98/8 Doc IIIA section	7.1.1.1.2/0	Phototransformation in water including identity of the produts of transformation
No.	3	

91/414 Annex II - 7.2.1.2 /03

General Information	
Title of the study:	Photodegradation of [Phenyl(U)-14C]Propiconazole in Aqueous Solution buffered at pH 7 under Artificial Conditions
Report and /or project number:	ISSI No. 90070
Author:	Y.T. Das
Syngenta File Number (SAM):	64250 / 1825
Name and address of testing facility:	Innovative Scientific Services, Inc. (ISSI), Piscataway, NJ 08854/USA
Study period:	August 17, 1990 to November 26, 1990
Date of report:	November 26, 1990
Compliance with GLP	Yes [X] No, but complies with sound scientific principles []
Test guideline(s) used:	US EPA Subdivision N, Section 161-2
Deviations from test guideline:	

Test substance	
Test substance (code number):	Propiconazole (CGA 64250)
Batch:	
14-C-labeled test substance:	yes
if yes, give specific activity	
Position of labeling:	[U]-Phenyl
Purity of test substance:	
Structural formula: (* = position of label)	
Formulation used for study: Type of formulation (if used):	no
Solvent for application (if used):	Acetonitrile

Test system	
Test concentration (mg/L)	10.8
Water solubility (mg/L)	110
Irradiation:	artificial (X) natural ()
if artificial, type of light source:	Xenon arc lamp
if natural irradiation	Latitude: Longitude:
Filter used to exclude wavelength < 290 nm	Yes (X) No ()
If artificial irradiation, correlation made to natural	Yes (X) No ()
sunlight intensity:	
Dark control:	Yes (X) No ()
Test duration:	30 days
Sampling intervals :	0, 1, 3, 7, 14, 21 and 30 days
Sterilisation of test system:	Yes (X) No ()
pH	7
Test temperature :	25 ± 1°C
Test buffer system:	Yes (X) No ()
if Yes, ionic strength < 0.01 m:	Yes $(X) = 0.01M$ No $()$

Test results		
Half life (DT 50)	Experimental:	249 days
300-07 See	Corrected to natural sunlight:	(HE
Photodegradation products:	> 10 % :	No
Quantum yield:	(at nm)	No
Calculated half life (DT50)		
Mass balance:	Yes:	100.4% (non-irradiated), 100.6% (irradiated)

Doc IIIA 7 (F&B) 8 of 91

Volatiles:	Organic:	No
	CO 2:	No

Summary of findings

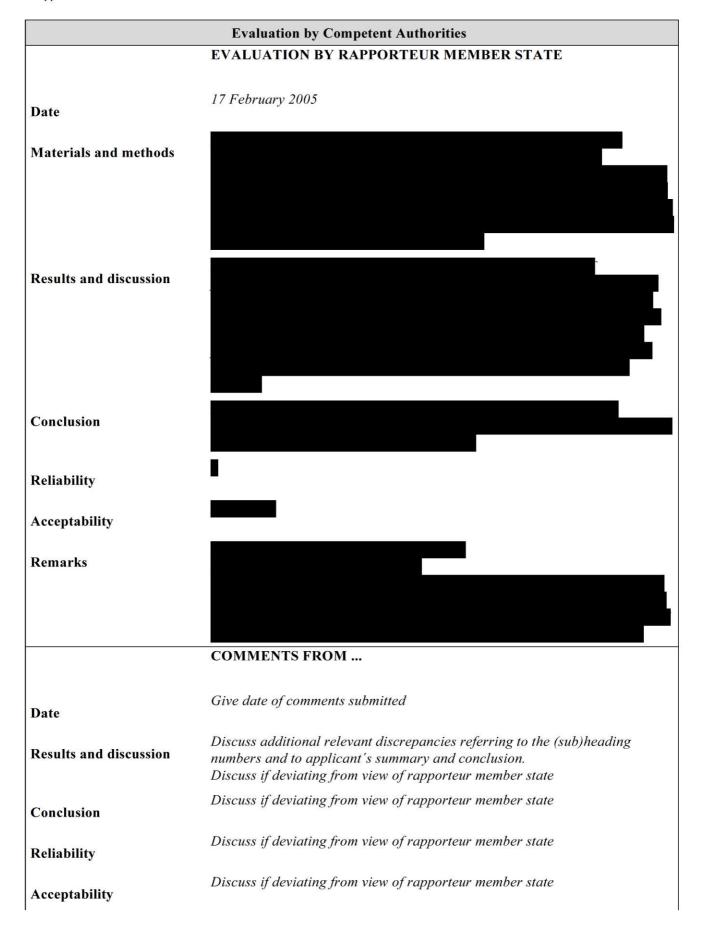
Irradiation significantly contributed to the breakdown of 14C-propiconazole in aqueous solution buffered at pH 7. The half-life value was 249 days, based on 12-hr darkness and 12-hr irradiation per day. There was no significant breakdown under non-irradiated conditions. There were no major degradates either under irradiated or under non-irradiated conditions.

