Section A7.3.2/01-02 Fate and behaviour in air, further studies

Annex Point IIIA, XII. 3

[redacted]

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1 REFERENCE

1.1 References

[1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine.
Doc. No. 581-009 (published); Section A7.3.2/01.

[2] Krone, C.; Kirbach. I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine 127^{I} in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain.
Doc. No. 781-004; Section A7.3.2/02.

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Not applicable.

2.2 GLP Not applicable.

2.3 Deviations Not applicable.

3 MATERIALS AND METHODS

3.1 Test material [redacted]

4 RESULTS

4.1 Transfer into the atmosphere [redacted] X1

4.2 Transformation processes and Iodine species in air [redacted]

Section A7.3.2/01-02 Fate and behaviour in air, further studies

Annex Point IIIA, XII. 3

[redacted]

4.3	Transfer into surfce water and soils	X2
4.4	Impact on global warming and acid rain	X3

Section A7.3.2/01-02 Fate and behaviour in air, further studies

Annex Point IIIA, XII. 3

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion Adequate information is available pertaining to the chemical species and reactions that take place at and above the ocean surface that are responsible for the production of volatile forms of Iodine. There is a good body of literature on the photochemical reactions of Iodine, both in the gaseous phase and in/on particulates or water droplets.

5.3.1 Reliability [redacted] X4

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Results and discussion [redacted]

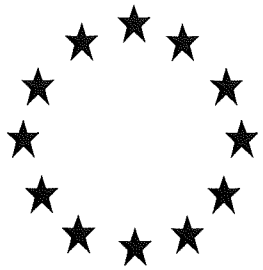
Section A7.3.2/01-02 Fate and behaviour in air, further studies

Annex Point IIIA, XII. 3

	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Competent Authority Report

Work Programme for Review of Active Substances in Biocidal Products Pursuant to Council Directive 98/8/EC



IODINE (PT1, PT3, PT4, PT22)

DOCUMENT III-A 7.4-7.6

Ecotoxicology

Rapporteur Member State: Sweden

Draft Final May 2013

KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Index:

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

[redacted]

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1 REFERENCE

1.1	**Reference**	Laverock, M.J., Stephenson, M., Macdonald, C.R., Arch. Environ. Contam. Toxicol., 29, 344-350 (1995): Toxicity of Iodine, Iodide, and Iodate to *Daphnia magna* and Rainbow Trout (*Oncorhynchus mykiss*); Doc. No. 892-002 (publication); Section A7.4.1.1/01
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not indicated [redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	– Iodide [redacted] – Iodate [redacted] – Iodine [redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

[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**	X
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	*Oncorhynchus mykiss*, details are given in Table A7.4.1.1/01-3.
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[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	X [redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

[redacted]

4.2.2 Actual concentrations of test substance

[redacted]

4.2.3 Comparison of final to initial concentrations

[redacted]

4.2.4 Effect data (Mortality)

[redacted] X

[redacted] the following LC_{50} values for *Oncorhynchus mykiss* were derived:

LC_{50} = 3780 I^- mg/L

LC_{50} = 350 IO_3^- mg/L

LC_{50} = 1.67 I_2 mg/L

Oncorhnychus mykiss [redacted]

For the I^- and IO_3^- species, the lowest LC_{50} values were found when using dilution water of low hardness:

LC_{50} = 860 I^- mg/L

LC_{50} = 220 IO_3^- mg/L

For the I_2 species, the lowest LC_{50} values was found when using dilution water of high hardness:

LC_{50} = 0.53 I_2 mg/L

[redacted]

4.2.5 Concentration / response curve

[redacted]

4.2.6 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

[redacted]

4.4.1 Concentrations

[redacted]

4.4.2 Results

[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The testing of acute toxicity of Iodine species iodide (I^-), iodate (IO_3^-), and elemental Iodine (I_2) in *Oncorhynchus mykiss* was conducted over 96-h (static) using seven different kind of dilution waters (standard of medium hardness, low chloride content, and low TOC; soft and hard; medium and high chloride content; medium and high TOC). The design basically followed OECD 203. [redacted]

5.2 Results and discussion

[redacted]

5.2.1 LC_{50}

I^-: 3780 mg/L (96 hours, in standard / culture water)

IO_3^-: 220 mg/L (96 hours in standard / culture water)

I_2: 1.67 mg/L (96 hours in standard / culture water)

5.2.2 Other results

[redacted]

5.3 Conclusion

Most of the validity criteria were fulfilled. The deficiencies (see 5.3.3) were compensated by the multitude of tests in different dilution waters.

The EC_{50} values in standard water were calculated to be 3780 mg/L for iodide, 220 mg/L for iodate, and 1.67 mg/L for elemental Iodine

(all based on mean measured values).

5.3.1 Other Conclusions

[redacted]

5.3.2 Reliability

[redacted]

5.3.3 Deficiencies

[redacted]

Section A7.4.1.1 Acute toxicity to fish
Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

Evaluation by Competent Authorities	
	[redacted]
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.4.1.1 Acute toxicity to fish
Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

Table A7.4.1.1/01-1: Preparation of Iodine test solution

Criteria	Details
NaI	[redacted]
$NaIO_3$	[redacted]
I_2	[redacted]
Vehicle	[redacted]
Non-active substance	[redacted]
Concentration of vehicle	[redacted]
Concentration of non-active substance	[redacted]
Vehicle control performed	[redacted]
Control of non-active substance performed	[redacted]
Other procedures	[redacted]

Section A7.4.1.1 Acute toxicity to fish
Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

Table A7.4.1.1/01-2: Dilution waters

Criteria	Details
Number of differing dilution waters	
Source	
Preparation	
Alkalinity (as $CaCO_3$)	
Hardness (as $CaCO_3$)	
pH	
Oxygen content	
Conductance	
Control analysis	
Culture water different from dilution water	

Section A7.4.1.1 Acute toxicity to fish
Annex Point IIA VII.7.1 *Oncorhynchus mykiss*

Table A7.4.1.1/01-3: Test organisms

Criteria	Details
Species	*Oncorhynchus mykiss*
Source	Certified disease-free commercial hatcheries (not specified)
Wild caught	[redacted]
Weight / length	[redacted]
Kind of food	[redacted]
Amount of food	[redacted]
Feeding frequency	[redacted]
Pretreatment	[redacted]
Feeding of animals during test	[redacted]

Table A7.4.1.1/01-4: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels	[redacted]
Volume/animal	[redacted]
Number of animals/vessel	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7.4.1.1/01-5: Test conditions

Criteria	Details
Test temperature	[redacted]
Dissolved oxygen	[redacted]
pH	[redacted]
Adjustment of pH	[redacted]
Aeration of dilution water	[redacted]
Intensity of irradiation	[redacted]
Photoperiod	[redacted]

Table A7.4.1.1/01-6: Effect data

Criteria [a]	**Median lethal toxic concentration (LC_{50}) of Iodine species in mg/L to *Oncorhynchus mykiss* (95% confidence ranges in brackets) All LC_{50} values were calculated using the Spearman-Karber method**						
	Dilution water						
	(1.) Standard	(2.) Soft	(3.) Hard	(4.) Medium Cl^-	(5.) High Cl^-	(6.) Medium TOC	(7.) High TOC
I^-	3780 (2730-5230)	**860** [1)]	8230 (6300-12400)	4500 (3730-5440)	5480 (3000-10000)	2800 (1900-4200)	4560 (3280-6350)
IO_3^-	350 (250-490)	**220** (160-310)	280 (190-400)	320 (230-450)	340 (240-480)	420 (300-600)	420 (300-600)
I_2	1.67 (1.51-1.84)	4.19 (4.02-4.37)	**0.53** (0.48-0.58)	1.73 (1.0-3.0)	1.73 (1.0-3.0)	4.2 (3.0-6.0)	> 10 [1)]

[1)] confidence range not calculated

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

[redacted]

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1 REFERENCE

1.1	**Reference**	Laverock, M.J., Stephenson, M., Macdonald, C.R., Arch. Environ. Contam. Toxicol., 29, 344-350 (1995): Toxicity of Iodine, Iodide, and Iodate to *Daphnia magna* and Rainbow Trout (*Oncorhynchus mykiss*); Doc. No. 892-002 (publication); A7.4.1.2/01.
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not indicated [redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted] Iodide [redacted] Iodate – Iodine [redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Composition of Product	[redacted]
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

[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**		X
3.4.1	Dilution water	[redacted]	
3.4.2	Test organisms	*Daphnia magna*, [redacted]	
3.4.3	Test system	[redacted]	
3.4.4	Test conditions	[redacted]	
3.4.5	Duration of the test	[redacted]	
3.4.6	Test parameter	Immobility (In the study "death" was defined as no visible internal movement. Therefore, "death" is equal to immobility and consequently LC_{50} equal to EC_{50}.)	
3.4.7	Sampling	[redacted]	
3.4.8	Monitoring of TS concentration	[redacted]	
3.4.9	Statistics	[redacted]	

4 RESULTS

4.1	**Limit Test**	[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**	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

4.2.1	Initial concentrations of test substance	[redacted]	X
4.2.2	Final concentrations of test substance	[redacted]	
4.2.3	Comparison of final to initial concentrations	[redacted]	
4.2.4	Effect data (Immobility)	[redacted] the following LC_{50} values for *Daphnia* were derived: LC_{50} = 0.83 I^- mg/L LC_{50} = 58.5 IO_3^- mg/L LC_{50} = 0.60 I_2 mg/L [redacted] The lowest LC_{50} values were found when using dilution water of low hardness: LC_{50} = 0.17 I^- mg/L LC_{50} = 10.3 IO_3^- mg/L LC_{50} = 0.16 I_2 mg/L [redacted]	X
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]	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

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 testing of acute toxicity of iodine species iodide (I^-), iodate (IO_3^-), and elemental iodine (I_2) in *Daphnia magna* was [redacted]
5.2	**Results and discussion**	[redacted]
5.2.1	EC_{50} (LC_{50})	I^-: 0.83 mg/L (48 hours, in standard / culture water) IO_3^-: 58.5 mg/L (48 hours in standard / culture water) I_2: 0.60 mg/L (48 hours in standard / culture water)
5.2.2	Other results	[redacted]
5.3	**Conclusion**	[redacted] The EC_{50} values in standard water were calculated to be 0.83 mg/L for iodide, 58.5 mg/L for iodate, and 0.60 mg/L for elemental iodine (all based on mean measured values). The values for iodine and iodide are more or less identical due to fast conversion (see expert statement on aqueous speciation of iodine, Doc. No. Doc. No. 181-001; Section A7.1.1.1.1/13).
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

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

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

Table A7.4.1.2/01-1: Preparation of iodine test solution

Criteria	Details
NaI	[redacted]
$NaIO_3$	[redacted]
I_2	[redacted]
Vehicle	[redacted]
Non-active substance	[redacted]
Concentration of vehicle	[redacted]
Concentration of non-active substance	[redacted]
Vehicle control performed	[redacted]
Control of non-active substance performed	[redacted]
Other procedures	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

Table A7.4.1.2/01-2.1: Dilution waters

Criteria	Details
Number of differing dilution waters	
Source	
Preparation	
Alkalinity (as $CaCO_3$)	
Hardness (as $CaCO_3$)	
pH	
Oxygen content	
Conductance	
Control analysis	
Culture water different from dilution water	

Section A7.4.1.2 Acute toxicity to invertebrates
Annex Point IIA, VII.7.2 *Daphnia magna*

Table A7.4.1.2/01-3.1: Test organisms

Criteria	Details
Species	*Daphnia magna*
Source	Stocks of *Daphnia magna* [redacted]
Age	[redacted]
Kind of food	[redacted]
Amount of food	[redacted]
Feeding frequency	[redacted]
Pretreatment	[redacted]
Feeding of animals during test	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates
Annex Point IIA, VII.7.2 *Daphnia magna*

Table A7.4.1.2/01-3.2: Culture water for raising *Daphnia magna* [a]

Criteria	Details
Source	[redacted]
Alkalinity (as $CaCO_3$)	[redacted]
Hardness (as $CaCO_3$)	[redacted]
pH	[redacted]
Dissolved oxygen	[redacted]
Conductivity	[redacted]

[redacted]

Table A7.4.1.2/01-4: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels / test solution	[redacted]
Volume/animal/day	[redacted]
Number of animals/vessel	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7.4.1.2/01-5: Test conditions

Criteria	Details
Test temperature	[redacted]
Dissolved oxygen	[redacted]
pH	[redacted]
Adjustment to replace the loss of active substance / test solution during the test period	[redacted]
Adjustment of pH	[redacted]
Aeration of dilution water	[redacted]
Quality/Intensity of irradiation	[redacted]
Light-control	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

Table A7.4.1.2/01-6: Effect data

Criteria [a]	Median lethal toxic concentration (LC_{50}) of iodine species in mg/L to *Daphnia magna* (95% confidence ranges in brackets) All LC_{50} values were calculated using the Spearman-Karber method						
	Dilution water						
	(1.) Standard	(2.) Soft	(3.) Hard	(4.) Medium Cl^-	(5.) High Cl^-	(6.) Medium TOC	(7.) High TOC
I^-	0.83 (0.68 ± 1.01)	**0.17** (0.16 ± 0.18)	0.78 (0.60 ± 1.00)	0.23 (0.15 ± 0.35)	**0.17** (0.10 ± 0.30)	0.78 (0.59 ± 1.18)	0.43 (0.39 ± 0.48)
IO_3^-	58.5 (50.7 ± 67.7)	**10.3** (0.3 ± 334.0)	54.8 (30.0 ± 100.0)	58.7 (47.9 ± 71.8)	129 (83 ± 199)	54.8 (30.0 ± 100.0)	54.9 (47.7 ± 63.2)
I_2	0.59 (0.51 ± 0.68)	**0.16** (0.14 ± 0.19)	0.55 (0.30 ± 1.00)	1.75 (1.54 ± 1.99)	1.73 (1.00 ± 3.00)	0.85 (0.55 ± 1.32)	0.59 (0.51 ± 0.68)

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

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1 REFERENCE

1.1 Reference

Mead, C.; Mullee, D.M. (2002): Iodine – Algal inhibition test. Safepharm Laboratories Limited, report number 1580/004, report date: 07.05.2002 (unpublished).

