

Section A7.1.1.1 Hydrolysis as a function of pH and identification of breakdown products
Annex Point IIA7.6.2.1

		[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
3.4.7	Analytical methods	[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
		[REDACTED]
3.5	Preliminary test	[REDACTED]

4 RESULTS

4.1	Concentration and hydrolysis values	See table A7_1_1_1_1-2
4.2	Hydrolysis rate constant (k_h)	See table A7_1_1_1_1-2
4.3	Dissipation time	See table A7_1_1_1_1-2
4.4	Concentration – time data	[REDACTED]
		[REDACTED]
4.5	Specification of the transformation products	[REDACTED]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	[REDACTED]
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Section A7.1.1.1.1 Hydrolysis as a function of pH and identification of breakdown products
Annex Point IIA7.6.2.1

- 5.2 Results and discussion** The half-lives and hydrolysis rate constants of tolylfluanid for pH range of 4 through 9 at the different temperatures are given in table A7_1_1_1_1-2.
- The test substance is degradable according to Directive 92/69/EC at pH range of 4 - 9. Tolyfluanid hydrolysed rapidly in neutral and alkaline conditions. The hydrolysis was also dependent on temperature: it was fastest at high temperatures.
- 5.2.1 k_h [REDACTED]
- 5.2.2 DT_{50} See table A7_1_1_1_1-2
- 5.2.3 r^2 See table A7_1_1_1_1-2
- 5.3 Conclusion** Validity criteria can be considered as fulfilled.
- 5.3.1 Reliability [REDACTED]
- 5.3.2 Deficiencies [REDACTED]

Evaluation by Competent Authorities	
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EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>

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

Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	



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



Table A7_1_1_1_1-2: Half lives and hydrolysis rate constants of tolyfluanid

Guideline/ Test method	pH	Temperature [°C]	Reaction rate constant, K_h [1/s]	Half-life, DT_{50} [h]	DT_{90} [h]	Coefficient of correlation, r^2
OECD, 111, Directive 92/69/EC, C.7	4	10	4.84×10^{-8}	3980 h	13225 h	0.997
	4	20	2.10×10^{-7}	916 h	3042 h	0.997
	4	25	3.93×10^{-7}	490 h	1628.2 h	0.998
	5	10	5.85×10^{-8}	3293 h	10942 h	0.996
	5	20	2.39×10^{-7}	807 h	2681 h	0.998
	5	25	4.91×10^{-7}	392 h	1302 h	0.999
	6	10	1.38×10^{-7}	1394 h	4632 h	0.999
	6	20	6.39×10^{-7}	302 h	1002 h	0.998
	6	25	1.21×10^{-6}	159 h	529 h	0.999
	7	10	1.20×10^{-6}	161 h	535 h	0.999
	7	20	4.81×10^{-6}	40.0 h	133 h	0.999
	7	25	9.41×10^{-6}	20.5 h	68 h	0.999
	8	10	1.13×10^{-5}	17.0 h	56.4 h	0.999
	8	20	4.52×10^{-5}	4.3 h	14.1 h	0.999
	8	25	7.96×10^{-5}	2.4 h	8.0 h	0.999
	8.2*	10	3.26×10^{-5}	5.9 h	19.6 h	0.996
	8.2*	20	9.70×10^{-5}	2.0 h	6.6 h	0.993
	8.2*	25	1.67×10^{-4}	1.2 h	3.8 h	0.998
9	10	1.24×10^{-4}	1.6 h	5.1 h	0.999	
9	20	3.94×10^{-4}	0.49 h	1.6 h	0.999	
9	25	6.77×10^{-4}	0.29 h	0.95 h	0.999	

* the only solution prepared with artificial seawater

[REDACTED]

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

Section A7.1.1.1.2 Phototransformation in water including identity of transformation products
Annex Point IIA7.6.2.2

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		1 REFERENCE
1.1	Reference	Hellpointner, E. (1992): Assessment of the environmental half-life of the direct photodegradation of Tolyfluanid in water. Bayer AG, Report No. PF-3661, 1992-02-03. [Redacted]
1.2	Data protection	[Redacted]
1.2.1	Data owner	[Redacted]
1.2.2	Companies with letter of access	[Redacted]
1.2.3	Criteria for data protection	[Redacted]

		2 GUIDELINES AND QUALITY ASSURANCE
2.1	Guideline study	[Redacted] UBA-guidelines (Phototransformation of Chemicals in Water, Part A, 1990)
2.2	GLP	[Redacted]
2.3	Deviations	None

		3 MATERIALS AND METHODS
		[Redacted]

		4 RESULTS
		The UV-VIS absorption spectrum of tolyfluanid in acetonitrile/water showed a typical maximum at 192-198 nm and further a typical shoulder of absorption at 220-222 nm. There was no absorption above 280 nm.
		As the UV absorption data showed that in aqueous solution tolyfluanid did not absorb any light at wavelengths above 290 nm, the molar extinction coefficient was calculated to be <10. [Redacted]
		[Redacted]

Section A7.1.1.1.2 Phototransformation in water including identity of transformation products
Annex Point II A7.6.2.2

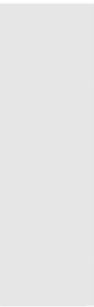
5 CONCLUSION

5.1 Conclusion

[REDACTED]

5.1.1 Reliability

[REDACTED]



Section 7.1.1.1.2 Phototransformation in Water including identity of the products of transformation
Annex Point IIA 7.6.2.2

JUSTIFICATION FOR NON-SUBMISSION OF DATA

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Other existing data Technically not feasible Scientifically unjustified
 Limited exposure [...] Other justification

Detailed justification:

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

Undertaking of intended data submission

Section 7.1.1.1.2	Phototransformation in Water including identity of the products of transformation
Annex Point IIA 7.6.2.2	
Evaluation by Competent Authorities	
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Evaluation of applicant's justification	██
Conclusion	██
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
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Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.1.1.2.1 Biodegradability (ready)

**Annex Point IIA
VII.7.6.1.1**

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		1 REFERENCE
1.1	Reference	<p>Yoshida, K. (1992): Ready biodegradability test of Preventol A 5. Mitsubishi-kasei Institute of Toxicological and Environmental Sciences, MITES, Japan, Report No. 1B504G, 1992-06-15.</p> <p>Additional statement: Schoefer, S. (2002): Statement on the validity of the study "Yoshida, K. (1992): Ready biodegradability test of Preventol A-5, Bayer report No. 1B5046". Bayer AG, Report No. MR-450/02, 2002-10-31.</p> <p>[REDACTED]</p>
1.2	Data protection	[REDACTED]
1.2.1	Data owner	[REDACTED]
1.2.2	Companies with letter of access	[REDACTED]
1.2.3	Criteria for data protection	[REDACTED]

		2 GUIDELINES AND QUALITY ASSURANCE
2.1	Guideline study	<p>[REDACTED]</p> <p>OECD guideline 301C (Modified MITI Test)</p>
2.2	GLP	Yes
2.3	Deviations	None

		3 MATERIALS AND METHODS
		<p>The ready biodegradability of tolyfluanid was investigated in a modified MITI test.</p> <p>[REDACTED]</p> <p>[REDACTED]</p>

		4 RESULTS
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Section A7.1.1.2.1 Biodegradability (ready)

Annex Point II A
VII.7.6.1.1

The results of the measurements at day 28 are presented in Table
A7.1.1.2.1-1.

The table content is completely redacted with black boxes.

A new peak was found on HPLC chromatograms, which was considered to be a transformation product of the test substance.

5 CONCLUSION

5.1 Conclusion

The table content is completely redacted with black boxes.

5.1.1 Reliability

2

Evaluation by Competent Authorities

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EVALUATION BY RAPPORTEUR MEMBER STATE FI

Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]

COMMENTS FROM ...

Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Table A7_1_1_2_1-1: The measured values and calculated degradability results in the ready biodegradability test (day 28).