Material balance was 100.4 ±1.8 % under non-irradiated conditions and 100.6±2.4 % under irradiated conditions

AK/PP2.54/May 9, 1994

Reliability indicator	1
Data Protection Claim	Yes

Doc IIIA 7 (F&B) 9 of 91



Doc IIIA 7 (F&B) 10 of 91

Remarks

	Ken	iarks	
L	No.	Doc IIIA section 7.1.1.1.2/05	Phototransformation in water including identity of the produts of transformation
		4 Annex II addressed 7.2.1.2	Photochemical degradation
	1.2	Title	Sunlight Photolysis of 1,2,4-H-Triazole in Distilled Water and Humic acid solutions
	1.3	Report and/or project N° Syngenta File N° (SAM)	Not specified 71019/19
	1.4	Lab. Report N°	Not specified
	1.5	91/414 Cross Reference to original study / report	7.2.1.2 /06
	1.6	Authors	Report: Miller, G. C. Summary: Trewhitt, M.
	1.7	Date of report	8 August 1983
	1.8	Published / owner	Unpublished/ Ciba Geigy Limited
	2.1	Testing facility	Department of Biochemistry, University of Nevada Reno, Reno, NV, USA
	2.2	Dates of experimental work	Not specified in the report
	3.	Objectives	To determine the sunlight photoreactivity of 1,2,4-H-triazole in distilled water and in humic acid
	4.1	Test substance	Common name: Trade name: Batch: 14C-labelled test substance Specific activity of [14C] 1,2,4-H-Triazole Radiochemical purity of the test substance: Structural formula: (position of label) 1,2,4-H-triazole Not applicable Yes [x] No [] Not specified
	4.2	Specification	See 4.1
	4.3	Storage stability	Not specified in the report
	4.4	Stability in vehicle	Not specified in the report
	4.5	Homogeneity in vehicle	Prepared as a solution in acetonitrile
	4.6	Validity	Not applicable
	5	Vehicle / solvent	Acetonitrile
	6	Physical form	Solution in acetonitrile
	7.1	Test method	The method developed was designed to meet international regulatory requirements for assessing the aqueous photolysis of chemicals
	7.2	Justification	Not applicable
	7.3	Copy of method	Details of the method used are described in the report
	8	Choice of method	Not applicable
	9	Deviations	None
	10.1	Certified laboratory	Not specified in the report
		Certifying authority	Not applicable
	10.3	GLP	No

Doc IIIA 7 (F&B)

January 2015

10.4 Justification

Although the study was not conducted in compliance with the principles of GLP there is no reason to doubt the scientific validity of the results.

11.1 GEP

Not applicable.

11.2 Type of facility (official or officially recognised)

Not applicable.

