisms [REDACTED]

3.4.3 Test system [REDACTED]

3.4.4 Test conditions [REDACTED]

3.4.5 Duration of the test 48 hours

3.4.6 Test parameter Mortality and other abnormal effects such as surfacing, erratic movements and/or daphnids laying on the bottom

3.4.7 Sampling Sampling interval start (0 hours) and end (48 hours)

3.4.8 Monitoring of TS concentration [REDACTED]

3.4.9 Statistics [REDACTED]

4 Results

4.1 Limit Test Performed /

4.1.1 Concentration 0.1, 1.0 and 10.0 mg/L

4.1.2 Number/ percentage of animals showing adverse effects [REDACTED]

4.1.3 Nature of adverse effects [REDACTED]

4.2 Results test substance

4.2.1 Initial concentrations of test substance [REDACTED]

4.2.2 Actual concentrations of test substance [REDACTED]

4.2.3 Effect data (Mortality) [REDACTED]

[REDACTED]

	[REDACTED]
	[REDACTED]
4.2.4 Concentration / response curve	[REDACTED]
4.2.5 Other effects	[REDACTED]
4.3 Results of controls	[REDACTED]
4.4 Test with reference substance	[REDACTED]
4.4.1 Concentrations	[REDACTED]
4.4.2 Results	[REDACTED]

5 Applicant's Summary and conclusion

5.1 Materials and methods	The study was carried out according to the U.S. EPA guideline "Methods for acute toxicity tests with fish macroinvertebrates and amphibians, Ecological Research Series, EPA-660/3-75-009 (April 1975)". The test system was flow through and <i>Daphnia magna</i> was the test organism.	
5.2 Results and discussion	The study was conducted using a stock solution to allow testing at up to 1.0 mg/L. Summary	
5.2.1 EC ₀	0.043mg/L	X
5.2.2 EC ₅₀	24 hours: 0.54 mg/L (95 % confidence limits 0.43-0.60mg/L), based on measured concentrations 48 hours 0.4 mg/L (95 % confidence limits 0.35-0.46mg/L) , based on measured concentrations	X
5.2.3 EC ₁₀₀	Not calculated	X
5.3 Conclusion	The validity criteria [REDACTED] were met with the exception that the mean concentration of the test substance was lower than 80% of the initial concentration. However, effect data was based on measured concentrations	
5.3.1 Reliability	[REDACTED]	
5.3.2 Deficiencies	[REDACTED]	

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Section A7.4.1.2/02 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

1 Reference

Official
use only

1.1 Reference

[Redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

OECD Guideline 202

2.2 GLP

[Redacted]

2.3 Deviations

[Redacted]

[Redacted]

3 Materials and Methods

3.1 Test material

[Redacted]

3.1.1 Lot/Batch number

[Redacted]

3.1.2 Specification

[Redacted]

3.1.3 Purity

[Redacted]

3.1.4 Composition of Product

[Redacted]

3.1.5 Further relevant properties	Not applicable
3.1.6 Method of analysis	[REDACTED]
3.2 Preparation of TS solution for poorly soluble or volatile test substances	[REDACTED]
3.3 Reference substance	[REDACTED]
3.3.1 Method of analysis for reference substance	[REDACTED]
3.4 Testing procedure	
3.4.1 Dilution water	[REDACTED]
3.4.2 Test organisms	[REDACTED]
3.4.3 Test system	[REDACTED]
3.4.4 Test conditions	[REDACTED]
3.4.5 Duration of the test	48 hours
3.4.6 Test parameter	Immobility
3.4.7 Sampling	Samples taken at Test initiation (0 hours) and at termination (48 hours)
3.4.8 Monitoring of TS concentration	[REDACTED]
3.4.9 Statistics	[REDACTED]

4 Results

4.1 Limit Test	Performed
4.1.1 Concentration	10 and 100 mg a.s./L
4.1.2 Number/ percentage of animals showing adverse effects	[REDACTED]
4.1.3 Nature of adverse effects	[REDACTED]
4.2 Results test substance	
4.2.1 Initial concentrations of test substance	[REDACTED]
4.2.2 Actual concentrations of test substance	[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]			
	[REDACTED]		[REDACTED]	
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Section A7.4.1.2/03 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