Parameter	Measured value				Theoretical value	Degradability/ disappearance rate (%)		
	Bottle 3	Bottle 4	Bottle 5	Bottle 6		Bottle 3	Bottle 4	Bottle 5
BOD (mg)	3.6*	3.9*	-5.7*	3.5	44.9	8	9	-13
DOC (mg/L)	15.9*	20.7*	17.6*	6.9	34.6	n.c.	n.c.	n.c.
Test substance (mg/L)	59.1	46.2	53.0	85.1	100.0	n.c./41**	n.c./54**	n.c./47**

* = value corrected with BOD or DOC value of bottle 2

** = calculated by following equation:

Rate = (theoretical value – residual concentration)/theoretical value x 100

n.c. = not calculated

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII.2.1

Official
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1 REFERENCE

- 1.1 Reference
 - Scholz, K. (1987): Degradation of Tolyfluanid in the Water-Sediment System. Bayer AG, Report No. PF-2783, 1987-04-24.
 - Calculations:
 - Krauskopf, B. (1995): Calculation of DT50- and DT90-values of DMST in two water/sediment-systems. Bayer AG, Report No. M9194, 1995-08-09.
 - Schad, T. (2002): Calculation of DT50 of tolylfluanid-dimethylsulfo-toluidide (DMST) generated in aerobic water-sediment systems. Bayer AG, Report No. MR-467/02, 2002-11-29.
- 1.2 Data protection
 - 1.2.1 Data owner
 - 1.2.2 Companies with letter of access
 - 1.2.3 Criteria for data protection

2 GUIDELINES AND QUALITY ASSURANCE

- 2.1 Guideline study
 - The test guideline was not reported.
- 2.2 GLP
 - No
- 2.3 Deviations
 -

3 MATERIALS AND METHODS

[Phenyl-UL-¹⁴C]tolylfluanid (purity %) was applied to two different water/sediment systems

[REDACTED]

Section A7.1.2.2.2**Water/sediment degradation study****Annex Point IIIA XII.2.1****4 RESULTS**

[REDACTED]

[REDACTED]

[REDACTED] Tolyfluanid dissipated rapidly in both water/sediment systems IJzendoorn and Lienden so that already at the first sampling date on day 14 it was no longer detectable. Therefore on the basis of this study no half-life for tolyfluanid could be calculated. The main metabolite was DMST (II) which reached levels of > 90 % of the applied radioactivity (day 14), most of it being found in the water phase. DMST was further degraded via the demethylated compound methylaminosulfotoluidide (IX), and was finally mineralized to $^{14}\text{CO}_2$. Methylaminosulfotoluidide (IX) never reached concentrations above 10 % (max. 7.6 %), $^{14}\text{CO}_2$ was formed from 14.5 % to 28.0 % of the applied radioactivity after 120 days.

For the degradation of DMST half-lives were calculated [REDACTED]

[REDACTED] In the water/sediment systems IJzendoorn and Lienden DMST degraded during the course of the experiment with half-lives of 42.1 and 75.8 days in the supernatant water (Table A7_1_2_2_2-4).

Additionally first order DT_{50} values of DMST were calculated (Schad, 2002a) for the dissipation of the metabolite from the sediment phase as well as from the total water-sediment systems. [REDACTED]

[REDACTED]

The results obtained in calculations are presented in Table A7_1_2_2_2-5.

5 CONCLUSION**5.1 Conclusion**

[REDACTED]

Section A7.1.2.2.2 Water/sediment degradation study

Annex Point IIIA XII2.1



5.1.1 Reliability

[REDACTED]

[REDACTED]	[REDACTED]			[REDACTED]	[REDACTED]	[REDACTED]
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Table A7_1_2_2_2-4 Calculated DT_{50} -values and DT_{90} -values of DMST for the supernatant water of the water/sediment system.

System	DT_{50}	DT_{90}	Order	r^2
Lienden	42.1 days	139.9 days	1 st	0.9761
IJzendoorn	75.8 days	not evaluable	1 st	0.9587

Table A7_1_2_2_2-5 Calculated first order DT_{50} -values of DMST in sediment phase and total water-sediment system.

System	Sediment phase			Total water-sediment system		
	DT_{50} (days)	Dissipation rate (days ⁻¹)	r^2	DT_{50} (days)	Dissipation rate (days ⁻¹)	r^2
Lienden	33.9	0.02047	0.984	43.6	0.01588	0.993
IJzendoorn	76.5	0.00906	0.934	81.1	0.00855	0.977

Section A7.1.2.2.2 Water/sediment degradation study (3)**Annex Point IIIA XII2.1**Official
use only**1 REFERENCE****1.1 Reference**

Scholz, K. (1997): Aerobic degradation of tolylfluanid in water-sediment. Bayer AG, Report No. PF4282, 1997-09-04.

Additional Calculations:

Schad, T. (2001d): Calculation of half-lives of tolylfluanid and its metabolite DMST generated by aerobic water-sediment systems. Bayer AG, Report No. MR-517/00, 2001-03-07.

1.2 Data protection**1.2.1 Data owner****1.2.2 Companies with letter of access****1.2.3 Criteria for data protection****2 GUIDELINES AND QUALITY ASSURANCE****2.1 Guideline study**

BBA-Guidelines for Testing of Plant Protectants in the Registration Process. Part IV, 5-1, Degradability and Fate of Plant Protectants in the Water/Sediment System, 1990

2.2 GLP**2.3 Deviations**

Additional experiments with surface water only

3 MATERIALS AND METHODS

The experiments were carried out with aquatic model ecosystems consisting of sediment and water samples originating from two different ponds (Hönniger-Weiher, Germany and Angler-Weiher, Germany)

Section A7.1.2.2.2 Water/sediment degradation study (3)**Annex Point IIIA XII2.1****4 RESULTS**

[REDACTED] The half-lives of tolyfluanid in water/sediment systems are summarized in Table A7_1_2_2_2-4 and the half-lives obtained in additional calculations are presented in Table A7_1_2_2_2-5.

After an incubation time of 7 days no tolyfluanid was detectable in any system. The parent dissipated rapidly with half-lives of 1.4 - 6 hours. As quickly as tolyfluanid dissipated from the system, the metabolite DMST was formed. Other metabolites occurred in negligible quantities only, max. 2.8 % of the applied radioactivity was attributed to max. 5 unknown metabolites.

Concerning the distribution between water and sediment (experiment II), only small amounts of tolyfluanid reached the sediment. On the other hand the metabolite DMST was distributed evenly between sediment and water. At the last sampling date (7 days) DMST was found at about 40 % of the applied radioactivity in the supernatant water and at about 47 % in the sediment in both systems. The DT_{50} values of DMST in the water were calculated to be 20.6 - 21.7 days and in the sediment more than one year. The amount of bound residues was 2.6 - 3 % of the applied radioactivity and the rate of mineralization was 0.4 % at day 7 after application.

Section A7.1.2.2.2 Water/sediment degradation study (3)

Annex Point IIIA XII2.1

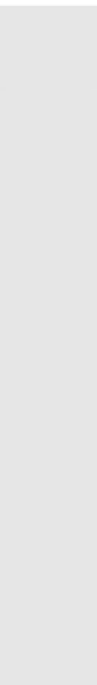
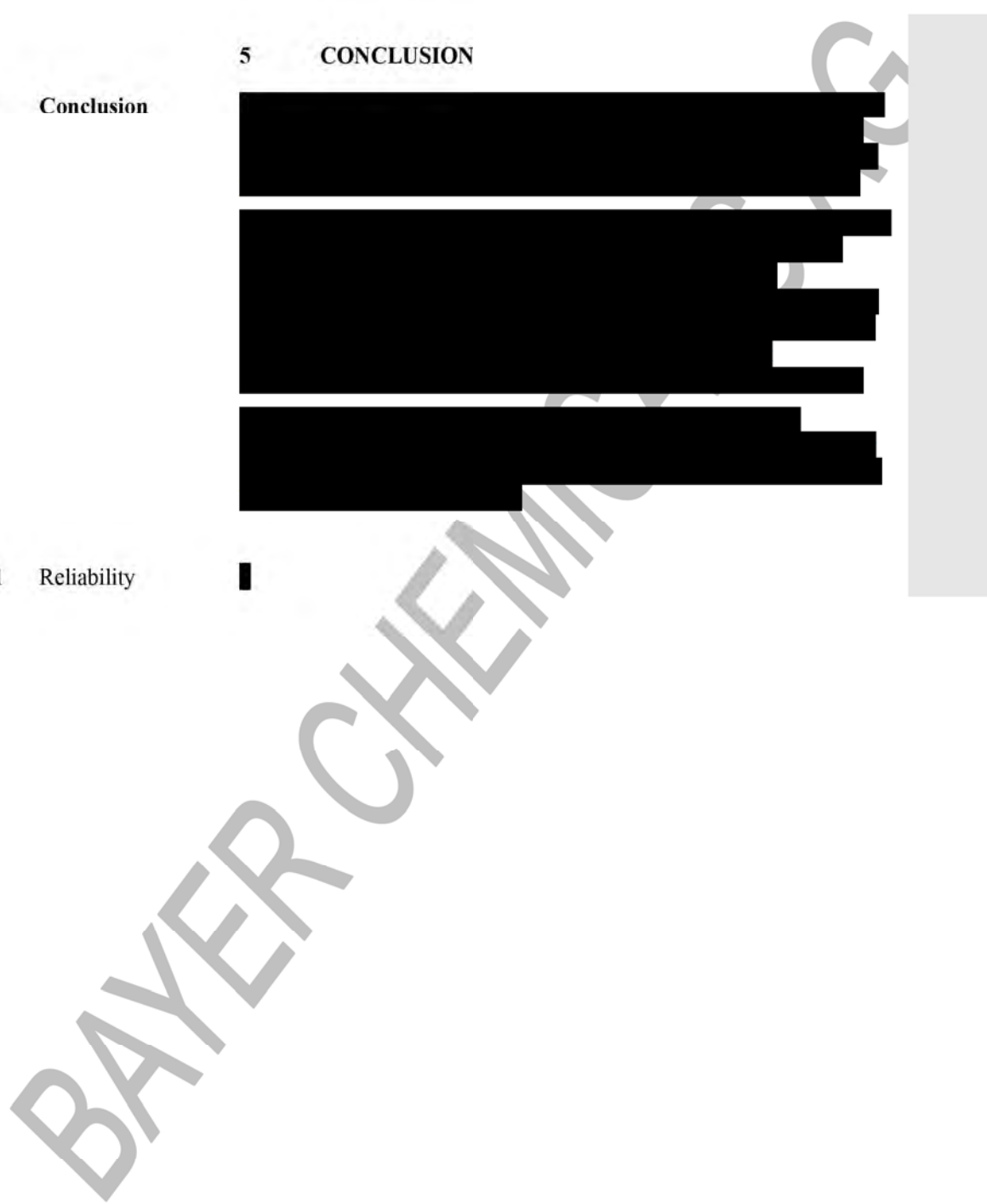
5 CONCLUSION