11.3 Justification

Not applicable

12 Test system

Test concentration in distilled water(mg/l)	≈ 80
Test concentration in humic acid (mg/l)	≈ 80
Water solubility (mg/l)	Not specified
Irradiation:	artificial [] natural [x]
if artificial, type of light	artificial [] matural [A]
source	
if natural, irradiation	Latitude: Not specified
	Longitude: Not specified
Filter used to exclude wavelength < 290 nm	Yes [] No
0.59	[x]
If artificial irradiation, correlation made to	Yes [] No
natural sunlight intensity	[]
Dark control	Yes [x] No
	[]
Test duration	30 days
Sampling intervals	0, 3, 7 and 30 days
Sterilisation of the test system	Yes [] No
6/40	[x]
pH (water) initial / final	6.4 / 7.6
pH (humic acid) initial / final	7.8 / 7.6
Test temperature	Not specified
Test buffer system:	Yes [] No
If yes, ionic strength < 0.01	[x]
M	Yes [] No
Composition of buffer	[]
solution:	

Details of analytical techniques used:	Thin layer chromatography (TLC) and
COMP. 10.1.00 10.1.4- May 1.1.00 10.1.	liquid scintillation counting (LSC)

13 Findings

Summary of findings

No degradation of 1,2,4-H-triazole in distilled water was observed following exposure to natural sunlight for 30 days. However, loss of compound was evident by volatilisation. Recovery of radioactivity from non-irradiated samples exceeded 90% of the applied radioactivity. Similarly, there was no degradation of 1,2,4-H-triazole in humic acid, however, the humic acid solution underwent photochemical bleaching during the irradiation. Analysis of UV spectra of samples indicated a substantial loss of the visible and ultraviolet absorbing materials after eight days of irradiation. Though this presumably generated radioactive intermediates, it had no appreciable effect on the triazole. It was concluded that 1,2,4-triazole does not appreciably absorb sunlight and that it does not undergo appreciable direct photolysis in sunlight. Humic acid and acetone did not have any significant effect on increasing the rate of loss by indirect photochemical reactions.

14 Statistics None
15 References (published) None
16 Unpublished data None
17 Reliability Indicator 1

Data Protection Claim	Yes

Doc IIIA 7 (F&B) 12 of 91

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 February 2005
Materials and methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
	COMMENTS FROM
Date	Give date of comments submitted
Results and discussion	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
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

PP 2.505/MT/3.4.1995

Doc IIIA 7 (F&B) 13 of 91

98/8 Doc IIIA section	7.1.1.2.1	Ready biodegradability
No.		

91/414 Annex II - 7.2.1.3.1 /01

General Information	
Title of the study:	Report on the test for ready biodegradability in the Modified Sturm Test of CGA 64250
Report and/or project number:	901111
Author of the study:	U. Bader
Author of the summary:	A. Keller
Syngenta File Number (SAM):	64259 / 230
Publication status:	Final report
Name and address of testing facility:	Ciba - Geigy Ltd., Basle / Switzerland
Period(s) of experimental work:	March 07 to April 04, 1990
Date of report:	April 24, 1990

Test substance	
Common name/Code:	Propiconazole (CGA 64250)
Batch number:	
Purity/Specification number:	
(appendix 1)	
Vehicle / solvent:	solubilized with TWEEN 80
Physical form:	liquid

Test system		
Objectives:	Biodegradation	
Test guideline(s) used:	OECD No. 301B (of May 12, 1981)	
Rationale for choice of test method:	Registration	
Deviations from the test guideline:	The volume of the test solution was reduced from 3.0 to 1.5 l. The CO2 formed was absorbed with NaOH and determined on a carbon analyzer. Due to the poor solubility of the test substance in water, an emulsifier was used to achieve a better distribution in the medium.	
Compliance with GLP:	Yes [X] No, but complies with sound scientific principles []	
Test system:	Bacteria collected from a sewage treatment plant.	

Findings

CGA 64250 is not biodegradable in this test.

