Section A6.10 Toxicity studies with compounds other than the a.s.

Annex Point IIA VI.6.10.1/03

Ames test (+/- S9) using *S. typhimurium* with TI-435 metabolite TZNG

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (1999c); [redacted] 03.06.1999
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	Data submitted on existing a.s. for its first entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes 2000/32/EC (method B13/14), OECD no. 471 (1983), EPA OPPTS 870.5265 (1998)
2.2	**GLP**	Yes
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	[redacted]
3.1.2.1	Description	White powder
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	Stable under conditions of this study (test-article/vehicle solutions were used within 4 hours after preparation)
3.2	**Study Type**	Bacterial reverse mutation test
3.2.1	Organism/cell type	*S. typhimurium*: TA 1535, TA 1537, TA 98, TA 100, TA 102
3.2.2	Deficiencies / Proficiencies	Histidine deficient
3.2.3	Metabolic activation system	S9 mix [redacted]

Section A6.10	**Toxicity studies with compounds other than the a.s.**
Annex Point IIA VI.6.10.1/03	Ames test (+/- S9) using *S. typhimurium* with TI-435 metabolite TZNG

3.2.4	Positive control	In absence of S9: 2-Nitrofluorene (2NF) at 5 µg/plate for TA 98 Sodium azide (NaN_3) at 2 µg/plate for TA 100 and TA 1535 9-Aminoacridine (ACA) at 50 µg/plate for TA 1537 Glutaraldehyde (GLU) at 25 µg/plate for TA 102 In presence of S9: 2-Aminoantracene (AAN) at 5 µg/plate for TA 98, TA 100 and TA 1535
3.3	**Administration / Exposure; Application of test substance**	
3.3.1	Concentrations	Pre-test: 0, 8, 40, 200, 1000, 5000 µg/plate Main test: 0, 8, 40, 200, 1000, 5000 µg/plate in experiment 1 (plate incorporation assay, +/- S9) 0, 156.3, 312.5, 625, 1250, 2500, 5000 µg/plate in experiment 2 (pre-incubation assay, +/- S9)
3.3.2	Way of application	[redacted]
3.3.3	Pre-incubation time	[redacted]
3.3.4	Other modifications	-
3.4	**Examinations**	[redacted]

4 RESULTS AND DISCUSSION

4.1	**Genotoxicity**	Non-entry field
4.1.1	without metabolic activation	[redacted]
4.1.2	with metabolic activation	[redacted]

Section A6.10	**Toxicity studies with compounds other than the a.s.**
Annex Point IIA VI.6.10.1/03	Ames test (+/- S9) using *S. typhimurium* with TI-435 metabolite TZNG

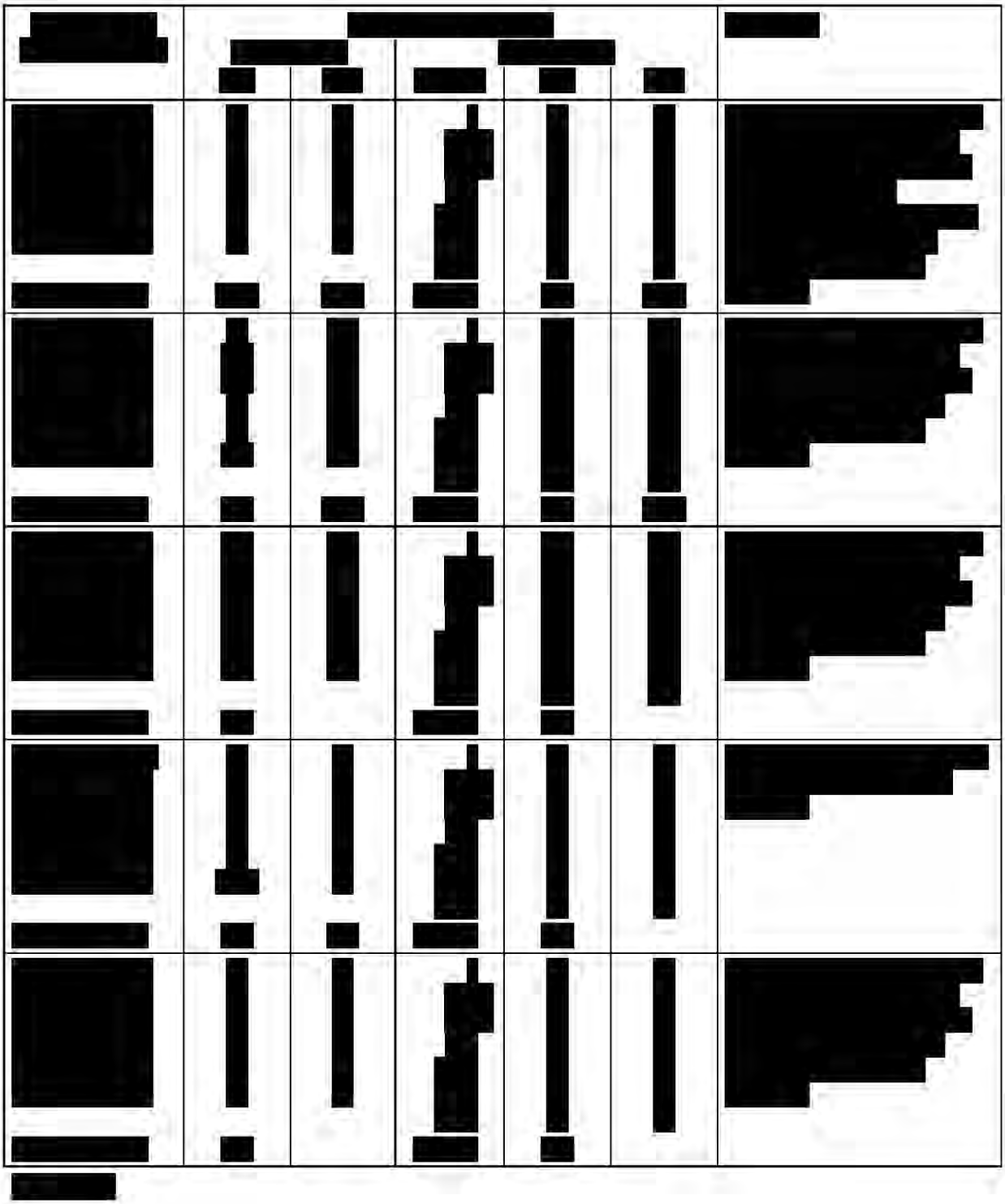
4.2	**Cytotoxicity**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Evaluation of the *in vi*tro gene mutation potential in *S. typhimurium* strains; no relevant deviation from guidelines (2000/32/EC B13/14, OECD 471, EPA FIFRA 84-2, Japan Maff)
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	TZNG and/or its metabolites were considered to be not mutagenic in this *in vitro* test system.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
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	

[redacted]



Section A6.10 Toxicity studies with compounds other than the a.s.

Annex Point IIA VI.6.10.1/04

Acute oral toxicity study in rats (LD_{50}) with the [redacted] metabolite TMG

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] TMG: [redacted] 05.07.1999
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 92/69/EEC (method B1), OECD guideline no. 401 (February 1987), EPA OPPTS 870.1100 (August 1998), Japan MAFF (59 NohSan No. 4200, 1985)
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	Not applicable
3.1.2.1	Description	Yellow solid
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	Considered stable under conditions of this study (test-article/vehicle formulations prepared at the day of dosing)
3.2	**Test Animals**	[redacted] female fasted rats per group (Crl:CD.BR strain [redacted] in addition [redacted] male [redacted] were treated at the approximate median lethal dose to demonstrate that males were not more susceptible to the toxic effects of TMG; No control group
3.3	**Administration/ Exposure**	Oral
3.3.1	Postexposure period	14 days

Section A6.10 **Toxicity studies with compounds other than the a.s.**

Annex Point IIA VI.6.10.1/04 Acute oral toxicity study in rats (LD_{50}) with the TI-435 metabolite TMG

3.3.2	Type	Gavage
3.3.3	Concentration	225, 650 and 1100 mg/kg bw (females) 550 mg/kg bw (males)
3.3.4	Vehicle	[redacted]
3.3.5	Concentration in vehicle	Prepared according to individual bw and dosing volume
3.3.6	Total volume applied	20 mL/kg bw
3.3.7	Controls	-
3.4	**Examinations**	[redacted]
3.5	**Method of determination of LD_{50}**	The acute median lethal dose and 95% confidence limits were estimated using probit analysis (Finney, D. J., 1971, Probit analysis, 3rd Ed., Cambridge University Press).
3.6	**Further remarks**	-

4 RESULTS AND DISCUSSION

4.1	**Clinical signs**	[redacted]
4.2	**Pathology**	[redacted]
4.3	**Other**	[redacted]
4.4	**LD_{50}**	567 mg/kg bw (females); treatment of males at a dose level of 550 mg/kg bw (with mortality in 3/5 animals) revealed that there is no relevant sex difference in susceptibility to toxic effects of TMG

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Toxicity evaluation (bw, clinical signs, *post mortem* examination) after acute oral application of the [redacted] metabolite TMG to rats (gavage); no relevant deviation from guidelines (92/69/EEC B1; EPA OPPTS 870.1100, Japan MAFF, OECD 401)
5.2	**Results and discussion**	Acute oral LD_{50} of [redacted] metabolite TMG in rats was 567 mg/kg bw.
5.3	**Conclusion**	Classification as harmful if swallowed (R22) is considered required for TI-453 metabolite TMG according to Directive 2001/59/EC (adaptation of 67/548/EEC). The same classification had been proposed for the parent TI-435.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A6.10 **Toxicity studies with compounds other than the a.s.**

Annex Point IIA VI.6.10.1/04 Acute oral toxicity study in rats (LD_{50}) with the TI-435 metabolite TMG

	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	
	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	

[redacted]

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

Section A6.10 Toxicity studies with compounds other than the a.s.

Annex Point IIA VI.6.10.1/05

Ames test (+/- S9) using *S. typhimurium* with [redacted] metabolite TMG

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] TMG: [redacted], 03.06.1999
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	Data submitted on existing a.s. for its first entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes 2000/32/EC (method B13/14), OECD no. 471 (1983), EPA OPPTS 870.5265 (1998)
2.2	**GLP**	Yes
2.3	**Deviations**	[redacted]

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	Not applicable
3.1.2.1	Description	Yellow solid
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	Stable under conditions of this study (test-article/vehicle solutions were used within 4 hours after preparation)
3.2	**Study Type**	Bacterial reverse mutation test
3.2.1	Organism/cell type	*S. typhimurium*: TA 1535, TA 1537, TA 98, TA 100, TA 102
3.2.2	Deficiencies / Proficiencies	Histidine deficient
3.2.3	Metabolic activation system	S9 mix [redacted]

Section A6.10 **Toxicity studies with compounds other than the a.s.**

Annex Point IIA VI.6.10.1/05 Ames test (+/- S9) using *S. typhimurium* with TI-435 metabolite TMG

3.2.4	Positive control	In absence of S9: 2[redacted]
3.3	**Administration / Exposure; Application of test substance**	
3.3.1	Concentrations	[redacted] Main test: 0, 8, 40, 200, 1000, 5000 µg/plate in experiment 1 (plate incorporation assay, +/- S9) 0, 156.3, 312.5, 625, 1250, 2500, 5000 µg/plate in experiment 2 (pre-incubation assay, +/- S9)
3.3.2	Way of application	[redacted]
3.3.3	Pre-incubation time	[redacted]
3.3.4	Other modifications	[redacted]
3.4	**Examinations**	[redacted]

4 RESULTS AND DISCUSSION

4.1	**Genotoxicity**	Non-entry field
4.1.1	without metabolic activation	[redacted]
4.1.2	with metabolic activation	[redacted]
4.2	**Cytotoxicity**	[redacted]

