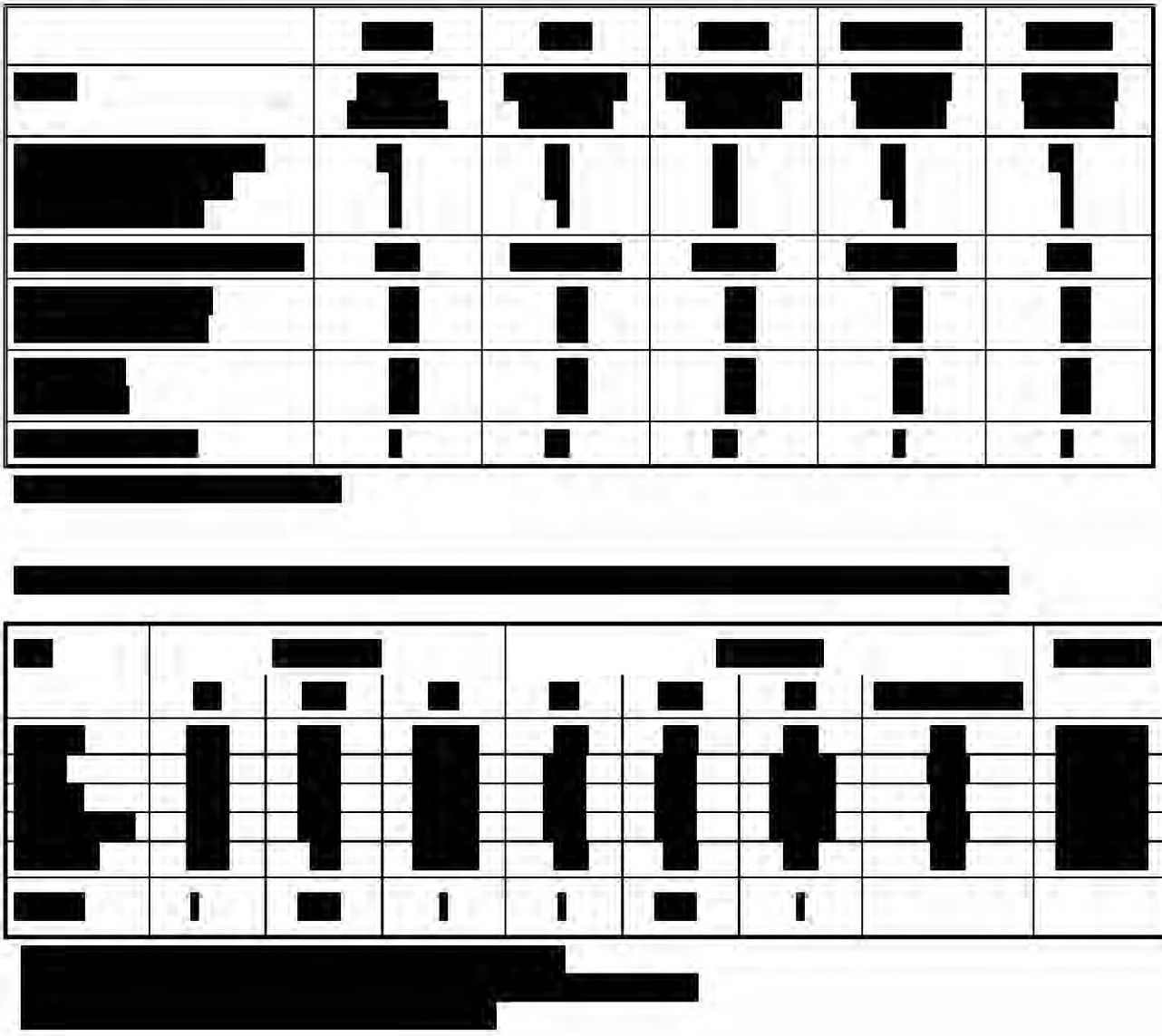
Section A7.2.3.1/01
Annex Point IIIA XII.1.2

Adsorption and desorption of metabolites and degradation products

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1_01-1: Classification and physico-chemical properties of soils used as adsorbents



Section A7.2.3.1/02 Annex Point IIIA XII.1.2 Adsorption and desorption of metabolites and degradation products

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]. (2000): [redacted]
1.2	**Data protection**	Yes
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 106 (1981), US EPA Subdivision N, § 163-1 (1982) and Environmental chemistry and fate guidelines for registration of pesticides in Canada: Trade Memorandum T-1-255, Section 6.2B
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Radiolabelled test material**	[redacted]
3.1.1	Molecular formula	[redacted]
3.1.2	Molecular weight	[redacted]
3.1.3	Lot/Batch number	[redacted]
3.1.4	Specific activity	[redacted]
3.1.5	Purity	[redacted]
3.1.6	Further relevant properties	None
3.1.7	Method of analysis	HPLC with Radio-HPLC-Detector and UV-Detector
3.2	**Degradation products**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Soil types**	See Table A7_2_3_1_02-1

Section A7.2.3.1/02
Annex Point IIIA XII.1.2

Adsorption and desorption of metabolites and degradation products

3.5 Testing procedure

3.5.1 Test system

[redacted]

3.5.2 Test solution and Test conditions

[redacted]

3.6 Test performance

3.6.1 Preliminary test

[redacted]

3.6.2 Screening test: Adsorption

[redacted]

3.6.3 Screening test: Desorption

[redacted]

3.6.4 HPLC-method

[redacted]

3.6.5 Other test

[redacted]

4.1 Preliminary test

[redacted]

4.2 Screening test: Adsorption

[redacted]

4.3 Screening test: Desorption

[redacted]

4.4 Material balance

[redacted]

Section A7.2.3.1/02 Adsorption and desorption of metabolites and degradation products
Annex Point IIIA XII.1.2

[redacted]

4.5 Calculations

4.5.1 Ka , Kd [redacted]

4.5.2 Ka_{oc} , Kd_{oc} [redacted]

4.6 Degradation product(s) [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Adsorption and desorption of [^{14}C]TZNG were measured using a batch equilibrium procedure according to OECD 106. The guideline is fulfilled, no relevant deviations from the guideline occurred.

5.2 Results and discussion

The Ka_{oc}–values varied between 204.5 and 432.5 and the Kd_{oc}–values between 270.8 and 527.2.

There was good correlation between the concentrations adsorbed and in solution for the concentration range tested ($r > 0.99$) in all soils.

5.2.1	Adsorbed amount [%]	The percentage adsorption of test substance varied between 22.7 and 82.3% of the applied amount depending on soil type and concentration.	
5.2.2	Ka	0.63 - 4.71 mg/g	
5.2.3	Kd	0.83 - 5.75 mg/g	
5.2.4	Ka_{oc}	204.5 - 432.5 mg/g (mean: 275.4 mg/g)	x
5.2.5	Ka/Kd	0.76 - 0.88 (mean: 0.81)	

5.3 Conclusion

Based on the classification of McCALL ET AL. (1980), TZNG is classified as being moderately mobile in soil.

5.3.1 Reliability 1

5.3.2 Deficiencies No

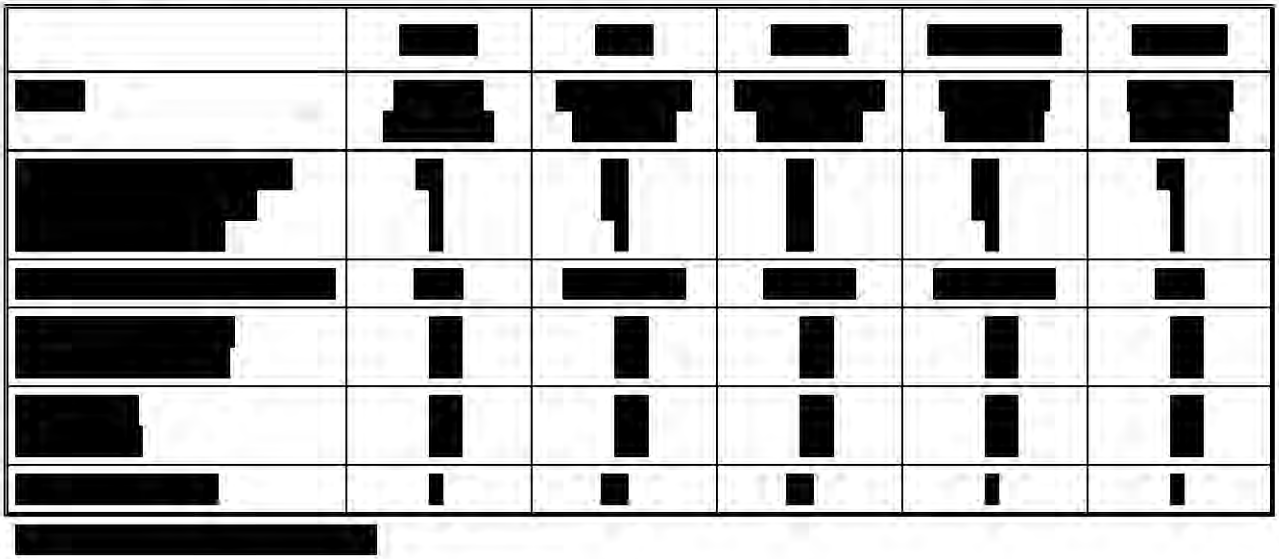
Section A7.2.3.1/02
Annex Point IIIA XII.1.2