1 Reference

Official
use only

1.1 Reference

[REDACTED]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company, Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

OECD Guideline 202

2.2 GLP

[REDACTED]

2.3 Deviations

[REDACTED]

3 Materials and Methods

3.1 Test material

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.3 Purity

[REDACTED]

3.1.4 Composition of Product

[REDACTED]

3.1.5 Further relevant properties

[REDACTED]

3.1.6 Method of analysis

[REDACTED]

3.2 Preparation of TS solution for poorly soluble or volatile test substances

[REDACTED]

3.3 Reference substance

No

	[REDACTED]
	[REDACTED]
4.2.4 Concentration / response curve	[REDACTED]
4.2.5 Other effects	[REDACTED]
4.3 Results of controls	[REDACTED]
4.4 Test with reference substance	[REDACTED]
4.4.1 Concentrations	[REDACTED]
4.4.2 Results	[REDACTED]

5 Applicant's Summary and conclusion

5.1 Materials and methods	This study was performed following OECD Guideline 202. The test system was flow through and <i>Daphnia magna</i> were used as the test organism
5.2 Results and discussion	The study was conducted using [REDACTED] delivered using a diluter system. Analyses of the solutions confirmed that the delivery apparatus maintained the expected concentration gradient
5.2.1 EC ₀	0.36 mg/L
5.2.2 EC ₅₀	1.8 mg/L
5.2.3 EC ₁₀₀	Not determined
5.3 Conclusion	The validity criteria [REDACTED] can be considered fulfilled. The EC 50 value was calculated to be 1.8mg/L
5.3.1 Reliability	[REDACTED]
5.3.2 Deficiencies	[REDACTED]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]			
[REDACTED]	[REDACTED]			
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

7.4.1.3 Growth inhibition test on algae

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA7.3

1 Reference

Official
use only

1.1 Reference

[REDACTED]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

OECD Guideline 201

2.2 GLP

[REDACTED]

2.3 Deviations

3 Materials and Methods

3.1 Test material

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.3 Purity

[REDACTED]

3.1.4 Composition of Product

[REDACTED]

3.1.5 Further relevant properties

Not applicable

3.1.6 Method of analysis

[REDACTED]

3.2 Preparation of TS solution for poorly soluble or volatile test substances

[REDACTED]

3.3 Reference substance

[REDACTED]

3.3.1 Method of analysis for

[REDACTED]

reference substance [REDACTED] y.

3.4 Testing procedure

3.4.1 Culture medium The culture medium contained –

Macronutrients:

NaNO ₃	25.5mg/L
NaHCO ₃	15.0 mg/L
MgSO ₄ •7H ₂ O	14.7 mg/L
MgCl ₂ •6H ₂ O	12.164 mg/L
CaCl ₂ •2H ₂ O	4.410 mg/L
K ₂ HPO ₄	1.044mg/L

Micronutrients:

MnCl ₂ •4H ₂ O	415.4 µg/L
Na ₂ EDTA•2H ₂ O	300 µg/L
H ₃ BO ₃	185.5 µg/L
FeCL ₃ •6H ₂ O	159.8 µg/L
Na ₂ MoO ₄ •2H ₂ O	7.3 µg/L
ZnCl ₂	3.3 µg/L
CoCl ₂ •6H ₂ O	1.4 µg/L
CuCl ₂ •2H ₂ O	12.0 ng/L

The medium was pH adjusted to 7.7 ±0.3 using NaOH and re-sterilised.

3.4.2 Test organisms [REDACTED]

3.4.3 Test system [REDACTED]

3.4.4 Test conditions [REDACTED]

3.4.5 Duration of the test 72 hours

3.4.6 Test parameter Cell multiplication inhibition

3.4.7 Sampling Sampling took place at 0, 24, 48 and 72 hours

3.4.8 Monitoring of TS concentration Yes, at 0 and 72 hours

3.4.9 Statistics [REDACTED]

4 Results

4.1 Limit Test Performed

4.1.1 Concentration 0.01, 0.10 and 0.50 mg/L

4.1.2 Number/ percentage of cells showing adverse effects [REDACTED]

4.2 Results test substance

4.2.1 Initial concentrations of test substance [REDACTED]

4.2.2 Actual concentrations
of test substance

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

4.2.3 Growth curves

[REDACTED]