Section A6.10 **Toxicity studies with compounds other than the a.s.**

Annex Point IIA VI.6.10.1/05 Ames test (+/- S9) using *S. typhimurium* with TI-435 metabolite TMG

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Evaluation of the *in vi*tro gene mutation potential in *S. typhimurium* strains; no relevant deviation from guidelines (2000/32/EC B13/14, OECD 471, EPA FIFRA 84-2, Japan Maff)

5.2 Results and discussion

[redacted]

5.3 Conclusion

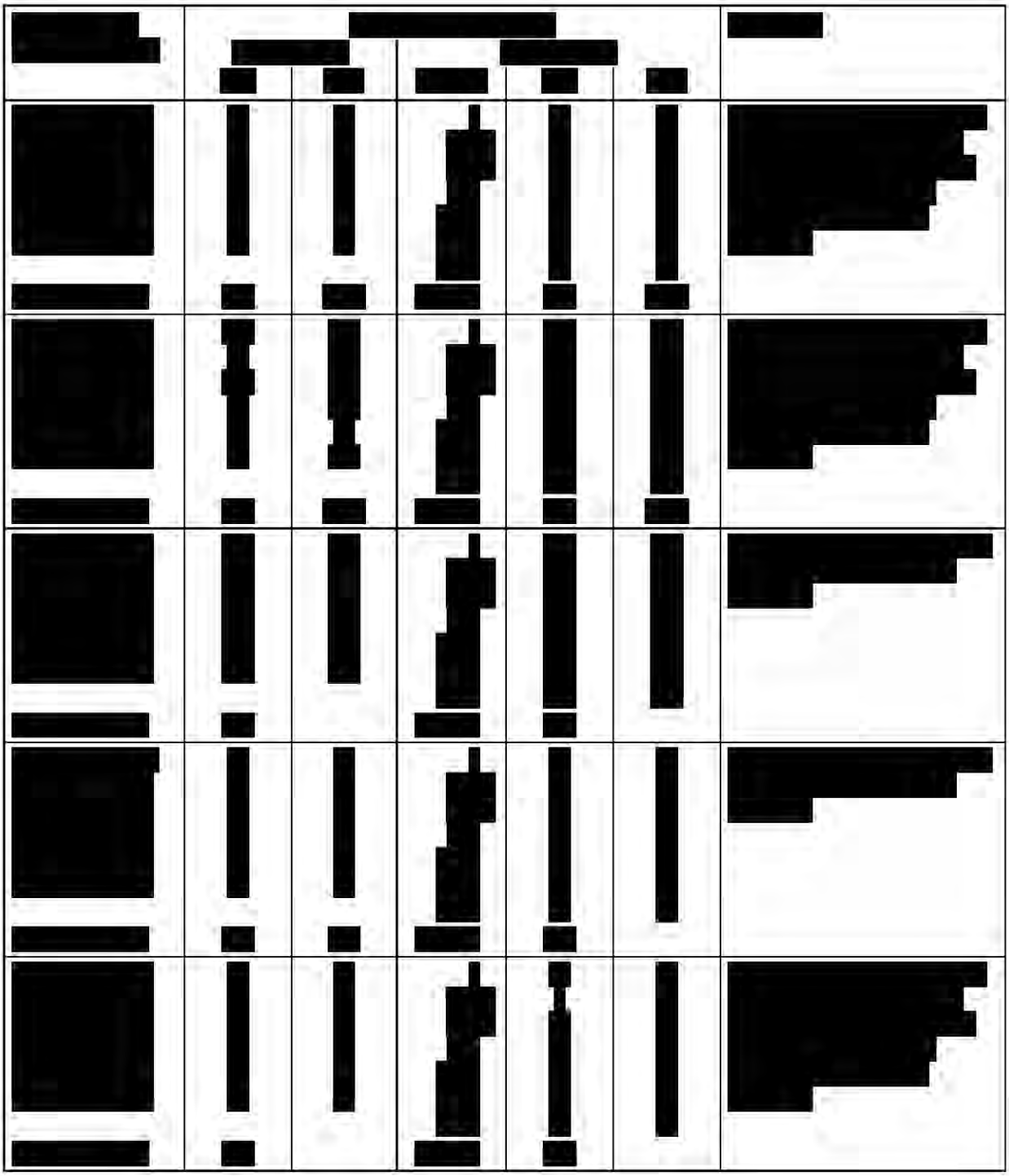
TMG and/or its metabolites were considered to be not mutagenic in this *in vitro* test system.

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	
	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	

[redacted]



Section A6.10 **Further study available with the a.s.**

Annex Point IIA VI.6.10.2/01 Pharmacological study with TI-435 in rats and mice

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2000); [redacted] 20.01.2000
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 No applicable EU guideline, Japan MAFF (59 NohSan 4200, 1985, revision of part 1997)
2.2	**GLP**	Yes
2.3	**Deviations**	-

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.2.1	Description	Pale, yellow powder
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	[redacted]
3.2	**Test Animals**	The rats used were CD (SD) strain ([redacted], the mice used were CD-1 (ICR) strain ([redacted].

Section A6.10 **Further study available with the a.s.**

Annex Point IIA VI.6.10.2/01 Pharmacological study with TI-435 in rats and mice

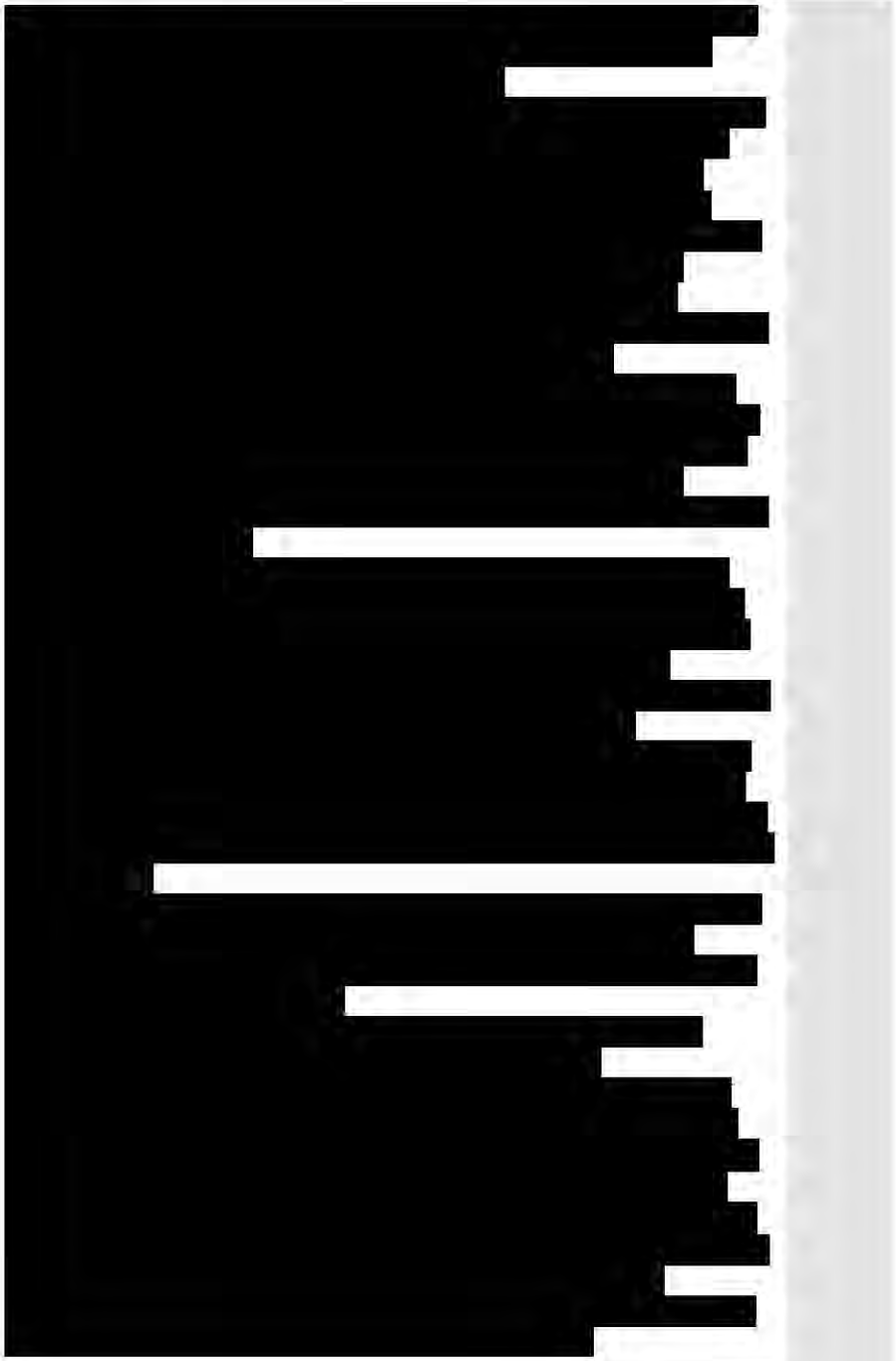
[redacted]

3.3	**Administration/ Exposure**	**Oral** (for *in vivo* experiments)
3.3.1	Postexposure period	See point 3.4
3.3.2	Type	Gavage
3.3.3	Concentration	[redacted]
3.3.4	Vehicle	[redacted]
3.3.5	Concentration in vehicle	Prepared according to individual bw and dosing volume
3.3.6	Total volume applied	[redacted]
3.3.7	Controls	Vehicle

Section A6.10 **Further study available with the a.s.**

Annex Point IIA VI.6.10.2/01 Pharmacological study with TI-435 in rats and mice

3.4 Examinations



3.5 Further remarks

4 RESULTS AND DISCUSSION

4.1 Results

4.1.1 Test 1 (Effects on the CNS – Irwin screen)

[redacted]

4.1.2 Test 2 (anaesthetic effects)

[redacted]

4.1.3 Test 3.1 (synergistic effects on convulsions)

[redacted]

4.1.4 Test 3.2 (synergistic effects on convulsions)

[redacted]

4.1.5 Test 4 (effects on body temperature)

[redacted]

4.1.6 Test 5 (effects on cardiovascular parameters)

[redacted]

4.1.7 Test 6 (effects on intestinal transport)

[redacted]

4.1.8 Test 7 (effects on skeletal muscle)

[redacted]

Section A6.10 **Further study available with the a.s.**

Annex Point IIA VI.6.10.2/01 Pharmacological study with TI-435 in rats and mice

[redacted]

4.1.9 Test 8 (effects on blood coagulation)

[redacted]

4.1.10 Test 9 (effects on the autonomic nervous system and smooth muscles)

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Evaluation of several parameters potentially interessant concenring a compounds pharmacological properties after single acute oral application [redacted] to rats or mice (gavage) or in an in vitro experiment (single exposure) with ilium from Guinea pigs; specific Japanese requirement - no EU guideline available

5.2 Results and discussion

[redacted]

5.3 Conclusion

The overall NOELs of effects where a potential relevance for human risk assessment for biocides might not be excluded was 25 mg/kg bw for mice and 100 mg/kg bw for rats.