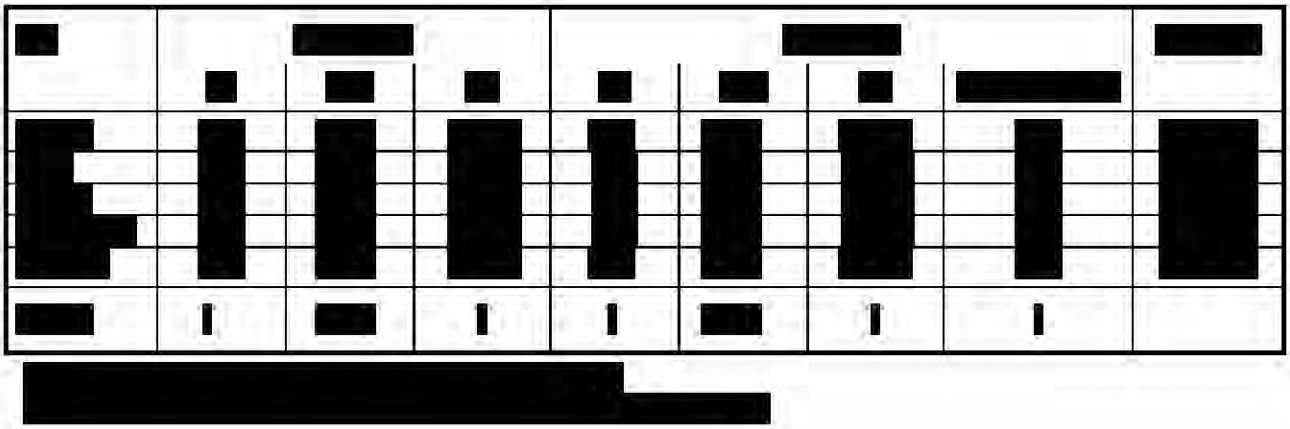
Adsorption and desorption of metabolites and degradation products

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

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_2_3_1_02-1: Classification and physico-chemical properties of soils used as adsorbents





Section A7.2.3.2/01 Annex Point IIIA XII.1.3 Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]. (2001b): [redacted]
1.2	**Data protection**	Yes
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 Germany BBA Part IV, 4-3
2.2	**GLP**	Yes
2.3	**Deviations**	No major deviations

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Radiolabelling	[redacted]
3.1.2	Lot/Batch number	[redacted]
3.1.3	Specific radioactivity	[redacted]
3.1.4	Purity	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Degradation products**	[redacted]
3.2.1	Method of analysis for degradation products	[redacted]
3.3	**Reference substance**	[redacted]

Section A7.2.3.2/01
Annex Point IIIA XII.1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

[redacted]

3.3.1 Method of analysis for reference substance

[redacted]

3.4 Soil types

[redacted]

3.5 Testing procedure

3.5.1 Test system

[redacted]

3.5.2 Test substance application

[redacted]

3.5.3 Test conditions

[redacted]

3.6 Sampling and work-up

3.6.1 Leachates

[redacted]

[redacted]

3.6.2 Soil

[redacted]

3.6.3 Plants

[redacted]

4 RESULTS

4.1 Material balance

[redacted]

4.2 Leachates

[redacted]

Section A7.2.3.2/01
Annex Point IIIA XII.1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

4.3 Soil

[redacted]

4.4 Plants

[redacted]

5.1 Materials and methods

The German BBA guideline for lysimeter studies is an internationally accepted guideline. No relevant deviations from the guideline occurred.

5.2 Results and discussion

[redacted]

5.3 Conclusion

On the basis of these findings, TI-435 and its degradation products are not expected to occur in relevant amounts in groundwater. Degradation in soil continuous. No accumulation in plants is to be expected.

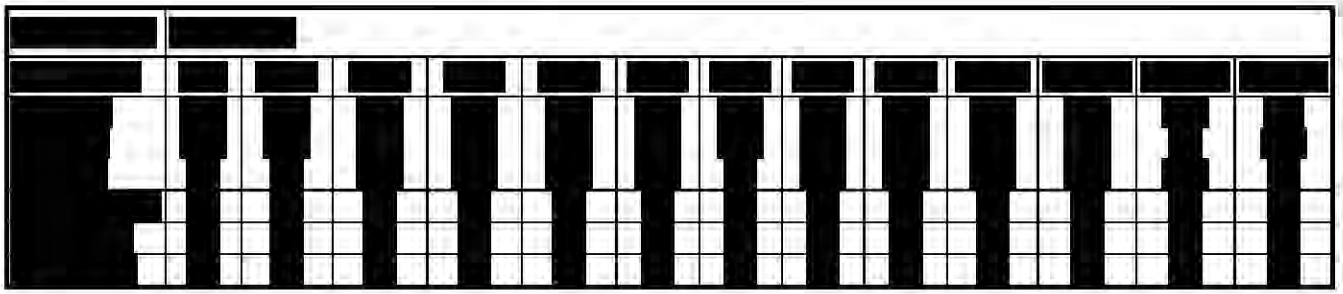
5.3.1 Reliability 1

5.3.2 Deficiencies None

Section A7.2.3.2/01 **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
Annex Point IIIA XII.1.3

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	2004/11/19
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[redacted]



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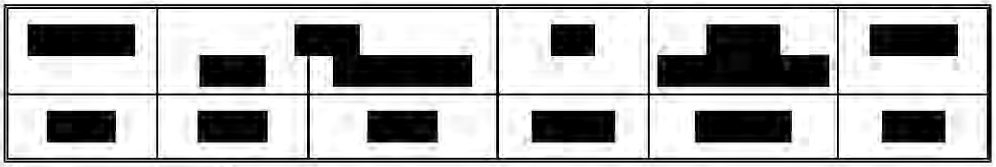

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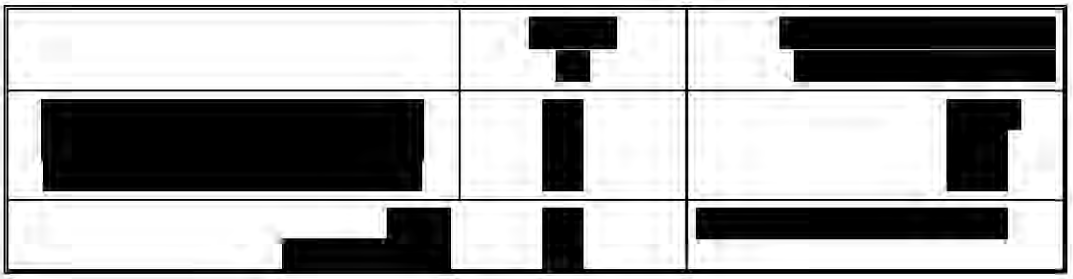
[redacted]



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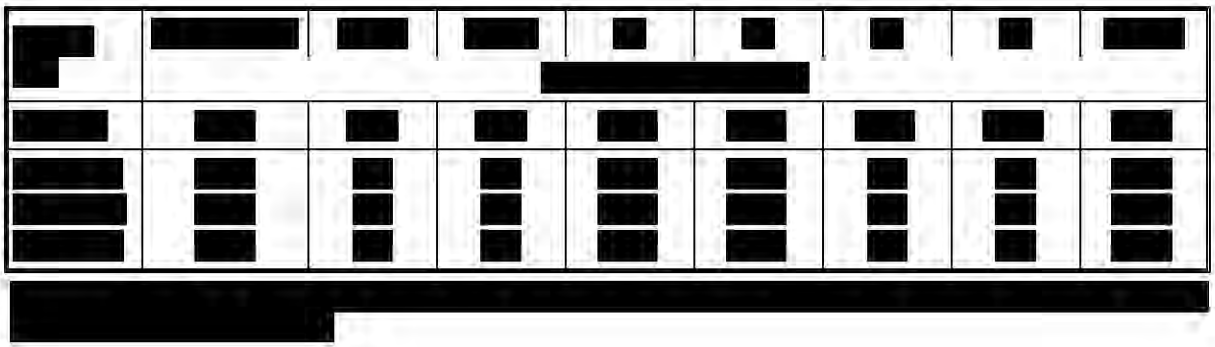
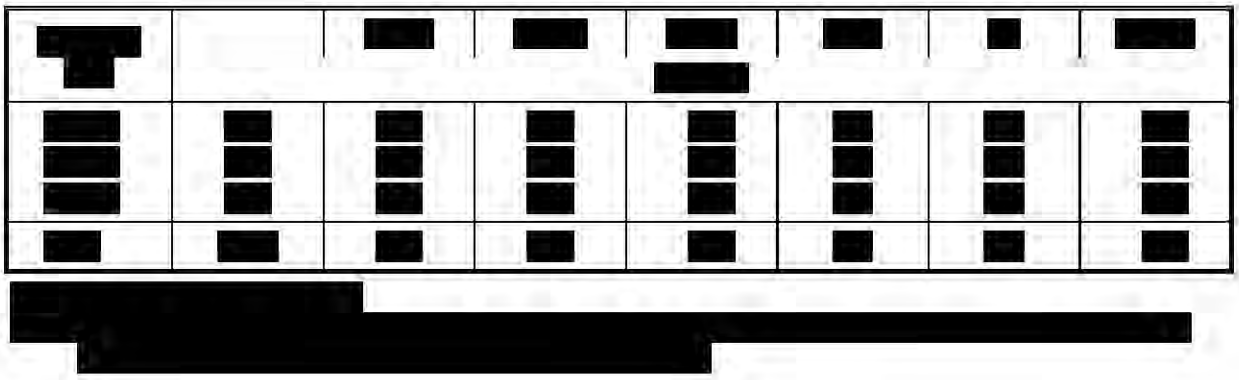


