

98/8 Doc IIIA section No.	7.1.2.2/0 5	Water / sediment degradation study
---------------------------	----------------	------------------------------------

1. Annex point(s)	7.1.2.2
2. Location in Dossier	Section 7
3. Authors (year) Title Report No., Date Syngenta File N° (SAM) Owner	Reischmann, F.J. (1999) Metabolism of ¹⁴ C-triazole labelled CGA 64250 in two aerobic aquatic systems under laboratory conditions 98RF03, 02.11.1999 64250/4247 Syngenta Crop Protection AG
4. Testing facility	Novartis Crop Protection AG, Basel, Switzerland
5. Dates of work	November 05, 1998 – November 08, 1999
6. Test substance	ISO common name propiconazole. Company Code: CGA 64250, batch : ██████████
7. Test method	Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC, Annex II: 7.2.1.3.2 water / sediment study
8. Deviations	None
9. GLP	yes

Material and methods

The degradation and metabolism of propiconazole (purity ██████████) was studied in two aquatic model systems: river and pond. The test was conducted according to BBA-guidelines. Natural sediment and water samples were taken from Rhine river and a pond. The properties of the water and sediment are presented in Table 1. Prior to the application of the test substance, the water/sediment-systems were equilibrated for about eight weeks until parameters reached stability. The systems were treated with ¹⁴C-triazole-ring labelled propiconazole at a concentration corresponding to a field rate of 0.127 kg/ha and incubated in the dark at 20 C ± 2 °C. 24 samples (included also reserve samples) were taken from Rhine aquatic system and 18 (included also reserve samples) from the pond aquatic system. The sampling dates were 0, 14, 33, 63, 90, 119, and 175 days after treatment in the pond system. The respective dates in Rhine system were 0, 14, 33, 63, 90, 119 and 175 days. The test included also an aquatic system treated with 0.625 kg/ha propiconazole and an untreated system from which biomass samples were taken and reference flasks. The temperature was continuously monitored and the systems were also aerated. Redox potential, pH and oxygen concentration were determined on untreated reference flasks and on treated flasks at the sampling days.

Table 1. The properties of water and sediment in Rhine river- and pond water/sediment systems

Aquatic system	Pond		River	
	Water	Sediment	Water	Sediment
PH	7.7	7.07	8.4	7.3
Temperature (°C)	15.8		19.4	
Oxygen (mg/l)	1.6		6.2	
Redox potential (mV)	40		85	
Organic carbon (mg/l)		4.09		1.71
TOC (mg/l)	4.0		1.4	
CEC (mmol/ z / 100 g sediment)		22.55		11.16
Particle size:				
Clay (%)		19.90		12.09
Silt (%)		54.42		45.83
Sand (%)		25.68		42.08
Water content		1.247		0.899

(g H ₂ O/g dry sediment				
Microbial biomass (mg C/ 100 g sediment, at start		56.89		46.01

Results

The results from the study are presented in Tables 2-4

For all the samples of pond and Rhine aquatic system the total radioactivity ranged from 98.1 to 107.4 %.

Pond water aquatic system

After the treatment, the amount of radioactivity in the pond water decreased from 98.1 % at day 0 to 10.7 % at day 33. From day 63 on the radioactivity slowly decreased from 8.4 % to 7.1 % at day 175. Immediately after application of the test substance, the extractable amount of radioactivity was 2.0 % of the applied dose. It reached a maximum of 91 % at day 33, thereafter slowly decreased to 83.0 % at the end of the study. The amount of non-extractable radioactivity increased to 7.9 % of the applied dose at day 90 and was 7.6 % at the end of the study.

Rhine water aquatic system

After the treatment, the amount of radioactivity in the Rhine water decreased from 96.5 % at day 0 to 10.0 % at day 33. From day 63 on the radioactivity remained at a level between 6.7 % and 8.6 % and amounted to 8.4 % at day 175. At the beginning of the study, the extractable amount of radioactivity was 2.0 % of the applied dose and increased to a plateau in the range of 86.2 % to 88.7 % from day 33 onwards until end of the study. The amount of non-extractable radioactivity increased to 10.1 % of the applied dose at day 90 and was 9.1 % at the end of the study.