5.3.1 Reliability 1

5.3.2 Deficiencies No

Section A6.10 **Further study available with the a.s.**

Annex Point IIA VI.6.10.2/01 Pharmacological study with TI-435 in rats and mice

	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	1
Acceptability	acceptable
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	

Section A7.1.1.1.1 Annex Point IIA7.6.2.1 Hydrolysis as a function of pH and identification of breakdown 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 92/69/EEC, C.7 and US EPA, Subdivision N, Section 161-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	None (to EC directive)	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specific activity	[redacted]	
3.1.3	Purity	[redacted] Chemical purity: 98.3%	X
3.1.4	Further relevant properties	[redacted]	
3.2	**Reference substance**	[redacted]	
3.3	**Test solution**	See Tables A7_1_1_1_1-1 and A7_1_1_1_1-2	X
3.4	**Testing procedure**		
3.4.1	Test system	See Table A7_1_1_1_1-3	
3.4.2	Temperature	Preliminary study: 50°C (pH 4, 7 and 9) Definitive study: 25°C (pH 5, 7 and 9) Additional definitive study: 62°C and 74°C (pH 9)	
3.4.3	pH	All vials tested were within +/- 0.2 pH units of the intended pH both after sterilization and at the end of the experiment.	
3.4.4	Duration of the test	Preliminary study: 5 days (pH 4 and 7), 25 days (pH 9) Definitive study: 33 days (pH 5, 7 and 9) Additional definitive study (pH 9): 7 days (62°C) and 1.9 days (74°C)	
3.4.5	Number of replicates	As given in Table A7_1_1_1_1-2	

Section A7.1.1.1.1
Annex Point IIA7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products

3.4.6	Sampling	Sampling intervals: Preliminary study: 0, 0.1, 1 and 5 days (pH 4 and 7) and 0, 0.1, 1, 5, 11, 15, 19 and 25 days (pH 9) Definitive study: 0, 5, 9, 15, 20, 27 and 33 days (pH 5, 7 and 9) Additional definitive study (pH 9): 0, 1, 3 and 7 days (62°C) and 0, 0.25, 1 and 1.9 days (74°C)
3.4.7	Analytical methods	[redacted]
3.5	**Preliminary test**	Yes, see above for description.

4 RESULTS

4.1	**Concentration and hydrolysis values**	See Table A7_1_1_1_1-4 to Table A7_1_1_1_1-11
4.2	**Hydrolysis rate constant**	See Table A7_1_1_1_1-12
4.3	**Dissipation time**	See Table A7_1_1_1_1-12 The half-life at 20°C and pH 9 was calculated from the Arrhenius plot. The calculated rate constant was 0.000494 day^{-1} and from this a half-life of 1401 days (*ca.* 3.8 years) was calculated.
4.4	**Concentration time data**	See Figure A7_1_1_1_1-1 to A7_1_1_1_1-3 Since TI-435 was stable at pH 4, 5 and 7 (25°C and 50°C) and at pH 9 (25°C) no concentration-time plot is provided.
4.5	**Specification of the transformation products**	See Table A7_1_1_1_1-13 No transformation products were found at pH 4, 5 and 7 (25°C and 50°C) and only trace amounts were found at pH 9 (25°C). Figure A7_1_1_1_1-4 shows the Proposed hydrolysis pathways of TI-435.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Degradation – abiotic degradation hydrolysis as a function of pH: 92/69/EEC, C.7 and US EPA, Subdivision N, Section 161-1; Deviations (to EC directive): none
5.2	**Results and discussion**	The radiochemical purity of the application solution was determined at each time of dosing (preliminary, definitive and additional definitive study) and was at any time >98%. The results of the study are summarised in Tables A7_1_1_1_1-4 to A7_1_1_1_1-11. The half-lives were calculated using first-order kinetics. The total recovery of the applied radioactivity was in the range of 96% to 103%. A half-life of 1401 days for a temperature of 20°C and a pH-value of 9 was calculated according to the Arrhenius equation using the data from the tests performed at 50°C, 62°C and 74°C.
5.2.1	k_H	pH 9: 0.048 (50°C), 0.188 (62°C), 1.013 (74°C)
5.2.2	DT_{50}	pH 9: 14.4 days (50°C), 3.7 days (62°C), 0.68 days (74°C)
5.2.3	r^2	pH 9: 0.997 (50°C, 62°C and 74°C)
5.3	**Conclusion**	TI-435 is stable in sterile buffer solutions at pH 4, 5 and 7, but degrades

Section A7.1.1.1.1
Annex Point IIA7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products

at pH 9. However, at relevant temperatures of 20°C the degradation is very slow (calculated half-life: 1401 days). Relevant amounts of metabolites were formed only at elevated temperatures.

5.3.1 Reliability 1

5.3.2 Deficiencies None

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

Results and discussion [redacted]

< 2 days.

Conclusion [redacted]

Reliability [redacted]

Section A7.1.1.1.1 Annex Point IIA7.6.2.1 Hydrolysis as a function of pH and identification of breakdown products

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

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Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of the products of transformation

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**	[redacted]
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

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	UV/VIS absorption spectra and absorbance value	See Figure A7_1_1_1_2-1
3.1.6	Further relevant properties	[redacted]

3.2	**Reference substances**	[redacted]
3.3	**Test solution**	See Table A7_1_1_1_2-1
3.4	**Testing procedure**	
3.4.1	Test system	See Table A7_1_1_1_2-2
3.4.2	Properties of light source	See Table A7_1_1_1_2-2
3.4.3	Determination of irradiance	[redacted]
3.4.4	Temperature	25±1°C
3.4.5	pH	[redacted]
3.4.6	Duration of the test	18 days
3.4.7	Number of replicates	One test vessel per radiolabel. Initial test volume: 200 mL.
3.4.8	Sampling	[redacted]
3.4.9	Analytical methods	[redacted]

[redacted]

3.5	**Transformation products**	Transformation products tested: Yes
3.5.1	Method of analysis for transformation products	As described in Section 3.4.9.
		4 RESULTS
4.1	**Screening test**	Not performed
4.2	**Actinometer data**	[redacted]
4.3	**Controls**	[nitroimino-^{14}C]TI-435: C_0 = 100.1% AR, C_{end} = 93.8% AR [thiazolyl-2-^{14}C]TI-435: C_0 = 95.0% AR, C_{end} = 104.1% AR
4.4	**Photolysis data**	
4.4.1	Concentration values	See Table A7_1_1_1_2-3
4.4.2	Mass balance	See Table A7_1_1_1_2-3
4.4.3	k^e_p	No actinometer study
4.4.4	Kinetic order	pseudo first order
4.4.5	k^e_p / k^a_p	No actinometer study
4.4.6	Reaction quantum yield (ϕ^e_E)	No actinometer study
4.4.7	k_{pE}	No actinometer study
4.4.8	Half-life ($t_{1/2E}$)	Experimental half-life: 3.3 hours (mean of two radiolabel studies). Corresponding half-life under summer (June) solar light conditions at Phoenix/USA: 0.6 days. Corresponding half-life under winter (December) solar light conditions at Phoenix/USA: 1.6 days.
4.5	**Specification of the transformation products**	See Table A7_1_1_1_2-3
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	Test guidelines: SETAC and US EPA 161-2 Deviations (to SETAC): temperature 25±1°C instead of 20±3°C [redacted]

x

5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	The degradation in the dark controls was negligible. Sterile conditions and a pH-value of 7 were maintained throughout the test. Validity criteria of the test can be considered as fulfilled. Considering the rapid photolytic breakdown determined at a pH value and a temperature typical for a natural environment, solar radiation will significantly contribute to the degradation of the test substance in aquatic test systems. It can also contribute to the elimination of residues of TI-435 by means of mineralization of the thiazole ring.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

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	

Section A7.1.1.1.2
Annex Point IIA7.6.2.2

Phototransformation in water including identity of the products of transformation

	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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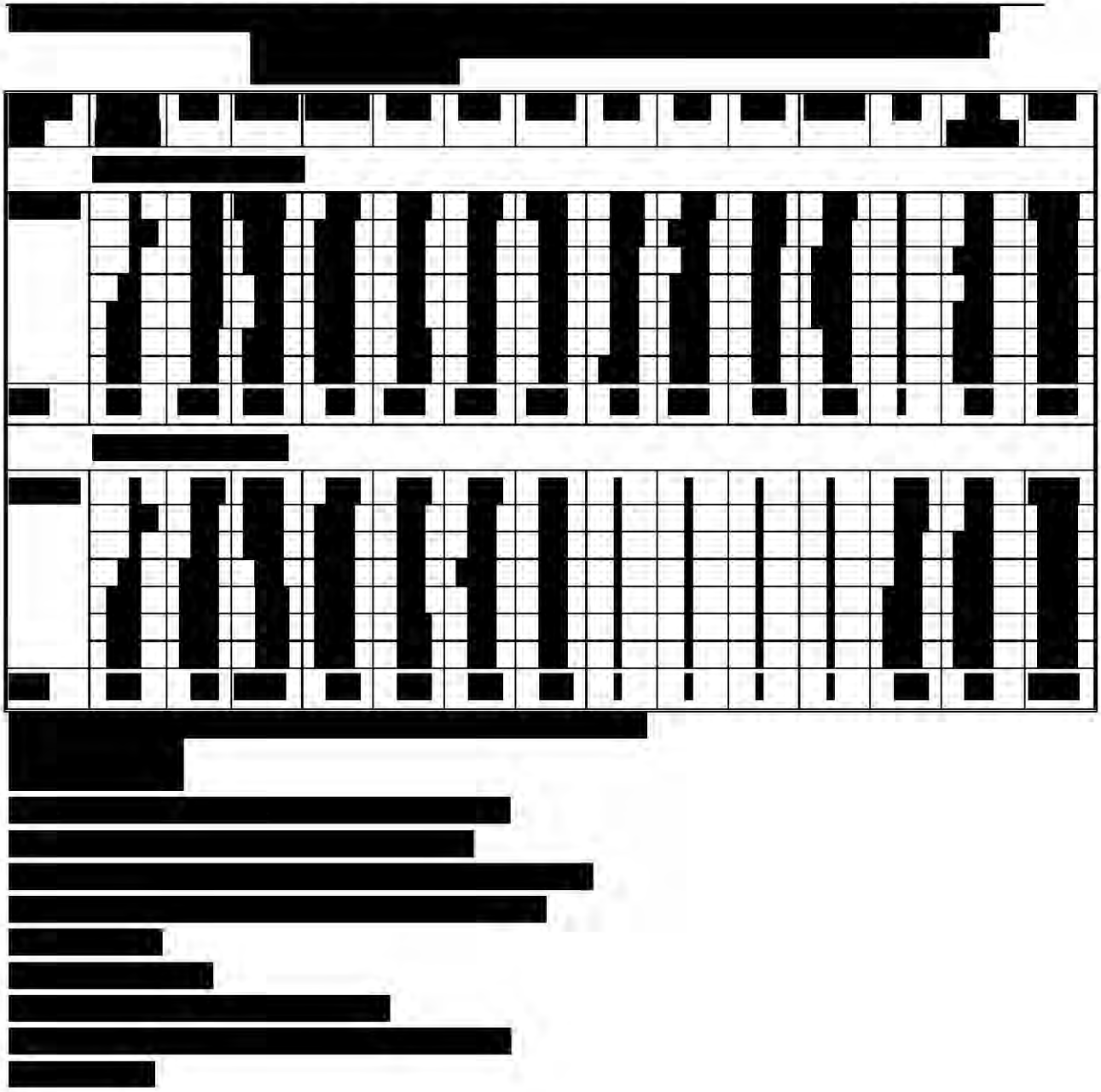

Figure A7_1_1_1_2-1: UV Spectrum of TI-435

Section A7.1.1.2.1 Ready biodegradability
Annex Point IIA7.6.1.1

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 Directive 92/69/EEC, C.4-C
2.2	**GLP**	Yes
2.3	**Deviations**	Yes On day 20, the minimum temperature recorded was 18.5°C (guideline requirement: 22 ± 2°C), but this was not considered to have influenced the outcome of the study.