[redacted]

[redacted]

[redacted]



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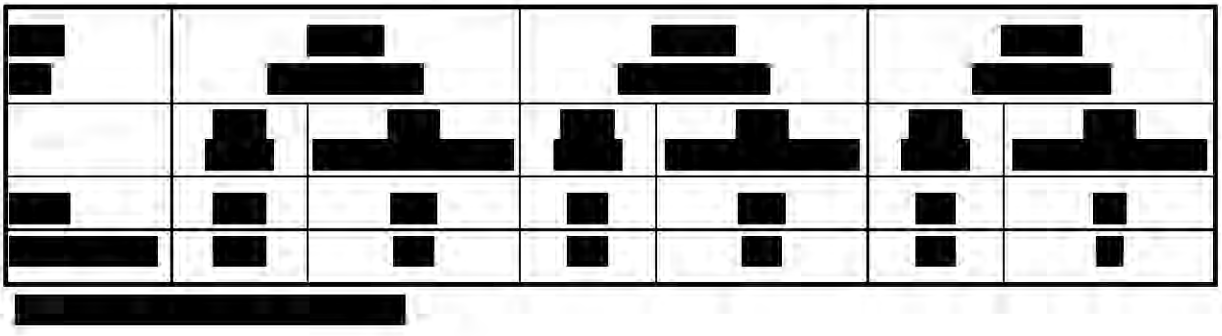

[redacted]

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

[redacted]

Section A7.2.3.2/02
Annex Point IIIA XII.1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2001c): [redacted]
1.2	**Data protection**	Yes
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 Germany BBA Part IV, 4-3
2.2	**GLP**	Yes
2.3	**Deviations**	No major deviations

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Radiolabelling	[redacted]
3.1.2	Lot/Batch number	[redacted]
3.1.3	Specific radioactivity	[redacted]
3.1.4	Purity	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Degradation products**	[redacted]
3.2.1	Method of analysis for degradation products	[redacted]
3.3	**Reference substance**	[redacted]

Section A7.2.3.2/02
Annex Point IIIA XII.1.3

Mobility in at least three soil types and where relevant mobility of metabolites and degradation products

[redacted]

3.3.1 Method of analysis for reference substance

[redacted]

3.4 Soil types

[redacted]

3.5 Testing procedure

3.5.1 Test system

[redacted]

3.5.2 Test substance application

[redacted]

3.5.3 Test conditions

[redacted]

3.6 Sampling and work-up

3.6.1 Leachates

[redacted]

Section A7.2.3.2/02 **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
Annex Point IIIA XII.1.3

[redacted]

3.6.2 Soil

[redacted]

3.6.3 Plants

[redacted]

4.1 Material balance

[redacted]

4.2 Leachates

[redacted]

Section A7.2.3.2/02 **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
Annex Point IIIA XII.1.3

4.3 Soil

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The German BBA guideline for lysimeter studies is an internationally accepted guideline. No relevant deviations from the guideline occurred.

5.2 Results and discussion

Distribution of radioactivity

The major part of the applied radioactivity recovered was found in the soil (about 44% of applied). About 55% of the applied radioactivity could not be recovered and was attributed to losses by mineralisation.

Degradation and residues in soil and leachate

The parent compound and the metabolites MNG, TZNG and NTG were identified in the soil samples.

In the total leachates, about 1.2% of applied radioactivity was detected. The highest annual concentration was found for the 2nd year and was about 0.383 µg parent equivalent/L. TI-435 was not detected in any of the leachates. The metabolites MNG and NTG were identified at maximum concentrations of 0.066 µg/L and 0.031 µg/L, respectively, in the third year. Unknown metabolites amounted to less that 0.05 µg parent equivalent/L.

5.3 Conclusion

On the basis of these findings, TI-435 and its degradation products are not expected to occur in relevant amounts in groundwater. Degradation in soil continuous. No accumulation in plants is to be expected.

5.3.1 Reliability 1

5.3.2 Deficiencies None

Section A7.2.3.2/02 **Mobility in at least three soil types and where relevant mobility of metabolites and degradation products**
Annex Point IIIA XII.1.3

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7_2_3_2_02-1: Soil characteristics

Classification	Sandy loam											
Depth [cm)]	0-10	10-20	20-30	30-40	40-50	50-60	60-70	70-80	80-90	90-100	100-110	110-120	120-130
sand [%]	70.8	69.4	68.3	67.5	70.3	71.7	75.5	73.2	68.7	70.2	78.0	77.3	815
silt [%]	20.7	22.2	21.1	20.7	18.0	15.2	15.1	13.0	12.8	12.2	10.4	8.8	10.2
clay [%]	8.6	8.5	10.6	11.8	11.8	12.6	9.4	13.8	18.5	17.6	11.6	13.8	8.3
organic C [%]	1.8	1.1	0.7	0.5	0.3	0.2	0.2	0.2	0.2	0.2	0.1	0.1	0.1
pH (water)	7.2	7.2	7.2	7.3	7.5	7.5	7.6	7.7	7.7	7.7	7.7	7.7	7.7
pH ($CaCl_2$)	6.6	6.4	6.3	6.5	6.5	6.5	6.5	6.5	6.6	6.6	6.6	6.6	6.7

Table A7_2_3_2_02-2: Balance of Total Radioactive Residues (100% = 120.63 MBq (Lys. 17) and 122.81 (Lys. 18) resulting from two applications each)

	Leachates	Plants	Soil	Losses (mineralisation)	TOTAL
Lysimeter 17	1.07%	not analysed	42.46%	56.47%*	100%
Lysimeter 18	1.34%	not analysed	44.75%	53.91%*	100%

* calculated value

Table A7_2_3_2_02-3: Annual amounts of leachates and total radioactive residues

	Amount [L]		Total radioactive residues [µg parent equivalent/L]	
	Lys. 17	Lys. 18	Lys. 17	Lys. 18
1st year (July 1997 to July 1998)	353	352	0.080	0.124
2nd year (July 1998 to July 1999)	582	583	0.349	0.417
3rd year (July 1999 to July 2000)	346	353	0.317	0.396
Sum :	1281	1288	Mean :	0.281
Mean per year :	427	429		

Table A7_2_3_2_02-4: Distribution of radioactivity in annual leachates of lysimeter 17 and 18 (Craig partition)

Sample date	Total char.	Origin	TI-435	MNG	NTG	U2	U3	U4	U5	U6	U7	Diffuse
	[µg/L]*											
Lysimeter 17												
1st year	0.070	0.002	n.d.	0.004	0.001	0.009	0.031	n.d.	0.003	0.011	0.001	0.008
2nd year	0.261	0.025	n.d.	0.043	0.011	0.034	0.049	n.d.	n.d.	0.029	0.009	0.061
3rd year	0.191	0.013	n.d.	0.063	0.024	0.025	0.030	n.d.	n.d.	n.d.	0.007	0.029
Lysimeter 18												
1st year	0.113	0.094	n.d.	0.004	0.001	n.d.	0.002	n.d.	0.002	0.001	0.003	0.006
2nd year	0.118	0.021	n.d.	0.047	0.017	n.d.	0.002	n.d.	n.d.	n.d.	0.008	0.023
3rd year	0.140	0.013	n.d.	0.068	0.037	n.d.	n.d.	n.d.	n.d.	n.d.	0.009	0.013

* Not identified radioactivity was calculated as TI-435 parent equivalent
n.d. not detected (<0.001 µg/L)

Table A7_2_3_2_02-5: Distribution of radioactivity in the soil profile (sampling at the end of the study), mean of two lysimeters

Soil layer [cm]	Total radioactive residue [µg parent equivalent/kg soil]	Radioactivity [% of applied]
0-10	65.65	30.4
10-20	15.12	7.3
20-30	4.00	2.2
30-40	2.23	1.2
40-50	1.24	0.8
50-60	0.83	0.5
60-70	0.53	0.3
70-80	0.40	0.2
80-90	0.32	0.2
90-100	0.28	0.2
100-110	0.21	0.1
110-120	0.17	0.1
120-130	0.16	0.0
TOTAL	-	43.6

Table A7_2_3_2_02-6: Distribution of radioactivity in soil extracts (sum of cold and hot extract), mean of two lysimeters

Soil layer [cm]	Origin	TI-435	MNG	TZNG	NTG	TMG	U5	Diffuse
	[µg/kg]*							
0 - 10	2.38	17.23	1.54	3.14	0.71	n.d.	0.45**	0.75
10 - 20	0.45	4.29	1.07	0.58	0.57	n.d.	n.d.	0.43
20 - 30	0.09	0.65	0.41	n.d.	0.21	n.d.	n.d.	0.14

n.d. not detected (<0.01 µg/kg)

* Not identified zones (origin, U5 and diffuse radioactivity) were calculated as TI-435 equivalents. MNG, TZNG and TMG were calculated based on their molecular weight.