4.2.4 Concentration /
response curve

[REDACTED]

4.2.5 Cell concentration data

[REDACTED]

4.2.6 Effect data
(cell growth)

[REDACTED]

4.2.7 Other observed effects

Not applicable

4.3 Results of controls

[REDACTED]

**4.4 Test with reference
substance**

[REDACTED]

4.4.1 Concentrations

[REDACTED]

4.4.2 Results

[REDACTED]

5 Applicant's Summary and conclusion

5.1 Materials and methods

This study was conducted according to OECD Guideline 201. The test system was static, and *Selenastrum capricornutum* Printz was the test organism

5.2 Results and discussion

The study was conducted using stock solutions prepared in acetone at concentrations up to 0.4 mg/L

Reliability

Acceptability

Remarks

[REDACTED]

[REDACTED]	[REDACTED]							
	[REDACTED]				[REDACTED]			
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]		[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

Section A7.4.1.3/02 Growth inhibition test on algae

Annex Point IIA7.3

1 Reference

Official
use only

1.1 Reference

[Redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

OECD Guideline 201

2.2 GLP

[Redacted]

2.3 Deviations

[Redacted]

[Redacted]

3 Materials and Methods

3.1 Test material

[Redacted]

3.1.1 Lot/Batch number

[Redacted]

3.1.2 Specification

[Redacted]

3.1.3 Purity

[Redacted]

3.1.4 Composition of Product

[Redacted]

3.1.5 Further relevant properties

[Redacted]

3.1.6 Method of analysis

[Redacted]

3.2 Preparation of TS solution for poorly soluble or volatile test substances

[Redacted]

3.3 Reference substance

3.3.1 Method of analysis for reference substance

3.4 Testing procedure

3.4.1 Culture medium The culture medium contained:

Compound	Concentration
NaNO ₃	25.5mg/L
MgCl ₂ •6H ₂ O	16.16 mg/L
CaCl ₂ •2H ₂ O	4.41 mg/L
MgSO ₄ •7H ₂ O	14.7 mg/L
K ₂ HPO ₄ •3H ₂ O	1.368 mg/L
NaHCO ₃	15.0 mg/L
H ₃ BO ₃	185.5 µg/L
Na ₂ SeO ₄	1.88 µg/L
MnCl ₂ •4H ₂ O	4.15 µg/L
ZnCl ₂	3.270 µg/L
CoCl ₂ •6H ₂ O	1.43 µg/L
CuCl ₂ •6H ₂ O	0.012 µg/L
Na ₂ MoO ₄ •2H ₂ O	7.26 µg/L
FeCl•3H ₂ O	159.8 µg/L
NaEDTA•2H ₂ O	300 µg/L

The medium was pH adjusted to 7.5 ± 0.1 with 0.1 N NaOH or 0.1 N HCl

3.4.2 Test organisms

3.4.3 Test system

3.4.4 Test conditions

3.4.5 Duration of the test 72 hours

3.4.6 Test parameter Biomass accumulation and growth rate.

3.4.7 Sampling Samples were taken at 0, 24, 48 and 72 hours.

3.4.8 Monitoring of TS concentration

3.4.9 Statistics

4 Results

4.1 Limit Test No

4.1.1 Concentration Not applicable

4.1.2 Number/ percentage of animals showing adverse effects Not applicable

4.2 Results test substance

4.2.1 Initial concentrations of test substance [redacted]

4.2.2 Actual concentrations of test substance [redacted]

4.2.3 Growth curves [redacted]

4.2.4 Concentration / response curve [redacted]

4.2.5 Cell concentration data [redacted]

4.2.6 Effect data (cell multiplication inhibition) [redacted]

4.2.7 Other observed effects

4.3 Results of controls [redacted]

4.4 Test with reference substance Not performed

4.4.1 Concentrations Not applicable

4.4.2 Results Not applicable

5 Applicant's Summary and conclusion

5.1 Materials and methods The study was conducted according to OECD guideline 201. The test system was static and *Pseudokirchneriella subcapitata* was the test organism