Table 2. Balance of radioactivity applied to pond and Rhine river water aquatic system treated with propiconazole (values are given % in the applied radioactivity)

Incubation days	Volatiles		Water		Extractables		Non-extractables		Recovery	
	Pond	Rhine	Pond	Rhine	Pond	Rhine	Pond	Rhine	Pond	Rhine
0	n.p.	n.p.	98.1	96.5	2.0	2.0	0.4	0.4	100.6	98.9
14	<0.1	0.2	22.5	16.3	80.2	81.6	3.1	2.6	105.8	100.7
33	0.2	0.3	10.7	10.0	91.0	88.7	3.2	4.4	105.1	103.3
63	0.2	0.3	8.4	6.7	88.7	87.9	4.4	4.8	101.7	99.7
90	0.3	0.4	9.9	7.6	89.3	86.2	7.9	10.1	107.4	104.2
119	0.3	0.3	8.3	8.6	90.3	87.7	7.3	9.3	106.2	105.9
175	0.4	0.4	7.1	8.4	83.0	87.5	7.6	9.1	98.1	105.3

n.p. = not performed

Pond and Rhine water aquatic system

In the both systems volatiles were formed in very low amounts of 0.4 % of the applied dose at day 175. The concentration of propiconazole in the total pond system decreased at the initiation of the study from 100.2 % to 77.6 % at the end of the study. Respective values in the Rhine water system were 98.5 % and 83.7 %. Eight metabolites were found: CGA 217495 2.8 - 2.9 %, CGA 91305 3.1 - 5.0 %, M3 (unknown) 3.1 - 4.4 % and 1,2,4-triazole 2.1-2.3 % after 90 to 175 days. All other metabolites were found at concentrations below 1.3 %.

The dissipation half-life of propiconazole was determined to be in Rhine water 5.5 days and in the pond water 6.4 days. The total degradation half-life was 485 days for the pond system and 636 days for Rhine river system.

Table 3. Distribution pattern of ¹⁴C-propiconazole in pond aquatic system (values are give in % of the applied radioactivity)

Incubat. days	Compartment	SUBSTANCE			
		Propiconazole CGA 64250	METABOLITE		
			CGA 217 495	CGA 91305	CGA 71019 1,2,4-triazole
0	Water	98.1	< LD	< LD	< LD
	Sediment	2.0	< LD	< LD	< LD
14	Water	20.0	1.1	< LD	< LD
	Sediment	79.7	< LD	< LD	< LD
33	Water	7.4	1.0	< LD	0.6
	Sediment	91.0	< LD	< LD	< LD
63	Water	2.9	1.7	0.4	1.2
	Sediment	84.4	< LD	2.6	0.5
90	Water	2.7	2.2	0.5	1.3
	Sediment	85.6	< LD	0.9	< LD
119	Water	1.2	2.4	0.1	1.2
	Sediment	87.0	0.4	0.9	0.7
175	Water	0.9	2.0	0.1	1.0
	Sediment	76.8	0.9	3.0	1.0

LD = limit of detection

Table 4. Distribution pattern of ¹⁴C-propiconazole in Rhine water aquatic system (values are give in % of the applied radioactivity)

Incubat. days	Compartment	SUBSTANCE			
		Propiconazole CGA 64250	METABOLITE		
			CGA 217 495	CGA 91305	CGA 71019 1,2,4-triazole
0	Water	96.5	< LD	<LD	< LD
	Sediment	2.0	< LD	< LD	< LD
14	Water	15.1	< LD	0.7	0.2
	Sediment	81.6	< LD	< LD	< LD
33	Water	7.0	0.5	1.1	0.6
	Sediment	85.5	< LD	2.3	< LD
63	Water	3.2	1.0	0.8	0.7
	Sediment	84.2	0.3	3.1	< LD
90	Water	2.9	1.3	1.1	1.0
	Sediment	81.9	< LD	1.2	< LD
119	Water	2.3	2.0	1.1	1.2
	Sediment	80.3	< LD	4.0	1.1
175	Water	2.0	2.3	0.8	1.1
	Sediment	81.7	0.5	3.5	0.8