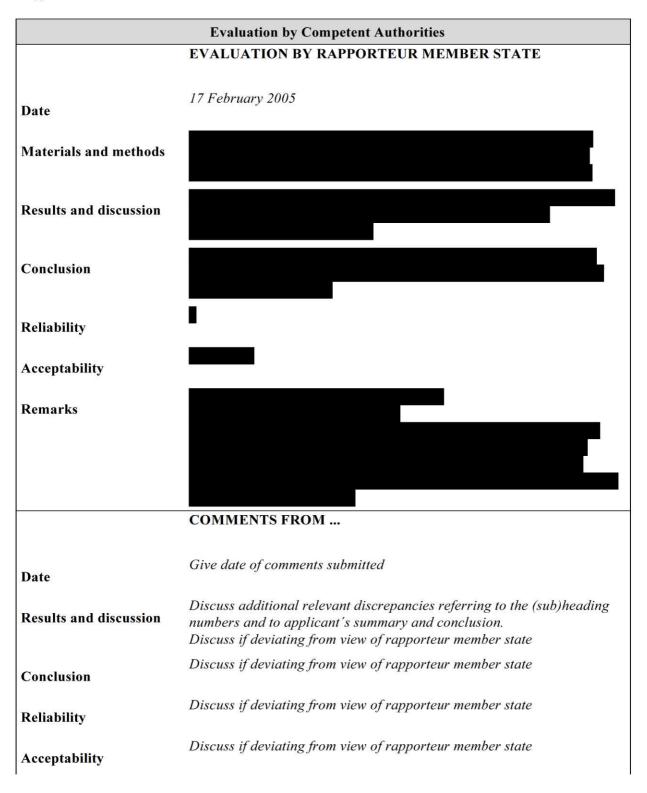
AK / PP 2.54 / July 20, 1994

Statistics: --

Reference to literature and unpublished reports used in this summary:

Reliability indicator 1
Data Protection Claim Yes

Doc IIIA 7 (F&B) 14 of 91



Aerobic Riodegradation		
Actobic blodegradation		
	Aerobic Biodegradation	Aerodic Biodegradation

See annex point 7.4.1.4 (ecotox section)

Bader, U. 1990. Report on the test for inhibitory concentration on aerobic bacteria CGA 64250, Syngenta Crop Protection AG, Basel, CH, Rep. N° 901112, 28.03.1990; Internal Syngenta N° SAM 64250/188

Doc IIIA 7 (F&B) 15 of 91

RMS: The study on aerobic biodegradation in biological sewage treatment is under 7.4.1.4/02 (Spare W.C. 1980).

98/8 Doc IIIA section	7.1.2.2.2/0	Water / sediment degradation study
No.	3	

91/414 Annex II -7.2.1.3.2 /04

General Information	
Title of the study:	Anaerobic Aquatic Soil Metabolism of CGA-64250 (Propiconazole)
Report and /or project number:	Biospherics #85E468AM-Anaerobic
Author of the study:	Y.T. Das
Author of the summary:	A. Keller
Syngenta File Number (SAM):	64250 / 266
Name and address of testing facility:	Biospheric Inc. Rockville, Maryland 20852 / USA
Period(s) of experimental work:	August 27, 1985 to June 12, 1987
Date of report:	August 10, 1987
Publication status:	Final report
Objectives:	
Test guideline(s) used:	US-EPA, Subdivision N, Section 162-3
Rationale for choice of test method:	Registration
Deviations from the test guidelines:	
Compliance with GLP	Yes [X] No, but complies with sound scientific standards []

Test substance 1	
Test substance (code number):	Propiconazole (CGA 64250)
Batch:	
14-C-labeled test substance:	Yes [X] No []
if yes, give specific activity	
Position of labeling:	Triazole
Purity of test substance:	
Structural formula: (* = Position of labeling)	
Formulation used for study:	Yes [] No [X]
Type of formulation (if used):	
Solvent for application (if used):	methanol