** U5 was found in one soil preparation of lysimeter 17.

Section A7.3.1 Phototransformation in air (estimation method)
Annex Point IIIA VII.5

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]. (1998): [redacted]	
1.2	**Data protection**	Yes	
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 [redacted]	X
2.2	**GLP**	No (not relevant)	
2.3	**Deviations**	Not relevant	
		3 MATERIALS AND METHODS	
3.1	**Substance**	TI-435	
3.2	**Model calculation**	The computer program AOPWIN version 1.87 (8/98) was used.	X
		4 RESULTS	
4.1	**Photochemical reactions**	[redacted]	
4.2	**Half-life in air**	[redacted]	X

Section A7.3.1 Phototransformation in air (estimation method)
Annex Point IIIA VII.5

		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The chemical lifetime of TI-435 in the troposphere was calculated using the computer program AOPWIN version 1.87 (8/98).	
5.2	**Results and discussion**	A half-life of 1 hour for TI-435 in air is assumed corresponding to a chemical lifetime of 1.4 hours using a 12-hour day which is regarded as the global 12-hour day time concentration (excluding the night).	X
5.3	**Conclusion**	Based on the relatively short chemical lifetime of TI-435, accumulation in the air is not to be expected.	X
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date 2006-05-19

Guideline and Quality Assurance [redacted]

Materials and Methods [redacted]

Section A7.3.1 **Phototransformation in air (estimation method)**
Annex Point IIIA VII.5

Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	1
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*

Section A7.3.1 Phototransformation in air (estimation method)
Annex Point IIIA VII.5

Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1998): [redacted]
1.2	**Data protection**	Yes
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 No. 203 (1992) in compliance with the Directive 92/69/EEC C.1
2.2	**GLP**	Yes
2.3	**Deviations**	No (to EC Directive)

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	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]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

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	[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	[redacted]
4.2.2	Actual concentrations of test substance	[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**	[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

[redacted]

5.1	**Materials and methods**	The acute toxicity of TI-435 Technical to fish (rainbow trout) was determined in a static limit test according to OECD No. 203 (1992) in compliance with the Directive 92/69/EEC C.1. The nominal test concentration was 100 mg a.s./L.
5.2	**Results and discussion**	None of the seven test animals died during exposure for 96 h and none of the control animals died within this time.
5.2.1	LC_0	100 mg/L
5.2.2	LC_{50}	> 100 mg/L
5.2.3	LC_{100}	> 100 mg/L
5.3	**Conclusion**	The validity criteria can be considered as fulfilled. Validity criteria are summarised in Table A7_4_1_1-6.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]pplicant's version[redacted]
Reliability	[redacted]
Acceptability	acceptable[redacted]
[redacted]	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_4_1_1-1: Test organisms

Criteria	Details
Species/strain	Rainbow trout (*Oncorhynchus mykiss*)
Source	Forellenhof Fredelsloh, D-37186 Moringen
Wild caught	No
Age/size	Average total length at study start: 4.9 cm Average body weight at study start: 1.2 g
Kind of food	Kronen Fish Allround 2 mm
Amount of food	4% of the fish body weight per feeding day
Feeding frequency	Three times per week
Pretreatment	Acclimation period
Feeding of animals during test	No

Table A7_4_1_1-2: Test system

Criteria	Details
Test type	Static
Volume of test vessels	15 L (test volume: 10 L)
Volume/animal	1.43 L/animal
Number of animals/vessel	7
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_1_1-3: Test conditions

Criteria	Details
Test temperature	13.5 - 14.0°C
Dissolved oxygen	92 - 99% of saturation
pH	7.03 - 7.65
Adjustment of pH	No
Aeration of dilution water	Yes
Intensity of irradiation	0.1 - 10 µmol/m² (6.7-670 Lx)
Photoperiod	12 h photoperiod daily

Table A7_4_1_1-4: Mortality data

Test-Substance Concentration (nominal) [mg/L]	Mortality							
	Number				Percentage			
	24	48 h	72 h	96 h	24 h	48 h	72 h	96 h
100	0	0	0	0	0	0	0	0
0 (Control)	0	0	0	0	0	0	0	0
Temperature [°C]	14.0/14.0*	13.7/13.9*	13.6/13.6*	13.5/13.7*				
pH	7.65/7.59*	7.48/7.47*	7.18/7.03*	7.48/7.31*				
Oxygen saturation [%]	97/99*	92/99*	95/98*	98/99*				

* 100 mg/L/control

Table A7_4_1_1-5: Effect data

	48 h [mg/l]	95% c.l.	96 h [mg/l]	95% c.l.
LC_{50}	> 100 (n)	n.a.	> 100 (n)	n.a.

(n): nominal
n.a.: not applicable

Table A7_4_1_1-6: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fulfilled
Mortality of control animals <10%	x	
Concentration of dissolved oxygen in all test vessels > 60% saturation	x	
Concentration of test substance ≥80% of initial concentration during test	x	

Section A7.4.1.2/01
Annex Point IIA7.2

Acute toxicity to invertebrates
Daphnia magna

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000b): [redacted]
1.2	**Data protection**	Yes
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 No. 202 (1984) and Directive 92/69/EEC C.2
2.2	**GLP**	Yes
2.3	**Deviations**	No (to EC Directive)

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]
3.4	**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]

Section A7.4.1.2/01
Annex Point IIA7.2

Acute toxicity to invertebrates
Daphnia magna

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]
4.2	**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 (Immobilisation)	[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]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The acute toxicity of TI-435 Technical to invertebrates (*Daphnia magna*) was determined in a static test according to OECD No. 202 (1984) in compliance with the Directive 92/69/EEC C.2. Duplicate test solutions with the following nominal test concentrations were used: 0, 7.5, 15, 30, 60 and 120 mg a.s./L.	
5.2	**Results and discussion**	None of the daphnids in the test and control solutions showed any adverse effects.	
5.2.1	EC_0	120 mg a.s./L	X
5.2.2	EC_{50}	> 120 mg a.s./L	X
5.2.3	EC_{100}	> 120 mg a.s./L	X
5.3	**Conclusion**	The validity criteria can be considered as fulfilled. Validity criteria are summarised in Table A7_4_1_2_01-7.	
5.3.1	Reliability	1	
5.3.2	Deficiencies	No	

Section A7.4.1.2/01
Annex Point IIA7.2

Acute toxicity to invertebrates
Daphnia magna

	Evaluation by Competent Authorities Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Section A7.4.1.2/02 **Acute toxicity to invertebrates**
Annex Point IIA7.2 ***Daphnia magna***

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1997): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Sumitomo Chemical Takeda Agro Co., Ltd.
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD No. 202 (1984) and Directive 92/69/EEC C.2
2.2	**GLP**	Yes
2.3	**Deviations**	No

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]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]

Section A7.4.1.2/02 **Acute toxicity to invertebrates**
Annex Point IIA7.2 ***Daphnia magna***

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]
4.2	**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 (Immobilisation)	[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 acute immobilisation toxicity of TI-435 Technical to invertebrates (*Daphnia magna* STRAUS) was determined in a static test according to OECD No. 202 (1984) and Directive 92/69/EEC C.2. The following nominal test concentrations were used: 0, 1.0, 3.2, 10, 32, 100 and 270 mg/L. No deviations to the test guidelines occurred.