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	PAI
3.1.3	Purity	99.7%
3.1.4	Further relevant properties	[redacted]
3.1.5	Composition of Product	Not applicable
3.1.6	TS inhibitory to micro-organisms	No
3.1.7	Specific chemical analysis	None
3.2	**Reference substance**	Yes Sodium benzoate
3.2.1	Initial concentration of reference substance	According to guideline
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	See Table A7_1_1_2_1-1
3.3.2	Test system	See Table A7_1_1_2_1-2
3.3.3	Test conditions	See Table A7_1_1_2_1-3

Section A7.1.1.2.1 **Ready biodegradability**
Annex Point IIA7.6.1.1

3.3.4	Method of preparation of test solution	[redacted]
3.3.5	Initial TS concentration	51.9 - 52.0 mg TS/L corresponding to a nominal concentration of 15 mg DOC/L
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	CO_2 evolution
3.3.8	Sampling	2, 4, 6, 8, 10, 15, 16, 19, 23, 28 days
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Reference substance control without test substance; reference substance control with test substance (toxicity control).
3.3.12	Statistics	None

4 RESULTS

4.1	**Degradation of test substance**	
4.1.1	Graph	See Figure A7_1_1_2_1-1
4.1.2	Degradation	[redacted]
4.1.3	Other observations	None
4.1.4	Degradation of TS in abiotic control	No abiotic control
4.1.5	Degradation of reference substance	See Figure A7_1_1_2_1-1
4.1.6	Intermediates/ degradation products	Not determined

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Directive 92/69/EEC, C.4-C, CO_2 Evolution Test (Modified Sturm Test) [redacted]
5.2	**Results and discussion**	The blank-corrected CO_2 yield of TI-435 after 28 days of incubation was only 1.5% (mean of two trials) of the theoretical maximum yield (165 mg CO_2). Therefore, TI-435 cannot be classified as readily biodegradable.

Section A7.1.1.2.1 Ready biodegradability
Annex Point IIA7.6.1.1

		The biodegradation of the reference substance sodium benzoate was clearly above 60% of the theoretical yield within 14 days and the 10-day period (10% in the first 4 days). TI-435 present in the toxicity control did not inhibit the microbial degradation of the reference substance.
5.3	**Conclusion**	The biodegradation of the reference substance sodium benzoate was above 60% of the theoretical yield within 14 days and the differences in degradation between the replicates was by less than 20%. This demonstrates the validity of the test. Under the test conditions, TI-435 was not readily biodegradable. In the toxicity control, TI-435 did not inhibit the microbial degradation of the reference substance.
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	2005-08-17
Materials and Methods	applicant's version is acceptable
Results and discussion	applicant's version is adopted
Conclusion	applicant's version is adopted
Reliability	1
Acceptability	acceptable
Remarks	none
	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 A7.1.2/02 and A7.1.2.2.2/02
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]. (2000[redacted]	x
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 Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate §162-3 Anaerobic Aquatic Metabolism, 1982	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	x
		3 METHOD	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Purity	See 3.1.2	
3.1.4	Further relevant properties	[redacted]	
3.2	**Reference substance**	[redacted]	
3.3	**Test system**		
3.3.1	Water/sediment systems	[redacted]	

Section A7.1.2/02 and A7.1.2.2.2/02
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

3.3.2	Test system sampling	[redacted]	
3.3.3	Test system equilibration	Prior to the start of the test, water and sediment were separated by [redacted]	
3.3.4	Test conditions	Test vessels: 250 mL Erlenmeyer flasks to which an inert, gas-tight bag was connected for sampling of volatiles. Agitation: none; Oxygen conditions: anaerobic; Light conditions: dark; Temperature: 20 ±1°C.	
3.3.5	Rate of application	[redacted] a nominal amount of 3.0 µg a.s. was applied to each test system taking into account the total water volume of 200mL.	
3.3.6	Preparation of application solution	[redacted]	
3.3.7	Application	[redacted]	x
3.3.8	Duration of test	360 days	
3.3.9	Sampling and extractions	[redacted]	x

Section A7.1.2/02 and A7.1.2.2.2/02
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

[redacted]

3.3.10 Controls

[redacted]

3.3.11 Analytical methods

[redacted]

3.3.12 Intermediates/ degradation products

No degradate was formed at amounts >4.5% of the applied radioactivity, therefore identification was not feasible.

[redacted]

3.3.13 Calculation of dissipation rates

[redacted]

4 RESULTS

4.1 Test conditions during incubation

[redacted]

4.2 Recovery

[redacted]

Section A7.1.2/02 and A7.1.2.2.2/02
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

[redacted]

4.3	**Distribution of radioactivity**	[redacted]	x
4.4	**Identification of radioactivity**		
4.4.1	Degradation of the test substance	[redacted]	x
4.4.2	Formation of degradation products	[redacted]	
4.4.3	Mineralisation & volatile organic compounds	[redacted]	
4.5	**Half-life of the test substance**	[redacted]	x

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate §162-3 Anaerobic Aquatic Metabolism, 1982.

[redacted]

Section A7.1.2/02 and A7.1.2.2.2/02
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

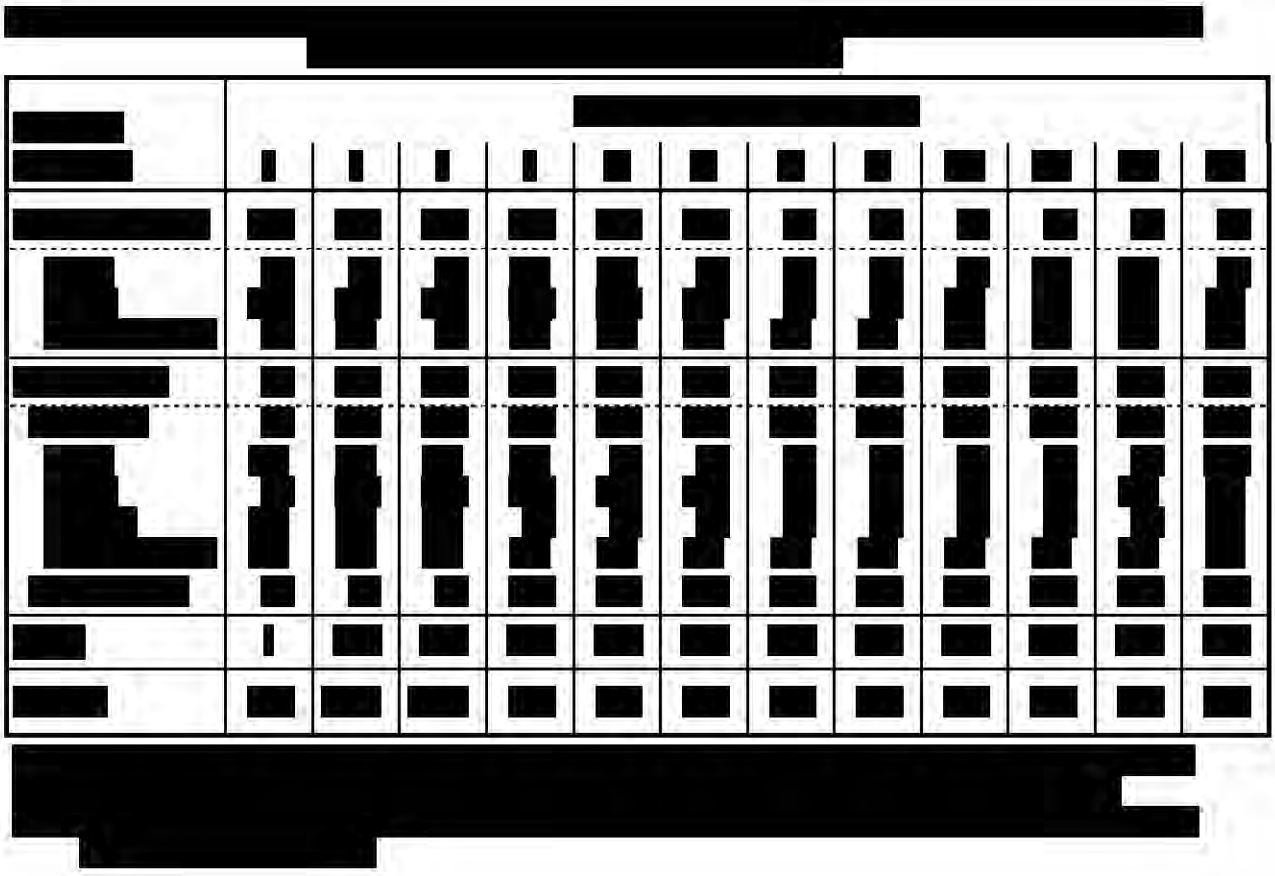
Water/sediment degradation study

5.2	**Results and discussion**	The amount of radioactivity detected in the water phase rapidly decreased within the course of the study to levels of ≤1.4% of the applied radioactivity on day 360. Bound residues in the sediment reached on average 81% at the end of incubation.
		[redacted]
		DT_{50} of TI-435 was calculated to be 4, 11 and 21 days for the water phase, sediment phase and the whole system, respectively.
		Total recoveries of the applied radioactivity ranged from 95.1% to 101,7%. Validity criteria of the test can be regarded as fulfilled.
5.3	**Conclusion**	Under anaerobic conditions, TI-435 disappears rapidly from the water phase to the sediment, with non-extractable residues forming the major sink in time.
5.3.1	Reliability	1
5.3.2	Deficiencies	None

	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	1
Acceptability	acceptable
Remarks	none
	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 A7_1_2_2_2/02-1: Water/sediment characteristics



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exposed to anaerobic conditions

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Section A7.1.2 and A7.1.2.2.2
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

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 SETAC (1995) and German BBA guideline Part IV, 5-1 (1990)
2.2	**GLP**	[redacted]
2.3	**Deviations**	[redacted]

3 METHOD

[redacted]		[redacted]
[redacted]		[redacted]
3.1.2	Specification	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	[redacted]
3.2	**Reference substance**	[redacted]
3.3	**Test system**	
3.3.1	Water/sediment systems	[redacted]

Section A7.1.2 and A7.1.2.2.2
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

3.3.2	Test system sampling	[redacted]
3.3.3	Test system equilibration	[redacted]
3.3.4	Test conditions	[redacted]
3.3.5	Method of preparation of test solution	[redacted]
3.3.6	Rate of application	[redacted]
3.3.7	Duration of test	100 days
3.3.8	Sampling and extractions	[redacted]
3.3.9	Controls	[redacted]
3.3.10	Analytical methods	[redacted]
3.3.11	Intermediates/ degradation	[redacted]

products

[redacted]

4 RESULTS

4.1 Test conditions during incubation

[redacted]

4.2 Recovery

[redacted]

4.3 Distribution of radioactivity

[redacted]

4.4 Identification of radioactivity

4.4.1 Degradation of the test substance

[redacted]

2.

4.4.2 Formation of degradation products

[redacted]

Section A7.1.2 and A7.1.2.2.2
Annex Point IIIA XII 2.1

Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

Water/sediment degradation study

[redacted]

4.4.3 Mineralisation

[redacted]

4.5 Half-life of the test substance

The half-lives of TI-435 in the water phase and the entire system were calculated according to TIMME ET AL. (1986) assuming first order kinetics. The values are presented in Table A7_1_2_2_2-3.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

SETAC (1995) and German BBA guideline Part IV, 5-1 (1990). No deviations (to SETAC) occurred.

[redacted]

The test systems were incubated in the dark at 20°C for 100 days and 0, 3, 7, 14, 30, 58 and 100 days after treatment, duplicate vessels were processed.

5.2 Results and discussion

[redacted]

5.3 Conclusion

Half-lives of TI-435 were calculated to be 31 and 50 days for the water phase and 48 and 65 days for the entire system in Hönniger Weiher and Anglerweiher, respectively (first order).

Total recoveries of the applied radioactivity ranged from 95.2% and 103.6%. Validity criteria of the test can be regarded as fulfilled.