Test system		Rice paddy sediment with the standing water.I	II
Water characteristics	Origin	delivered by W.R. Landis Assoc., Inc., Valdosta, Georgia/USA	
	рН	7.1	
	Oxygen content (mg/l)	8.4	
	Redox Pot. (mV)		
	Organic Carbon (%)		
	TOC (mg/l)	75	
	Total suspended solids	332 mg/l	
	Total Nitrogen (mg/l)	==	
	Total Phosphor (mg/l)		
	Hardness	45 mg CaCO3/I	
Sediment Characteristics	Origin	delivered by W.R. Landis Assoc., Inc., Valdosta, Georgia/USA	
	рН	7.5	
	Redox Pot. (mV)		
	Organic Carbon (%)	55	
	Organic Matter (%)	1.3	
	Total Nitrogen (%)	#	
	Total Phosphor (%)		

Doc IIIA 7 (F&B) 16 of 91

Test system		Rice paddy sediment with the standing water.I	П
	Cation Ex. Capacity (meq/100g soil)	15	
	Particle size distrib.		
	% silt	47.2	
	% sand	34.0	
	% clay	18.8	
	Classification (USDA)	Loam	
	Microbial biomass (mg/100g dry soil)	=	
Equilibrium of test system and treatment			
	Incubation conditions	Anaerobic	
	Height of water		
	Height of sediment]
	Temperature	25 +/- 1°C	
	Exclusion of light	Yes [X] No []	
	Equilibrium time of test	about 4 months	
	system		
	Treatment rate	9.9 mg/l	
	Sampling intervals	11	
	Replicates	Yes [X] No []]

Test results		Test system I	Test system II
Substance		ĺ	
Dissipation time	DT 50 (water)	10 days (n=6)	
of parent	DT 90 (water)	33 days	
	DT 50 (system)	37 days (n=6)	
	DT 90 (system)	124 days	
	Total recoveries (%) (mean)	101.6+/- 5.0	
Balance (after 95 days)	Parent (%)	60.6	
	Non-extractables	17.7	
	Metabolites CGA 91305 (not ident.) Unknowns	1.8 1.1	
	CO2 in water	#	
	Volatiles total of which CO2 sulfuric acid trap	0.37	

Summary of findings

Under anaerobic aquatic soil conditions, CGA 64250 degraded with a calculated half-life of 37 days. There were no major metabolites in the extracts of soil and water. A minor metabolite reached a maximum of 1.8 % of the dose applied and appeared to be CGA 91305 (alkanol).

Statistics: $\begin{aligned} r &= -0.841499 \\ Y &= a + bx \end{aligned}$

a = 4.632090b = -0.018528

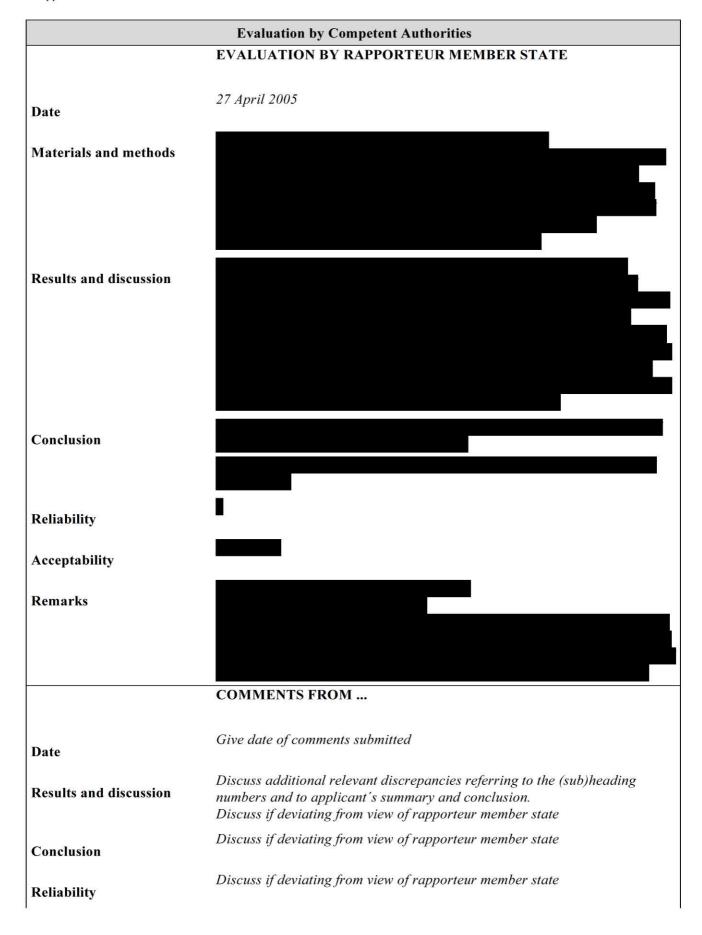
References to literature and unpublished reports -