Section A7.4.1.2/02 **Acute toxicity to invertebrates**
Annex Point IIA7.2 ***Daphnia magna***

5.2	**Results and discussion**	After 24 hours of exposure to TI-435 Technical, no immobility of daphnids was observed up to the highest test concentration. However, at the end of the test (48 hours), immobile daphnids were observed at test concentrations ≥ 10 mg/L.	
5.2.1	EC_0 (48 hours)	3.2 mg/L	
5.2.2	EC_{50} (48 hours)	40 mg/L (confidence interval: 31 – 51 mg/L)	X
5.2.3	EC_{100} (48 hours)	> 270 mg/L	
5.3	**Conclusion**	The validity criteria can be considered as fulfilled. Validity criteria are summarised in Table A7_4_1_2_02-6.	
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
	[redacted]
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
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Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Section A7.4.1.3
Annex Point IIA7.3

Growth inhibition test on algae

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000): [redacted]
1.2	**Data protection**	Yes
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 FIFRA Subdivision J Series 123-2
2.2	**GLP**	Yes
2.3	**Deviations**	Yes [redacted] X

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]
3.4	**Testing procedure**	
3.4.1	Culture medium	[redacted]

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

[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 [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 Not performed

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]	X
4.2.7	Other observed effects	[redacted]	
4.3	**Results of controls**	[redacted]	
4.4	**Test with reference substance**	[redacted]	

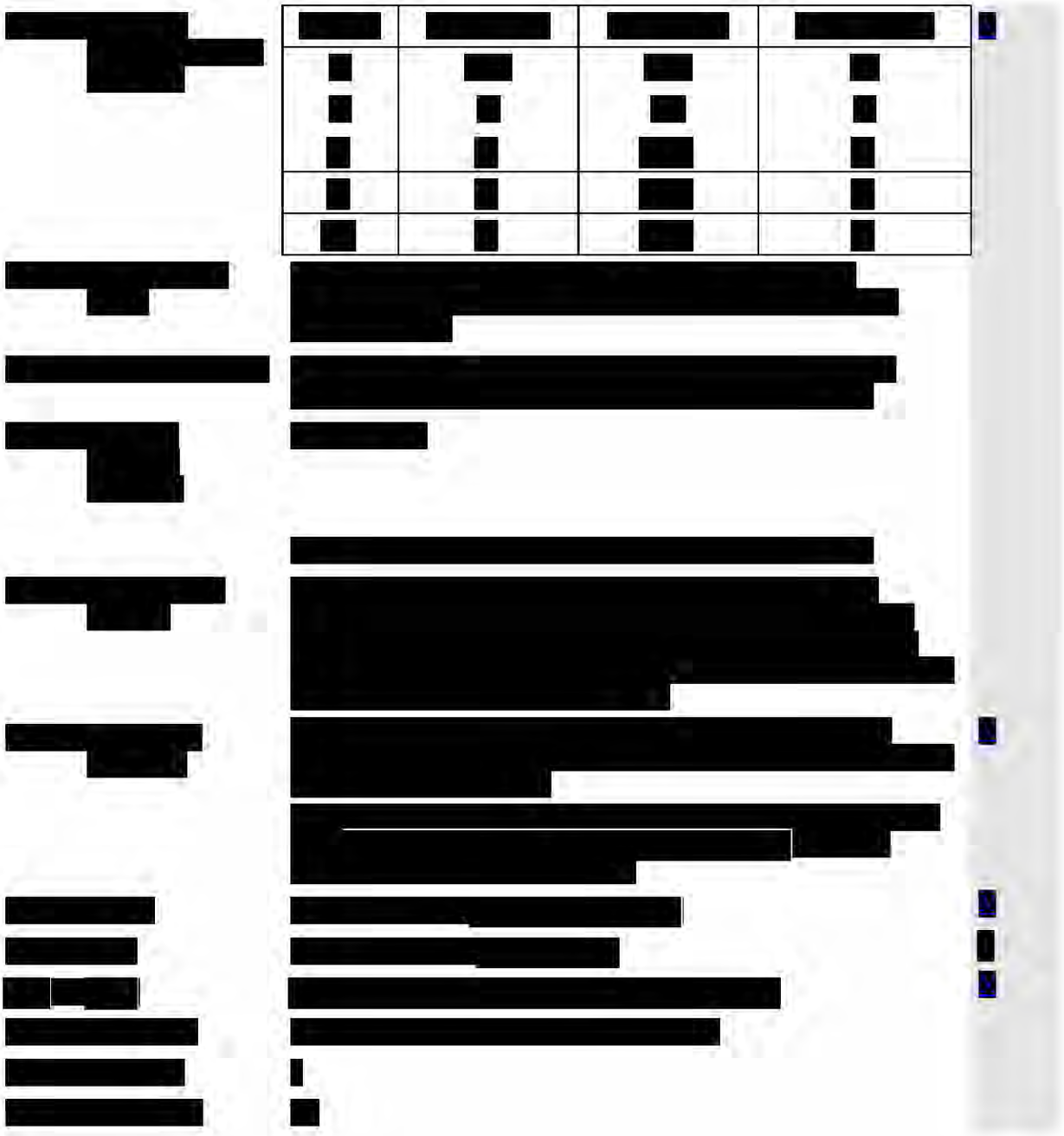
5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The toxicity of TI-435 towards the freshwater alga *Selenastrum capricornutum* was tested according to FIFRA Subdivision J Series 123-2 which is in compliance with EC Directive 92/69/EEC, C.3. A static test over 120 hours with nominal concentrations of 0, 3.8, 7.5, 15, 30, 60 and 120 mg a.s./L was performed.	
5.2	**Results and discussion**	The mean measured concentrations were 3.5, 7.3, 15, 30, 59, and 120 mg a.s./L. The water quality parameters (pH and temperature) were within the acceptable limits. The EC_{50}-value for cell density was calculated to be 75 mg a.s./L after 72 h. The values for biomass and growth are given below.	X
5.2.1	NOE_rC	15 mg a.s./L (72 h)	X
5.2.2	E_rC_{50}	> 120 mg a.s./L (72 h)	X
5.2.3	E_bC_{50}	70 mg a.s./L (72 h)	X
5.3	**Conclusion**	Validity criteria can be considered as fulfilled.	
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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted] e rel. high variability of the daily growth rate in control replicates (45 %))
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Annex 1

[redacted]



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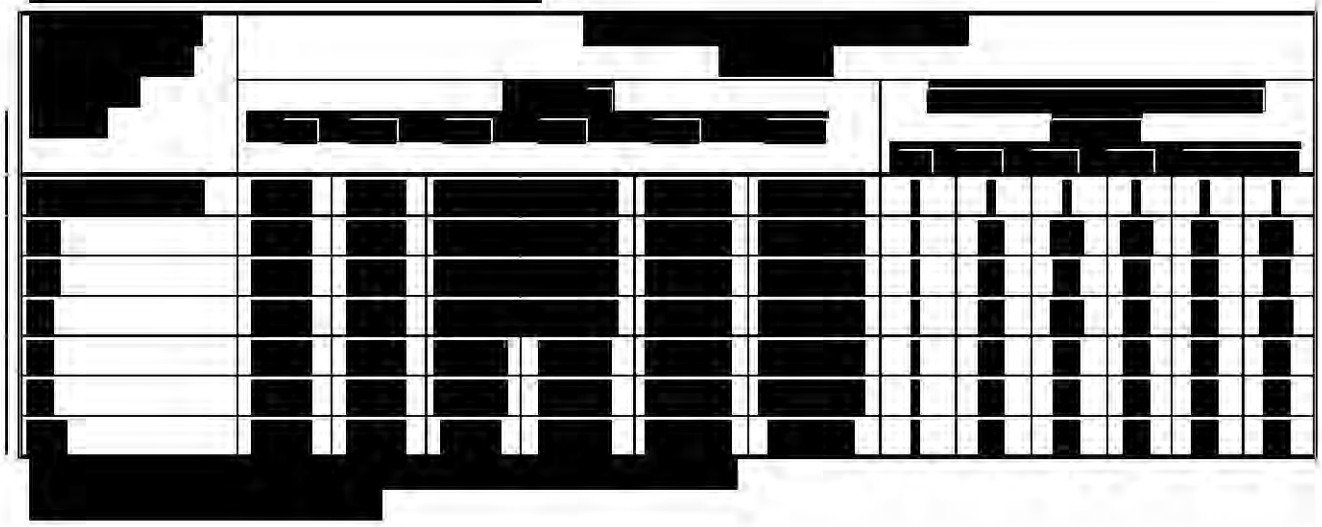

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000): [redacted]
1.2	**Data protection**	Yes
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 Directive 88/302/EEC, Part C, identical to OECD 209
2.2	**GLP**	Yes
2.3	**Deviations**	No

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	97.6%
3.1.4	Composition of Product	Not applicable
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	Culture medium	[redacted]
3.4.2	Inoculum / test organism	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	[redacted]

Section A7.4.1.4 Inhibition to microbial activity (aquatic)
Annex Point IIA7.4

3.4.5	Duration of the test	[redacted]
3.4.6	Test parameter	[redacted]
3.4.7	Analytical parameter	[redacted]
3.4.8	Sampling	[redacted]
3.4.9	Monitoring of TS concentration	[redacted]
3.4.10	Controls	[redacted]
3.4.11	Statistics	Linear regression analysis of log_{10} converted values (only for reference substance)