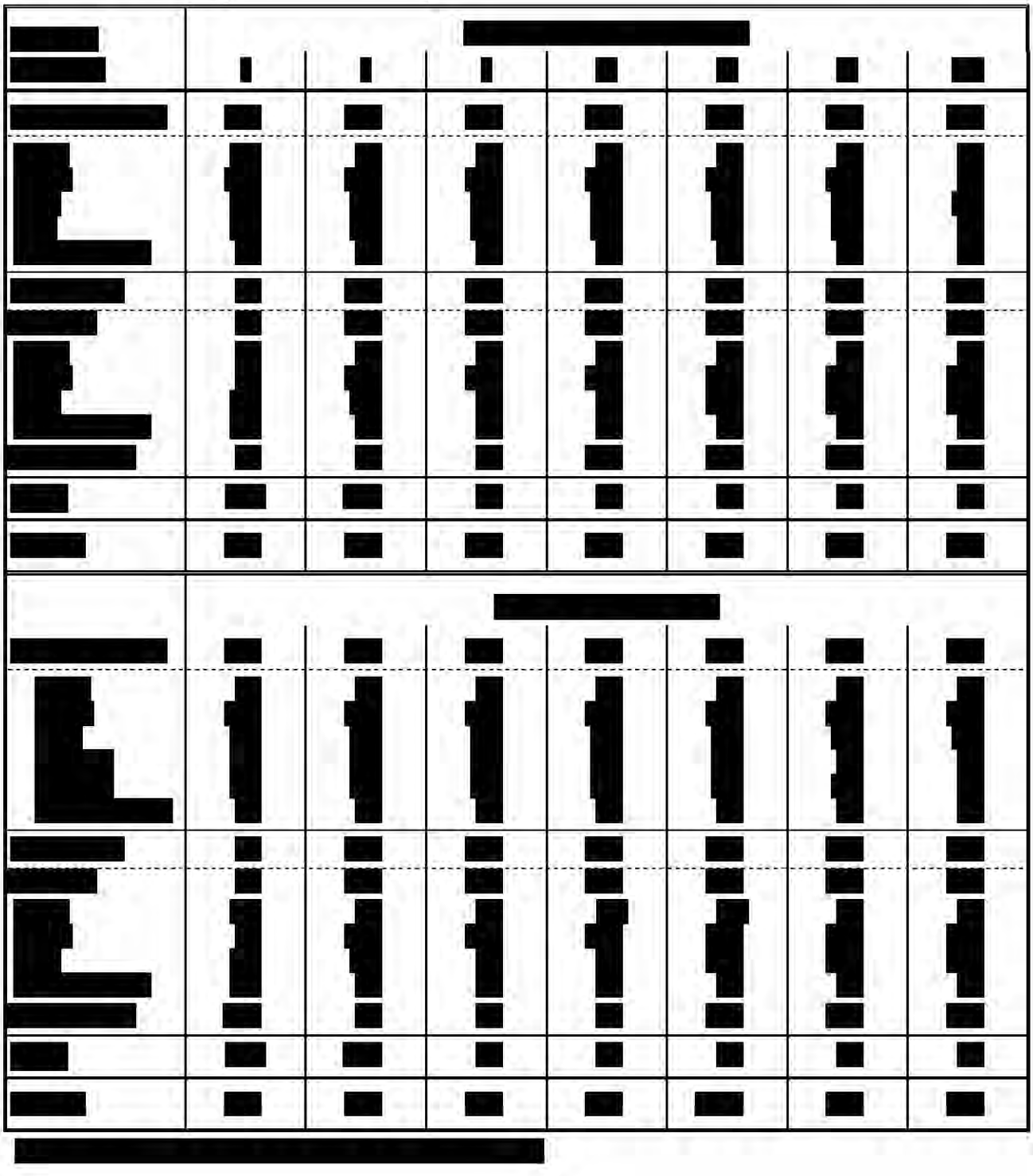
5.3.1 Reliability 1

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	
[redacted]	
[redacted]	

[redacted]

[redacted]



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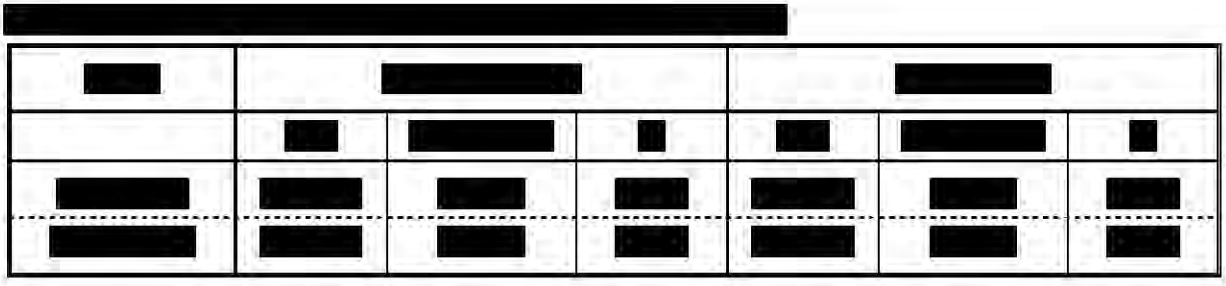

Section A7.1.3 Adsorption/desorption screening test
Annex Point IIA7.7

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 (May 1981) [redacted]
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	Specific activity	[redacted]
3.1.3	Purity	[redacted]
3.1.4	Further relevant properties	[redacted]
3.1.5	Method of analysis	[redacted]
3.2	**Degradation products**	Degradation products tested: Yes At any time of the test all degradation products accounted for < 1% of the a.s. added.
3.2.1	Method of analysis for degradation products	See 3.1.5
3.3	**Reference substances**	[redacted]

Section A7.1.3 **Adsorption/desorption screening test**
Annex Point IIA7.7

[redacted]

3.3.1 Method of analysis for reference substance — See 3.1.5

3.4 Soil types — Available data are given in Table A7_1_3-1

3.5 Testing procedure

3.5.1 Test system — [redacted]

3.5.2 Test solution and Test conditions — The test substance TI-435 was tested in a concentration range of 0.04 to 5.0 µg a.s./mL.

3.6 Test performance

3.6.1 Preliminary test — According to OECD 106 [redacted]

3.6.2 Screening test: Adsorption — According to OECD 106

3.6.3 Screening test: Desorption — According to OECD 106

3.6.5 Other test — None

4 RESULTS

4.1 Preliminary test — [redacted]

4.2 Screening test: Adsorption — [redacted]

4.3 Screening test: Desporption — [redacted]

Section A7.1.3 **Adsorption/desorption screening test**
Annex Point IIA7.7

[redacted]

4.4 Calculations

4.3.1 Ka, Kd [redacted]

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

4.5 Degradation products [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods The test system is described in 3.5.1 (batch equilibrium procedure). The OECD guideline is fulfilled, no relevant deviations from the guideline occurred.

5.2 Results and discussion [redacted]

5.2.1	Adsorbed a.s. [%]	The percentage adsorption of test substance varied between 24 and 90% of the applied a.s. depending on soil type and concentration.
5.2.2	Ka	0.52 - 4.14 mg/g
5.2.3	Kd	0.62 - 4.58 mg/g
5.2.4	Ka_{oc}	84 - 345 mg/g (mean: 160 mg/g)
5.2.5	Ka/Kd	0.69 - 0.90 (mean: 0.84)

5.3 Conclusion Based on the classification of MCCALL ET AL. (1980), TI-435 is classified as being medium to highly mobile in the soils tested.

5.3.1 Reliability 1

5.3.2 Deficiencies None

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Materials and Methods [redacted]

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

[redacted]

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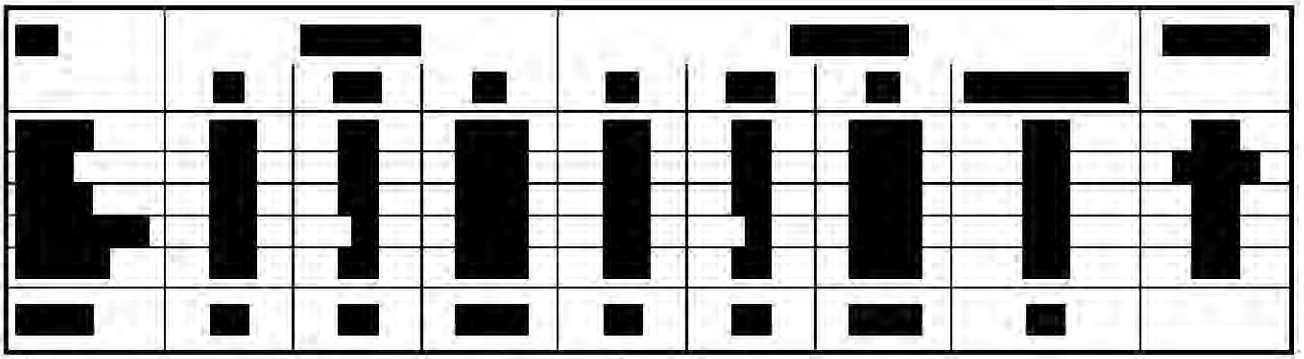
[redacted]

[redacted]



[redacted]

Section A7.2.1/02 and A7.2.2.1/02
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study

The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]2000c): [redacted]	x
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 (1995) and US EPA Subdivision N, 162-1	
2.2	**GLP**	Yes	
2.3	**Deviations**	No (to SETAC)	
		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	TS inhibitory to microorganisms	No	
3.2	**Reference substance**	[redacted]	
3.3	**Test system**		
3.3.1	Soils	The route and rate of degradation was investigated in 6 US soils (Crosby, Elder, Fuguay, Quincy, Sparta, Susan). [redacted]	

Section A7.2.1/02 and A7.2.2.1/02 **Annex Point IIIA XII 1.1**	**Aerobic degradation in soil, initial study** **The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

3.3.2	Test system sampling	All soils were taken freshly from US fields and shipped immediately to the test facility. Prior to the start of the test, they were stored for a few days in a refrigerator to maintain their biological activity.	
3.3.3	Test system preparation	[redacted]	
3.3.4	Test conditions	[redacted]	
3.3.5	Rate of application	13.3 µg a.s./100 g dry soil, [redacted]	
3.3.6	Preparation of test solution and application	[redacted]	
3.3.7	Control of moisture content	[redacted]	
3.3.8	Duration of test	181 days for all soils except Crosby for which an additional sampling was done after 379 days.	x
3.3.9	Sampling and extractions	[redacted]	x
3.3.10	Biomass determination	[redacted]	
3.3.11	Analytical methods	[redacted]	

Section A7.2.1/02 and A7.2.2.1/02
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study
The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

[redacted]

3.3.12 Intermediates/ degradation products

Identified

[redacted]

4 RESULTS

4.1 Recovery

[redacted]

4.2 Extracted and non-extracted radioactivity

[redacted]

4.3 Degradation of the test substance

[redacted]

4.4 Mineralisation

[redacted]

Section A7.2.1/02 and A7.2.2.1/02
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study
The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