Doc. No. 823-003; Section A7.4.1.3/01.

1.2 Data protection

[redacted]

1.2.1 Data owner

[redacted]

1.2.2 Companies with letter of access

[redacted]

1.2.3 Criteria for data protection

[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

OECD No 201(1984): Alga Growth Inhibition Test;

Method C.3 of Commission Directive 92/69/EEC

2.2 GLP

[redacted]

2.3 Deviations

The pH value of the control cultures increased from pH 7.5 to 10.3 during the exposure period, which is in excess of the 1.5 pH units recommended by the guideline. [redacted] this increase in pH value was considered to have no adverse effect on the validity of the study.

The measured test concentration for one test concentration at time 0 was 122 % of nominal, thus exceeding the range of 80 to 120 % of nominal (please refer to Table A7.4.1.3/01-9). This was considered to have no impact on the validity or integrity of the study due to the fact that all other test concentrations were within the recommended range.

3 MATERIALS AND METHODS

3.1 Test material

As given in section 2.

3.1.1 Lot/Batch number [redacted]

3.1.2 Specification [redacted]

3.1.3 Purity [redacted]

3.1.4 Description of test substance [redacted]

3.1.5 Composition of [redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

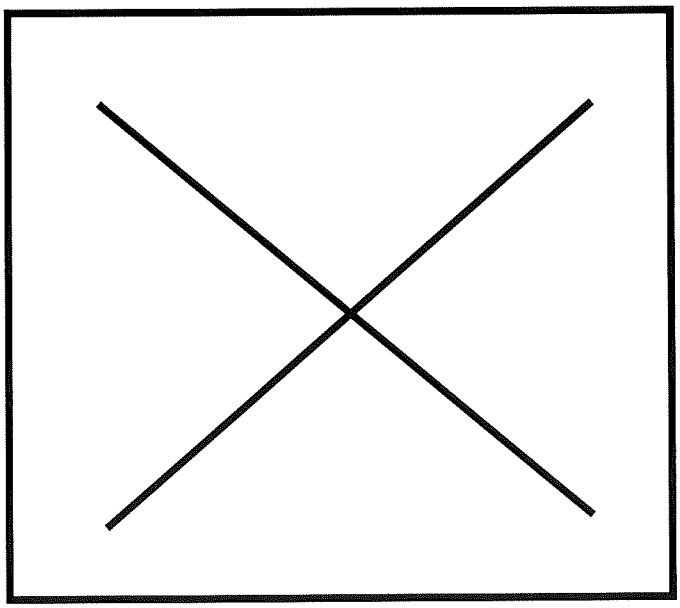
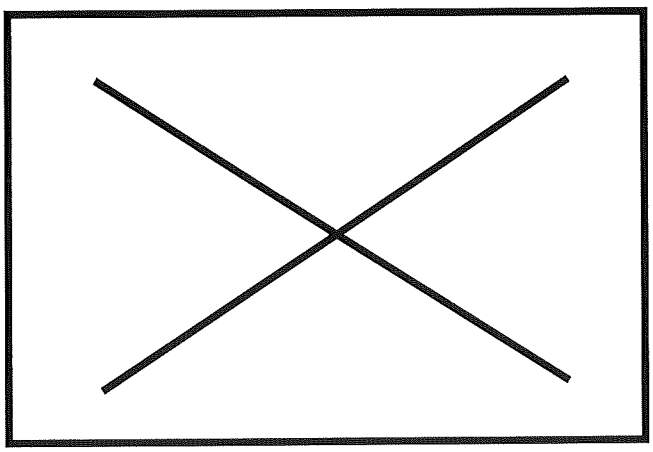
	Product	
3.1.6	Further relevant properties	[redacted]
3.1.7	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	The green algae *Desmodesmus subspicatus* (formerly named *Scendesmus subspicatus*; [redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]
3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	Area under growth curve (AUC) and growth rate calculated from cell densities.
3.4.7	Sampling	[redacted] X
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

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]	X
4.2.2	Actual concentrations of test substance	[redacted]	
4.2.3	Growth curves		
4.2.4	Concentration / response curve (based on nominal test concentrations)		

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

4.2.5	Cell concentration date	[redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other effects	[redacted]
4.3	**Results of controls**	
4.3.1	Nature of adverse effects	[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 test was conducted according to OECD No 201(1984). It is a static test-system and *Desmodesmus subspicatus* (formerly named *Scendesmus subspicatus*) was used as a test organism.
5.2	**Results and discussion**	[redacted]
5.2.1	NOEC (72 hours)	0.20 mg/L (based on nominal concentrations)
5.2.1	E_bC_{50} (72 h)	0.62 mg/L (based on nominal concentrations)
5.2.2	E_rC_{50} (0-72 h)	1.3 mg/L (based on nominal concentrations)
5.3	**Conclusion**	[redacted] the EC_{50} (cell numbers) was calculated to be 0.16 mg/L [redacted] The NOEC (cell numbers) was determined to be 0.061 mg/L [redacted] X
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	Minor deviations to the test guideline (for details, please refer to 2.3) occurred that are considered to have no impact on the validity or integrity of the study.

Evaluation by Competent Authorities
[redacted]
EVALUATION BY RAPPORTEUR MEMBER STATE
Date [redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	[redacted]
Vehicle	[redacted]
Concentration of vehicle	[redacted]
Vehicle control performed	[redacted]
Other procedures	[redacted]

Table A7.4.1.3/01-2: Culture medium (corresponding to AAP-medium described in OECD 201)

Nutrient	Concentration
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[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 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-3: Test organisms

Criteria	Details
Species/strain	*Desmodesmus subspicatus* (formerly named *Scendesmus subspicatus)* / strain CCAP 276/20
Source	[redacted]
Wild caught	[redacted]
Growth phase at test initiation	[redacted]
Culture medium	[redacted]
Maintenance temperature	[redacted]
Maintenance illumination	[redacted]

Table A7.4.1.3/01-4: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels	[redacted]
Volume of test solution	[redacted]
Cell density	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7.4.1.3/01-5: Test conditions

Criteria	Details
Test temperature	[redacted]
pH	[redacted]
Adjustment of pH	[redacted]
Aeration of dilution water	[redacted]
Shaking of test flasks	[redacted]
Intensity of irradiation	[redacted]
Photoperiod	[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-6: pH values measured during the test (three replicates each)

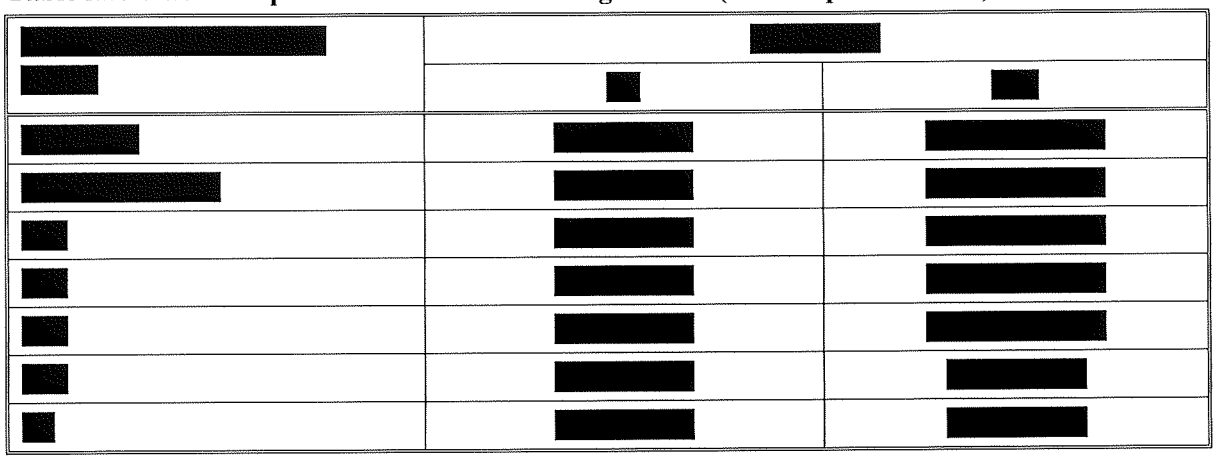


Table A7.4.1.3/01-7: Cell densities, inhibition of growth rate and area under curve (AUC) data

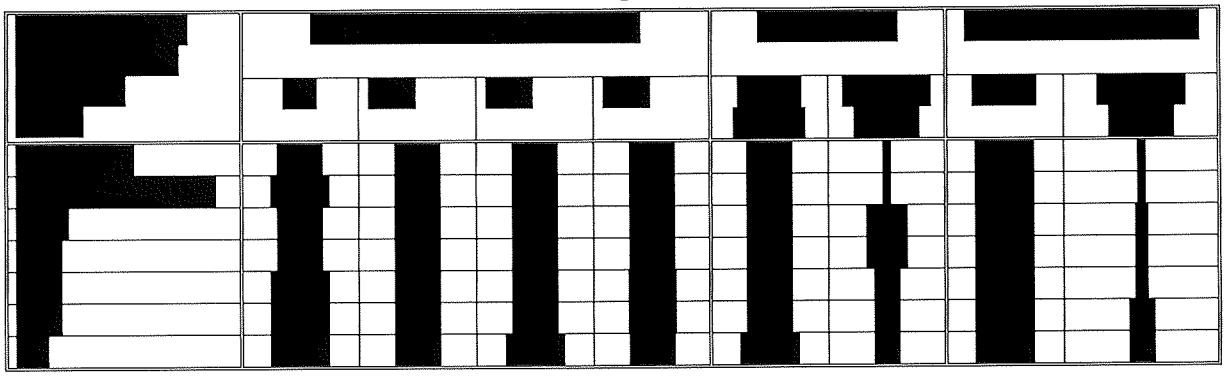
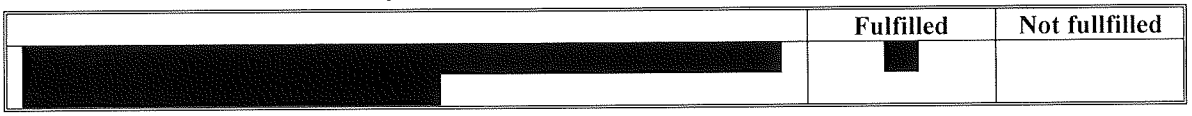


Table A7.4.1.3/01-8: Effect data

	E_bC_{50} (72 h) [mg/L]	95 % c.l. [mg/L]	E_rC_{50} (0-72 h) [mg/L]	95 % c.l. [mg/L]	NOEC [mg/L]
Based on nominal concentrations	0.62	0.56 – 0.68	1.3	1.1 – 1.5	0.20
Based on time-weighted mean measured concentrations	0.64	0.57 – 0.72	1.4	1.2 – 1.6	0.19