4 RESULTS

4.1	**Preliminary test**	Not performed
4.2	**Results test substance**	
4.2.1	Concentrations of test substance	1.0, 10, 100, and 1000 mg/L
4.2.2	Concentration/ response curve	Not applicable since the highest concentration tested did not result in inhibition of microbial activity.
4.2.3	Effect data	The treatment with TI-435 Technical did not result in significant inhibition at any of the concentrations (no reduction of the respiration rate compared to the controls). Accordingly, the EC_{50} for TI-435 Technical is > 1000 mg/L.
4.3	**Results of controls**	The 4 controls (without test substance) showed a mean respiration rate of 63.1 mg/L.
4.4	**Test with reference substance**	Performed
4.4.1	Concentrations	5, 15 and 45 mg/L
4.4.2	Results	EC_{50}: 8 mg/L Regression coefficient: 0.995

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	TI-435 Technical was tested for its inhibition to microbial activity according to Directive 88/302/EEC, Part C (identical to OECD 209). Activated sludge was exposed to 1.0, 10, 100, and 1000 mg a.s./L and the respiration rate measured in comparison to control solutions and to the reference substance 3,5-dichlorophenol.
5.2	**Results and discussion**	In a 3-hour range-finding test, TI-435 Technical did not inhibit the respiration of activate sludge at concentrations up to and including 1000 mg/L.
5.2.1	EC_{50}	> 1000 mg/L (nominal)

Section A7.4.1.4 Inhibition to microbial activity (aquatic)
Annex Point IIA7.4

5.3	**Conclusion**	The control respiration rates used to obtain the mean lay within 15% of each other. The EC_{50} of the reference inhibitor, 3,5-dichlorophenol, lay between 5 and 30 mg/L, indicating that the sludge used in this study was neither unusually sensitive nor abnormally robust. Thus, the validity criteria can be considered as fulfilled.
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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Section A7.4.3.2 Annex Point IIIA XIII 2.2 — Effects on reproduction and growth rate on an appropriate species of fish

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000): [redacted]
1.2	**Data protection**	Yes
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 US EPA OPPTS draft guideline No. 850.1400 (1996), US EPA-FIFRA Subdivision E, Series 72-4 (1982) and ASTM Standard E1241-88 (1988)
2.2	**GLP**	Yes
2.3	**Deviations**	No (to OECD 210)

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	Further relevant properties	[redacted]
3.1.5	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Handling of embryos and larvae (OECD 210/212)	[redacted]
3.4.4	Test system	[redacted]

Section A7.4.3.2 Annex Point IIIA XIII 2.2 — Effects on reproduction and growth rate on an appropriate species of fish

3.4.5 Test conditions [redacted]

3.4.6 Duration of the test [redacted]

3.4.7 Test substance concentrations [redacted]

3.4.8 Preparation of test solutions [redacted]

3.4.9 Controls [redacted]

3.4.10 Test parameters [redacted]

3.4.11 Examination/ Sampling [redacted]

3.4.12 Monitoring of TS concentration [redacted]

3.4.13 Monitoring of other parameters [redacted]

3.4.14 Statistics [redacted]

4 RESULTS

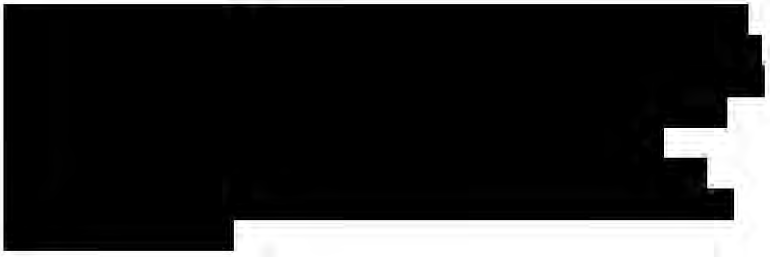
4.1 Range finding test [redacted]

4.2 Results test substance [redacted]

4.3 Hatching

4.3.1 Hatching time [redacted]

Section A7.4.3.2 Annex Point IIIA XIII 2.2 — Effects on reproduction and growth rate on an appropriate species of fish

4.3.2	**Hatching success**	
4.4	**Mortality**	
4.5	**Growth**	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The early life-stage toxicity of TI-435 Technical to fish (fathead minnow) was tested according to US EPA OPPTS draft guideline No. 850.1400 (1996), US EPA-FIFRA Subdivision E, Series 72-4 (1982) and ASTM Standard E1241-88 (1988). The guidelines are in compliance with OECD 210. Fathead minnows were exposed 28 days post-hatch to nominal concentrations of 0, 1.3, 2.5, 5.0, 10 and 20 mg a.s./L. Hatching, mortality and growth of the fish was observed.
5.2	**Results and discussion**	Exposure to TI-435 at the concentrations tested showed no statistically significant effects on hatching success, larval survival, total length, wet weight or dry weight as compared to the controls. Additionally, time to hatch did not appear to be influenced.
5.2.1	NOEC	20 mg a.s./L (nominal)
5.2.2	LOEC	> 20 mg a.s./L (nominal)
5.2.3	MATC	> 20 mg a.s./L (nominal)
5.3	**Conclusion**	The validity criteria can be considered as fulfilled (see Table A7_4_3_2-5).
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.4.3.2
Annex Point IIIA XIII 2.2

Effects on reproduction and growth rate on an appropriate species of fish

[redacted]

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
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Section A7.4.3.4
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an appropriate invertebrate species

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1998): [redacted]
1.2	**Data protection**	Yes
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 No. 211 (revised draft, April 1997)
2.2	**GLP**	Yes
2.3	**Deviations**	None

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	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	Reference substance concentrations	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]

Section A7.4.3.4
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an appropriate invertebrate species

3.4.2	Test organisms	
3.4.3	Handling of offspring	
3.4.4	Test system	
3.4.5	Test conditions	
3.4.6	Duration of the test	
3.4.7	Test substance concentrations	
3.4.8	Preparation of test solutions	
3.4.9	Controls	
3.4.10	Test parameter	
3.4.11	Examination/ sampling	
3.4.12	Monitoring of TS concentration	
3.4.13	Statistics	
4.1	**Range finding test**	
4.2	**TS concentrations during the test**	
4.3	**Mortality**	
4.4	**Number of young *Daphnia***	
4.5	**First appearance of juveniles**	
4.6	**Test of the reference substance**	

Section A7.4.3.4
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an appropriate invertebrate species

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The toxicity of TI-435 Technical to *Daphnia magna* reproduction was tested according to OECD No. 211 (revised draft, April 1997). No deviations to the guideline occurred. *Daphnia magna* STRAUS (Clone 5) were exposed in a semi-static test to nominal concentrations of 0.041, 0.12, 0.37, 1.1, 3.3, 9.9 and 29.7 mg/L for 21 days.
5.2	**Results and discussion**	Significant mortality of parent test organisms occurred at test concentrations ≥ 1.1 mg/L. At test concentrations ≥ 0.37 mg/L the number of juveniles per parent was significantly reduced compared to the control. First appearance of juveniles was significantly delayed at the concentrations 9.9 and 29.7 mg/L.
5.2.1	NOEC (reproduction)	0.12 mg/L (nominal)
5.2.2	LOEC (reproduction)	0.37 mg/L (nominal)
5.2.3	EC50 (reproduction)	5.7 mg/L
5.2.4	NOEC (mortality of parental)	0.37 mg/L (nominal)
5.2.5	LOEC (mortality of parental)	1.1 mg/L (nominal)
5.2.6	EC_{50} (mortality of parental)	29.7 mg/L (nominal)
5.3	**Conclusion**	Mortality of female *Daphnia* did not exceed 20% at the end of the test. The mean number of living offspring produced per parent animal surviving at the end of the test was > 60 in the control groups. The validity criteria can be considered as fulfilled (see Table A7_4_3_4-4).
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.4.3.4
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an appropriate invertebrate species

	Evaluation by Competent Authorities
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Remarks	

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Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
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Section A7.4.3.5.1/01 Effects on sediment dwelling organisms

Annex Point IIIA XIII 3.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1999): [redacted]
1.2	**Data protection**	Yes
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 Proposal for a BBA guideline "Effects of plant protection products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system." (1995)
2.2	**GLP**	Yes
2.3	**Deviations**	No

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	Method of analysis	TI-435 in test water was analysed by HPLC using direct injection and on-line solid phase extraction. LOQ: 0.3 µg a.s./L
3.2	**Reference substance**	No
3.3	**Testing procedure**	
3.3.1	Test water	[redacted]
3.3.2	Test sediment	[redacted]

Section A7.4.3.5.1/01 **Effects on sediment dwelling organisms**
Annex Point IIIA XIII 3.4

[redacted]

3.3.3	Test organisms	See Table A7_4_3_5_1_01-1
3.3.4	Test system	See Table A7_4_3_5_1_01-2
3.3.5	Test conditions	See Table A7_4_3_5_1_01-3
3.3.6	Duration of the test	28 days
3.3.7	Test substance concentrations	Nominal concentrations: 0.1, 0.32, 0.56, 1.0, 1.8, 3.2 and 10 µg/L
3.3.8	Preparation of test solutions and application	[redacted]
3.3.9	Controls	[redacted]
3.3.10	Test parameter	[redacted]
3.3.11	Monitoring of TS concentration	[redacted]
3.3.12	Monitoring of other parameters	[redacted]
3.3.13	Statistics	The EC-values were calculated by Probit analysis. The χ^2-test was performed to establish different sensitivities of sexes (p=0.05).