5.1 Conclusion

[REDACTED]

5.1.1 Reliability

[REDACTED]



Evaluation by Competent Authorities	
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Date	[REDACTED]
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Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
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COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

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[REDACTED]
[REDACTED]
[REDACTED]

BAYER CHEMICALS AG

[REDACTED]

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

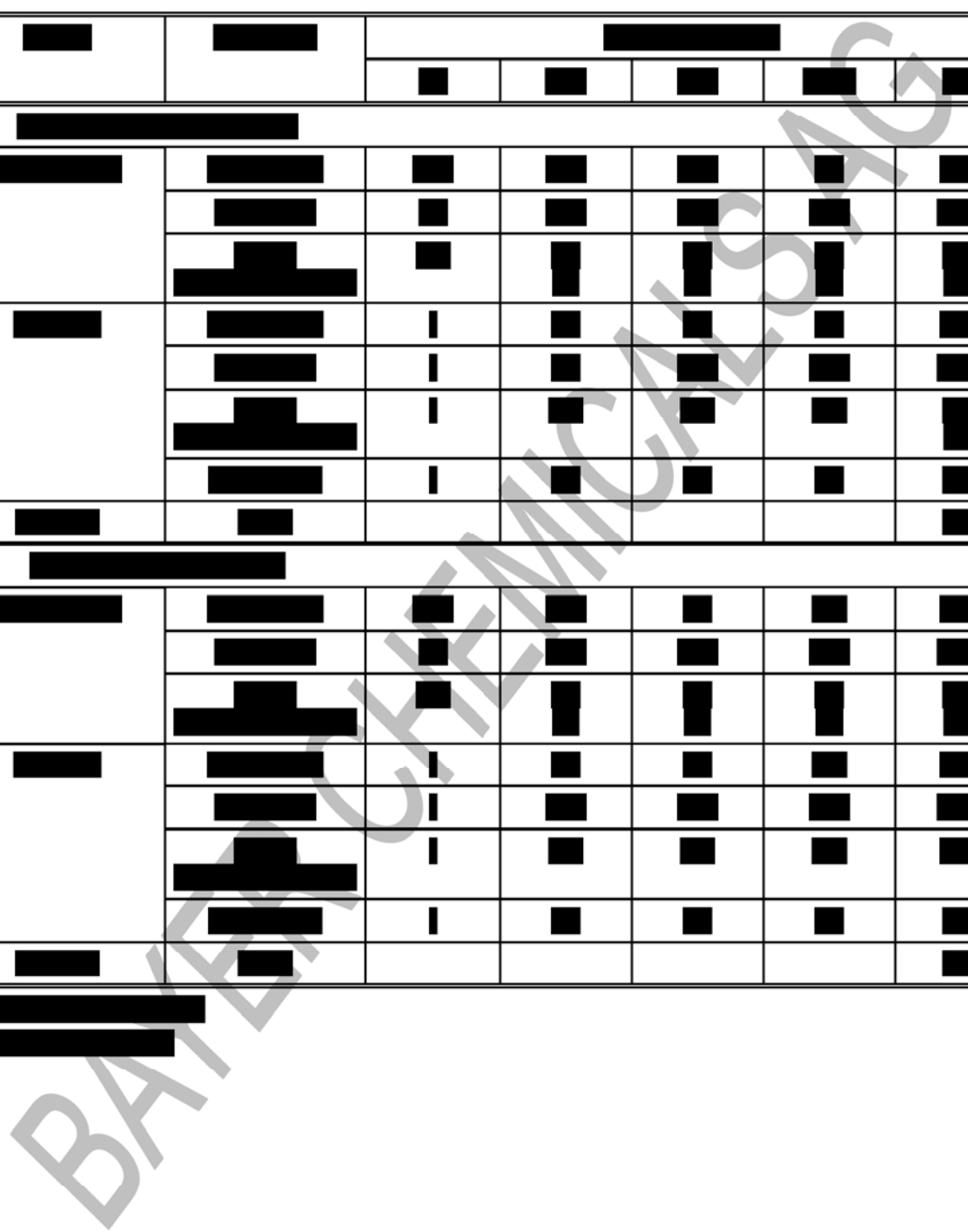


Table A7_1_2_2_2-4 Calculated first order dissipation DT_{50} - and DT_{90} -values of tolyfluanid for the surface water only, the supernatant water of a water/sediment system and the entire water/sediment systems (Scholz, 1997).

System	Compartment	DT_{50} (hours)	DT_{90} (hours)
Hönniger-Weiher	Surface water only (experiment I)	4.1	13.8
	Supernatant water of water/sediment system (experiment II)	4.0	13.2
	Water/sediment system (experiment II)	5.0	16.8
Angler-Weiher	Surface water only (experiment I)	2.2	7.1
	Supernatant water of water/sediment system (experiment II)	1.4	4.7
	Water/sediment system (experiment II)	1.5	5.1

Table A7_1_2_2_2-5 Calculated first order DT_{50} -values of tolyfluanid and DMST for the supernatant water and for the sediment phase (Schad, 2001d).

System	Compartment	DT_{50}		r^2
		Tolyfluanid	DMST	
Hönniger-Weiher	Supernatant water (experiment II)	0.25 days (6.0 hours)	20.6 days	0.992
	Sediment (experiment II)	0.20 days (4.8 hours)	>365 days	
Angler-Weiher	Supernatant water (experiment II)	0.15 days (3.6 hours)	21.7 days	0.994
	Sediment (experiment II)	0.11 days (2.6 hours)	>365 days	

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA.7.7

Official
use only

1 REFERENCE
1.1 Reference Sommer, H. (2000): Estimation of the adsorption coefficient (Koc) of Tolyfluanid on soil using High Performance Liquid Chromatography (HPLC). Bayer AG, Report No. MR-428/00, 2000-12-06.

[Redacted]

1.2 Data protection

[Redacted]

1.2.1 Data owner

[Redacted]

1.2.2 Companies with letter of access

[Redacted]

1.2.3 Criteria for data protection

[Redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

[Redacted]

OECD Guideline 121 (Draft document, 1999)

2.2 GLP

Yes

2.3 Deviations

None

3 MATERIALS AND METHODS

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

Section A7.1.3**Adsorption / Desorption screening test****Annex Point IIA.7.7**

[REDACTED]

4 RESULTS

The mean log k' values and the literature K_{oc} values for the reference substances are presented in Table A7_1_3-1. Linear regression of the measured k' values against the literature K_{oc} values yielded a line with slope of 3.01, an intercept of 2.05 and a correlation coefficient r^2 of 0.8999. The mean log k' value measured for tolylfluanid was 0.4318 and the mean estimated K_{oc} value was 2220 (presented in Table A7_1_3-1).

5 CONCLUSION**5.1 Conclusion**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5.1.1 Reliability

[REDACTED]

Table A7_1_3-1 The mean log k' and K_{oc} values for the reference substances and tolyfluanid.

Substance	Mean log k'	K _{oc} (mean of two values)
██████████	██	██
██████████████████	██	██
██████	██	██
██████████	██	██
██████	██	██
██████████	██	██
██████	██	██
██████████	██	██
██████	██	██
██████████	██	██
██████	██	██
██████████	██	██
██████████	██	██
██████	██	██
Tolyfluanid	0.4318	2220

Section A7.2.1 Aerobic degradation in soil

Annex Point: IIIA XII 1.1

Official use only

1 REFERENCE

1.1 Reference

Scholz, K. (1988): Metabolism of [benzene ring-U-14C] tolylfluanid (Euparen M) in soil under aerobic conditions. Bayer AG, Report No. PF2984, 1988-03-07.

Calculations:
 Schaefer, H. (1995): Calculation of DT-50 values of the Tolyfluanid metabolite Dimethylaminosulfotoluidide in soil under aerobic conditions. Bayer AG, Report No. MR-875/95, 1995-08-10, amended: 2001-05-15

Schad, T. (2001b): Predicted environmental concentrations of tolylfluanid and tolylfluanid-dimethylaminosulfotoluidide (DMST) in groundwater recharge based on calculations with FOCUS-PELMO. Use in apples, grapes, strawberries. Bayer AG, Report No. MR-044/01, 2001-02-05.