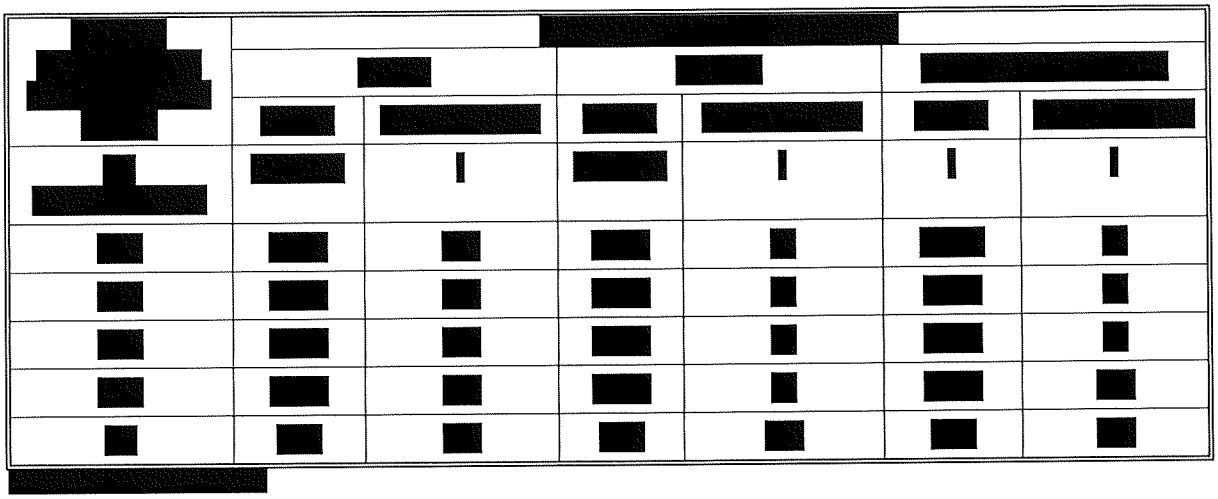
Table A7.4.1.3/01-9: Validity criteria for acute fish test according to OECD Guideline 201



Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-10: Actual concentrations of test substance



Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	[redacted]
Vehicle	[redacted]
Concentration of vehicle	[redacted]
Vehicle control performed	[redacted]
Other procedures	[redacted]

Table A7.4.1.3/01-2: Culture medium (corresponding to AAP-medium described in OECD 201)

Nutrient	Concentration
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[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 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-3: Test organisms

Criteria	Details
Species/strain	*Desmodesmus subspicatus (*formerly named *Scendesmus subspicatus)* / strain CCAP 276/20
Source	[redacted]
Wild caught	[redacted]
Growth phase at test initiation	[redacted]
Culture medium	[redacted]
Maintenance temperature	[redacted]
Maintenance illumination	[redacted]

Table A7.4.1.3/01-4: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels	[redacted]
Volume of test solution	[redacted]
Cell density	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7.4.1.3/01-5: Test conditions

Criteria	Details
Test temperature	[redacted]
pH	[redacted]
Adjustment of pH	[redacted]
Aeration of dilution water	[redacted]
Shaking of test flasks	[redacted]
Intensity of irradiation	[redacted]
Photoperiod	[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-6: pH values measured during the test (three replicates each)

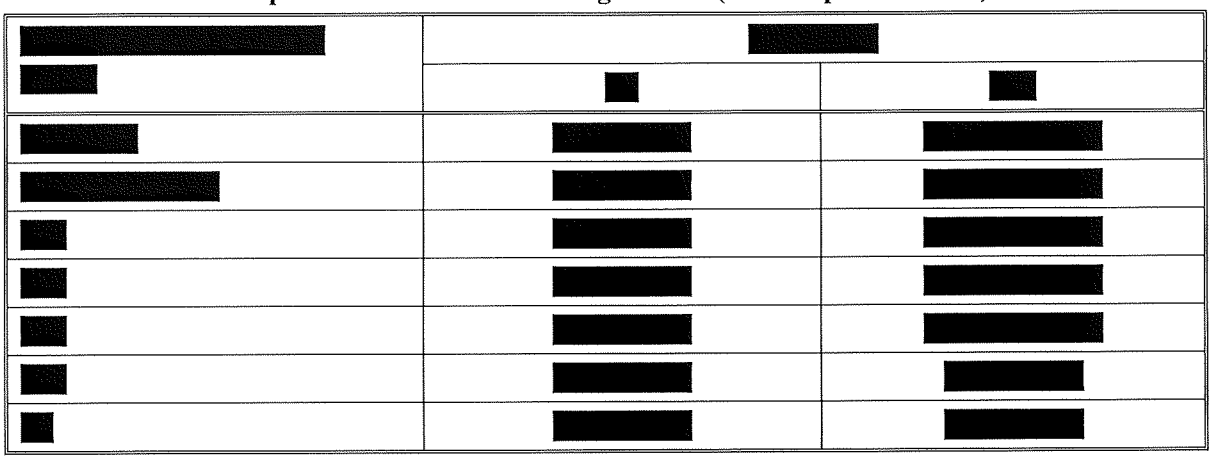


Table A7.4.1.3/01-7: Cell densities, inhibition of growth rate and area under curve (AUC) data

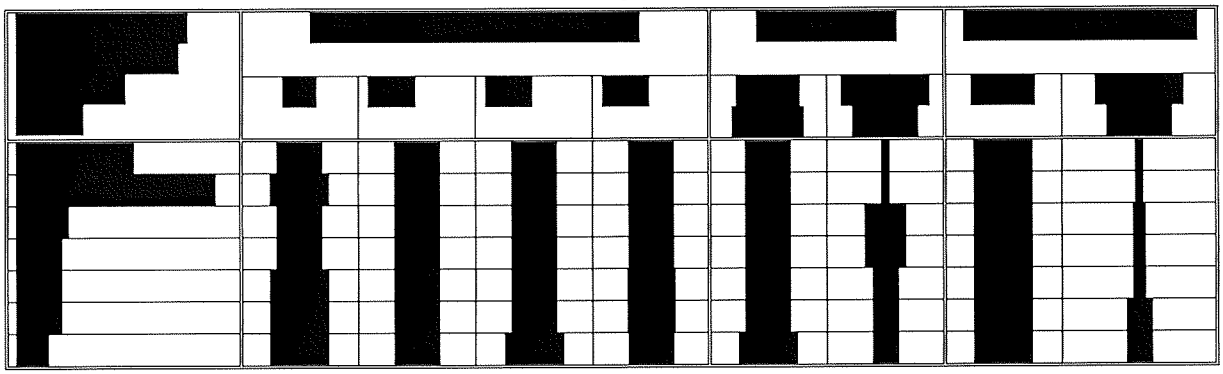


Table A7.4.1.3/01-8: Effect data

	E_bC_{50} (72 h) [mg/L]	95 % c.l. [mg/L]	E_rC_{50} (0-72 h) [mg/L]	95 % c.l. [mg/L]	NOEC [mg/L]
Based on nominal concentrations	0.62	0.56 – 0.68	1.3	1.1 – 1.5	0.20
Based on time-weighted mean measured concentrations	0.64	0.57 – 0.72	1.4	1.2 – 1.6	0.19

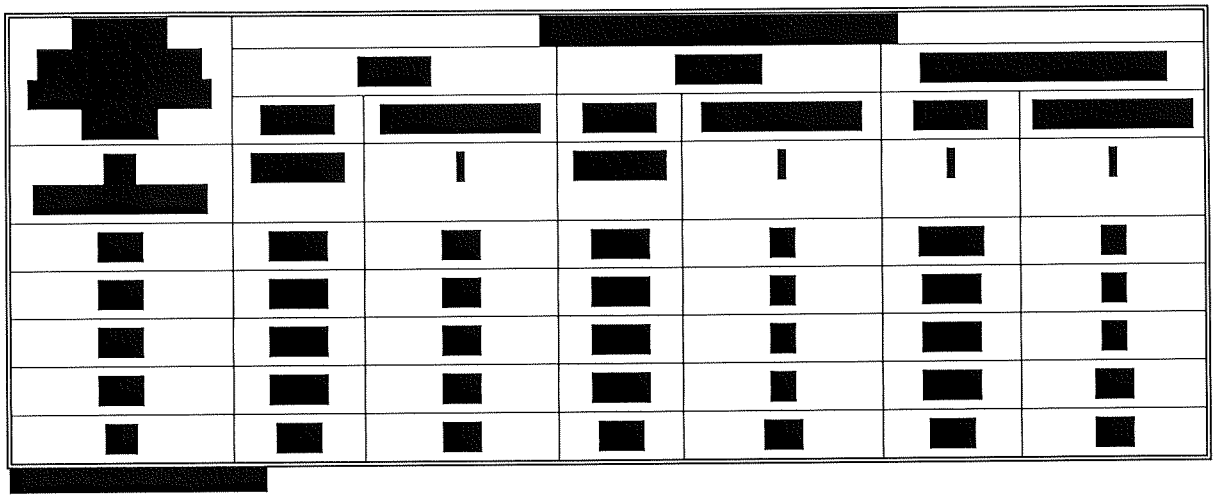
Table A7.4.1.3/01-9: Validity criteria for acute fish test according to OECD Guideline 201

	Fulfilled	Not fullfilled
		

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA, VII.7.3

Table A7.4.1.3/01-10: Actual concentrations of test substance



Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 Activated sludge

			Official use only
		1 REFERENCE	
1.1	**Reference**	Mead, C., 2002, Iodine – assessment of the inhibitory effect on the respiration of activated sludge, Safepharm Laboratories Limited, report number 1580/005, report date: 07.05.2002. Doc. No. 842-001; Section A7.4.1.4/01	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data proection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	OECD No 209 (1984): Activated Sludge, Respiration Inhibition Test; EEC Commission Directive 87/302/EEC; US EPA Draft Ecological Test Guidelines OPPTS 850.6800.	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	As given in section 2.	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	[redacted]	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]	X
3.3	**Reference substance**	[redacted]	
3.3.1	Method of analysis for reference	[redacted]	

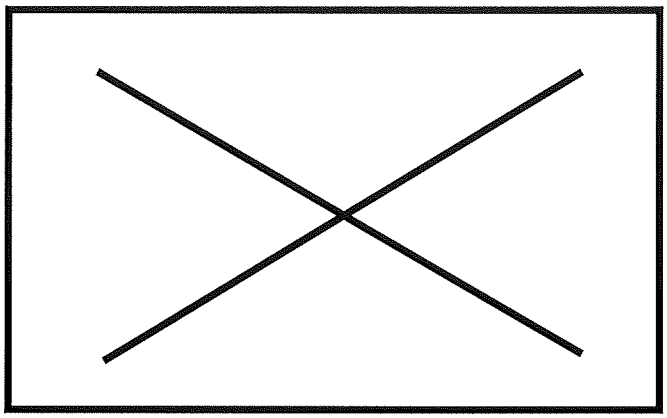
Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 Activated sludge

	substance	
3.4	**Testing procedure**	
3.4.1	Dilution water	
3.4.2	Inoculum / test organisms	
3.4.3	Test system	
3.4.4	Test conditions	
3.4.5	Duration of the test	
3.4.6	Test parameter	Respiration rate
3.4.7	Analytical parameter	
3.4.8	Sampling	
3.4.9	Monitoring of TS concentration	
3.4.10	Controls	X
3.4.11	Statistics	
	4 RESULTS	
4.1	**Limit Test**	
4.1.1	Concentration	
4.1.2	Number/ percentage of animals showing adverse effects	
4.1.3	Nature of adverse effects	
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	X
4.2.2	Actual concentrations of test substance	

Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 Activated sludge

4.2.3	Concentration / response curve	
4.2.4	Effect data	[redacted] X
4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted] EC_{50}: 11 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to OECD Guideline No 209. Activated sludge from aeration stage was used.
5.2	**Results and discussion**	
5.2.1	NOEC (3 hours)	320 mg/L
5.2.1	LC_{50} (3 hours)	1600 mg/L X
5.3	**Conclusion**	[redacted] - The EC_{50} [redacted] range of 5 to 30 mg/L for 3,5- Dichlorophenol.
5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	None
5.3.4		

Evaluation by Competent Authorities
[redacted]
EVALUATION BY RAPPORTEUR MEMBER STATE
[redacted]

Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 Activated sludge

Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 *Activated sludge*

Table A7.4.1.4/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	[redacted]
Vehicle	[redacted]
Concentration of vehicle	[redacted]
Vehicle control performed	[redacted]
Other procedures	[redacted]

Table A7.4.1.4/01-2 Dilution water

Criteria	Details
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Section A7.4.1.4 Inhibition to microbial activity
Annex Point IIA, VII.7.4 *Activated sludge*

Table A7.4.1.4/01-3 Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	Mixed population of activated sewage sludge micro-organisms.
Strain	Details are not provided.
Source	[redacted]
Sampling site	[redacted]
Laboratory culture	[redacted]
Method of cultivation	[redacted]
Preparation of inoculum for exposure	[redacted]
Pre-treatment	[redacted]
Initial concentration	[redacted]

Table A7.4.1.4/01-4 Test system

Criteria	Details
Culturing apparatus	[redacted]
Number of culture flasks/concentration	[redacted]
Aeration device	[redacted]
Aeration rate	[redacted]
Measuring equipment	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7.4.1.4/01-5 Test conditions

Criteria	Details
Test duration	[redacted]
Test temperature	[redacted]
Irradiation	[redacted]
pH (at the end of exposure period)	[redacted]
Aeration of dilution water	[redacted]
Adjustment of pH	[redacted]
Suspended solids concentration	[redacted]

Section A7.4.1.4 Inhibition to microbial activity

Annex Point IIA, VII.7.4 *Activated sludge*

Table A7.4.1.4/01-6: O_2 concentrations, respiration and inhibition rates of the TS

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

Table A7.4.1.4/01-6: Validity criteria for respiration inhibition test according to OECD Guideline 209

	Fulfilled	Not fulfilled
[redacted]		
[redacted]		

Section A7.4.2 Bioconcentration in aquatic organisms

Annex Point IIIA, XIII.2.3

[redacted]

Official use only

1 REFERENCE

1.1 References

[1] U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (2004): Toxicological Profile for Iodine.
Doc. No. 581-009 (published); Section A7.4.2/01.