4 RESULTS

4.1 TS concentrations during the test

[redacted]

4.2 Physical and chemical parameters

[redacted]

4.3 Emergence rate

[redacted]

Section A7.4.3.5.1/01 Effects on sediment dwelling organisms
Annex Point IIIA XIII 3.4

[redacted]

4.4 Development rate

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The effects of TI-435 technical on larvae of *Chironomus riparius* in a water-sediment system was tested according to the proposed BBA guideline "Effects of plant protection products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system." (1995). In a static test, first instars (L1) larvae were exposed to nominal concentrations of 0.1, 0.32, 0.56, 1.0, 1.8, 3.2 and 10 µg a.s./L for 28 days and emergence and development of midges was observed.

5.2 Results and discussion

Emergence was not reduced at the initial nominal test concentrations of 0.10, 0.32 and 0.56 µg a.s./L. At the initial test concentration of 1.0 µg a.s./L, the emergence of midges was significantly lower than in the control. No adult midges emerged in the higher concentrations of 1.8 to 10 µg/L.

There was no statistical difference in development rate between the test concentrations with emergence and the control.

These results demonstrate the higher sensitivity of the emergence rate in comparison to the development rate.

5.2.1	EC_{15}/NOEC (emergence rate)	0.00072 mg a.s./L
5.2.2	EC_5 (emergence rate)	0.00057 mg a.s./L
5.2.3	EC_{10} (emergence rate)	0.00065 mg a.s./L
5.2.4	EC_{50} (emergence rate)	0.00106 mg a.s./L

5.3 Conclusion

Guideline requirements were fulfilled since 90% of the inserted larvae matured to adults in the controls.

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
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Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
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Table A7_4_3_5_1_01-1: Test organisms

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Section A7.4.3.5.1/02 Effects on sediment dwelling organisms
Annex Point IIIA XIII 3.4

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (1998): [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Sumitomo Chemical Takeda Agro Co., Ltd.
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes Proposal for a BBA guideline "Effects of plant protection products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system." (1995)
2.2	**GLP**	Yes
2.3	**Deviations**	No
		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	Appearance	[redacted]
3.1.5	Method of analysis	[redacted]
3.2	**Reference substance**	No
3.3	**Testing procedure**	
3.3.1	Test water	[redacted]
3.3.2	Test sediment	[redacted]

Section A7.4.3.5.1/02 Effects on sediment dwelling organisms
Annex Point IIIA XIII 3.4

[redacted]

3.3.3 Test organisms [redacted]

3.3.4 Test system [redacted]

3.3.5 Test conditions [redacted]

3.3.6 Duration of the test [redacted]

3.3.7 Test substance concentrations [redacted]

3.3.8 Preparation of test solutions and application [redacted]

3.3.9 Controls [redacted]

3.3.10 Test parameter [redacted]

3.3.11 Monitoring of TS concentration [redacted]

3.3.12 Monitoring of other parameters [redacted]

3.3.13 Statistics

The U-test (non-parametric test for non homogeneous data) was performed for statistical analysis of the emergence rate. The χ^2-test was performed to establish different sensitivities of sexes (p=0.05).

4 RESULTS

4.1 TS concentrations during the test [redacted]

4.2 Physical and chemical parameters [redacted]

4.3 Emergence rate [redacted]

Section A7.4.3.5.1/02 Effects on sediment dwelling organisms
Annex Point IIIA XIII 3.4

[redacted]

4.4	**Development rate**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effects of TMG (tech.) on larvae of *Chironomus riparius* in a water-sediment system was tested according to the proposed BBA guideline "Effects of plant protection products on the development of sediment-dwelling larvae of *Chironomus riparius* in a water-sediment system." (1995). In a static test, first instars (L1) larvae were exposed to a single nominal concentration of 0.1 mg TMG/L for 28 days and emergence and development of midges was observed.
5.2	**Results and discussion**	For the number of emerged midges a minimal statistical difference between control and the test concentration of 0.1 mg TMG/L (U-test, p=0.05) was evaluated, but was not considered as relevant. For the development rate a statistical delay was not observed at 0.1 mg TMG/L (STUDENT t-test, p=0.05).
5.2.1	EC_{15}/NOEC (emergence rate and development rate)	≥ 0.1 mg TMG/L
5.3	**Conclusion**	Guideline requirements were fulfilled since 100% of the inserted larvae matured to adults in the controls.
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
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Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
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Section A7.4.3.6 **Mesocosm study**
Annex Point IIIA XIII.2

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2001): [redacted]
1.2	**Data protection**	Yes
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 SETAC guidance document on testing procedures for pesticides in freshwater mesocosms (1991) OECD draft guidance document: Freshwater lentic field tests (1996)
2.2	**GLP**	Yes
2.3	**Deviations**	No

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	Appearance	[redacted]
3.1.5	Method of analysis	[redacted]
3.2	**Reference substance**	No
3.3	**Testing procedure**	
3.3.1	Test sediment	[redacted]

[redacted]

3.3.2 Test water

[redacted]

3.3.3 Test organisms

[redacted]

3.3.4 Test system

[redacted]

3.3.5 Establishment of the test conditions

[redacted]

3.3.6 Application date

[redacted]

3.3.7 Test substance concentrations

[redacted]

3.3.8 Preparation of test solutions and application

[redacted]

[redacted]

3.3.9 Controls

3.3.10 Duration of the test

3.3.11 Test parameter

3.3.12 Sampling

[redacted]

[redacted]

3.3.13 Monitoring of TS concentration

3.3.14 Statistics

[redacted]

[redacted]

4 RESULTS

4.1 TS concentrations during the test

[redacted]

4.2 Physical and chemical parameters

[redacted]

4.3 Effects on aquatic organisms

[redacted]

Section A7.4.3.6 **Mesocosm study**
Annex Point IIIA XIII.2

[redacted]

4.4	**Effects on freshwater insects**	X

Section A7.4.3.6 **Mesocosm study**
Annex Point IIIA XIII.2

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Toxic effects of TI-435 on a freshwater ecosystem was tested in accordance with the relevant guidelines at the time the study was performed, i.e. SETAC guideline and OECD draft for freshwater outdoor studies. No deviations from the guidelines occurred.
5.2	**Results and discussion**	
5.2.1	EAC (Ecologically Acceptable Concentration)	10 µg/L TI-435 (corresponding to 20 µg/L TI-435 50 WG)
5.3	**Conclusion**	The quality and validity criteria mentioned in the OECD guidance documents (i.e. both of 1996 and 2000) were fulfilled. The used mesocosm ponds modelled a realistic freshwater ecosystem with sufficient representation from all different trophic levels. The study focussed on the toxicity to aquatic insects, because earlier studies indicated that this might be of concern. Clear concentration-effect relationships were obtained in case of toxic effects. Based on these relationships and univariate statistics NOEC's as well as an EAC based on recovery data were obtained. The study period was sufficient to demonstrate complete recovery of the affected populations. The concentrations of the test substance were analytically verified in the application solutions, in the water columns as well as in sediment samples.
5.3.1	Reliability	1 X
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
Date	13.10.2004
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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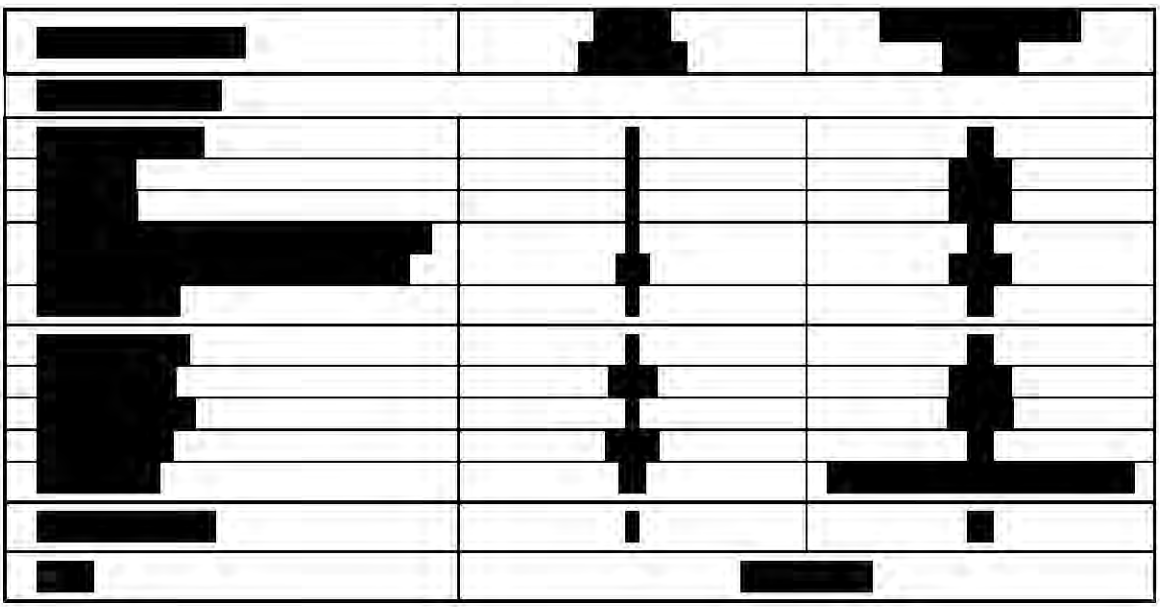