5.2 Results and discussion The test was conducted using stock solutions at concentrations of [redacted] up to 100 mg/L

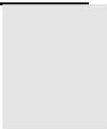
5.2.1 NOE_rC 22 mg/L

5.2.2 E_rC₅₀ 30 mg/L

5.2.3 E_bC₅₀ 26 mg/L

5.3 Conclusion The validity criteria in Table A7.4.1.3/11 can be considered fulfilled. The E_bC₅₀ of 26 mg/L indicates that [redacted] can be classified as "harmful or slightly toxic" according to the EU classification

5.3.1 Reliability 1
 5.3.2 Deficiencies No



Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
Comments from ...	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[Redacted]

[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]				
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

Section A7.4.1.3/03 Growth inhibition test on algae

Annex Point IIA7.3

1 Reference

Official
use only

1.1 Reference

[REDACTED]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

OECD Guideline 201

2.2 GLP

[REDACTED]

2.3 Deviations

[REDACTED]

3 Materials and Methods

3.1 Test material

[REDACTED]

3.1.1 Lot/Batch number

[REDACTED]

3.1.2 Specification

[REDACTED]

3.1.3 Purity

[REDACTED]

3.1.4 Composition of Product

[REDACTED]

3.1.5 Further relevant properties

[REDACTED]

3.1.6 Method of analysis

[REDACTED]

3.2 Preparation of TS solution for poorly soluble or volatile test substances

[REDACTED]

3.3 Reference substance

No

3.3.1 Method of analysis for reference substance

Not applicable

3.4 Testing procedure

3.4.1 Culture medium The culture medium contained:

Compound	Concentration
NaNO ₃	25.5mg/L
MgCl ₂ •6H ₂ O	16.16 mg/L
CaCl ₂ •2H ₂ O	4.41 mg/L
MgSO ₄ •7H ₂ O	14.7 mg/L
K ₂ HPO ₄ •3H ₂ O	1.368 mg/L
NaHCO ₃	15.0 mg/L
H ₃ BO ₃	185.5 µg/L
Na ₂ SeO ₄	1.88 µg/L
MnCl ₂ •4H ₂ O	4.15 µg/L
ZnCl ₂	3.270 µg/L
CoCl ₂ •6H ₂ O	1.43 µg/L
CuCl ₂ •6H ₂ O	0.012 µg/L
Na ₂ MoO ₄ •2H ₂ O	7.26 µg/L
FeCl ₃ •3H ₂ O	159.8 µg/L
NaEDTA•2H ₂ O	300 µg/L

The medium was pH adjusted to 7.5 ± 0.1 with 0.1 N NaOH or 0.1 N HCl

3.4.2 Test organisms [REDACTED]

3.4.3 Test system [REDACTED]

3.4.4 Test conditions [REDACTED]

3.4.5 Duration of the test 72 hours

3.4.6 Test parameter Biomass, growth rate

3.4.7 Sampling Samples taken at 24, 48 and 72 hours.

3.4.8 Monitoring of TS concentration [REDACTED]

3.4.9 Statistics [REDACTED]

4 Results

4.1 Limit Test Performed

4.1.1 Concentration 0.0001, 0.001, 0.01, 0.1 and 1.0 mg/L

4.1.2 Number/ percentage of animals showing adverse effects Cells exposed to all treatment levels and controls were observed to be normal

4.2 Results test substance

4.2.1 Initial concentrations of test substance [REDACTED]

4.2.2 Actual concentrations of test substance



4.2.3 Growth curves

[Redacted]

4.2.4 Concentration /
response curve

[Redacted]

4.2.5 Cell concentration data

[Redacted]

4.2.6 Effect data
(cell multiplication
inhibition)

[Redacted] [Redacted] [Redacted] [Redacted]
[Redacted] [Redacted] [Redacted] [Redacted]

4.2.7 Other observed effects

4.3 Results of controls

[Redacted]

4.4 Test with reference substance

Not performed

4.4.1 Concentrations

Not applicable

4.4.2 Results

Not applicable

5 Applicant's Summary and conclusion

5.1 Materials and methods

This study was conducted according to OECD Guideline 201. The test system was static and *Pseudokirchneriella subcapitata* was used as the test organism