LD = limit of detection

Table 5: Detailed results on the pattern of metabolites in the River aquatic system treated with ¹⁴C-propiconazole

Radioactive fractions (% AR)		Incubation time (days)						
		0	14	33	63	90	119	175
Propiconazole	Water	96.5	15.1	7.0	3.2	2.9	2.3	2.0
	Sediment	2.0	81.6	85.5	84.2	81.9	80.3	81.7
	Total	98.5	96.7	92.6	87.4	84.7	82.6	83.7
M1 (CGA 217495)	Water	*	*	0.5	1.0	1.3	2.0	2.3
	Sediment	*	*	*	0.3	*	*	0.5
	Total	*	*	0.5	1.2	1.3	2.0	2.8
M2 (CGA 91305)	Water	*	0.7	1.1	0.8	1.1	1.1	0.8
	Sediment	*	*	2.3	3.1	1.2	4.0	3.5
	Total	*	0.7	3.4	3.9	2.3	5.0	4.3
M3 (unknown)	Water	*	0.2	0.6	1.0	1.4	2.1	2.1
	Sediment	*	*	*	*	1.5	0.5	1.0
	Total	*	0.2	0.6	1.0	2.9	2.6	3.1
M4 (unknown)	Water	*	*	0.1	*	*	*	*
	Sediment	*	*	*	*	*	*	*
	Total	*	*	0.1	*	*	*	*
M5 (CGA 71019)	Water	*	0.2	0.6	0.7	1.0	1.2	1.1
	Sediment	*	*	*	*	*	1.1	0.8
	Total	*	0.2	0.6	0.7	1.0	2.3	1.9
M6 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	0.8	0.3	0.3	0.9	*
	Total	*	*	0.8	0.3	0.3	0.9	*
M7 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	<0.1	*	*	*	*	*	*
	Total	<0.1	*	*	*	*	*	*
M8 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	*	*	1.3	1.0	*
	Total	*	*	*	*	1.3	1.0	*
Volatiles		Not done	0.2	0.3	0.3	0.4	0.3	0.4
Unextracted		0.4	2.6	4.4	4.8	10.1	9.3	9.1
Unanalysed		0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total		98.9	100.7	103.3	99.7	104.2	105.9	105.3

Table 6: Detailed results on the pattern of metabolites in the Pond aquatic system treated with ¹⁴C-propiconazole

Radioactive fractions (% AR)		Incubation time (days)						
		0	14	33	63	90	119	175
Propiconazole	Water	98.1	20.0	7.4	2.9	2.7	1.2	0.9
	Sediment	2.0	79.7	91.0	84.4	85.6	87.0	76.8
	Total	100.2	99.7	98.4	87.3	88.3	88.3	77.6
M1 (CGA 217495)	Water	*	1.1	1.0	1.7	2.2	2.4	2.0
	Sediment	*	*	*	*	*	0.4	0.9
	Total	*	1.1	1.0	1.7	2.2	2.8	2.9
M2 (CGA 91305)	Water	*	*	*	0.4	0.5	0.1	0.1
	Sediment	*	*	*	2.6	0.9	0.9	3.0
	Total	*	*	*	3.0	1.4	1.0	3.1
M3 (unknown)	Water	*	1.1	1.6	2.3	3.2	3.3	3.1
	Sediment	*	*	*	0.8	1.1	0.5	1.0
	Total	*	1.1	1.6	3.2	4.4	3.8	4.1
M4 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	*	*	*	*	*