[Redacted]

1.2 Data protection

[Redacted]

1.2.1 Data owner

[Redacted]

1.2.2 Companies with letter of access

[Redacted]

1.2.3 Criteria for data protection

[Redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

[Redacted]

The study was performed according to BBA Guideline IV, 4-1 (1986).

2.2 GLP

[Redacted]

2.3 Deviations

None

3 MATERIALS AND METHODS

The aerobic soil metabolism of tolylfluanid was investigated in a X laboratory trial.

[Redacted]

[Redacted]

Section A7.2.1

Aerobic degradation in soil

Annex Point: IIIA XII 1.1

[Redacted text block]



Section A7.2.1

Aerobic degradation in soil

Annex Point: IIIA XII 1.1

[REDACTED]

4 RESULTS

[REDACTED]

X

DT50 and DT90 –calculations: DT₅₀ and DT₉₀ values with statistical evaluation and test conditions are summarized in Tables A7_2_1-6 (tolylfluanid) and A7_2_1-7 (DMST). The DT values are based on results reported in Table A7_2_1-3.

The DT₅₀ values for [phenyl-UL-¹⁴C]tolylfluanid relative to extractable

Section A7.2.1 Aerobic degradation in soil

Annex Point: IIIA XII 1.1

radioactivity were low (0.4-2.2 days, 22 °C). [REDACTED]

The DT₅₀ values at 10 °C were calculated to range from 1.0 to 5.7 days. The recalculated DT₉₀ values for tolyfluanid ranged from 1.3-7.3 days (22 °C,) to 3.4-18.8 days (10 °C).

The only major metabolite of tolyfluanid formed in soil was DMST. The DT₅₀ values for it ranged from 1.1 to 5.7 days (22 °C) and the r² values (0.855-0.999) indicated a good fit to the data. DT₅₀ values at 10 °C were calculated to be 3.6-14.7 days. The DT₉₀ values for DMST varied from 3.7-18.9 days (22 °C) to 9.5-48.7 days (10 °C).

The mineralization rate for tolyfluanid ranged from 24.7 to 40.0 % and the amount of bound residues was 52.2-72.3 % of the applied radioactivity at the end of the study (99 days after application).

Metabolic pathway in soil proposed by Bayer:

Tolyfluanid is degraded in first step via hydrolytic cleavage of the N-S bond yielding dimethylaminosulfo-toluidide (DMST, metabolite II) and probably dichlorofluoromethanesulfenic acid. In further steps DMST is oxidised and/or demethylated via 4-(dimethylaminosulfonylamino) benzoic acid (XI) or methylaminosulfo-toluidide (IX) resulting in 4-(methylaminosulfonylamino)benzoic acid (XII). Final degradation product is CO₂.



Proposed degradation pathway of tolyfluanid in soil has been presented in Figure A7_2_1-1.

5 CONCLUSION

5.1 Conclusion

[REDACTED]

X

Section A7.2.1 Aerobic degradation in soil

Annex Point: IIIA XII 1.1

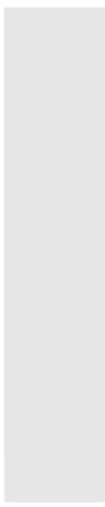
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5.1.1 Reliability

■



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[REDACTED]	[REDACTED]	[REDACTED]

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Table A7_2_1-6

Summary of laboratory studies on the degradation of [phenyl-UL-¹⁴C]tolyfluanid (ph) and [dichlorofluoromethyl-^{13,14}C]tolyfluanid (dic) in soil.

Report	Conditions	Label	Soil type	Light	Statistical evaluation					CO ₂ (%) ^a	Bound res. (%) ^a
					DT ₅₀ (days)	DT ₉₀ (days)	Order	k (day ⁻¹)	r ²		
Scholz, 1988a	Aerobic 22 °C 40 % WHC	ph	Loamy sand (Monh.)	Dark	2.2	7.3 ^d	1 st	0.317	0.616	34.0	56.0
					2.6(20°C) ^b	8.6(20°C) ^{db}					
					5.7(10°C) ^c	18.8(10°C) ^{dc}					
Schäfer, 1995	for 99 days	ph	Clay silt (Höfch.)		1.7	5.6 ^d	1 st	0.414	0.270	38.8	61.0
					2.0(20°C) ^b	6.6(20°C) ^{db}					
					4.4(10°C) ^c	14.4(10°C) ^{dc}					
Schad, 2001b		ph	clay silt (Laach.)		1.6	5.3 ^d	1 st	0.422	- ^e	24.7	72.3
					1.9(20°C) ^b	6.5(20°C) ^{db}					
					4.1(10°C) ^c	13.7(10°C) ^{dc}					
					0.4	1.3 ^d					
					0.5(20°C) ^b	1.7(20°C) ^{db}					
		1.0(10°C) ^c	3.4(10°C) ^{dc}								

a = at the end of the study

b = transformed by Schad (2001b)

c = transformed by the rapporteur

d = no data for DT₉₀ in the test report, values calculated by the notifier using equation $DT_{90} = DT_{50} \times \ln 10 / \ln 2$

e = the model does not adequately represent the experimental data to permit the calculation of a meaningful % variation explained

ph = phenyl-labelled

dic = dichlorofluoromethyl-labelled

WHC = water holding capacity

Table A7_2_1-7 Summary of laboratory studies on the degradation of dimethylaminosulfotoluidide (DMST) in soil.

Report	Conditions	Soil Type	Light	Statistical evaluation				
				DT ₅₀ (days)	DT ₉₀ (days)	Order	k (day ⁻¹)	r ²
Scholz, 1988a	Aerobic 22 °C 40% WHC for 99 days	Loamy sand (Monheim)	Dark	3.7	12.3 ^d	1 st	0.187	0.917
4.3 (20 °C) ^b				14.3 (20 °C) ^{d,b}				
9.5 (10 °C) ^c		31.7 (10 °C) ^{d,c}						
Schäfer, 1995		Clay silt (Höfchen)		1.4	4.7 ^d	1 st	0.484	0.993
1.6(20 °C) ^b	5.3 (20 °C) ^{d,b}							
		3.6 (10 °C) ^c	12.1 (10 °C) ^{d,c}					
Schad, 2001b		Clay silt (Laacherhof)		1.1	3.7 ^d	1 st	0.623	0.855
			1.3(20 °C) ^b	4.3 (20 °C) ^{d,b}				
			2.8 (10 °C) ^c	9.5 (10 °C) ^{d,c}				
		Loamy silt (Speyer)		5.7	18.9 ^d	1 st	0.122	0.999
			6.7(20 °C) ^b	22.3 (20 °C) ^{d,b}				
			14.7 (10 °C) ^c	48.7 (10 °C) ^{d,c}				

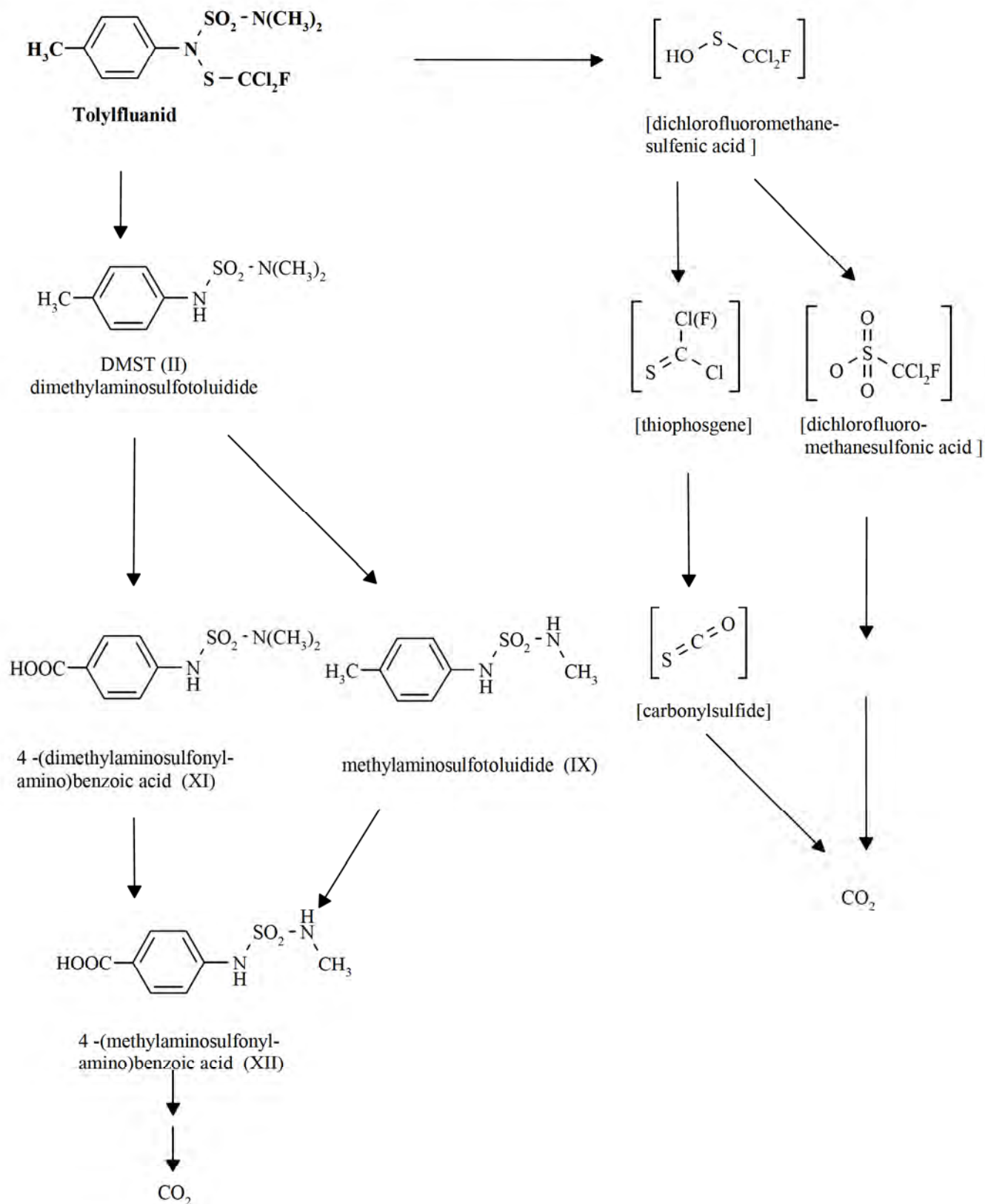
b = transformed by Schad (2001b)