5.2 Results and discussion

The study was conducted using stock solutions prepared with dimethyl formamide to allow testing up to 2 mg/L, the water solubility limit of [Redacted] n

5.2.1 NOE_rC

0.5 mg/L

5.2.2 E_{r50}

>2.5 mg/L

5.2.3 E_bC₅₀

>2.5 mg/L

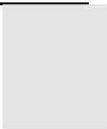
5.3 Conclusion

The validity criteria for OECD guideline 201 were met. The result showed that the EC₅₀ for both biomass and growth rate exceed the water solubility limit

5.3.1 Reliability



5.3.2 Deficiencies



Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

Evaluation by Rapporteur Member State

Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks



[REDACTED]

[REDACTED]	[REDACTED]			
	[REDACTED]			
	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]				[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

[Redacted]				
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	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
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[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]

7.4.1.4 Inhibition to microbiological activity

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

Reference

1.1 Reference

[Redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

Official use only

1.2.3 Criteria for data protection Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study Yes


OECD Guideline 209

2.2 GLP 

2.3 Deviations 

3 Materials and Methods

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 Not applicable

3.1.6 Method of analysis 

3.2 Preparation of TS solution for poorly soluble or volatile test substances Not applicable

3.3 Reference substance Yes

3,5-dichlorophenol

3.3.1 Method of analysis for reference substance 

3.4 Testing procedure

3.4.1 Culture medium Not applicable

3.4.2 Inoculum / test organism 

3.4.3 Test system 

3.4.4 Test conditions 

3.4.5 Duration of the test 3 hours

3.4.6 Test parameter Respiration inhibition

3.4.7 Analytical parameter	Oxygen measurement
3.4.8 Sampling	After 3 hours of aeration/contact time the contents of the test flask were poured into a measuring flask and the oxygen concentration was determined for a period of approximately 10 minutes
3.4.9 Monitoring of TS concentration	No
3.4.10 Controls	Control without test item
3.4.11 Statistics	EC ₅₀ calculated according to Probit analysis

4 Results

4.1 Preliminary test Not performed

4.1.1 Concentration Not applicable

4.1.2 Effect data Not applicable

4.2 Results test substance

4.2.1 Initial concentrations of test substance 1, 3.16, 10, 31.6 and 100 mg/L

4.2.2 Actual concentrations of test substance Not measured

4.2.3 Growth curves Not recorded

4.2.4 Cell concentration data Not recorded

4.2.5 Concentration/response curve Not recorded

4.2.6 Effect data



4.2.7 Other observed effects

4.3 Results of controls



4.4 Test with reference substance Performed

3,5-dichlorophenol

4.4.1 Concentrations 4, 12, 36 mg/L

4.4.2 Results



Comments from ...	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

[REDACTED]

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

7.4.2 Bioconcentration

Section A7.4.2 Bioconcentration in aquatic/terrestrial organisms

Annex Point IIA7.5

1 Reference

Official
use only

1.1 Reference

[Redacted]

[Redacted]

[Redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd

1.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study

Yes

EPA Subdivision. N, 165-4, Ref. 1

2.2 GLP

[Redacted]

2.3 Deviations

[Redacted]

3 Materials and Methods

3.1 Test material

[Redacted]

3.1.1 Lot/Batch number

[Redacted]

3.1.2 Specification

[Redacted]

3.1.3 Purity

[Redacted]

3.1.4 Further relevant properties

[Redacted]

3.1.5 Radiolabelling

[REDACTED]

[REDACTED]

3.1.6 Method of analysis

[REDACTED]

[REDACTED]

[REDACTED]

3.2 Reference substance

[REDACTED]

3.2.1 Method of analysis for reference substance

[REDACTED]

3.3 Testing/estimation procedure

[REDACTED]

3.3.1 Test system/performance

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

3.3.2 Estimation of
bioconcentration

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

4 Results

4.1 Experimental data

4.1.1 Mortality/behaviour

[REDACTED]

4.1.2 Lipid content

No data available

4.1.3 Concentrations of test
material during test

[REDACTED]

[REDACTED]

[Redacted]

[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
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