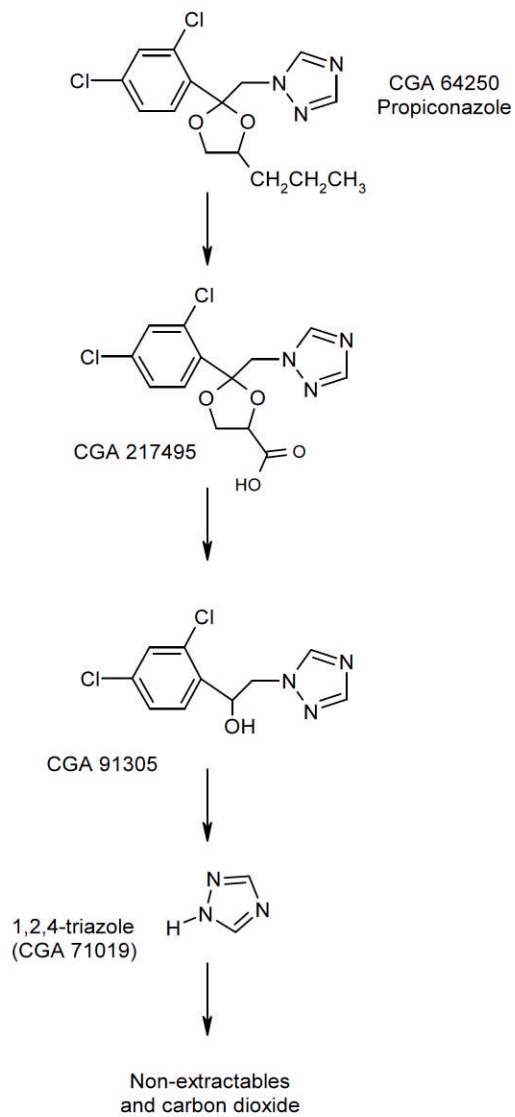
Radioactive fractions (% AR)		Incubation time (days)						
		0	14	33	63	90	119	175
	Total	*	*	*	*	*	*	*
M5 (CGA 71019)	Water	*	*	0.6	1.2	1.3	1.2	1.0
	Sediment	*	*	*	0.5	*	0.7	1.0
	Total	*	*	0.6	1.7	1.3	1.9	2.1
M6 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	*	0.4	0.3	*	0.4
	Total	*	*	*	0.4	0.3	*	0.4
M7 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	*	*	*	*	*
	Total	*	*	*	*	*	*	*
M8 (unknown)	Water	*	*	*	*	*	*	*
	Sediment	*	*	*	*	1.3	0.8	*
	Total	*	*	*	*	1.3	0.8	*
Volatiles		Not done	<0.1	0.2	0.2	0.3	0.3	0.4
Unextracted		0.4	3.1	3.2	4.4	7.9	7.3	7.6
Unanalysed		*	*	0.8	0.1	*	*	*
Total		100.6	105.8	105.1	101.7	107.4	106.2	98.1

Reliability Indicator

1

Data Protection Claim	Yes
-----------------------	-----

Degradation scheme of propiconazole in water/sediment system



Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>27 April 2005, 14 August 2012</i>
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>
Results and discussion	<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>
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>

98/8 Doc IIIA section No.	7.1.3	Adsorption / desorption screening test
---------------------------	-------	--

Adsorption / desorption studies submitted under annex points 7.2.3.1

98/8 Doc IIIA section No.	7.1.4	Further studies on adsorption and desorption in water / sediment systems, and where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary
----------------------------------	--------------	--

98/8 Doc IIIA section No.	7.1.4.1	Field study on accumulation in the sediment
----------------------------------	----------------	--

Not applicable

Justification : non extractable residues are not formed exceeding 70% of the initial dose in the water sediment study

RMS: Justification can not be accepted because mineralisation rate was less than 5% of the initial dose in the water sediment study. MS authorising products may require a field study on accumulation in the sediment.