c = transformed by the rapporteur

d = no data for DT₉₀ in the report, values calculated by the notifier using equation $DT_{90} = DT_{50} \times \ln 10 / \ln 2$

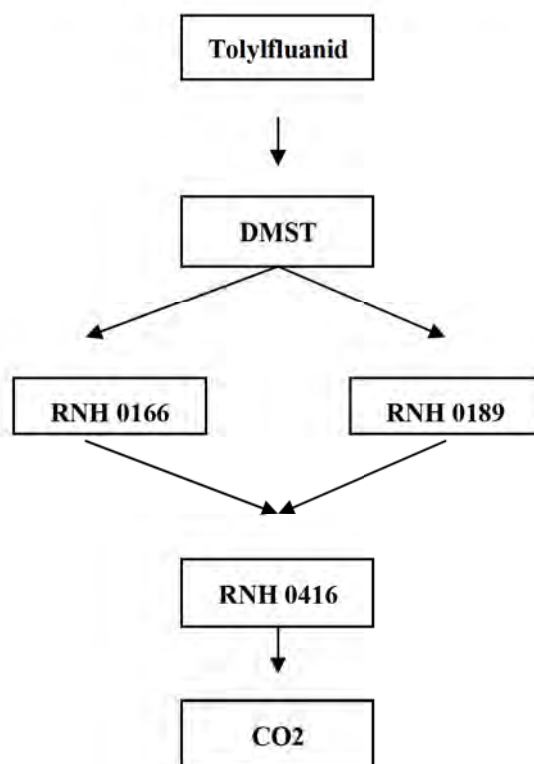
WHC = water holding capacity

Figure A7_2_1-1 Proposed degradation pathway of tolyfluanid in soil.



[...] = proposed structure of postulated intermediates

Figure A7_2_1-2 Degradation pathways of [phenyl-UL-¹⁴C]tolylfluamid



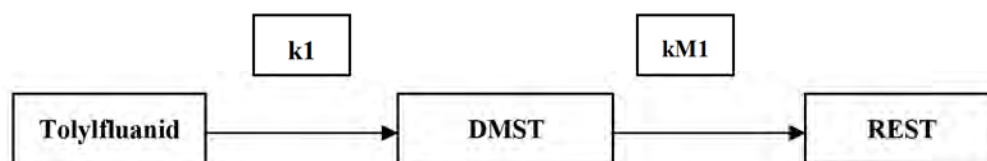
DMST = dimethylaminosulfotoluidide (metabolite II)

RNH 0166 = 4-(dimethylaminosulfonylamino)benzoic acid (metabolite XI)

RNH 0189 = methylaminosulfotoluidide (metabolite IX)

RNH 0416 = 4-(methylaminosulfonylamino)benzoic acid (metabolite XII)

Figure A7_2_1-3 Simplified degradation pathways of [phenyl-UL-¹⁴C]tolyfluanid.



k = reaction rate constant

DMST = dimethylaminosulfotoluidide (metabolite II)

REST = pseudospecies, comprising CO₂, bound residues and all metabolites except DMST

Section A7.3.1 Phototransformation in air (estimation method)**Annex Point: IIIA 12.3**Official
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	1 REFERENCE	
1.1 Reference	Hellpointner, E. (1995): Calculation of the Chemical Lifetime of Tolyfluanid in the Troposphere. Bayer AG, Report No. MR-1121/95, 1995-10-24 and 1 st Amendment Report No. MR-227/99, 1999-04-19.	
1.2 Data protection		
1.2.1 Data owner		
1.2.2 Companies with letter of access		
1.2.3 Criteria for data protection		
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study		
	The study was conducted according to BBA-Guidelines for Testing of Plant Protectants in the Registration Process. Part IV, 6-1, Determination of the volatilisation and the fate of plant protectants in the air, 1990	
2.2 GLP		
2.3 Deviations	None	
	3 MATERIALS AND METHODS	
	The chemical lifetime of tolyfluanid and DMST in air was calculated	
	4 RESULTS	
	With the improved software- the half-life of tolyfluanid in air was calculated to be 7.2 hours. This corresponds to a chemical lifetime in air of 10.4 hours. The half-life of DMST in air was calculated to be 2.3 hours, which corresponds to a chemical lifetime in the air of 3.3 hours. These estimations were carried out with respect to the OH radical reaction, only, and using a 12-hours-day with 1.5×10^6 OH radicals/cm ³ .	

Section A7.3.1 Phototransformation in air (estimation method)

Annex Point: IIIA 12.3

5 Conclusion

4.1 Conclusion

[Redacted]

4.1.1 Reliability

[Redacted]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[Redacted]
Materials and Methods	[Redacted]
Results and discussion	[Redacted]
Conclusion	[Redacted]
Reliability	[Redacted]
Acceptability	[Redacted]
Remarks	
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.4 Annex Point IIIA7.4	Use of aqua-toxicity test data from products ([REDACTED]) in the scope of the biocidal active dossier
JUSTIFICATION FOR NON-SUBMISSION OF DATA	
Other existing data <input checked="" type="checkbox"/> Limited exposure [...]	Technically not feasible [] Scientifically unjustified [] Other justification <input checked="" type="checkbox"/>
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Undertaking of intended data submission []	-
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[REDACTED]
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]

Section A7.4	Use of aqua-toxicity test data from products ()
Annex Point IIIA7.4	in the scope of the biocidal active dossier
Remarks	
	COMMENTS FROM OTHER MEMBER STATE (specify)
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Attachment:

[REDACTED], July 01, 2013

[REDACTED]

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

[REDACTED]

¹ Euparen M WG 50 contains approx. 50 % tolyfluanid

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

- Product Safety Manager -

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 Euparen M [REDACTED]

(*Salmo gairdneri*)

		Official use only
1 REFERENCE		
1.1 Reference	[REDACTED] (1989): Acute toxicity of Euparen M [REDACTED] to rainbow trout (<i>Salmo gairdneri</i>) in a flow through test; [REDACTED] [REDACTED]	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED]	
2 GUIDELINES AND QUALITY ASSURANCE		
2.1 Guideline study	[REDACTED] OECD 203 and EEC 79/831, 5.1.1.	
2.2 GLP	[REDACTED]	
2.3 Deviations	None	
3 MATERIALS AND METHODS		
	The acute toxicity of the [REDACTED] Euparen M [REDACTED] (active ingredient tolyfluanid, [REDACTED] to rainbow trout (<i>Salmo gairdneri</i>) [REDACTED] [REDACTED] was tested in flow-through system for 96 hours. [REDACTED] [REDACTED] [REDACTED]	
	4 RESULTS	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA VII.7.1 Euparen M [REDACTED]

(Salmo gairdneri)

	<p>The LC₅₀ for Euparen M [REDACTED] to rainbow trout was determined to be [REDACTED] mg ai/L (0.016 mg/l for active ingredient) (Table A7_4_1_1-1). <u>The mortality data are summarized in Table A7_4_1_1-3.</u></p> <p>[REDACTED]</p> <p>Therefore, the lowest lethal concentration (LLC) and NOEC values were [REDACTED] and 0. [REDACTED] mg test substance/L, equivalent to 0.022 and 0.11 mg ai/L respectively (Table A7_4_1_1-1).</p> <p>[REDACTED]</p> <p>The reported results were related to the nominal concentrations of the test substance. As can be seen in Table A7_4_1_1-2, [REDACTED]</p> <p>[REDACTED]</p>	X
--	--	---

5 CONCLUSION

5.1 Conclusion The test procedure corresponded to the given guidelines. The product Euparen M [REDACTED] as well as tolyfluanid has a very high acute toxicity to rainbow trout.