[2] Krone, C.; Kirbach. I. (2007): Expert Evaluation provided for Dossier Preparation in Accordance with Directive 98/8/EC: Occurrence, fate and behaviour of stable Iodine 127^{I} in the environment including its geochemical and biochemical circulation and possible effects on global warming and contribution to acid rain.
Doc. No. 781-004; Section A7.4.2/02.

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Not applicable.

2.2 GLP [redacted]

2.3 Deviations [redacted]

3 MATERIALS AND METHODS

3.1 Test material [redacted]

4 RESULTS

4.1 Bioconcentration in fish [redacted]

4.2 Bioconcentration in aquatic invertebrates [redacted]

4.3 Bioconcentration in aquatic plants [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and [redacted]

Section A7.4.2 Bioconcentration in aquatic organisms

Annex Point IIIA, XIII.2.3

	methods	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	High bioconcentration factors are usually associated with the relatively high levels of Iodine as occuring in seawater.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A7.4.3 Effects on aquatic organisms, further studies

Section A7.4.3.1-7.4.3.5.1

Annex Point IIIA, XIII.2

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [...]	**Technically not feasible [ ]** **Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	

EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	
Remarks	

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

[redacted] **Official use only**

1 REFERENCE

1.1 Reference

[redacted] J. (1999): Tolerance test for Rainbow trout (*Oncorhynchus mykiss*) eggs to new formulation of [redacted] 06.01.1999 ([redacted]

1.2 Data protection

[redacted]

1.2.1 Data owner

[redacted]

1.2.2 Companies with letter of access

[redacted]

1.2.3 Criteria for data protection

[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

No

CEFAS Standard Operation Procedures (CEFAS SOP 103) were employed. Final report and raw data were archived.

2.2 GLP

[redacted]

2.3 Deviations

No

3 METHOD

3.1 Test material

[redacted]

3.1.1 Lot/Batch number

[redacted]

3.1.2 Specification

[redacted]

3.1.3 Content of active ingredient

[redacted]

3.1.4 Composition of Product

[redacted]

3.1.5 Further relevant properties

[redacted]

3.1.6 Method of analysis

[redacted]

3.2 Reference substance

[redacted]

3.2.1 Method of analysis for reference substance

[redacted]

3.3 Testing procedure

X

3.3.1 Dilution water

[redacted]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

3.3.2 Test organisms [redacted]

3.3.3 Test system [redacted]

3.3.4 Test conditions [redacted]

3.3.5 Duration of the test [redacted]

3.3.6 Test parameter(s) [redacted]

3.3.7 Examination / Sampling [redacted]

3.3.8 Monitoring of TS concentration [redacted]

3.3.9 Statistics [redacted]

4 RESULTS

4.1 Range finding test [redacted]

4.1.1 Concentrations [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 Effect data (Mortality) [redacted] X

[redacted]

4.2.3 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]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

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 testing of effects of a twice disinfection with [redacted] to green and eyed eggs of *Oncorhynchus mykiss* was conducted over 5 weeks using five different concentrations of the test substance and four different durations compared to a non-treated control. The design of the study followed the OECD 210. X

5.2 Results and discussion [redacted]

5.2.1 NOEC = 800 mg/L

5.3 Conclusion [redacted] (details are given in tables A7.4.3.2-5 and A7.4.3.2-6).

5.3.1 Other Conclusions [redacted]

5.3.2 Reliability [redacted]

5.3.3 Deficiencies [redacted]

Evaluation by Competent Authorities
[redacted]
EVALUATION BY RAPPORTEUR MEMBER STATE
Date [redacted]
Materials and Methods [redacted]

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section 7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA XIII 2.2

Table A7.4.3.2/01-1: Dilution water

Criteria	Details
Source	[redacted]
Salinity	[redacted]
Hardness	[redacted]
pH	[redacted]
Oxygen content	[redacted]
Conductance	[redacted]
Holding water different from dilution water	[redacted]

Table A7.4.3.2/01-2: Test organisms

Criteria	Details
Species/strain	Eggs of Rainbow trout (*Oncorhynchus mykiss*)
Source	[redacted]
Wild caught	[redacted]
Age/size	[redacted]
Treatment for disease within 2 weeks preceding test	[redacted]

Table A7.4.3.2/01-3: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels	[redacted]
Volume/animal	[redacted]
Number of animals/vessel	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Section 7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA XIII 2.2

Table A7.4.3.2/01-4: Test conditions

Criteria	Details
Test temperature	
Dissolved oxygen	
pH	
Adjustment of pH	
Aeration of dilution water	
Intensity of irradiation	
Photoperiod	

Table A7.4.3.2/01-5: Validity criteria for fish tests according to OECD Guidelines 210/212

Table A7.4.3.2/01-6: Validity criteria for fish test according to OECD Guideline 215

Section A7.4.3.2/01 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

Table A7.4.3.2/01-7: Initial and final egg numbers – Overall mortality rates

	[redacted]		[redacted]		[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[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 A7.4.3.2/02 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

[redacted] **Official use only**

1 REFERENCE

1.1	**Reference**	[redacted](2001): Tolerance test for Atlantic salmon (*Salmo salar* L.) eggs to new [redacted] 06.03.2001 [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No CEFAS Standard Operation Procedures (CEFAS SOP 103) were employed. Final report and raw data were archived.
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 METHOD

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.3	Content of active ingredient	[redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Method of analysis for reference substance	[redacted]
3.3	**Testing procedure**	X
3.3.1	Dilution water	[redacted]
3.3.2	Test organisms	[redacted]

Section A7.4.3.2/02 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

3.3.3	Test system	[redacted]
3.3.4	Test conditions	[redacted]
3.3.5	Duration of the test	[redacted]
3.3.6	Test parameter(s)	[redacted]
3.3.7	Examination / Sampling	[redacted]
3.3.8	Monitoring of TS concentration	[redacted]
3.3.9	Statistics	[redacted]

4 RESULTS

4.1	**Range finding test**	[redacted]
4.1.1	Concentrations	[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	Effect data (Mortality)	[redacted] X
4.2.3	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**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

Section A7.4.3.2/02 Effects on reproduction and growth rate of fish
Annex Point IIIA XIII 2.2 **(Confidential)**

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The testing of effects of a twice disinfection with [redacted] to green and eyed eggs of *Salmo salar* L. was conducted over 5 weeks using five different concentrations of the test substance and four different durations compared to a non-treated control. The design of the study followed the OECD 210. X

5.2 Results and discussion

[redacted] the observed mortality rates were similar to the control.

5.3 Conclusion

[redacted] (details are given in tables A7.4.3.2/02-5 and A7.4.3.2/02-6).

5.3.1 Other Conclusions [redacted]

5.3.2 Reliability [redacted]

5.3.3 Deficiencies [redacted]

- [redacted] NOEC and EC_{50} were not indicated

Evaluation by Competent Authorities

[redacted]

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Section A7.4.3.2/02 Effects on reproduction and growth rate of fish (Confidential)

Annex Point IIIA XIII 2.2

Acceptability	[redacted]
Remarks	[redacted]

Section 7.4.3.2/02 Effects on reproduction and growth rate of fish

Annex Point IIIA XIII 2.2

Table A7.4.3.2/02-1: Dilution water

Criteria	Details
Source	[redacted]
Salinity	[redacted]
Hardness	[redacted]
pH	[redacted]
Oxygen content	[redacted]
Conductance	[redacted]
Holding water different from dilution water	[redacted]

Table A7.4.3.2/02-2: Test organisms

Criteria	Details
Species/strain	Eggs of Atlantic salmon (*Salmo salar* L.)
Source	[redacted]
Wild caught	[redacted]
Age/size	[redacted]
Treatment for disease within 2 weeks preceding test	[redacted]

Table A7.4.3.2/02-3: Test system

Criteria	Details
Test type	[redacted]
Renewal of test solution	[redacted]
Volume of test vessels	[redacted]
Volume/animal	[redacted]
Number of animals/vessel	[redacted]
Number of vessels/ concentration	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Section 7.4.3.2/02 Effects on reproduction and growth rate of fish

Annex Point IIIA XIII 2.2

Table A7.4.3.2/02-4: Test conditions

Criteria	Details
Test temperature	
Dissolved oxygen	
pH	
Adjustment of pH	
Aeration of dilution water	
Photoperiod	
Treatment	

Table A7.4.3.2/02-5: Validity criteria for fish tests according to OECD Guidelines 210/212

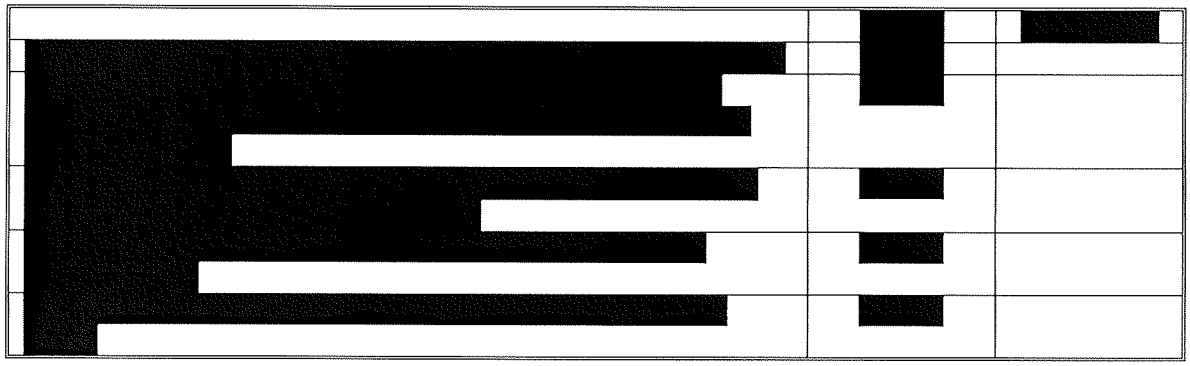
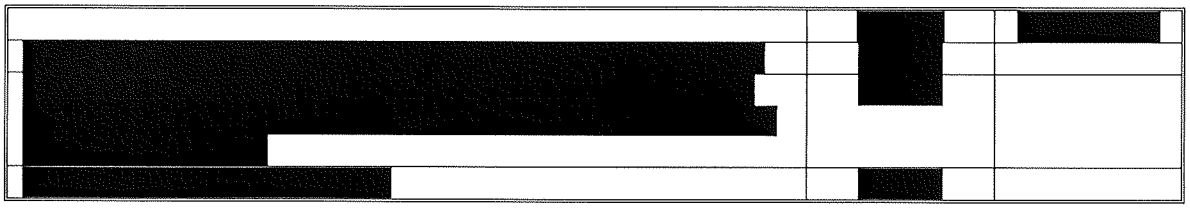