98/8 Doc IIIA section No.	7.2.1 / 01	Aerobic degradation in soil, initial study
----------------------------------	-------------------	---

91/414 Annex II - 7.1.1.1 / 01

General Information	
Title of the study:	Degradation of CGA 64250 (TILT)® in Soil under Aerobic, Aerobic/Anaerobic and Sterile/Aerobic Conditions
Report and /or project number:	Project Report 22/80
Author:	A. Keller / M. Schneider
Syngenta File Number (SAM):	64250 / 260
Name and address of testing facility:	CIBA - GEIGY Ltd., Basle / Switzerland
Study period:	not mentioned
Date of report:	June 24, 1980
Compliance with GLP:	Yes [] No, but complies with sound scientific standards [X]
Test guideline(s) used:	not mentioned
Deviations from the test guideline:	not mentioned

Test substance	
Test substance (code number):	Propiconazole (CGA 64250)
Batch:	██████████
14-C-labeled test substance : If yes, give specific activity:	Yes [X] No [] ██
Position of label:	Triazole
Purity of test substance:	██████████
Structural formula: (* =Position of label)	
Formulation used for study: Type of formulation (if used):	Yes [] No [X]
Solvent for application (if used):	Water - ethanol (3:1)

Test system		1	2
Origin of soil:		Les Barges VS / Switzerland	
Batch-No:			
Analysis date:		not mentioned	
Classification (USDA):		silty loam	
Particle size distribution:	% silt	61.7	
	% sand	33.5	
	% clay	4.8	
Clay classification:		not mentioned	
Organic matter content:	(%)	4.7	
Organic carbon content: (**)	(%)	2.7	
Total nitrogen:	(%)	not mentioned	
pH:		7.6	
CaCO ₃ :	(%)	not mentioned	
Cation exchange capacity:	(meq/100g soil)	17.8	
Bulk density (air dried and sieved (2 mm) soil)	(g/ml)	--	
Maximum water holding capacity (MWC; pF<0.3):	(ml H ₂ O/100g dry soil)	--	
Field capacity (FC; pF=2.5):	(ml H ₂ O/100g dry soil)	32.6	
Microbial biomass (mg/100 dry soil):	at start	--	
	at end	--	
Soil conditions	aerobic	yes	
	anaerobic	yes	
	aerobic sterile	yes	
Soil moisture	% - MWC	--	
Soil moisture	% - FC	70	
Test conditions		1	2
Incubation temperature(s)	(°C)	25	
Treatment rate:	(mg a.i./kg soil)	1	
Sampling intervals:	(days)	0, 28, 56, 84, 168 and 364 (aerobic)	
No. of samples taken for analysis:		1 pro interval	
Methods used for analysis	HPLC / LC	no	
	TLC	yes	
	GLC	yes	
Methods for identification of degradates		TLC and GLC - MS	
Reliability of statistics / kinetics		--	

Test results		1	2
Disappearance times	DT 50 (days)*	83 (aerobic, calculated) >> 84 (anaerobic and sterile/aerobic)	
	DT 90 (days)*	275 (aerobic, calculated)	
Material balance		Recovery: 86.5 to 94.1%	
Distribution pattern degradates		yes	
Degradation pathway		no	

*) If not in original report, calculated from raw data.

Summary of findings

Under aerobic conditions, the degradation of CGA 64250 was best described by a first order kinetic with a calculated half-life (DT₅₀) of 83 days and a DT₉₀ of 275 days (best fit according to *Timme and Frehse [1980]* and *Timme et al. [1986]*). No significant degradation was found under anaerobic and sterile/aerobic conditions.

The major metabolite U3 was analyzed by GLC-MS and characterized as 1-[2-(2',4'-dichlorophenyl)-4-propanolyl]-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole. Its amount increased steadily during the experiment and reached 22.2 % of the applied radioactivity after 84 days of incubation. It decreased thereafter to 5.4 % after 364 days.

At least three unknown metabolites were detected, two of which amounting to less than 10 %. The third unknown metabolite (U1) amounted to 23.6 % after 364 days. The identification of this degradation product is described in a separate report (Project Report 45/82 of September 15, 1982). Evolution of ¹⁴CO₂ was low (3.1% after 364 days), thus indicating the relative stability of the triazole-moiety in soil.

Non-extractable radioactivity increased during the whole incubation period and reached 62.0 % after 364 days.