5.1.1 Reliability	[REDACTED]	
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Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
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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: The acute toxicity (96 h, flow-through) of tolyfluanid [REDACTED] to Rainbow Trout (*Salmo gairdneri*)

TEST SUBSTANCE	[REDACTED]	RELATED TO AI
LC ₅₀ mg/L	[REDACTED]	0.016
Lowest lethal concentration (LLC) mg/L	[REDACTED]	0.022
No observed effect concentration (NOEC) mg/L	[REDACTED]	0.011

[REDACTED]

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

[REDACTED]

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

[REDACTED]

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

[REDACTED]

[REDACTED]

Section A7.4.1.2 Acute toxicity to invertebrates (1)

Annex Point IIA VII.7.2 *Daphnia magna*

Official use only

1 REFERENCE

1.1 Reference Hendel, B. & Sommer, H. (2001): Acute Toxicity of Tolyfluanid (tech.) under Flow Through Test Conditions to Waterfleas (*Daphnia magna*); Bayer AG, unpublished report No.: HDB/Dm 246.

[Redacted]

1.2 Data protection

[Redacted]

1.2.1 Data owner

[Redacted]

1.2.2 Companies with letter of access

[Redacted]

1.2.3 Criteria for data protection

[Redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

[Redacted]

OECD 202, adopted version 4 April, 1984 and Draft document, October 2000

2.2 GLP

[Redacted]

2.3 Deviations

None

3 MATERIALS AND METHODS

The acute toxicity of tolyfluanid (tech., purity [Redacted] %) to *Daphnia magna* (1st instars < 24 h old) was studied in a flow through test system

[Redacted]

4 RESULTS

Section A7.4.1.2**Acute toxicity to invertebrates (1)****Annex Point II A VII.7.2***Daphnia magna*

[REDACTED]

Based upon mean measured concentrations, the EC₅₀(24 hours, flow-through) was determined to be > 0.66 mg ai/l (95% confidence limits: not calculable) and the EC₅₀(48 hours, flow-through) was determined to be 0.19 mg ai/l (95% confidence limits: 0.12 – 0.30 mg ai/l).

Based upon mean measured concentrations, the lowest-observed-effect-concentration (LOEC) was 0.26 mg ai/l after 24 h and 0.071 mg/l after 48 h, the NOEC was 0.14 mg ai/l after 24 h and 0.033 mg ai/l after 48 h.

5 CONCLUSION**5.1 Conclusion****5.1.1 Reliability**

Evaluation by Competent Authorities FI	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	30.6.2005
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA VII.7.3

*Pseudokirchneriella subcapitata*Official
use only

		1 REFERENCE
1.1	Reference	Anderson, J.P.E. 1997: Influence of Euparen M [REDACTED] on the Growth of the Green Alga, <i>Pseudokirchneriella subcapitata</i> (formerly <i>Selenastrum capricornutum</i>). Bayer AG, unpublished report No: AJO/158097. [REDACTED]
1.2	Data protection	[REDACTED]
1.2.1	Data owner	[REDACTED]
1.2.2	Companies with letter of access	[REDACTED]
1.2.3	Criteria for data protection	[REDACTED]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	Guideline study	[REDACTED] EEC Directive 79/831/E, C.3 (1992), OECD 201 (1984), ISO 8692 (1989)
2.2	GLP	[REDACTED]
2.3	Deviations	No
		3 MATERIALS AND METHODS
3.1	Test material	Euparen M [REDACTED]
3.1.1	Lot/Batch number	[REDACTED]
3.1.2	Specification	
3.1.3	Purity (content)	Formulation with [REDACTED] % active ingredient tolyfluanid.
3.1.4	Composition of Product	Investigation was performed with Euparen M [REDACTED] containing [REDACTED] % tolyfluanid.
3.1.5	Further relevant properties	-
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]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA VII.7.3 *Pseudokirchmeriella subcapitata*

3.4 Testing procedure

- 3.4.1 Culture medium [REDACTED]
- 3.4.2 Test organisms see table A7_4_1_3-1
- 3.4.3 Test system see table A7_4_1_3-2
- 3.4.4 Test conditions see table A7_4_1_3-3
- 3.4.5 Duration of the test 96 hours
- 3.4.6 Test parameter Influence on the growth and biomass
- 3.4.7 Sampling [REDACTED]
- 3.4.8 Monitoring of TS concentration Yes [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]
- 4.2 **Results test substance**
- 4.2.1 Initial concentrations of test substance [REDACTED]
[REDACTED]
Nominal concentrations (pure active tolyfluanid):
0.0501, 0.0902, 0.1603, 0.2805, 0.501, 0.902 1.603, 2.806, 5.01 mg/l

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 (growth rate)	<p>E_rC_{50} after 72 hours was > 10 mg/l [REDACTED] which corresponded to a measured initial concentration of 0.6 mg/l tolyfluanid.</p> <p>Based on the growth inhibition curve, the NOE_{1C} and LOE_{1C} values for Euparen M [REDACTED] after 72 hours were [REDACTED] mg/l and [REDACTED] mg/l which corresponded to nominal a.i. concentrations of 0.5 and 0.9 mg/l and initial measured concentrations of tolyfluanid of 0.0125 and 0.0051 mg/l.</p>
4.2.7	Other observed effects	-
4.3	Results of controls	[REDACTED]
4.4	Test with reference substance	[REDACTED]
4.4.1	Concentrations	Control, 0.1, 0.18, 0.32, 0.56, 1.0 and 1.8 mg/l
4.4.2	Results	[REDACTED]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	<p>The influence of Euparen M [REDACTED] on the growth of the green alga <i>Pseudokirchneriella subcapitata</i> was investigated in a 96 hours static test according to OECD guideline No. 201.</p> <p>[REDACTED]</p>
5.2	Results and discussion	<p>E_rC_{50} after 72 hours was [REDACTED] or > 5,01 mg/l (nominal a.i.), which corresponded to a measured initial concentration of 0.6 mg/l tolyfluanid.</p> <p>Based on the growth inhibition curve, the NOE_{1C} and LOE_{1C} values for Euparen M [REDACTED] after 72 hours [REDACTED] which corresponded to nominal a.i. concentrations of 0.5 and 0.9 mg/l and initial measured concentrations of tolyfluanid of 0.0125 and 0.0051 mg/l.</p> <p>[REDACTED]</p>

[REDACTED]

[REDACTED]

- 5.2.1 NOE_C 0.5 mg/l (nominal a.i.), measured initial concentration 0.0125 mg/l tolyfluanid after 72 hours. TWA NOEC for one generation (10.06 h) is 0.238 mg/l and for 72 hours is 0.04 mg/l.
- 5.2.2 E_rC₅₀ 5,01 mg/l (nominal a.i.), measured initial concentration: 0.6 mg/l tolyfluanid after 72 hours. TWA EC50 for one generation (10.06 h) is >2.38 mg/l and for 72 hours is 0.4 mg/l.

Section A7.4.1.3

Growth inhibition test on algae

Annex Point IIA VII.7.3

Scenedesmus Subspicatus

5.3 Conclusion

[REDACTED]

5.3.1 Reliability

2

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 FI	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
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Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

[REDACTED]

The table consists of several rows and columns. The top row is mostly redacted. The second row contains two columns of redacted text. The third row contains two columns of redacted text. The fourth row contains a grid pattern with alternating black and white cells. The fifth row contains a grid pattern with alternating black and white cells. The sixth row contains a grid pattern with alternating black and white cells. Below the table, there are four lines of redacted text.