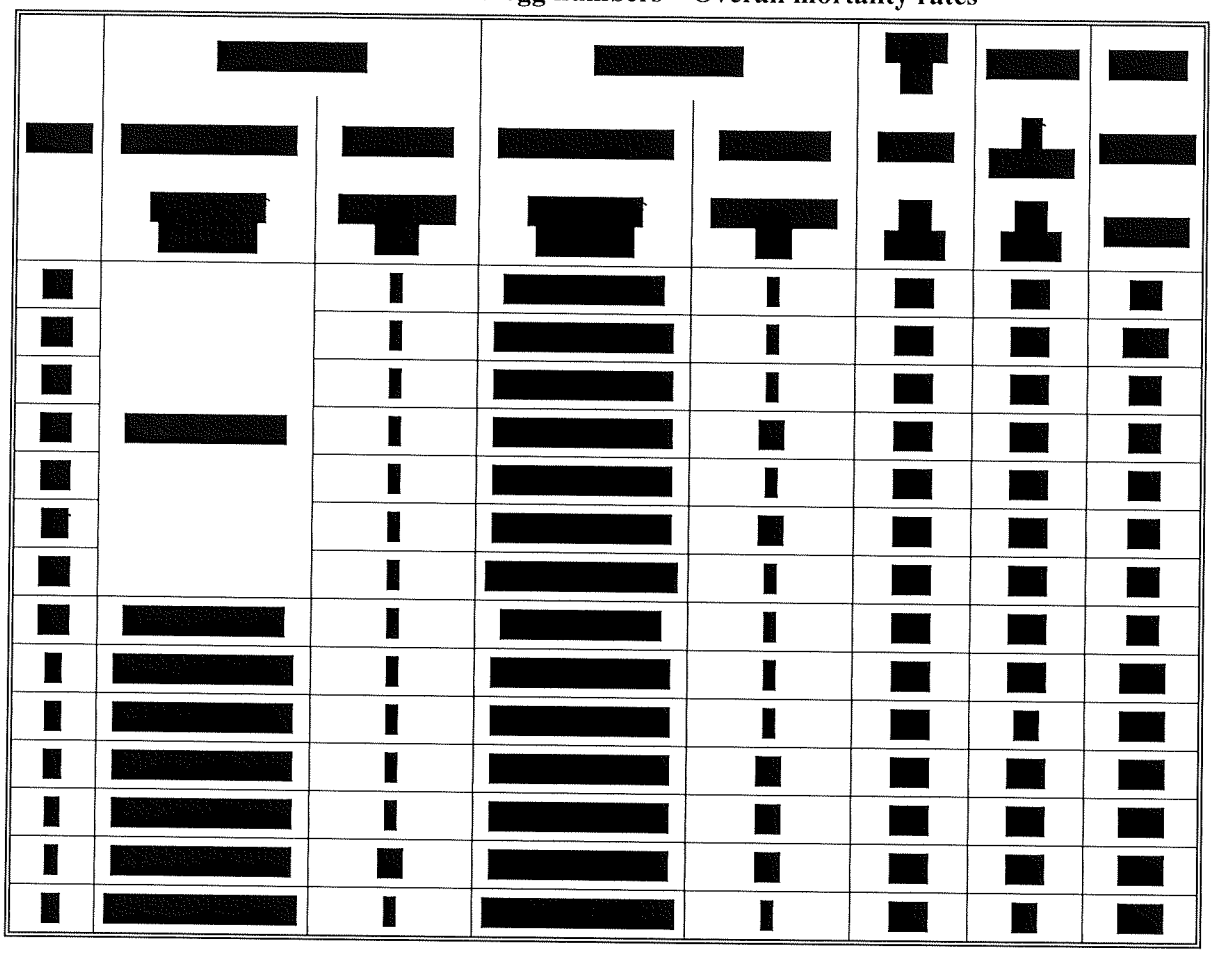
Table A7.4.3.2/2-6: Validity criteria for fish test according to OECD Guideline 215



Section A7.4.3.2/02 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

Table A7.4.3.2/02-7: Initial and final egg numbers – Overall mortality rates



Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

		Official use only
	1 REFERENCE	
1.1 Reference	Schulz, L. (2009): Iodine – Effects on the activity of soil microflora (Nitrogen and carbon transformation tests); BioChem Agrar, Gerichshain, Germany; Report No. 09 10 48 024 C/N; 10.11.2009; Doc. No. 841-001 (unpublished) and Knoch, E. (2009): Iodine –Determination of Iodine in Soils; SGS Institut Fresenius, Taunusstein, Germany; IF-09/01448579, 06.11.2009; Doc. No. 434-002 (unpublished) submitted under Section point A7.5.1/01.	
1.2 Data protection	[redacted]	
1.2.1 Data owner	[redacted]	
1.2.2 Companies with letter of access	[redacted]	
1.2.3 Criteria for data protection	[redacted]	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes OECD 216 (2000) and OECD 217 (2000)	
2.2 GLP	[redacted]	
2.3 Deviations	No	
	3 MATERIALS AND METHODS	
3.1 Test material	As given in section 2	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	[redacted]	
3.1.3 Purity	[redacted] Iodine	
3.1.4 Description of test substance	[redacted]	
3.1.5 Composition of Product	[redacted]	
3.1.6 Further relevant properties	[redacted]	
3.1.7 Method of analysis	[redacted]	
3.2 Preparation of TS solution for poorly soluble or volatile test substances	[redacted]	
3.3 Reference substance	[redacted]	

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

[redacted]

3.3.1 Method of analysis for reference substance

3.4 Testing procedure

3.4.1 Soil sample / inoculum / test organism

3.4.2 Test system

3.4.3 Application of TS

3.4.4 Test conditions

3.4.5 Test parameter

3.4.6 Analytical parameter

3.4.7 Duration of the test

3.4.8 Sampling

3.4.9 Monitoring of TS concentration

3.4.10 Controls

3.4.11 Statistics

[redacted]

4 RESULTS

4.1 Range finding test

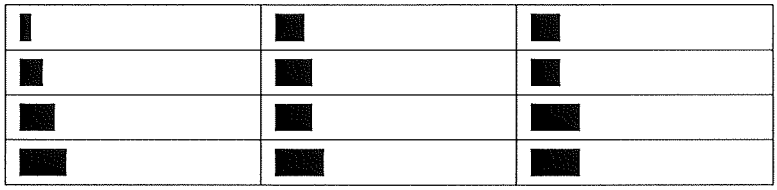
4.1.1 Concentration

4.1.2 Effect data

[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4



4.2 Results test substance

4.2.1 Initial concentrations of test substance

4.2.2 Actual concentrations of test substance

X1

4.2.3 Growth curves

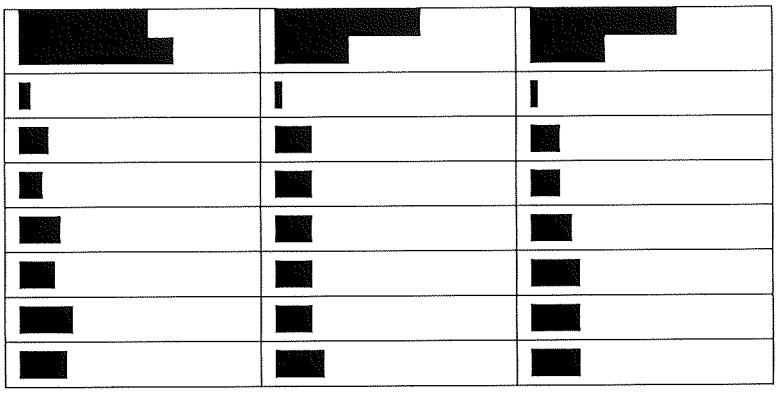
4.2.4 Cell concentration data

4.2.5 Concentration/ response curve

4.2.6 Effect data

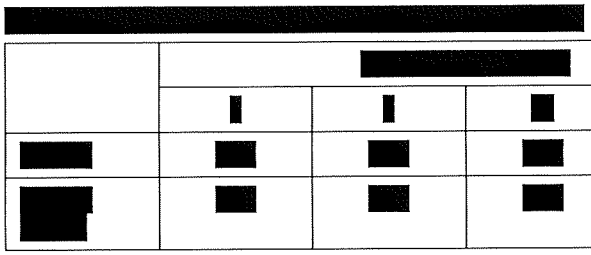
Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

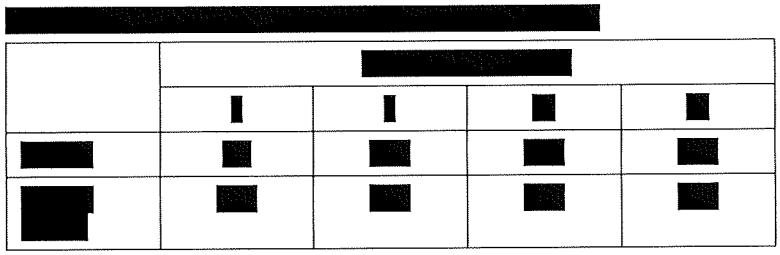
Annex Point IIA, VII.7.4



4.2.7 Other observed effects

4.3 Results of controls

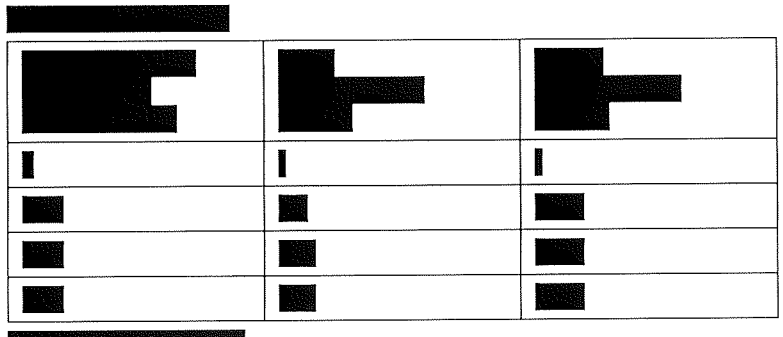


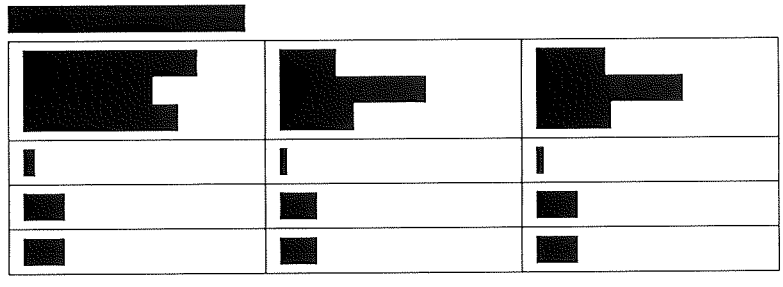


4.4 Test with reference substance

4.4.1 Concentrations

4.4.2 Results





Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

The test item caused a maximum inhibition of -90.2 % (nitrogen transformation) and of -92.6 % (carbon transformation) at 1000.0 mg/kg soil dry weight 28 days after application.

The NOEC of the test item was determined to be 10.0 mg/kg soil dry weight for the nitrogen transformation test and 100.0 mg/kg soil dry weight for the carbon transformation test after 28 days of exposure.

The EC_{50} was calculated to be 82.6 mg/kg soil dry weight for the nitrogen transformation test and 148.7 mg/kg soil dry weight for the carbon transformation test on day 28 after application.