4.5	**Metabolites and degradation products**	[redacted]
4.6	**Degradation rate**	For the degradation of TI-435 in soil DT_{50} values were calculated based on simple first order kinetics; the values should be treated carefully since they were extrapolated far beyond the experimental period: Crosby: 541 days Elder: 1328 days Fuguay: n.d. * Quincy: 549 days Sparta: 533 days Susan: 808 days * n.d. = a DT50 could not be calculated due to the varying residues (cf. Table A7_2_1_02-2).
4.7	**Degradation route**	The proposed degradation pathway of TI-435 in soil is presented in Figure A7_2_1_02-1.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Aerobic degradation and metabolism of TI-435 was investigated in six US soils according to SETAC (1995) and US EPA Subdivision N, 162-1. No deviations (to SETAC) occurred. The test substance was applied at a concentration of 13.3 µg a.s./100 g dry soil, equivalent to an annual application rate of approximately 300 g a.s./ha assuming 15cm soil depth and bulk density of 1.5. The soils were incubated in the dark at 20°C for 181 days, with the exception of soil Crosby that was incubated for 379 days.
5.2	**Results and discussion**	Total recoveries of applied radioactivity ranged between 87.1 and 105.0%. The amount of extracted radioactivity generally decreased with time due to the formation of bound residues and due to mineralisation. After 181 days, TI-435 represented between 63.6 and 95.3% of the applied radioactivity in the different soils, and decreased to 60.3% of applied radioactivity in soil Crosby by day 379. Two metabolites, i.e. TZNG and TZMU, were identified occurring at maximum amounts of 0.2 – 0.7% and 0.3 – 1.8% of applied radioactivity, respectively. DT_{50} values for the degradation of TI-435 in soil ranged between 533 and 1328 days. However, these values have to be treated very carefully since they were extrapolated far beyond the experimental period.
5.3	**Conclusion**	Validity criteria can be considered as fulfilled.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.2.1/02 and A7.2.2.1/02
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study

The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

	Evaluation by Competent Authorities Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2007-01-10
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	none

Section A7.2.1/02 and A7.2.2.1/02 **Annex Point IIIA XII 1.1**	**Aerobic degradation in soil, initial study** **The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

	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_1_02-1: Characteristic of the soils

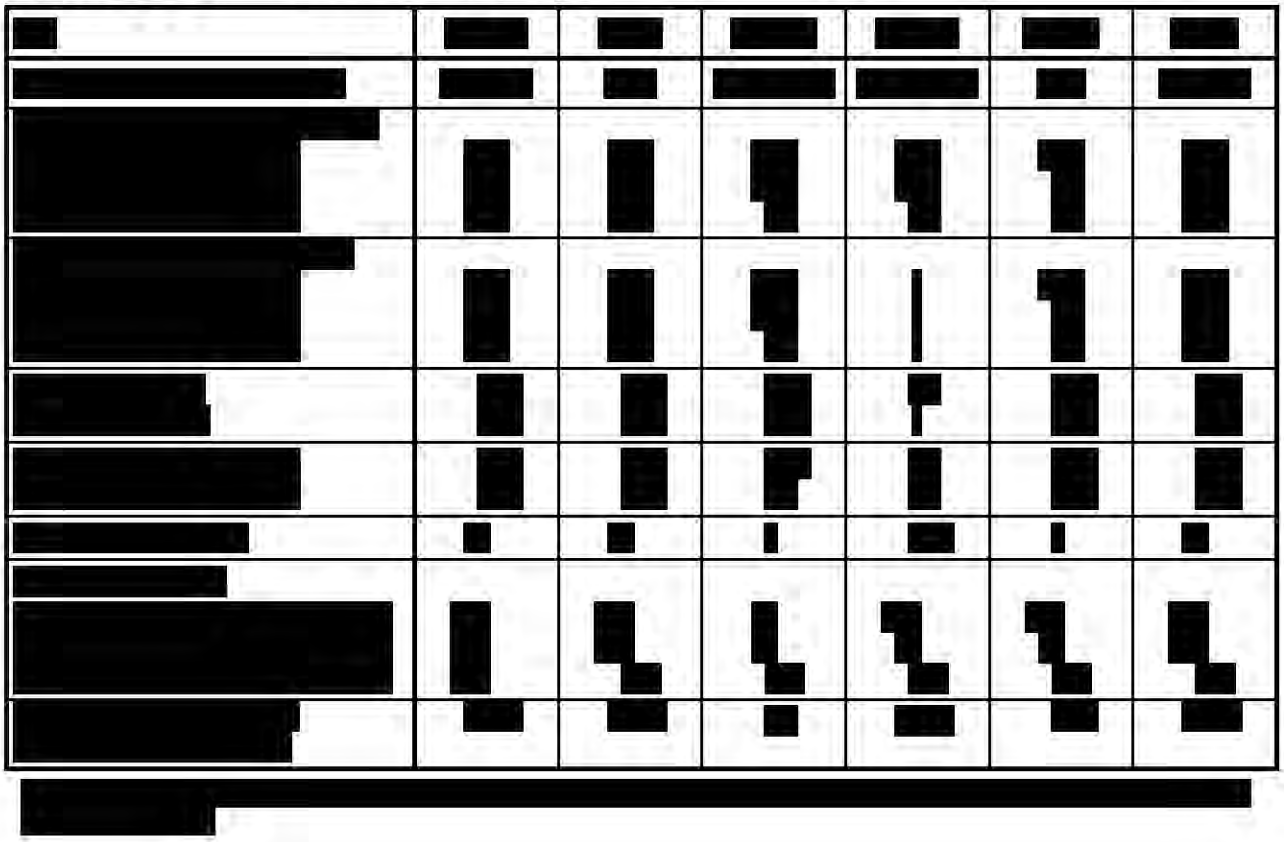


Table A7_2_1_02-2: **Recovery of radioactivity and distribution of the active substance and metabolites after application of [thiazolyl-2-^{14}C]TI-435 to six US soils and aerobic incubation at 20°C (values given in % of applied radioactivity)**

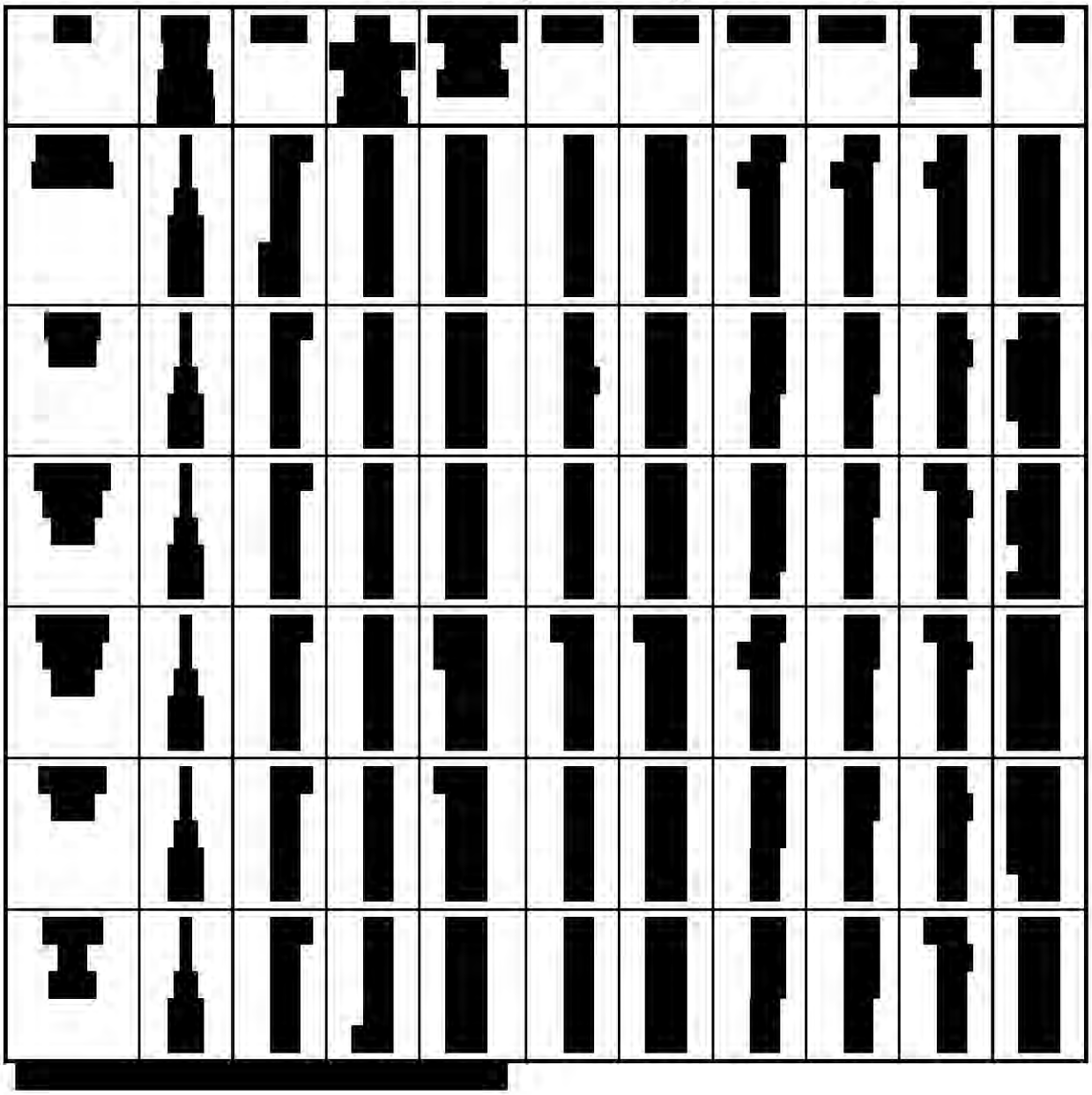


Figure A7_2_1-1: Proposed degradation pathway of TI-435 in six US soils

Section A7.2.1 and A7.2.2.1
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study

The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

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 SETAC (1995) and US EPA Subdivision N, 162-1
2.2	**GLP**	Yes
2.3	**Deviations**	No (to SETAC)

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	TS inhibitory to microorganisms	No

Section A7.2.1 and A7.2.2.1
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study

The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

3.2	**Reference substance**	[redacted]
3.3	**Test system**	
3.3.1	Soils	The route and rate of degradation was investigated in 3 European soils (Laacher Hof, Höfchen and BBA 2.2) and 1 US soil. For soil characteristics see Table A7_2_1-1.
3.3.2	Test system sampling	[redacted]
3.3.3	Test system preparation	[redacted]
3.3.4	Test conditions	[redacted]
3.3.5	Preparation of test solution and application	[redacted]
3.3.6	Rate of application	13.3 µg a.s./100 g dry soil, [redacted]
3.3.7	Duration of test	120 days (Laacher Hof and Höfchen) or 365 days (BBA 2.2 and Howe)

Section A7.2.1 and A7.2.1.1
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study

The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

3.3.8 Sampling and extractions

[redacted]

3.3.9 Biomass determination

[redacted]

3.3.10 Analytical methods

[redacted]

3.3.11 Intermediates/ degradation products

[redacted]

4 RESULTS

4.1 Recovery

[redacted]

4.2 Extracted and non-extracted radioactivity

[redacted]

4.3 Degradation of the test substance

[redacted]

Section A7.2.1 and A7.2.2.1
Annex Point IIIA XII 1.1

Aerobic degradation in soil, initial study
The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

4.4 Degradation rate

For the degradation of TI-435 in soil the following DT_{50} values were calculated based on simple first order kinetics (according to TIMME ET AL., 1986; recoveries on day 0 were set as 100%):

	DT_{50}	rate constant	R^2
Laacher Hof:	227 days	0.8654	0.0013
Höfchen:	143 days	0.9500	0.0021
BBA 2.2:	490 days	0.9549	0.0006
Howe:	1001 days	0.9342	0.0003

4.5 Mineralisation

After 120 days of incubation, 4.7 - 11.2% of the applied radioactivity were mineralised to $^{14}CO_2$ in the four soils tested. After one year of incubation of soils BBA 2.2 and Howe, 11.3% and 14.8% of the applied radioactivity were detected as $^{14}CO_2$, respectively. No other volatile products could be detected (<0.1% of applied radioactivity).

4.6 Metabolites and degradation products

[redacted]

For details see Table A7_2_1-2.