Section A7.5.1.1
Annex Point IIA7.4

Inhibition to microbial activity (terrestrial)

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1999): [redacted]
1.2	**Data protection**	Yes
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 no. 216 and 217 (drafts of January 1999)
2.2	**GLP**	Yes
2.3	**Deviations**	No

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	None
3.2	**Reference substance**	[redacted]
3.3	**Testing procedure**	
3.3.1	Soil sample	[redacted]
3.3.2	Test system	See Table A7_5_1_1-1

[1] Anderson, J.P.E. and Domsch, K.H. (1978): A physiological method for the quantitative measurement of microbial biomass in soils. Soil Biol. Biochem. 10, 215-221.

Section A7.5.1.1
Annex Point IIA7.4

Inhibition to microbial activity (terrestrial)

3.3.3 Application of TS

3.3.4 Test conditions

3.3.5 Test parameters and analytical methods

3.3.6 Duration of the test

3.3.7 Sampling

3.3.8 Monitoring of TS concentration

3.3.9 Controls

3.3.10 Statistics

4 RESULTS

4.1 Range finding test

4.2 Microbial biomass

4.3 Results test substance

[2] Dunnett, C.W. (1955): A multiple comparison procedure for comparing several treatments with a control. Journal Amer. Statist. Assoc. 50, 1096-1121.
Dunnett, C.W. (1964): New tables for multiple comparisons with a control., Biometrics 20, 482-491.

Section A7.5.1.1
Annex Point IIA7.4

Inhibition to microbial activity (terrestrial)

4.3.1 Soil respiration

[redacted]

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

[redacted]

4.3.2 Nitrogen transformation

[redacted]

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

[redacted]

4.4 Results of controls

4.4.1 Test with reference substance (positive control)

[redacted]

Section A7.5.1.1
Annex Point IIA7.4

Inhibition to microbial activity (terrestrial)

4.4.2	Nitrate control	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The effects of TI-435 50% WDG on respiration and nitrogen transformation of soil microflora under aerobic conditions was determined according to OECD 216 and 217. TI-435 50% WDG was incorporated into a sandy loam soil at treatment rates of 0.2 mg a.s./kg dw soil (equivalent to the maximum field application rate, i.e. 150 g a.s./ha) and 1.0 mg a.s./kg dw soil (equivalent to 5 x the maximum field application rate, i.e. 750 g a.s./ha).
5.2	**Results and discussion**	Short-term respiration and nitrogen transformation of soil treated with TI-435 50% WDG at up to 750 g a.s./ha deviated from the control by less than 25%.
5.3	**Conclusion**	Validity criteria can be considered as fulfilled (results of solvent controls and reference substance are in an acceptable range). Based on these results, TI-435 is no expected to adversely affect the soil microflora when applied up to 750 g a.s./ha (equivalent to 1.0 mg a.s./kg dry soil).
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
Date	2007-01-05
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	none
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.5.1.1
Annex Point IIA7.4

Inhibition to microbial activity (terrestrial)

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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Section A7.5.1.2/01 Annex Point IIIA XIII.3.2 Acute toxicity to earthworms or other soil non-target macro-organisms

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]. (1998b): [redacted]
1.2	**Data protection**	Yes
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 No. 207 (1984) and Directive 87/302/EEC, Part C
2.2	**GLP**	Yes
2.3	**Deviations**	[redacted]

3 METHOD

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	Not relevant
3.2	**Reference substance**	[redacted]
3.2.1	Method of analysis for reference substance	Not relevant
3.3	**Testing procedure**	
3.3.1	Preparation of the test substance	[redacted]
3.3.2	Application of the test substance	[redacted]
3.3.3	Test organisms	[redacted]
3.3.4	Test system	[redacted]

Section A7.5.1.2/01 Annex Point IIIA XIII.3.2 Acute toxicity to earthworms or other soil non-target macro-organisms

3.3.5	Test conditions	[redacted]
3.3.6	Test duration	[redacted]
3.3.7	Test parameter	[redacted]
3.3.8	Examination	[redacted]
3.3.9	Monitoring of test substance concentration	No
3.3.10	Statistics	The LC_{50} for the mortality was calculated by Probit analysis. The NOEC was determined for percentage weight change after 14 days and was analysed using one-way analysis of variance (ANOVA). Where this showed a significant treatment effect ($p<0.05$), pairwise comparison of each concentration versus control was made using Dunnett's test.

4 RESULTS

4.1	**Filter paper test**	Not performed
4.2	**Rangefinder test**	Performed
4.2.1	Concentration	0, 0.1, 1, 10, 100 and 1000 mg/kg dw artificial soil
4.2.2	Proposed LC_{50}	The rangefinder test indicated 7 and 14 day LC_{50} values between 10 and 100 mg/kg dw soil.
4.3	**Definite test**	
4.3.1	Initial concentrations of test substance	0, 10, 18, 32, 56 and 100 mg/kg dw artificial soil
4.3.2	Effect data (Mortality)	See Tables A7_5_1_2_01-4 and A7_5_1_2_01-5
4.3.3	Concentration / effect curve	See Figure A7_5_1_2_01-1
4.3.4	Other effects	The mean weight of the worms (per replicate) was between 376 mg and 507 mg on day 0. There was a significant reduction in mean body weight in TI-435 treatments of 24.5% at 10 mg/kg and of 22.4% at 18 mg/kg. Accordingly, the 14-day NOEC was <10 mg/kg. However, a loss of 7% in body weight was also seen in the control animals.
4.4	**Results of controls**	
4.4.1	Mortality	No mortalities occurred in the controls.
4.4.2	Number/ percentage of earthworms showing adverse effects	Earthworms of controls showed a 7% mean reduction in body weight at the end of the test (day 14).
4.4.3	Nature of adverse effects	See 4.4.2
4.5	**Test with reference substance**	Performed

Section A7.5.1.2/01 Annex Point IIIA XIII.3.2 — Acute toxicity to earthworms or other soil non-target macro-organisms

4.5.1	Concentrations	0, 10, 19, 34, 61 and 110 mg/kg dw artificial soil
4.5.2	Results	The 7 day and 14 day LC_{50} of 2-chloroacetamide to *Eisenia foetida* was calculated to be 30.83 and 26.55 mg/kg dw artificial soil, respectively, indicating an acceptable response of the test system.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The acute toxicity of TI-435 technical to earthworms was tested according to OECD No. 207 (1984) and Directive 87/302/EEC, Part C. *Eisenia foetida* were exposed to nominal concentrations of 0, 10, 18, 32, 56 and 100 mg a.s./kg dw artificial soil and effects on mortality and body weight were observed.
5.2	**Results and discussion**	After 7 days, there was 100% mortality in 56 and 100 mg/kg treatments, with some mortality in all TI-435 treatments. After 14 days, there was 100% mortality in 32, 56 and 100 mg/kg treatments, with some mortality in all lower TI-435 treatment replicates. There were no control mortalities. Surviving earthworms in the 10 and 18 mg/kg treatments showed a significant reduction in mean body weight at the end of the test.
5.2.1	NOEC	< 10 mg/kg dw soil (based on reduction in body weight)
5.2.2	LC_{50} (7 days exposure)	18.58 mg/kg dw soil (calculated)
5.2.3	LC_{50} (14 days exposure)	13.21 mg/kg dw soil (calculated)
5.2.4	LC_{100} (14 days exposure)	32 mg/kg dw soil (nominal)
5.3	**Conclusion**	Validity criteria can be considered as fulfilled since no mortalities occurred in the controls and the toxic reference test showed an acceptable response of the test system (see also Table A7_5_1_2_01-6).
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.5.1.2/01 Acute toxicity to earthworms or other soil non-target macro-organisms
Annex Point IIIA XIII.3.2

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table [redacted]

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