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

5.2.1	NOEC	The NOEC of the test item was determined to be 10.0 mg/kg soil dry weight for the nitrogen transformation test and 100.0 mg/kg soil dry weight for the carbon transformation [redacted]	X
5.2.2	EC_{50}	The EC_{50} was calculated to be 82.6 mg/kg soil dry weight for the nitrogen transformation test and 148.7 mg/kg soil dry weight for the carbon transformation [redacted]	
5.3	**Conclusion**	[redacted]. Up to an exogenous iodine concentration of 10 mg/kg soil dry weight no effects on the soil microflora were observed. At the next higher dose level the soil microflora recovered with respect to the nitrogen [redacted]	
5.3.1	Other Conclusions	[redacted]	
5.3.2	Reliability	[redacted]	
5.3.3	Deficiencies	No	

Evaluation by Competent Authorities	
	[redacted]
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

Table A7.5.1.1/01-1: Microbial sample / Inoculum (*if applicable; include separate table for different samples*)

Criteria	Details
Nature	soil sample
Sampling site:	[redacted]
Geographical reference on the sampling site	[redacted]
Data on the history of the site	[redacted]
Use pattern	[redacted]
Depth of sampling [cm]	[redacted]
Sand / Silt / Clay content [% dry weight]	[redacted]
pH	[redacted]
Organic carbon content [% dry weight]	[redacted]
Nitrogen content [% dry weight]	[redacted]
Cation exchange capacity [mmol/kg]	[redacted]
Initial microbial biomass	[redacted]
Reference of methods	[redacted]
Collection / storage of samples	[redacted]

	[redacted]
Preparation of inoculum for exposure	[redacted]
Pretreatment	[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

Table A7.5.1.1/01-2: Test system

Criteria	Details
Culturing apparatus	[redacted]
Number of vessels / concentration	[redacted]
Aeration device	[redacted]
Measuring equipment	[redacted]
Test performed in closed vessels	[redacted]

Table A7.5.1.1/01-3: Application of the test substance

Criteria	Details
Application procedure	[redacted]
Carrier	[redacted]
Concentration of liquid carrier [% v/v]	[redacted]
Liquid carrier control	[redacted]
Other procedures	[redacted]

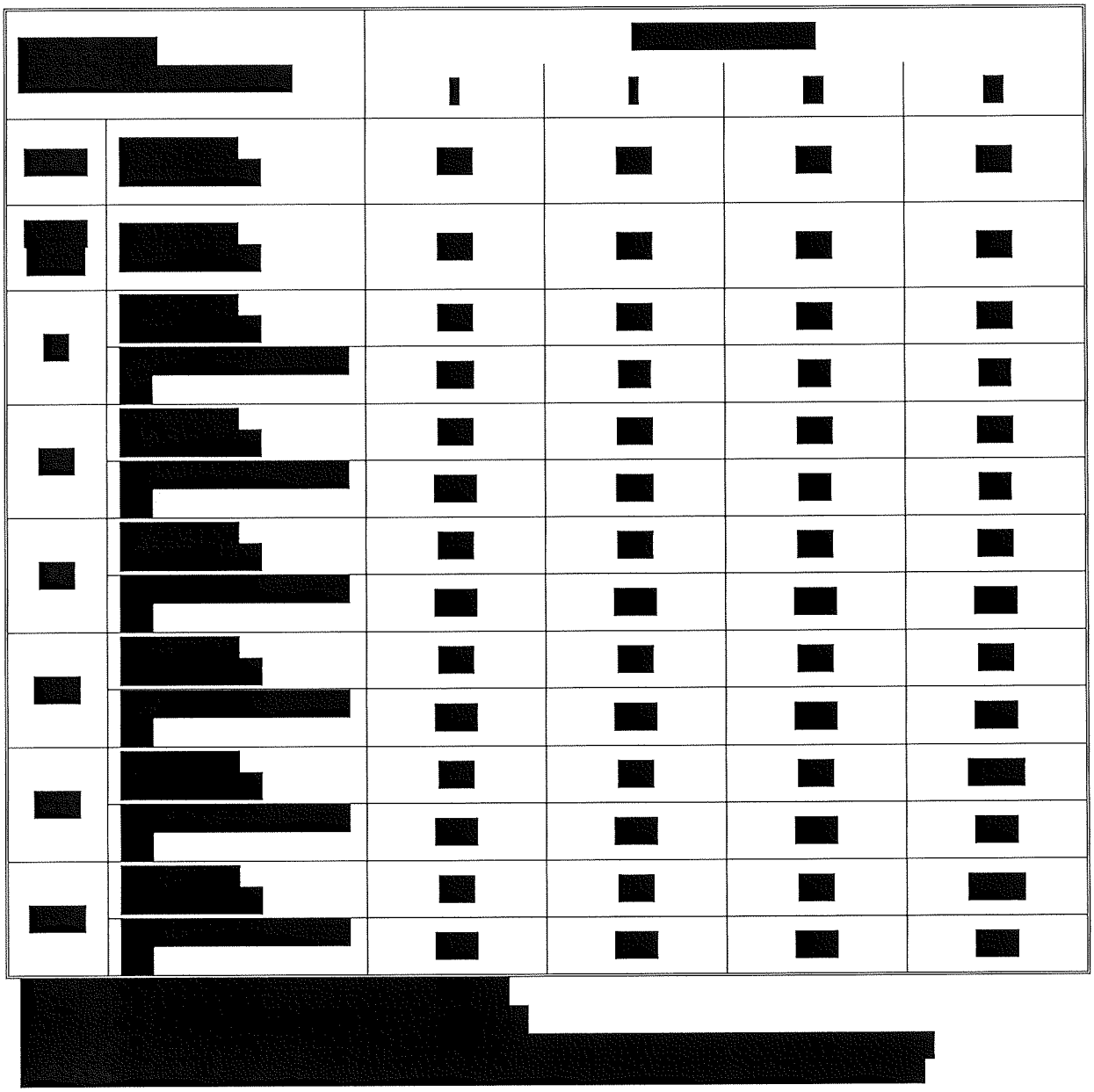
Table A7.5.1.1/01-4: Test conditions

Criteria	Details
Organic substrate	[redacted]
Incubation temperature	[redacted]
Soil moisture	[redacted]
pH of the soil	[redacted]
Method of soil incubation	[redacted]
Aeration	[redacted]

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

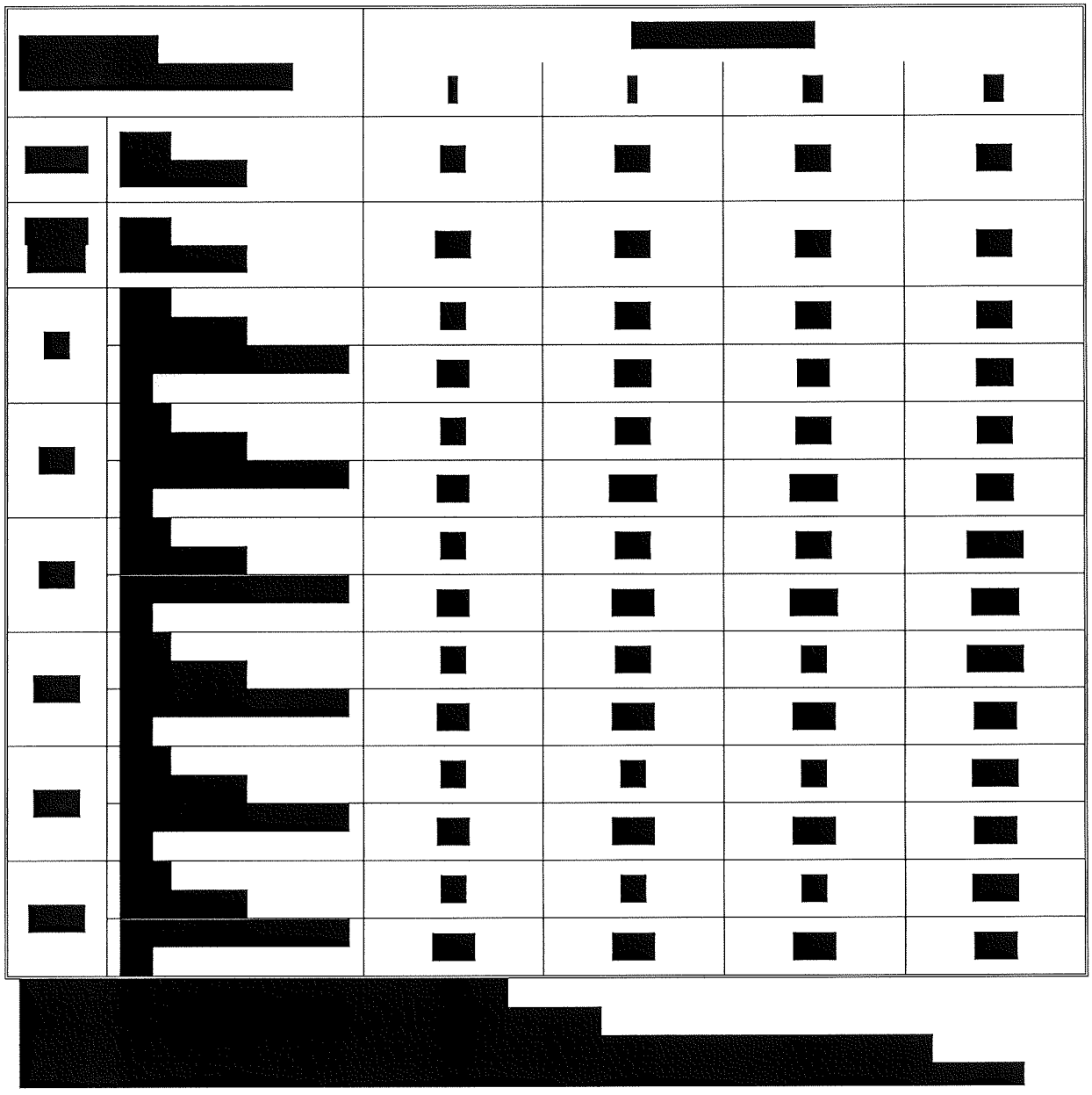
Table A7.5.1.1/01-5: Carbon Transformation Test - Effects on soil respiration (mean values)



Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

Table A7.5.1.1/01-6: Nitrogen Transformation Test - Effects on soil respiration (mean values)



Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Official use only

1 REFERENCE

1.1 Reference

Friedrich, S. (2009): Acute toxicity of Iodine to the earthworm Eisenia fetida; BioChem Agrar, Gerichshain, Germany; Report No. 09 10 48 022S; 10.11.2009; Doc. No. 833-001 (unpublished) and

Knoch, E. (2009): Iodine –Determination of Iodine in Soils; SGS Institut Fresenius, Taunusstein, Germany; IF-09/01448579, 06.11.2009; Doc. No. 434-002 (unpublished) submitted under Section point A7.5.1/01.

1.2 Data protection

[redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

Yes

OECD 207 (1984)

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 METHOD

3.1 Test material

As given in section 2

3.1.1 Lot/Batch number [redacted]

3.1.2 Specification [redacted]

3.1.3 Purity [redacted] Iodine

3.1.4 Description of test substance [redacted]

3.1.5 Composition of Product [redacted]

3.1.6 Further relevant properties [redacted]

3.1.7 Method of analysis [redacted]

3.2 Preparation of TS solution for poorly soluble or volatile

[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

test substances

3.3 Reference substance

3.3.1 Method of analysis for reference substance

3.4 Testing procedure

3.4.1 Preparation of the test substance

3.4.2 Application of the test substance

3.4.3 Test organisms

3.4.4 Test system

3.4.5 Test conditions

3.4.6 Test duration

3.4.7 Test parameter Mortality, change in biomass, abnormal behaviour or toxic symptoms

3.4.8 Examination

3.4.9 Monitoring of test substance concentration

3.4.10 Statistics

4 RESULTS

4.1 Filter paper test

4.1.1 Concentration

4.1.2 Number/ percentage of animals showing adverse effects

4.1.3 Nature of adverse effects

4.2 Soil test

4.2.1 Initial concentrations of test

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

substance

4.2.2 Actual concentrations of test substance

[redacted] X1

[redacted]

4.2.3 Effect data (Mortality)

[redacted]

4.2.4 Concentration / effect curve

[redacted]

4.2.5 Other effects

[redacted]

4.3 Results of controls

4.3.1 Mortality

[redacted]

4.3.2 Number/ percentage of earthworms showing adverse effects

[redacted]

4.3.3 Nature of adverse effects

[redacted]

4.4 Test with reference substance

4.4.1 Concentrations

[redacted]

4.4.2 Results

[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The acute toxicity of exogenous Iodine to earthworms, *Eisenia fetida*, was determined in a 14-day soil exposure laboratory study conducted according to OECD guideline 207.

[redacted]

5.2 Results and discussion

[redacted]

5.2.1 LC_0 125 mg Iodine/kg soil d.w.

5.2.2 LC_{50} >1000 mg Iodine/kg soil d.w.

5.2.3 LC_{100} >1000 mg Iodine/kg soil d.w.

5.3 Conclusion

[redacted] Iodine, when applied to soil, does not acutely affect earthworms up to a concentration of at least 125 mg Iodine/kg soil d.w.