[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 4 1 3-7: Toxicity of tolyfluanid to green algae (Effects on growth rate)

Study organism	Study Type / Duration	Endpoints based on nominal initial concentr. [mg a.i./l]	Endpoints based on TWA for one generation (10.06 h) [mg a.i./l]	Endpoints based on TWA for 72 hours [mg a.i./l]	Ref.
<i>Selenastrum capricornutum</i> (Study with Euparen M WG 50)	Effect on Growth rate and Biomass / 72 h (OECD 201)	ErC ₅₀ > 5.01 LOErC = 0.90 NOErC = 0.50	ErC ₅₀ > 2.380 LOErC = 0.428 NOErC = 0.238	ErC ₅₀ > 0.402 mg a.i./l LOErC = 0.072 mg a.i./l NOErC is 0.040 mg a.i./l	Anderson (1997)

Section A7.4.1.4 Inhibition to microbial activity (aquatic)**Annex Point IIA VII.7.4**

		Official use only
1 REFERENCE		
1.1 Reference	Müller, G. (1999): Investigation of the ecological properties of Tolyfluanid. Bayer AG, Institute of Environmental Analysis, unpublished report No. 851 A/99; 1999-06-24. [REDACTED]	
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED]	
2 GUIDELINES AND QUALITY ASSURANCE		
2.1 Guideline study	[REDACTED] Directive 88/302/EC, Official Journal of the EG L 133, part C : Biodegradability: Study of Respiration Inhibition; (corresponding to OECD 209)	
2.2 GLP	[REDACTED]	
2.3 Deviations	[REDACTED]	
3 MATERIALS AND METHODS		
	<p>Test material: Tolyfluanid, purity: [REDACTED] %; specification (Batch No. [REDACTED]).</p> <p>[REDACTED]</p> <p>Activated sludge was exposed for 3 hours to nominal concentrations ranging from 32 to 320 mg/L. <i>Details of the test conditions are summarised in Table 7_4_1_4-2.</i></p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA VII.7.4

	<p>[REDACTED]</p>	
<p>4</p>	<p>RESULTS</p>	
	<p><i>Respiratory rates and inhibitory effects (%) at the tested tolylfluanid concentrations are given in Table 7_4_1_4-3.</i></p> <p>The EC₅₀ was determined as 230 mg/l (EC₁₀ = 21 mg/l, EC₉₀ = 2530 mg/l).</p> <p>[REDACTED]</p> <p><i>No physico chemical oxygen consumption was determined at a test substance concentration of 10000 mg/l. Therefore lower concentrations of the test substance cause no physico chemical oxygen consumption (deduced values).</i></p> <p>[REDACTED]</p>	
<p>5.1 Conclusion</p>	<p>5 CONCLUSION</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	
<p>5.1.1 Reliability</p>	<p>[REDACTED]</p>	

Evaluation by Competent Authorities	
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Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
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Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

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

Table A7_4_1_4-3: Test results of test substance (based on nominal concentrations) and controls

<i>Test Compound [mg/l]</i>	<i>Respiratory Rate [mg O₂/l h]</i>	<i>Inhibition [%]</i>
32	30.0	19.1
56	29.3	21.0
100	27.8	25.1
180	20.6	44.5
320	14.3	61.5

<i>Control</i>	<i>Respiratory rate [mg O₂/l·h]</i>
<i>Control 1</i>	■
<i>Control 2</i>	■

Section A7.4.2

Bioconcentration in aquatic organisms (fish)

Annex Point IIA VII.7.5

*Lepomis macrochirus*Official
use only**1 REFERENCE****1.1 Reference**

█ (1991): Tolyfluanid, Bioconcentration in fish.
█ unpublished report No: BF-007.

1.2 Data protection

1.2.1 Data owner

1.2.2 Companies with
letter of access1.2.3 Criteria for data
protection**2 GUIDELINES AND QUALITY ASSURANCE****2.1 Guideline study**

█
U.S. EPA-FIFRA § 72-6 and § 165-4

2.2 GLP**2.3 Deviations**

None

3 MATERIALS AND METHODS

The bioaccumulation and elimination of Phenyl-U-[¹⁴C]-labelled Tolyfluanid (radiopurity: █ %, chemical purity: █ %) by bluegill (*Lepomis macrochirus*) was investigated in a flow-through system.

4 RESULTS

Section A7.4.2**Bioconcentration in aquatic organisms (fish)****Annex Point IIA VII.7.5***Lepomis macrochirus*

Tolyfluanid is accumulated and excreted very rapidly by Bluegill Sunfish with a mean BCF of 74 for whole fish. Accumulation in edible parts is less than in whole fish (Table A7_4_2-1). When exposure ceases, the radioactivity is depurated very quickly. After 14 days in uncontaminated water >90% of the mean plateau radioactivity was depurated from whole fish. All BCF values refer to the total amount of radioactivity (sum of radiolabelled parent, metabolites and mineralization products).

5 CONCLUSION**5.1 Conclusion**

[REDACTED]

5.1.1 Reliability

[REDACTED]

Table A7_4_2-1 Bioconcentration of Phenyl-U-[¹⁴C]-tolyfluanid by Bluegill Sunfish

Evaluated parts	Edible parts	Whole fish
Bioconcentration Factor (BCF)	55	74
Time to reach 90 % of Steady-State (days)	0.97	1.25
t(1/2) for Clearance (days)	0.29	0.38
Uptake Rate Constant (K1) (1/day)	130	136
Clearance Rate Constant (K2) (1/day)	2.4	1.8

Section A7.4.3.2 Annex Point IIIA12.2	Effects on reproduction and growth rate on an appropriate species of fish	
JUSTIFICATION FOR NON-SUBMISSION OF DATA		Official use only
Other existing data <input checked="" type="checkbox"/>	Technically not feasible <input type="checkbox"/>	Scientifically unjustified <input type="checkbox"/>
Limited exposure <input checked="" type="checkbox"/>	Other justification [...]	
Detailed justification:	<div style="background-color: black; width: 100%; height: 100%; min-height: 400px;"></div>	
Undertaking of intended data submission <input type="checkbox"/>	-	

Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[REDACTED]
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]
Remarks	
COMMENTS FROM OTHER MEMBER STATE <i>(specify)</i>	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section 7.4.3.4 Effects on reproduction and growth rate with an
Annex Point IIIA XIII 2.4 invertebrate species

Official
use only

1 REFERENCE

- 1.1 Reference Hendel, B. 2001a: Influence of Tolyfluanid (tech.) on the Reproduction Rate of Water Fleas.
Bayer AG, unpublished report No.: HDB/rDm 66.

[REDACTED]

1.2 Data protection

[REDACTED]

1.2.1 Data owner

[REDACTED]

1.2.2 Companies with letter of access

[REDACTED]

1.2.3 Criteria for data protection

[REDACTED]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

[REDACTED]

OECD 211, EPA 72-4.

2.2 GLP

[REDACTED]

2.3 Deviations

[REDACTED]

3 MATERIALS AND METHODS

The influence of Tolyfluanid (tech., purity: [REDACTED] %) on the reproduction and survival rate of [REDACTED] young *Daphnia magna* (1st instars, < 24 h old) per test concentration was studied [REDACTED]

[REDACTED]

Section 7.4.3.4 **Effects on reproduction and growth rate with an**
Annex Point IIIA XIII 2.4 **invertebrate species**

4 RESULTS

[REDACTED]

[REDACTED]

Therefore the NOEC (21 d, reproduction) is stated to be 0.10 mg ai/l, and the LOEC is 0.32 mg ai/l (Table A7_4_3_4-1). The results refer to nominal concentrations.

Since the average pH values of controls and solvent controls during the study was 8.2, a DT_{50} for tolylfluanid of 2.5 hours under the given test conditions was derived. Based on this degradation assumption, TWA extrapolations were calculated for the average exposure time of 2.33 days (Table A7_4_3_4-2).

However, if even the TWA extrapolation for a period of 2.33 days is not considered as relevant, the TWA based on a 21-day period would result for all endpoints in a LOEC of 0.0023 mg a.i./l and a NOEC of 0.0007 mg a.i./l, respectively.

5 CONCLUSION

5.1 Conclusion

[REDACTED]

5.1.1 Reliability

■

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[REDACTED]
Materials and Methods	[REDACTED]
Results and discussion	[REDACTED]
Conclusion	[REDACTED]
Reliability	[REDACTED]
Acceptability	[REDACTED]
Remarks	[REDACTED]
COMMENTS FROM ...	
Date	<i>Give date of comments submitted</i>
Materials and Methods	<i>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</i>
Results and discussion	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Reliability	<i>Discuss if deviating from view of rapporteur member state</i>
Acceptability	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Table A7_4_3_4-1



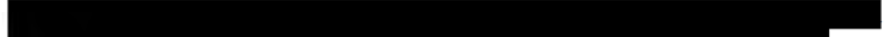

Toxicity of tolyfluanid (tech.) to the reproduction of waterfleas.

Parameters	sum of offspring per parent animal	number of offspring / parent / reproduction day	Body length of parent animals
Lowest observed effect concentration (LOEC) (mg ai/l)	0.32	0.32	0.32
No observed effect concentration (NOEC) (mg ai/l)	0.10	0.10	0.10

Table A7_4_3_4-2 Toxicity of tolyfluanid (tech.) to the reproduction of waterfleas.