used in this summary:

AK / PP 2.54 / July 12, 1994

Reliability indicator	1
Data Protection Claim	Yes

Doc IIIA 7 (F&B) 17 of 91



Doc IIIA 7 (F&B) 18 of 91

Acceptability

Discuss if deviating from view of rapporteur member state

98/8 Doc IIIA section No.	7.1.2.2.2/04	Water / sediment degradation study
91/414 Annex	II	Rate and route of degradation in aquatic systems - water / sediment study
Point addressed	7.2.1.3.2	500 999 \$

1.2 Title Metabolism of [Phenyl(U)-¹⁴C] propiconazole under anaerobic aquatic soil conditions.

 1.3
 Report and/or project N° Syngenta File N° (SAM)
 ISSI No. 90072 64250/2081

 1.4
 Lab. Report N° ISSI No. 90072

 1.5
 91/414 Cross Reference to original study / report
 7.2.1.3.2 /05

1.6 Authors Report: Das, Y. T. Summary: Osborn, D. J.

1.7 Date of report 20 July 1992

1.8 Published / owner Unpublished / Ciba Geigy Limited

2.1 Testing facility Innovative Scientific Service, Inc. (ISSI), 515 Blue Ridge, Piscataway, NJ 08854, USA.

2.2 Dates of experimental work 1 October 1990 - 14 July 1992

3. Objectives Investigation of the metabolism of propiconazole under anaerobic aquatic conditions.

4.1 Test substance ISO common name:

Trade name: Batch:

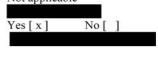
¹⁴C-labelled test substance Specific activity of [¹⁴C-(U)-phenyl]

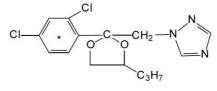
propiconazole

Radiochemical purity of the test substance:

Structural formula: (position of label)

Propiconazole Not applicable





Formulation used for study: Yes [] No [x]

Type of formulation (if used):

4.2 Specification See 4.1 above

4.3 Storage stability Stable for up to 620 days when stored at -20°C.

4.4 Stability in vehicle Not applicable

4.5 Homogeneity in vehicle The test substance was prepared as a solution in acetonitrile.

4.6 Validity Not applicable

5 Vehicle / solvent Acetonitrile (Lot no. D18092, Cat. no. 9017).

6 Physical form Clear yellow viscous liquid.

Doc IIIA 7 (F&B) 19 of 91

Competent Authority Report Rapporteur Finland Propiconazole as film preservative (PT7)

January 2015

7.1 Test method

US EPA Pesticide Assessment Guidelines, Subdivision N, Section 162-3, 18 October 1982

(40 CFR 158).

7.2 Justification The met

The method was selected to meet international regulatory requirements for assessing the

anaerobic aquatic metabolism of pesticides.

7.3 Copy of method Available on request.

8 Choice of method Not applicable.

9 Deviations None

10.1 Certified laboratory Not specified in the report.

10.2 Certifying authority Not applicable.

10.3 GLP The study was conducted in compliance with the FIFRA Good Laboratory Practice

Standards, Final Rule, 40 CFR Part 160, Federal Register Vol. 54, No. 158, Part IV, pp

34052 - 34074, 17 August 1989.