References: Timme, G. and Frehse, H. [1980]. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln I. Pflanzenschutz-Nachrichten Bayer 33/1980,1, p. 47 - 60

Timme, G., Frehse, H. and Laska, V. [1986]. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln II. Pflanzenschutz-Nachrichten Bayer 39/1986,2, p. 188 - 204
AK /PP 2.54; MS/AG 7.2; May 27, 1994

Reliability indicator	1
Data Protection Claim	Yes

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	7 July 2005
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>
Results and discussion	<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>
Conclusion	<i>Discuss if deviating from view of rapporteur member state</i>

Reliability

Discuss if deviating from view of rapporteur member state

Acceptability

Discuss if deviating from view of rapporteur member state

98/8 Doc IIIA section 7.2.1 / 02 Aerobic degradation in soil, initial study No.

91/414 Annex II - 7.1.1.1.1/ 02	
General Information	
Title of the study:	Degradation of CGA 64250 (TILT)® in Aerobic Soil. Isolation and Identification of the major, polar Soil Metabolite.
Report and /or project number:	Project Report 45/82 (Addendum to Project Report 22/80)
Author:	A. Keller
Syngenta File Number (SAM):	64250 / 263
Name and address of testing facility:	CIBA - GEIGY Ltd., Basle / Switzerland
Study period:	not mentioned
Date of report:	September 15, 1982
Compliance with GLP:	Yes [] No, but complies with sound scientific standards [X]
Test guideline(s) used:	not mentioned
Deviations from the test guideline:	not mentioned

Test substance	
Test substance (code number):	Propiconazole (CGA 64250)
Batch:	██████████
14-C-labeled test substance :	Yes [X] No []
If yes, give specific activity:	██████████
Position of label:	Triazole
Purity of test substance:	██████████
Structural formula: (* =Position of label)	
Formulation used for study:	Yes [] No [X]
Type of formulation (if used):	
Solvent for application (if used):	Water - ethanol (3:1)

Test system	not relevant	
Origin of soil:		
Batch-No:		
Analysis date:		
Classification (USDA):		
Particle size distribution:	% silt	
	% sand	
	% clay	
Clay classification:		
Organic matter content:	(%)	
Organic carbon content: (**)	(%)	
Total nitrogen:	(%)	
pH:		
CaCO ₃ :	(%)	
Cation exchange capacity:	(meq/100g soil)	
Bulk density (air dried and sieved (2 mm) soil)	(g/ml)	
Maximum water holding capacity (MWC; pF<0.3):	(ml H ₂ O/100g dry soil)	
Field capacity (FC; pF=2.5):	(ml H ₂ O/100g dry soil)	
Microbial biomass (mg/100 dry soil):	at start	
	at end	

Soil conditions	aerobic	
	anaerobic	
	aerobic sterile	
Soil moisture	% - MWC	
Soil moisture	% - FC	

Test conditions		Isolation of metabolite U1	2
Incubation temperature(s)	(°C)	--	
Treatment rate:	(mg a.i./kg soil)	--	
Sampling intervals:	(days)	--	
No. of samples taken for analysis:		--	
Methods used for analysis	HPLC / LC	--	
	TLC	yes	
	GLC	--	
Methods for identification of degradates		TLC and GLC - MS	
Reliability of statistics / kinetics		--	

Test results		Not relevant (Isolation of metabolite)	
Disappearance times	DT 50 (days)*	--	
	DT 90 (days)*	--	
Material balance	--		
Distribution pattern degradates	--		
Degradation pathway	--		

Summary of findings

Degradation of CGA 64250 in soil proceeded via hydroxylation of the n-propyl substituent in the dioxolane ring and mineralization of the phenyl and dioxolane ring systems to a polar metabolic fraction U1. Further experiments were carried out to identify this so far unknown metabolic fraction.

Chromatographic data obtained with appropriate systems indicated that metabolite U1 could be identical with 1,2,4-triazole. After bromination and methylation the compound U1 was identified by GLC-MS as 3,5-dibromo-2-methyl-1,2,4-triazole. This confirms that the unknown metabolite U1 is identical with 1,2,4-triazole.