Study organism	Study Type / Duration	Endpoints based on nominal concentrations [mg a.i./l]	Endpoints based on 2.33 d-TWA [mg a.i./l]	Endpoints based on 21 d-TWA [mg a.i./l]	Reference
<i>Daphnia magna</i>	Reproduction / 21 d (OECD 211)	Sum of offspring/parent animal NOEC = 0.10 LOEC = 0.32	Sum of offspring/parent animal NOEC = 0.0064 LOEC = 0.0206	Sum of offspring/parent animal NOEC=0.0007 LOEC=0.023	Hendel (2001a)
		Number of offspring/parent/ reproduction day NOEC = 0.10 LOEC = 0.32	Number of offspring/parent/ reproduction day NOEC = 0.0064 LOEC = 0.0206	Number of offspring/parent/ reproduction day NOEC=0.0007 LOEC=0.023	
		Body length of parent animals NOEC = 0.10 LOEC = 0.32	Body length of parent animals NOEC = 0.0064 LOEC = 0.0206	Body length of parent animals NOEC=0.0007 LOEC=0.023	

<p>Section A7.5 Annex Point IIIA12.3</p>	<p>Use of terrestrial eco-toxicity test data with single application for the terrestrial risk assessment on tolyfluanid in the context of its use as a wood preservative</p>	
<p>JUSTIFICATION FOR NON-SUBMISSION OF DATA</p>		<p>Official use only</p>
<p>Other existing data <input checked="" type="checkbox"/> [X] Limited exposure <input type="checkbox"/> [...]</p>	<p>Technically not feasible <input checked="" type="checkbox"/> [X] Scientifically unjustified <input type="checkbox"/> [] Other justification <input checked="" type="checkbox"/> [X]</p>	
<p>Detailed justification:</p>	<p>Studies on terrestrial toxicity of tolyfluanid were submitted under the Council Directive 98/8/EC, [REDACTED]</p> <p>The actual guidelines on terrestrial eco-toxicity in general are based on [REDACTED]</p> <p>Tolyfluanid has a very short half-live in soil (< 1 day). It therefore must be assumed that only at the beginning of the tests a full exposure of the test item to the respective organisms can be expected. The observed effects are therefore related to the initial concentration of tolyfluanid in the soil.</p> <p>Prior degradation of tolyfluanid before the beginning of the terrestrial tests [REDACTED]</p> <p>Repeated dosing during terrestrial tests is not foreseen in the respective guidelines and in many cases [REDACTED]</p> <p>[REDACTED]</p> <p>Considering the short half life in soil, the built up of residue of tolyfluanid is not to be expected. [REDACTED]</p> <p>A refined terrestrial risk assessment can be done taking into account the data on DMST the major metabolite of tolyfluanid in</p>	

Section A7.5 Annex Point IIIA12.3	Use of terrestrial eco-toxicity test data with single application for the terrestrial risk assessment on tolyfluanid in the context of its use as a wood preservative
	<p>soil. Nevertheless also DMST has only a half-live of up to 5 days in soil laboratory tests.</p> <p>Taking into account the above mentioned arguments which cover the formal OECD test requirements as well as scientific aspects and the specific exposure situation for a wood preservative active in hazard classes up to 3 it is justified to use the above mentioned terrestrial ecotoxicity data for the terrestrial risk assessment of tolyfluanid and its products.</p>
Undertaking of intended data submission []	<p>—</p>
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.5 Annex Point IIIA12.3	Use of terrestrial eco-toxicity test data from [REDACTED] in the scope of the biocidal active dossier	Official use only
JUSTIFICATION FOR NON-SUBMISSION OF DATA		
Other existing data <input checked="" type="checkbox"/> Limited exposure [...]	Technically not feasible <input type="checkbox"/> Scientifically unjustified <input type="checkbox"/> Other justification <input checked="" type="checkbox"/>	
Detailed justification:	<p>Because the data on terrestrial toxicity of tolylfluanid in the active dossier submitted under the Council Directive 98/8/EC are [REDACTED]</p> <p>[REDACTED] it is stated in chapter 2.4 that: "certain study types may be conducted with a formulated product instead of the active substance. This may be applicable to, for example, non-target arthropod studies, the earthworm reproduction test and the soil micro-flora".</p> <p>In many of the studies (e.g. toxicity against micro-organisms) application is done by [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p>	
Undertaking of intended data submission <input type="checkbox"/>	-	

Section A7.5	Use of terrestrial eco-toxicity test data from [REDACTED]
Annex Point IIIA12.3	[REDACTED] in the scope of the biocidal active dossier
Evaluation by Competent Authorities	
<i>Use separate "evaluation boxes" to provide transparency as to the comments and views submitted</i>	
EVALUATION BY RAPPORTEUR MEMBER STATE FI	
Date	[REDACTED]
Evaluation of applicant's justification	[REDACTED]
Conclusion	[REDACTED]
Remarks	
COMMENTS FROM OTHER MEMBER STATE (specify)	
Date	<i>Give date of comments submitted</i>
Evaluation of applicant's justification	<i>Discuss if deviating from view of rapporteur member state</i>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>
Remarks	

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)**Annex Point IIIA, XIII 3.3**Official
use only

		1 REFERENCE
1.1 Reference		Anderson, J.P.E. (1998b): Influence of Euparen M (Tolyfluanid) [REDACTED] on the microbial mineralization of nitrogen in soils. Bayer AG, unpublished report No. AJO/183298, 1998-11-13. [REDACTED]
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED]	

		2 GUIDELINES AND QUALITY ASSURANCE
2.1 Guideline study	[REDACTED]	BBA Part VI 1-1 (2 nd ed.), ISO/DIS 1036-6
2.2 GLP	[REDACTED]	
2.3 Deviations		None

3 MATERIALS AND METHODS

Euparen M (tolylfluanid), (purity [REDACTED] % ai; [REDACTED]). Two soils (silty sand and loamy silt) were exposed for 28 d to concentrations of 1.6 and 16.0 mg tolylfluanid [REDACTED] / kg d.wt.s. [REDACTED].

4 RESULTS

During the 28-day experiments the maximum field rate and the 10-fold overdose of tolylfluanid [REDACTED] had no influence on the turnover of nitrogen in either a silty sand or a loamy silt soil amended with lucerne-grass-green meal (Table A7_5_1_1-1).

When used as recommended up to 6.2 kg ai/ha, tolylfluanid [REDACTED] should have no negative influence on the turnover of nitrogen in soils.

Calculation of time-weighted average concentrations

Since no onset of effects could be observed from the study before the final evaluation after 28 days, a time window of 21 days was used for the TWA calculations for the reasons explained above. Based on a half-

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIIA, XIII 3.3

life of tolyfluanid in soil of 2.6 days (at 20°C), time-weighted average (TWA) extrapolations were calculated and summarized in Table A7_5_1_1-2. NOEC \geq 2.85 mg a.i./kg dry weight soil for the N-cycle was derived.

5 CONCLUSION

5.1 Conclusion

[REDACTED]

5.1.1 Reliability

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Table A7_5_1_1-1 Effects of tolyfluanid [REDACTED] on non-target soil micro-organisms.

Test substance	[REDACTED]	
Test object	Soil micro-organisms N-cycle (silty sand soil / loamy silt soil)	
Exposure	28 days	
mg/kg dry weight soil	1.60	16.0
kg/ha (kg ai/ha) (equivalent)	1.2 (0.62) (max. field rate)	12.0 (6.2) (10x max. field rate)
Result	No influence	no influence

Table A7_5_1_1-2: Effects of tolyfluanid on soil non-target micro-organisms

Type of study	Duration	Endpoints based on initial concentrations [mg a.i./kg dry weight soil]	Endpoints based on 21 d-TWA [mg a.i./kg dry weight soil]	Reference
N-cycle	28 d / OECD 216	No influence (NOEC) at 16.0	NOEC \geq 2.85	Anderson (1998b)

Section A7.5.1.1

Inhibition to microbial activity (terrestrial) (2)

Annex Point IIIA, XIII 3.3

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use only

		1 REFERENCE
1.1 Reference		Anderson, J.P.E. (1998a): Influence of Euparen M (Tolyfluanid) [REDACTED] on glucose stimulated respiration in soils. Bayer AG, unpublished report No. AJO/183198, 1998-11-13. [REDACTED]
1.2 Data protection	[REDACTED]	
1.2.1 Data owner	[REDACTED]	
1.2.2 Companies with letter of access	[REDACTED]	
1.2.3 Criteria for data protection	[REDACTED]	

		2 GUIDELINES AND QUALITY ASSURANCE
2.1 Guideline study	[REDACTED]	BBA Part VI 1-1 (2 nd ed.), ISO/DIS 1036-6
2.2 GLP	[REDACTED]	
2.3 Deviations		None

3 MATERIALS AND METHODS

Euparen M (tolyfluanid), (purity: KUE 13183B, [REDACTED] % ai; development No.: 00922153 [REDACTED])

4 RESULTS

[REDACTED] tolyfluanid [REDACTED] had no meaningful influence on soil respiration after addition of glucose to a silty sand or loamy silt soil. (Table A7_5_1_1-1).

When used as recommended up to [REDACTED], tolyfluanid [REDACTED] should have no negative influence on the turnover of organic carbon.

Calculation of time-weighted average concentrations

Since no onset of effects could be observed from the study before the final evaluation after 28 days, a time window of 21 days was used for the TWA calculations for the reasons explained above. Based on a half-life of tolyfluanid in soil of 2.6 days (at 20°C), time-weighted average

Section A7.5.1.1 Inhibition to microbial activity (terrestrial) (2)

Annex Point IIIA, XIII 3.3

(TWA) extrapolations were calculated and summarized in Table A7_5_1_1-2. NOEC \geq 2.85 mg a.i./kg dry weight soil for the C-cycle was derived.

5 CONCLUSION

5.1 Conclusion

[REDACTED]

5.1.1 Reliability

■