10.4 Justification Not applicable.

11.1 GEP Not applicable.

11.2 Type of facility (official

or officially recognised)

Not applicable.

11.3 Justification Not applicable.

12 Test system

Test system		
Water characteristics	Origin	Flooded Rice Field,
111000000 A LINE OF THE STATE O		Washington County,
		Mississippi, USA
	pН	7.6
	Oxygen content (mg/l)	8.28
	Redox potential (mV)	-274 at start of the study
		-273 at end of the study
	Organic carbon (%)	n.a.
	TOC (mg/l)	n.a.
	Total suspended solids (mg/l)	15
	Total nitrogen (mg/l)	n.a.
	Total phosphorus (mg/l)	n.a.
	Calcium (mg/l)	63
	Magnesium (mg/l)	17
	Alkalinity (as CaCO ₃)	235 mg/l
	Total hardness (as CaCO ₃)	227 mg/l

Doc IIIA 7 (F&B) 20 of 91

Sediment	Origin	Rice Field, Washington
characteristics		County, Mississippi, USA
	pH	6.7
	Redox potential (mV)	-274 at start of the study
		-273 at end of the study
	Organic carbon (%)	n.a.
	Organic matter (%)	2.1
	Total nitrogen (%)	n.a.
	Total phosphorus (%)	n.a.
	Cation exchange capacity	21.8
	(meq/100 g sediment)	
	Particle size distribution	
	- % sand	10
	- % silt	33
	- % clay	57
	Classification (USDA)	Clay
	Bulk density (g/cm ³)	1.26
	Field moisture capacity	42.72% (dry weight basis)
	Microbial biomass	1.9 x 10 ⁷ at start of the study
	(Colony forming units/g)	2.4×10^7 at end of the study

Equilibrium of test system and treatment	Incubation conditions	
	Height of water	20 cm ³ in a 40 cm ³ vial
	Height of sediment	20 g in a 40 cm ³ vial
	Temperature	25 ± 1°C
	Exclusion of light	Yes [x]
	90 TOC 1	No []
	Equilibrium time of test system	Seven weeks
	Treatment rate	10.6 mg/l
	Sampling intervals	0, 1, 3, 7, 14, 21, 30, 60, 90, 120, 180, 270 and 360 days.
	Replicates	Yes [x] No []

13 Findings

Test results			
Dissipation time of parent	DT ₅₀ (water)	n.a.	
.88	DT ₉₀ (water)	n.a.	
	DT ₅₀ (system)	363 days	
	DT ₉₀ (system)	n.a.	
Balance	Total recoveries (%)	$99.6 \pm 1.4\%$	
	Parent (%)	84.2 - 92.2	
	Non-extractables	Maximum of 7.6% of applied	
		after 270 days.	
	Metabolites: 1-[(2-phenyl-2-hydroxy)ethyl]- 1H-1,2,4-triazole 1-(2-phenyl-4-propyl-1,3- dioxalan-2-yl)methyl alcohol 1-[{2-(4-chlorophenyl)-4- hydroxymethyl-1,3-dioxalan-2- yl}methyl]-1H-1,2,4-triazole 1-[{2-(4-chlorophenyl)-4- propyl-1,3-dioxalan-2- yl}methyl]-1H-1,2,4-triazole	Mean maximum concentrations: 3.6% of applied radioactivity after 360 days. 2.8% of applied radioactivity after one day. 1.5% of applied radioactivity at start of the study. 2.4% of applied radioactivity after 180 days.	
	CO ₂ in water	n. a.	
	Volatiles total, of which CO ₂ sulfuric acid trap	< 0.1% of applied radioactivity	