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

5.3.1	Other Conclusions	[redacted]
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Table A7.5.1.2/01-1: Preparation of TS solution

Criteria	Details
In case of the use of an organic solvent	
Dispersion	[redacted]
Vehicle	[redacted]
Concentration of vehicle	[redacted]
Vehicle control performed	[redacted]
Other procedures	[redacted]

Table A7.5.1.2/01-2: Test organisms

Criteria	Details
Species/strain	earthworm *Eisenia fetida* ([redacted] subspecies *Eisenia fetida andrei* [redacted]
Source of the initial stock	[redacted]
Culturing techniques	[redacted]
Age/weight	[redacted]
Pre-treatment	[redacted]

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Table A7.5.1.2/01-3: Test system

Criteria	Details
Artificial soil test substrate	[redacted]
Test mixture	[redacted]
Size, volume and material of test container	[redacted]
Amount of artificial soil (kg)/ container	[redacted]
Nominal levels of test concentrations	[redacted]
Measured test concentrations at the start of the test	[redacted]
Number of replicates/concentration	[redacted]
Number of earthworms/test concentration	[redacted]
Number of earthworms/container	[redacted]
Light source	[redacted]
Test performed in closed vessels due to significant	[redacted]

volatility of test substrate	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Table A7.5.1.2/01-4: Test conditions

Criteria	Details
Test temperature	
Moisture content	
pH	
Adjustment of pH	
Light intensity / photoperiod	
Relevant degradation products	

Table A7.5.1.2/01-5:

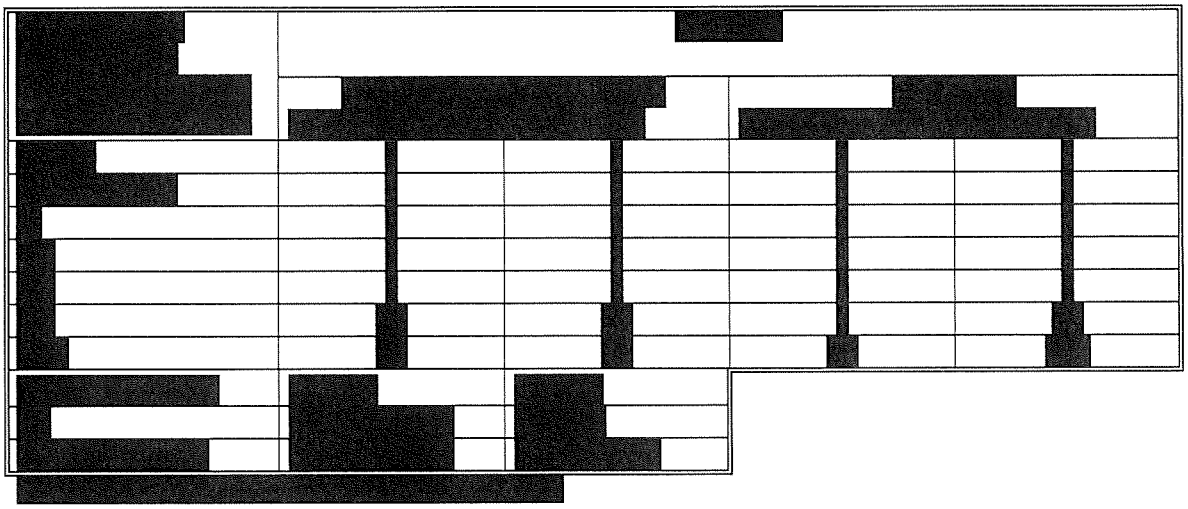


Table A7.5.1.2/01-6: Effect data (based on nominal concentrations)

	14 d [mg/kg soil][1]	95 % c.l.
NOEC	125	Not applicable
LC_{50}	>1000	Not calculated
LC_{100}	>1000	Not calculated

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

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2

Table A7.5.1.2/01-7: [redacted]

[redacted]	[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Table A7.5.1.2/01-8: [redacted]

[redacted]			
[redacted]			

Section 7.5.1.3 Acute toxicity to terrestrial plants

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Official use only

1 REFERENCE

1.1 Reference

Friedrich, S. (2009): Effects of Iodine on seedling emergence and seedling growth of non-target terrestrial plants; BioChem Agrar, Gerichshain, Germany; Report No. 09 10 48 010 S; 10.11.2009; Doc. No. 851-001 (unpublished) and

Knoch, E. (2009): Iodine –Determination of Iodine in Soils; SGS Institut Fresenius, Taunusstein, Germany; IF-09/01448579, 06.11.2009; Doc. No. 434-002 (unpublished) submitted under Section point A7.5.1/01.

1.2 Data protection [redacted]

1.2.1 Data owner [redacted]

1.2.2 Companies with letter of access [redacted]

1.2.3 Criteria for data protection [redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Yes, OECD 208 (2006)

2.2 GLP [redacted]

2.3 Deviations No

3 METHOD

3.1 Test material As given in section 2

3.1.1 Lot/Batch number [redacted]

3.1.2 Specification [redacted]

3.1.3 Purity [redacted]

3.1.4 Description of test substance [redacted]

3.1.5 Composition of Product [redacted]

3.1.6 Further relevant properties [redacted]

3.1.7 Method of analysis [redacted]

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

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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 plants

3.4.3 Test system

3.4.4 Test conditions

3.4.5 Test duration

3.4.6 Test parameter — Seedling emergence, biomass (shoot fresh weight) and visible detrimental effects (e.g. chlorosis and mortality).

3.4.7 Sampling

3.4.8 Method of analysis of the plant material

3.4.9 Quality control

3.4.10 Statistics

4 RESULTS

4.1 Range finding test

4.1.1 Concentration

4.1.2 Effect data

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[redacted]

[redacted]

4.2 Results test substance

4.2.1 Applied initial concentration [redacted]

4.2.2 Actual concentrations of test substance [redacted] X1

[redacted]

4.2.3 Phytotoxicity rating [redacted]

4.2.4 Plant height [redacted]

4.2.5 Plant dry weights [redacted]

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4.2.6 Root dry weights

4.2.7 Root length

4.2.8 Number of dead plants

4.2.9 Effect data

4.2.10 Concentration / response curve

4.2.11 Other effects

4.3 Results of controls

4.3.1 Number/ percentage of plants showing adverse effects

4.3.2 Nature of adverse effects

4.4 Test with reference substance

4.4.1 Concentrations

4.4.2 Results

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to OECD guideline 208 (2006). The test item was dissolved into acetone which was subsequently mixed with quartz sand. After evaporation of the solvent, the coated quartz sand was incorporated into the soil by mixing with the soil in a mixing machine. The EC_{50}, LOEC and NOEC-values were determined on the basis of the effects on shoot fresh weight determined 21 days after 50 % emergence. Seedling emergence and survival after emergence were recorded.

5.2 Results and discussion

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[redacted]

5.3 Results shoot fresh weight

5.3.1	EC_{25}	*Avena sativa:*	10.952
		Allium cepa:	18.080
		Brassica napus:	8.738
		Helianthus annuus:	6.949
		Lycopersicon esculentum:	11.997
		Cucumis sativa:	12.336
5.3.2	EC_{50}	*Avena sativa:*	13.408
		Allium cepa:	26.648
		Brassica napus:	22.146
		Helianthus annuus:	16.488
		Lycopersicon esculentum:	16.231
		Cucumis sativa:	14.228
5.3.3	EC_{75}	*Avena sativa:*	16.414
		Allium cepa:	39.276
		Brassica napus:	56.129
		Helianthus annuus:	39.121
		Lycopersicon esculentum:	21.960
		Cucumis sativa:	16.411
5.3.4	NOEC/LOEC	*Avena sativa:*	7.4 / 22.2
		Allium cepa:	7.4 / 22.2
		Brassica napus:	7.4 / 22.2
		Helianthus annuus:	7.4 / 22.2
		Lycopersicon esculentum:	7.4 / 22.2
		Cucumis sativa:	7.4 / 22.2

5.4 Conclusion

[redacted]. Iodine, when applied to soil as exogenous substance, did not affect seedling emergence nor shoot fresh weight nor any of the phytotoxicity parameters at concentrations of at least 7.4 mg Iodine/kg soil dry weight.

5.4.1 Other Conclusions [redacted]

5.4.2 Reliability [redacted]

5.4.3 Deficiencies [redacted]

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Evaluation by Competent Authorities	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

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Table A7.5.1.3/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	[redacted]
Vehicle	[redacted]
Concentration of vehicle	[redacted]
Vehicle control performed	[redacted]
Other procedures	[redacted]

Table A7.5.1.3/01-2: Test plants

	Family	Species	Common name	Source (seed/plant)
[redacted]	[redacted]	[redacted]	[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 7.5.1.3 Acute toxicity to plants

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Table A7.5.1.3/01-3: Test system

Criteria	Details
Test type	[redacted]
Container type	[redacted]
Seed germination potential	[redacted]
Identification of the plant species	[redacted]
Number of replicates	[redacted]
Numbers of plants per replicate per dose	[redacted]
Date of planting	[redacted]
Plant density	[redacted]
Date of test substance application	[redacted]
High of plants at application	[redacted]
Date of phytotoxicity rating or harvest	[redacted]
Dates of analysis	[redacted]

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Table A7.5.1.3/01-4: Test conditions

Criteria	
Test type	
Method of application	
Application levels	
Dose rates	
Substrate characteristics	
Watering of the plants	

Temperature	[redacted]
Thermoperiod	[redacted]
Light regime	[redacted]
Relative humidity	[redacted]
Wind volatility	[redacted]
Observation periods and duration of test	[redacted]
Pest control	[redacted]
Any other treatments and procedures	[redacted]

	[redacted]

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Table A7.5.1.3/01-5: Effects on seedling [redacted]

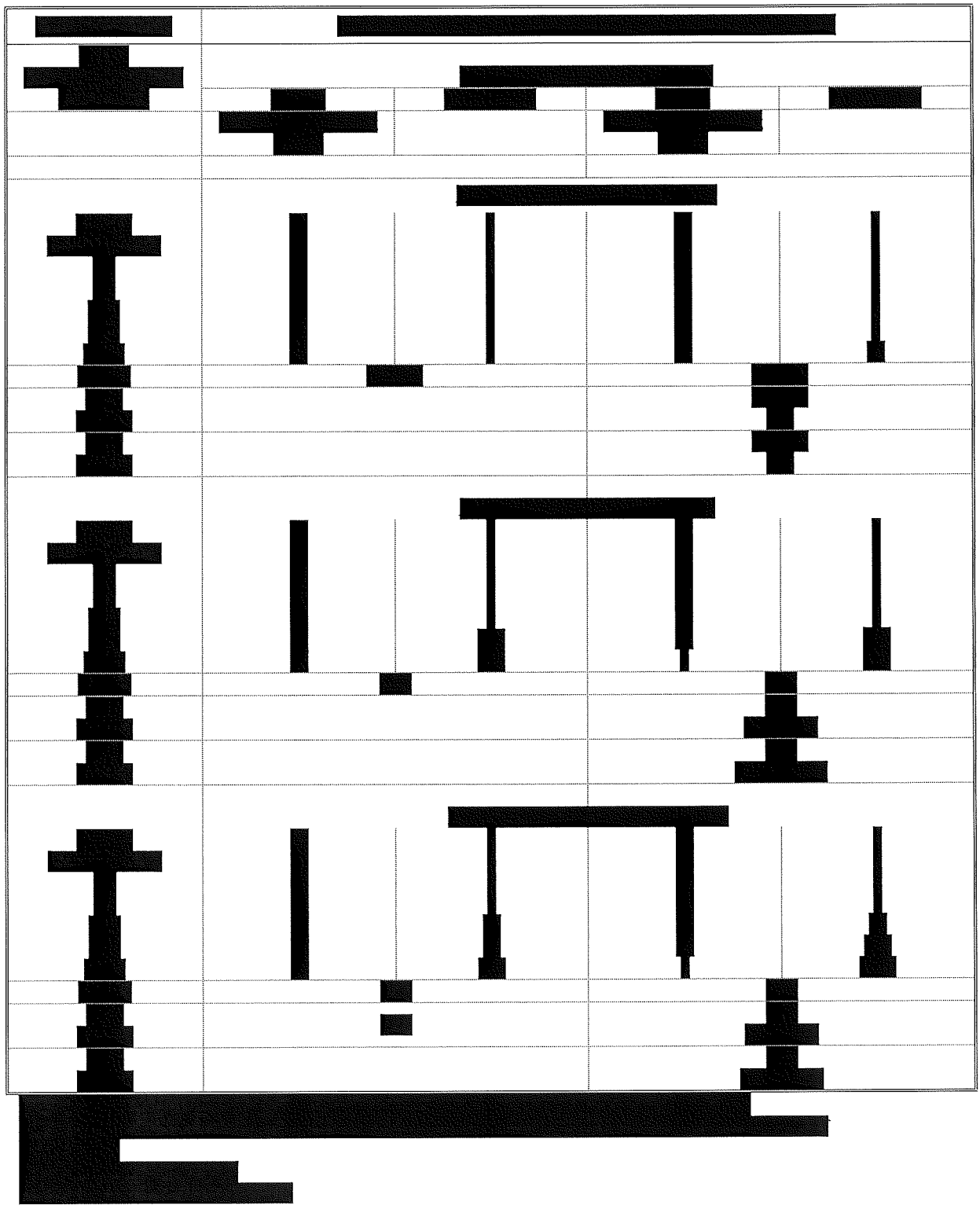

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Table A7.5.1.3/01-5: Effects on seedling