[redacted]

4.7 Degradation route

The proposed degradation pathway of TI-435 in soil is presented in Figure A7_2_1-1.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Aerobic degradation and metabolism of TI-435 was investigated in three German (silt loam, silt and loamy sand) and one US (sandy loam) soil according to SETAC (1995) and US EPA Subdivision N, 162-1. No deviations (to SETAC) occurred. The test substance was applied at a concentration of 13.3 µg a.s./100 g dry soil, equivalent to an annual rate of approximately 300 g a.s./ha. The soils were incubated in the dark at 20°C for either 120 (silt loam and silt) or 365 (loamy sand and sandy loam) days.

5.2 Results and discussion

[redacted]

DT_{50} values for the degradation of TI-435 in soil ranged between 143

Section A7.2.1 and A7.2.2.1 Annex Point IIIA XII 1.1	**Aerobic degradation in soil, initial study** **The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

		and 1001 days (first order).
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	2007-01-10
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	1
Acceptability	acceptable
Remarks	none
	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 A7.2.1 and A7.2.1.1 **Annex Point IIIA XII 1.1**	**Aerobic degradation in soil, initial study** **The rate and route of degradation including the identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**

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_1-1: Characteristic of the soils used in the present study

*

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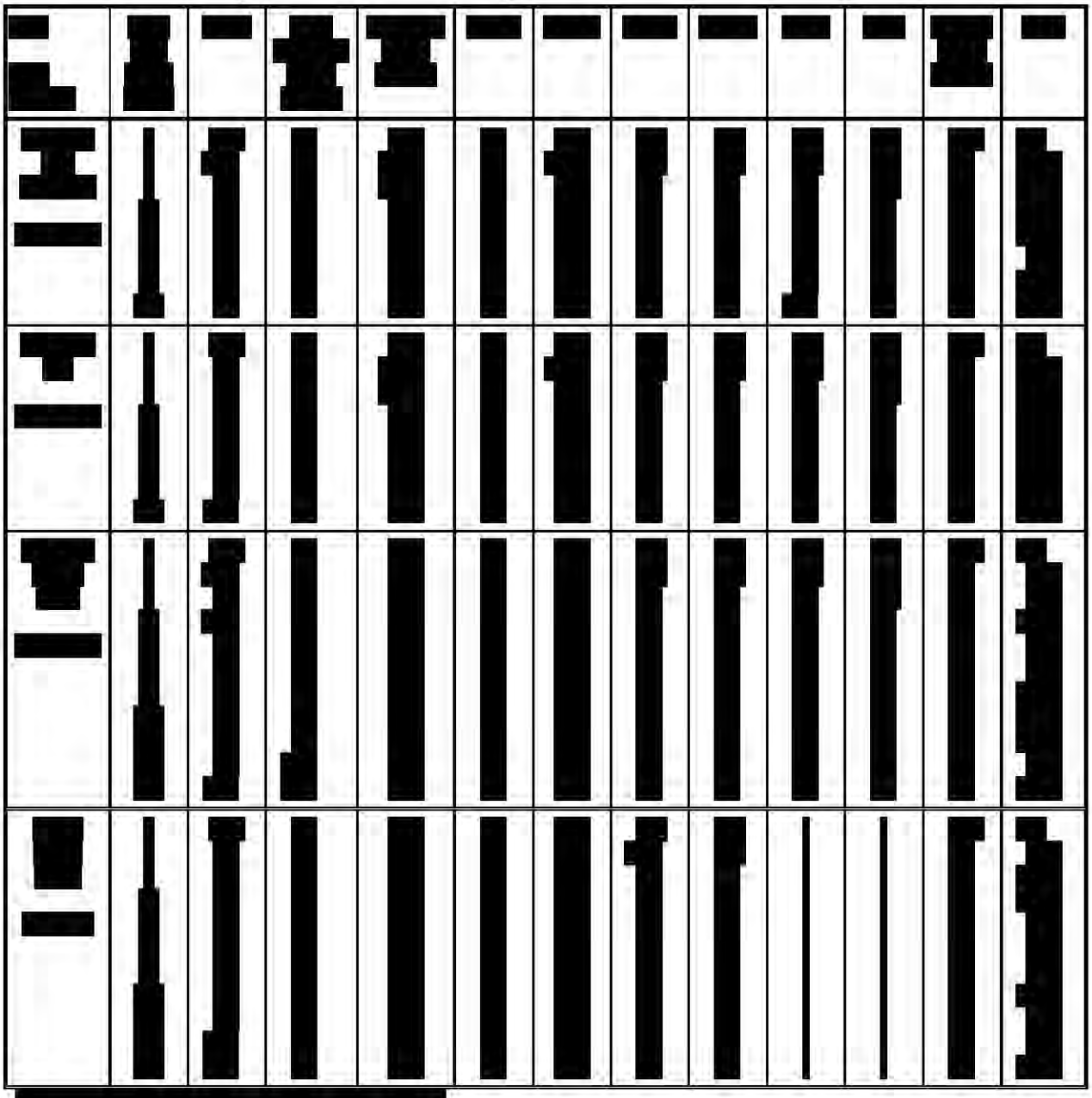


[redacted]

Section A7.2.2.2 Field soil dissipation and accumulation

Annex Point IIIA XII.1.1

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 SETAC (1995) and ECPA Guidance Document on Field Soil Dissipation Studies, D/97/NM/2047 (1997)
2.2	**GLP**	Yes
2.3	**Deviations**	Deviations (to SETAC): No crops were grown.

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Type of formulation	[redacted]
3.1.3	Content of a.s. (TI-435)	620.0 g/L
3.1.4	Further relevant properties	a.s. not inhibitory to microorganisms a.s. not volatile (vapour pressure: $1.3 \cdot 10^{-10}$ Pa)
3.1.5	Stability of the test substance	[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] d_3-MNG) were used to compensate for possible matrix effects in the

		MS/MS-detector.
3.3.1	Method of analysis for reference substance	As described in 3.1.6.
3.4	**Test system**	To determine the extent of dissipation of TI-435 (formulated as FS 600) in Northern European soils, four trials were settled in typical agricultural regions with different climates and soil types in Germany (Burscheid and Monheim), the UK (Bury St. Edmunds) and France (Guiseniers). They were conducted without vegetation.
3.5	**Soil types**	Soil characteristics of the field plots chosen for this study are summarised in Table A7_2_2_2-1.
3.6	**Testing procedure**	
3.6.1	Test substance application	A single spray application was made on bare soil in spring 1998 at a rate of equivalent 150 g a.s./ha with 300 L/ha water (plot sizes: 225 to 360 m^2).
3.7	**Sampling and work-up**	
3.7.1	Soil sampling	Samples were taken immediately after drying of the spray and at 11 intervals thereafter. The last samples were taken after about two years (725 to 750 days after application). From all trials, 20 treated and at least 10 control samples were taken (cores of 5 cm in diameter). The sampling spots were distributed statistically over the plots to get representative samples. Samples were deep frozen (≤ -18°C) until analysis.
3.7.2	Sample work-up	[redacted]

4 RESULTS

4.1	**Controls**	[redacted]
4.2	**Total residues**	[redacted]
4.3	**Residues of TI-435**	[redacted]
4.4	**Residues of MNG**	[redacted]
4.5	**Residues of TZNG**	[redacted]
4.6	**Degradation of**	[redacted]

	total residues in soil	
4.7	**Degradation of TI-435 in soil**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The field soil dissipation and accumulation of TI-435 was studied according to SETAC (1995) and ECPA Guidance Document on Field Soil Dissipation Studies, D/97/NM/2047 (1997). Deviating from SETAC, no crops were grown.
5.2	**Results and discussion**	After 24 months of test duration, a mean of 19% of the applied amount based on total residues was recovered from the soil. Total residues were recovered with half-life periods of 19 to 362 days, with a mean value of 135 days. After 24 months of tests duration, a mean of 19% of the applied amount based on the active substance was recovered from the soil. The active substance TI-435 was degraded with half-life periods of 16 to 258 days, with a mean value of 103 days. Translocation of TI-435 into deeper soil layers than 10-20 cm can be excluded down to a concentration of 2 µg/kg corresponding to less than 2% of the initial concentration of the active substance. Translocation of MNG and TZNG into deeper soil layers than 0-10 cm was not observed. The only exception was the UK trial (day 479), where residues of TZNG could be found above the LOQ (6.1 µg/kg) in the 0-10 cm layer. No translocation into soil layers below 20 cm was observed.
5.3	**Conclusion**	TI-435 is persistent in soil.
5.3.1	Reliability	1
5.3.2	Deficiencies	None

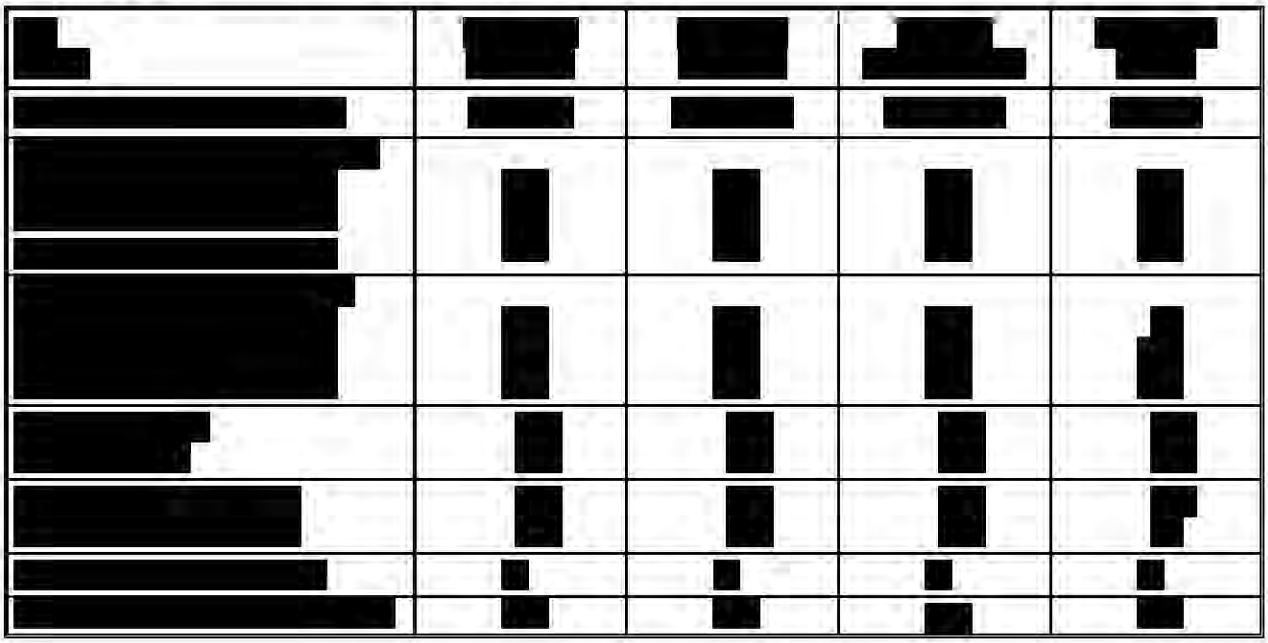
Section A7.2.2.2 Field soil dissipation and accumulation
Annex Point IIIA XII.1.1