n.a. = not available

Doc IIIA 7 (F&B) 21 of 91

Summary of findings

The radioactivity in the water declined rapidly with only 9.1% of the applied radioactivity remaining in the aqueous phase 30 days after dosing. Over the course of the study the radioactivity in the water declined from 93.2 to 3.1% of the applied radioactivity. Radioactivity in the soil extracts increased from an initial value of 6.7% to 89.3% of the applied radioactivity by the end of the study. There was no significant evolution of radioactivity (< 0.1% of the applied radioactivity) detected in the volatile trapping solutions. Unextractable radioactivity reached a maximum of 7.6% of the applied radioactivity after 270 days incubation. The majority of the radioactivity was present as propiconazole (declining from an initial value of 92.2 to 84.2% of the applied radioactivity).

High performance liquid chromatography analysis revealed the presence of four minor metabolites. The identity of these was confirmed by liquid chromatography and mass spectrometry as 1-[(2-phenyl-2-hydroxy)ethyl]-1H-1,2,4-triazole, 1-(2-phenyl-4-propyl-1,3-dioxalan-2-yl)methyl alcohol, 1-[{2-(4-chlorophenyl)-4-hydroxymethyl-1,3-dioxalan-2-yl}methyl]-1H-1,2,4-triazole and 1-[{2-(4-chlorophenyl)-4-propyl-1,3-dioxalan-2-yl}methyl]-1H-1,2,4-triazole at mean maximum concentrations of 3.6, 2.8, 1.5 and 2.4% of the applied radioactivity, respectively. These metabolites are formed by dechlorination of the phenyl ring, loss of triazole and oxidation of the propyl side chain.

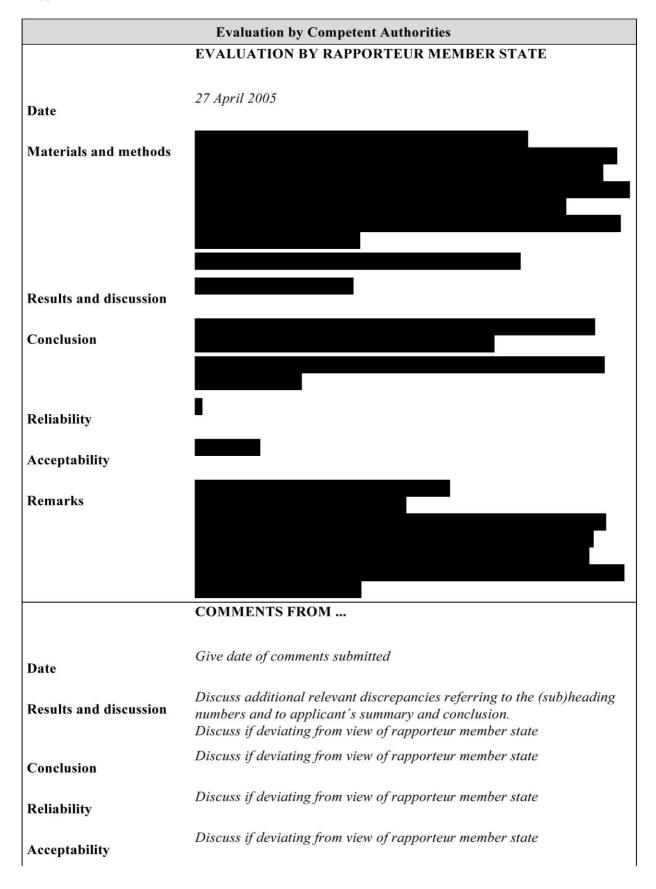
It was concluded that propiconazole was only slowly degraded under anaerobic aquatic conditions in the dark at 25°C, with a calculated DT_{50} of 363 days.

14 Statistics Pseudo first-order reaction kinetics was assumed to calculate the DT₅₀ values.

15 References (published) None.
16 Unpublished data None.
17 Reliability Indicator 1

Data Protection Claim Yes

Doc IIIA 7 (F&B) 22 of 91



PP 2.56/DJO/ 3.4.1995

Doc IIIA 7 (F&B) 23 of 91