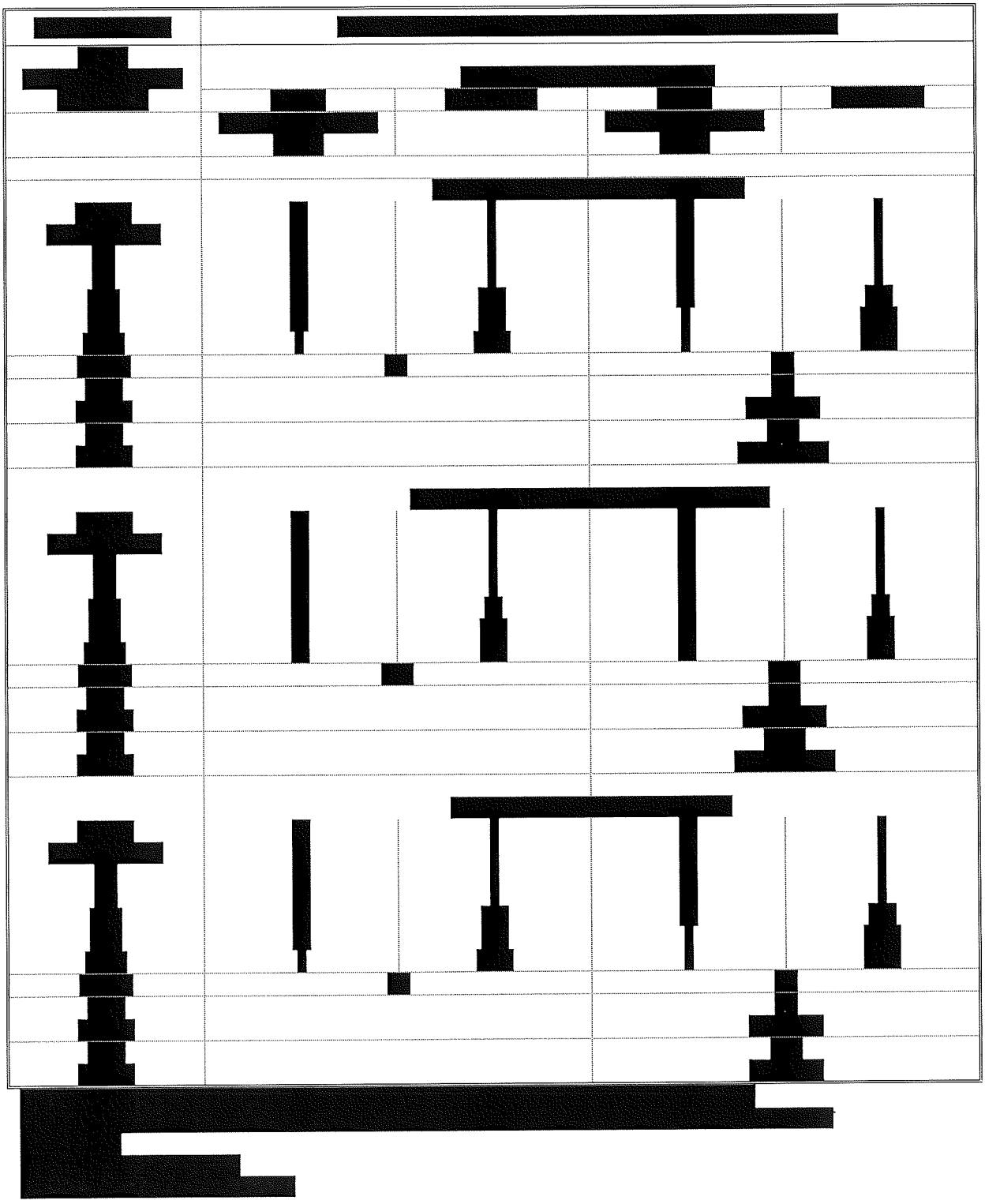

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Table A7.5.1.3/01-6: Effects on shoot

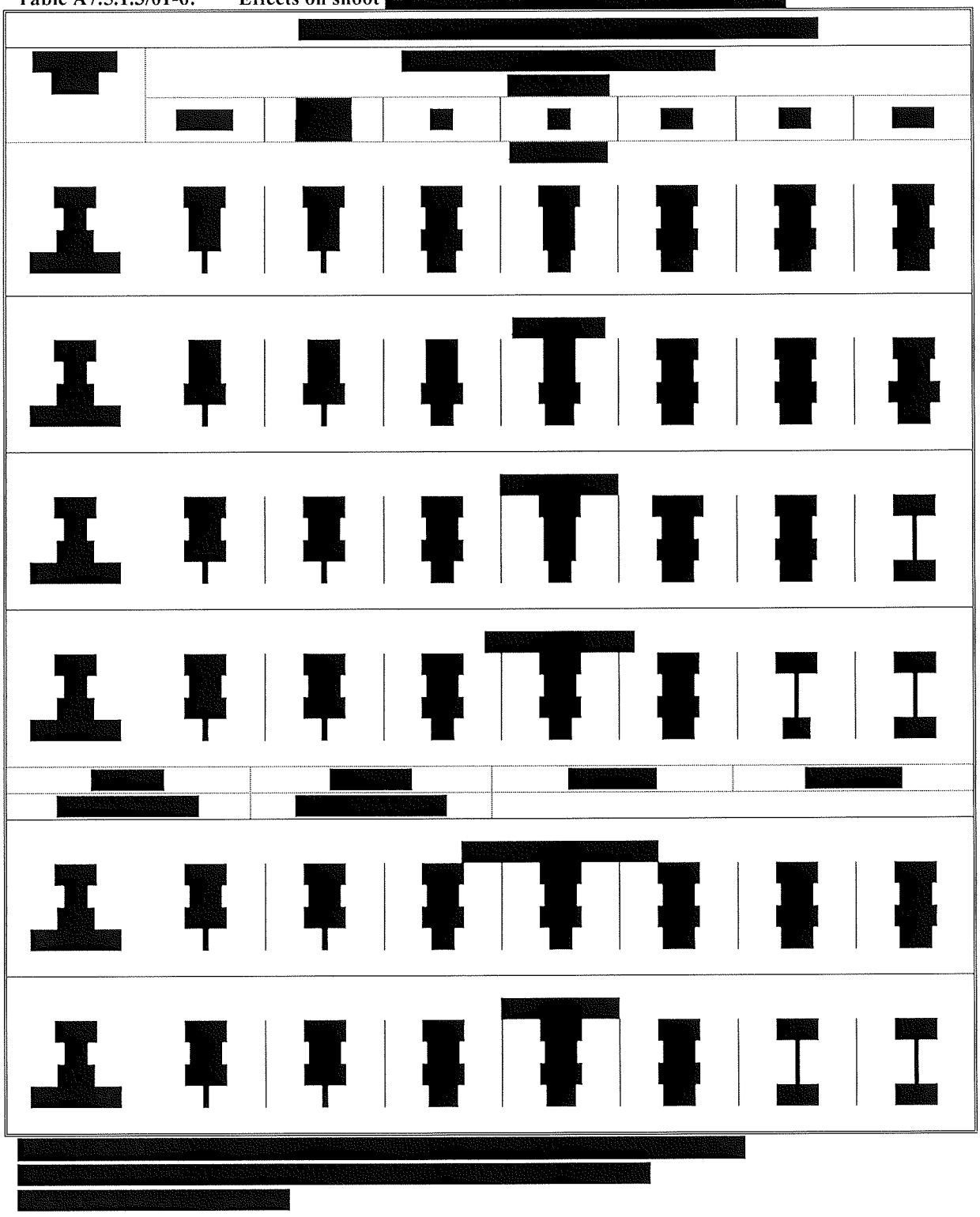

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Table A7.5.1.3/01-7: Other effects

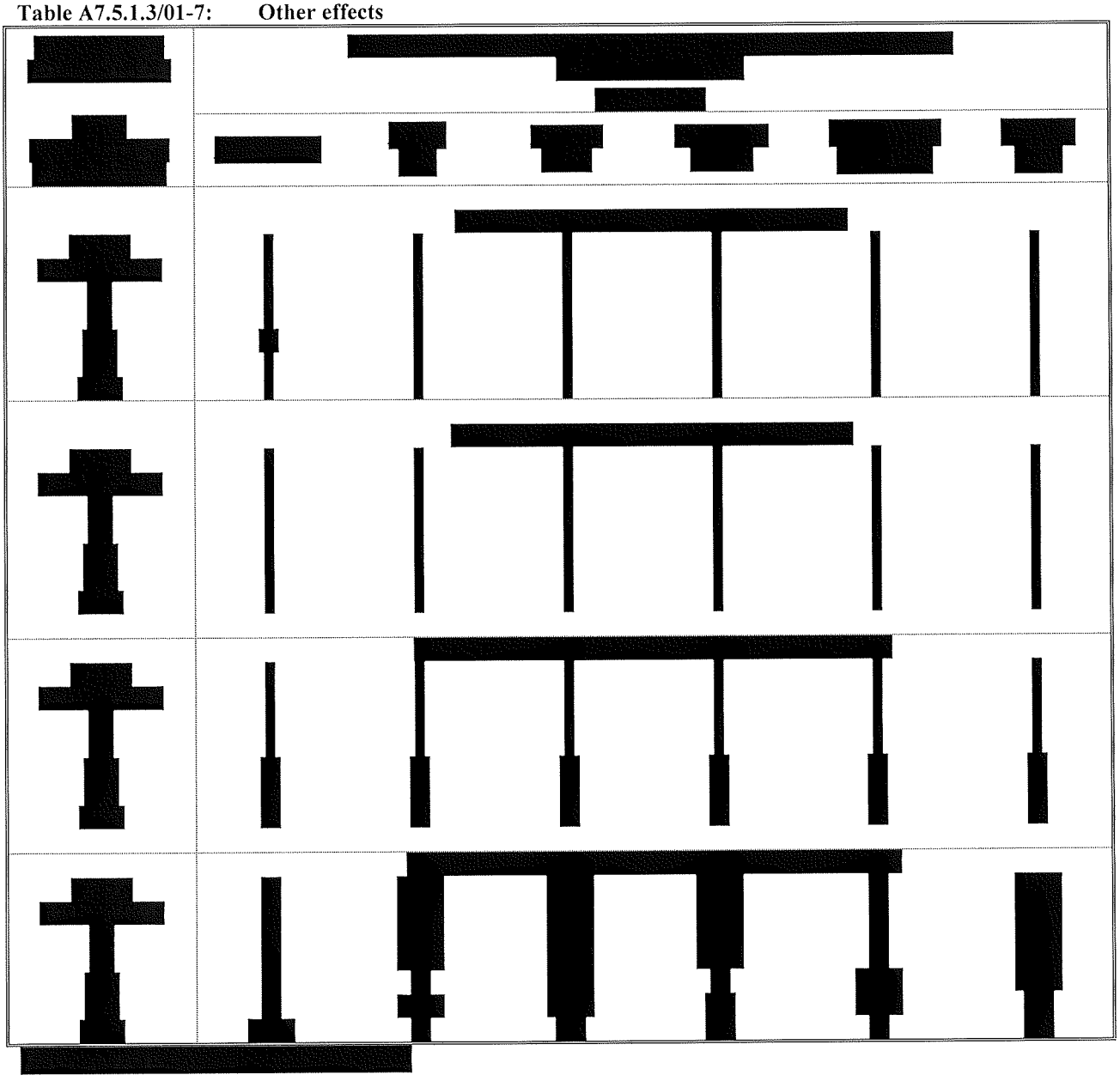
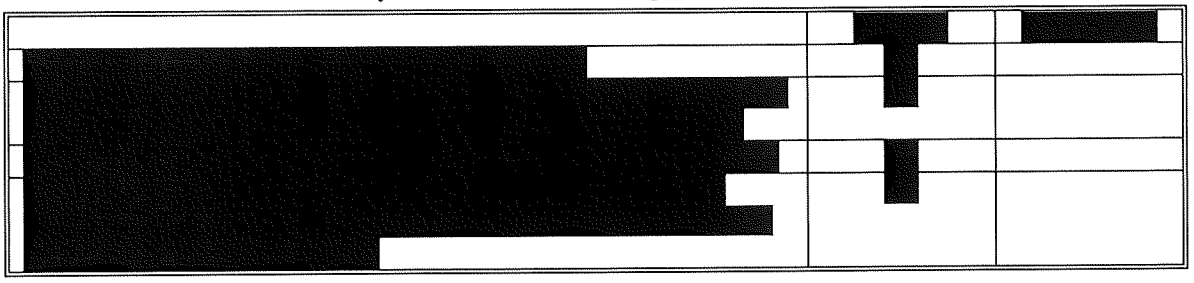


Table A7.5.1.3/01-8: Validity criteria for terrestrial plant toxicity according to OECD 208 (2006)



Section A7.5.2 Terrestrial tests, long-term tests

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	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	[redacted]	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	