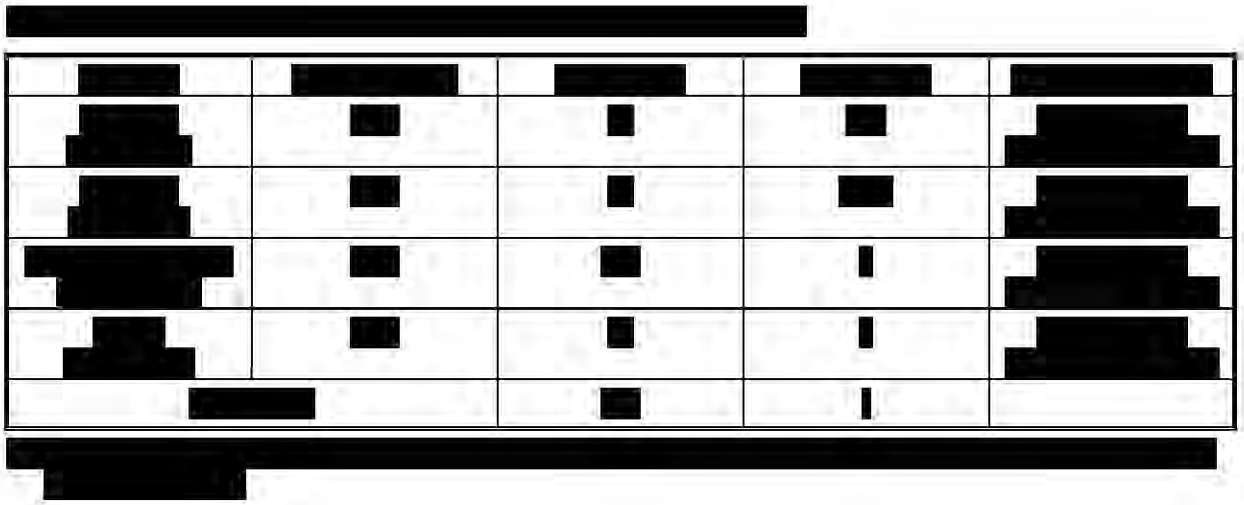
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE (*)
Date	2007-01-10
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

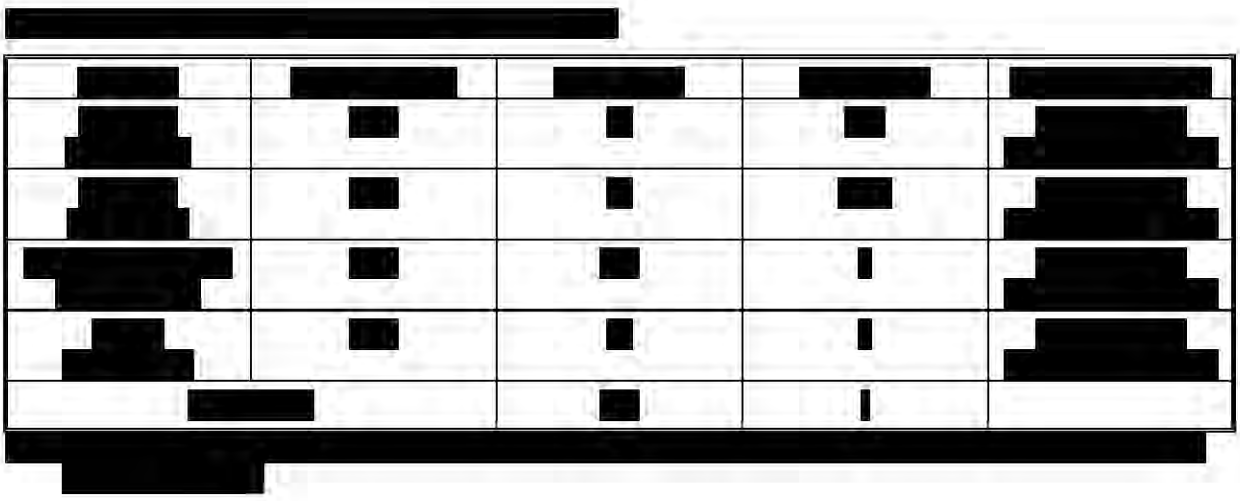
Section A7.2.2.2 Field soil dissipation and accumulation
Annex Point IIIA XII.1.1

Remarks	[redacted]
	COMMENTS FROM ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A7_2_2_2-1: Soil characteristics (0-30 cm layer)







tion A7.2.2.4 **Other soil degradation studies**
Annex Point AIII XII.1.4 **The rate and route of degradation of a metabolite**

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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 SETAC (1995)
2.2	**GLP**	Yes
2.3	**Deviations**	None (to SETAC)

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	Radiochemical purity	[redacted]
3.1.5	TS inhibitory to microorganisms	[redacted]
3.2	**Reference substance**	[redacted]
3.3	**Test system**	
3.3.1	Soils	[redacted]
3.3.2	Test system sampling	[redacted]
3.3.3	Test system preparation	[redacted]
3.3.4	Test conditions	Incubation system: 300 mL Erlenmeyer flasks closed with a trapping [redacted]

tion A7.2.2.4 **Other soil degradation studies**

Annex Point AIII XII.1.4 **The rate and route of degradation of a metabolite**

		[redacted]
3.3.5	Rate of application	9.5 µg/100 g dry soil
3.3.6	Preparation of test solution and application	[redacted]
3.3.7	Control of moisture content	The test vessels were weighed monthly. A loss of soil moisture was balanced by the addition of appropriate amounts of distilled water.
3.3.8	Duration of test	126 days
3.3.9	Sampling and extractions	[redacted]
3.3.10	Biomass determination	[redacted]
3.3.11	Analytical methods	[redacted]
3.3.12	Degradation products	Not identified.

x

tion A7.2.2.4 **Other soil degradation studies**
Annex Point AIII XII.1.4 **The rate and route of degradation of a metabolite**

4 RESULTS

4.1 Recovery

[redacted]

4.2 Extracted and non-extracted radioactivity

[redacted]

4.3 Degradation of the test substance

[redacted]

4.4 Mineralisation

[redacted]

4.5 Metabolites and degradation products

[redacted]

4.6 Degradation rate

For the degradation of MNG in soil the following DT_{50} values were calculated based on simple first order kinetics:

Laacher Hof AXXa: 86.4 days
Laacher Hof AIII: 108.0 days
Höfchen: 82.4 days

4.7 Route of degradation

Not applicable since identification of degradation products was not done.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Aerobic degradation of MNG was investigated in three German soils (sandy loam, silt loam and silt) according to SETAC (1995). No deviations to SETAC occurred. The test substance was applied on top of the soil at a concentration of 9.52 µg/100 g dry soil. The soils were incubated in the dark at 20°C for 120 days.

tion A7.2.2.4 **Other soil degradation studies**

Annex Point AIII XII.1.4 **The rate and route of degradation of a metabolite**

5.2	**Results and discussion**	Total recoveries of applied radioactivity ranged between 90.18 and 97.67%. The amount of extractable radioactivity decreased with time due to both the increase in the amount of bound residues (between 11.01 and 16.27% of applied radioactivity) and due to mineralisation (between 5.39 and 16.60% of applied radioactivity). After 120 days, MNG represented 40.60, 43.53 and 34.60% of the applied radioactivity in the sandy loam, the silt loam and the silt soil, respectively. DT_{50} values for the degradation of MNG in soil were calculated according to simple first-order model and were 86.4, 108.0 and 82.4 days for the sandy loam, the silt loam and the silt soil, respectively.
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]
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*

tion A7.2.2.4	**Other soil degradation studies**
Annex Point AIII XII.1.4	**The rate and route of degradation of a metabolite**

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	

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[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_2_2_4/01-2: Recovery and distribution of radioactivity after application of [^{14}C]MNG to three different soils and aerobic incubation at 20°C (values given in % of applied radioactivity)

Soil	Days after application	$^{14}CO_2$	Total extractable	Extracts			MNG	Not identified	Not extractable	Total
				ACN	$CaCl_2$	Soxhlet				
Laacher Hof AXXa (sandy loam)	0	n.m.	96.74	87.70	5.90	3.14	93.60	0.00	0.32	97.06
	1	0.74	94.60	81.56	6.74	6.30	90.93	3.67	1.88	97.22
	7	1.45	92.41	65.17	7.21	20.03	76.49	15.92	2.04	95.90
	14	1.57	91.56	58.11	8.86	24.59	66.03	25.53	3.44	96.57
	33	3.04	87.79	43.44	7.19	37.16	55.45	32.35	5.66	96.49
	61	4.10	82.50	38.06	6.41	38.03	48.20	34.30	8.45	95.05
	90	5.48	78.34	29.83	7.55	40.96	43.64	30.96	12.98	95.80
	120	5.39	80.14	27.40	5.03	47.71	40.60	39.55	11.01	96.54
Laacher Hof AIII (silt loam)	0	n.m.	97.12	89.00	5.39	2.73	94.38	0.00	0.48	97.60
	1	0.42	92.68	82.15	6.26	4.27	84.06	4.35	1.66	94.76
	7	1.20	92.62	72.27	6.18	14.17	82.69	9.93	2.20	96.02
	14	1.70	92.00	65.74	7.61	18.65	77.49	14.52	3.44	95.14
	33	3.40	87.54	54.16	5.82	27.56	65.34	22.35	6.72	97.66
	61	5.89	76.19	43.41	5.72	27.06	56.37	19.81	12.98	95.06
	90	5.31	71.25	34.75	6.28	30.22	50.33	20.91	13.62	90.18
	120	11.75	66.24	30.83	4.32	31.09	43.53	18.41	16.27	94.26
Höfchen (silt)	0	n.m.	96.74	90.67	4.35	1.72	89.30	1.37	0.93	97.67
	1	0.55	95.78	86.77	4.78	4.23	82.35	4.43	0.53	96.86
	7	1.39	92.13	77.73	4.90	9.50	76.62	10.62	1.91	95.43
	14	2.13	91.97	72.09	5.99	13.89	75.34	16.64	2.61	96.71
	33	4.80	87.01	60.08	5.19	21.74	64.45	22.56	5.66	97.47
	61	8.37	78.70	50.01	4.83	23.86	45.31	28.56	7.99	95.06
	90	12.60	71.81	40.79	4.99	26.03	40.22	26.60	9.78	94.19
	120	16.60	63.13	35.81	3.77	23.55	34.60	24.76	14.94	94.67

ACN = acetonitrile; n.m. = not measured

Section A7.2.3.1/01 Annex Point IIIA XII.1.2 Adsorption and desorption of metabolites and degradation products

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	1 REFERENCE	
1.1	**Reference**	[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]

Section A7.2.3.1/01 Adsorption and desorption of metabolites and degradation products
Annex Point IIIA XII.1.2

3.4 Soil types See Table A7_2_3_1_01-1

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 According to "OECD-HPLC-method": No

3.6.5 Other test None

4 RESULTS

4.1 Preliminary test [redacted]

4.2 Screening test: Adsorption [redacted]

4.3 Screening test: Desorption [redacted]

4.4	**Material balance**	[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]MNG 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 5.2 and 34.3 and the Kd_{oc}–values between 13.0 and 44.0. Due to the low adsorption on soils Quincy and BBA 2.1, no reliable data could be calculated for desorption. There was a good correlation between the concentrations adsorbed and in solution for the concentration range tested (r = 0.97-0.99). Only for the soil BBA 2.1, the correlation coefficient was lower (r = 0.89).
5.2.1	Adsorbed amount [%]	The percentage adsorption of test substance varied between 0.6 and 32.7% of the applied amount depending on soil type and concentration.
5.2.2	Ka	0.02 -0.37 mg/g
5.2.3	Kd	0.15 -0.48 mg/g (soils Elder, Crosby and Laacher Hof)
5.2.4	Ka_{oc}	5.2 -34.3 mg/g (mean: 20.5 mg/g) x
5.2.5	Ka/Kd	0.77 (soil Elder), 1.27 (soil Crosby), 0.72 (soil Laacher Hof)
5.3	**Conclusion**	Based on the classification of McCall et al. (1980), MNG is classified as being very highly mobile in soil.
5.3.1	Reliability	1
5.3.2	Deficiencies	No