Reliability indicator	1
Data Protection Claim	Yes

Evaluation by Competent Authorities

See 7.2.1 / 01

AK / PP 2.54/ May 27, 1994

98/8 Doc IIIA section 7.2.1 / 03 Aerobic degradation in soil, initial study
No.

91/414 Annex II - 7.1.1.1.1 / 03

General Information	
Title of the study:	Degradation of 14C-Dioxolane- and 14C-Phenyl-Ring Labelled CGA 64250 (TILT®) in Aerobic Soil
Report and /or project number: Author:	Project Report 08/82 A. Keller / M. Schneider
Syngenta File Number (SAM):	64250 / 262
Name and address of testing facility:	CIBA - GEIGY Ltd., Basle / Switzerland
Study period:	not mentioned
Date of report:	April 8, 1982
Compliance with GLP:	Yes [] No, but complies with sound scientific standards [X]

98/8 Doc IIIA section 7.2.1 / 03 Aerobic degradation in soil, initial study			
No.			
Test guideline(s) used:	not mentioned		
Deviations from the test guideline:	not mentioned		
Test substance			
Test substance (code number):	Propiconazole (CGA 64250)		
Batch:	[REDACTED]		
14-C-labeled test substance : If yes, give specific activity:	Yes [X] No [] [REDACTED]		
Position of label:	Dioxolane; Phenyl		
Purity of test substance:	[REDACTED]		
Structural formula: (* = Position of label)			
Formulation used for study: Type of formulation (if used):	Yes [] No [X]		
Solvent for application (if used):	Water - acetone (3:1)		
Test system		1	2
Origin of soil:		Les Barges VS / Switzerland	
Batch-No:		[REDACTED]	
Analysis date:		not mentioned	
Classification (USDA):		silty loam	
Particle size distribution:	% silt	59.0	
	% sand	35.6	
	% clay	5.3	
Clay classification:		--	
Organic matter content:	(%)	1.7	
Organic carbon content:	(%)	1.0	
Total nitrogen:	(%)	--	
pH:		7.4	
CaCO ₃ :	(%)	--	
Cation exchange capacity:	(meq/100g soil)	7.5	
Bulk density (air dried and sieved (2 mm) soil)	(g/ml)	--	
Maximum water holding capacity (MWC; pF<0.3):	(ml H ₂ O/100g dry soil)	--	
Field capacity (FC; pF=2.5):	(ml H ₂ O/100g dry soil)	30.6	
Microbial biomass (mg/100 dry soil):	at start	--	
	at end	--	
Soil conditions	aerobic	yes	
	anaerobic	no	
	aerobic sterile	no	
Soil moisture	% - MWC	--	
Soil moisture	% - FC	75	
Test conditions		1	2
Incubation temperature(s)	(°C)	25	
Treatment rate:	(mg a.i./kg soil)	1	
Sampling intervals:	(days)	0, 28, 56, 84 and 168	
No. of samples taken for analysis:		1 per interval	
Methods used for analysis	HPLC / LC	yes	
	TLC	yes	
	GLC	--	
Methods for identification of degradates		TLC and GLC - MS	
Reliability of statistics / kinetics		--	

Test results		¹⁴ C-Dioxolane	¹⁴ C-Phenyl
Disappearance times (best fit)	DT 50 (days)*	46	36
	DT 90 (days)*	242	320
Material balance	Recovery: 82.3 to 100.0 %		
Distribution pattern degradates	yes		
Degradation pathway	no		

Summary of findings

The degradation of ¹⁴C-Propiconazole was studied in a silty loam soil under aerobic conditions using two different labels. In contrast to the half-lives reported (DT_{50(dioxolane)} 43 days / DT_{50(phenyle)} 47 days), the following dissipation times were recalculated from the experimental data using optimum curve fitting as described by *Timme and Frehse [1980]* and *Timme et al. [1986]* :

	¹⁴ C-Dioxolane 46
days	
	¹⁴ C-Phenyl 36
days	

The corresponding DT_{90f} were calculated to be 242 and 320 days for the dioxolane- and phenyl-label, respectively.

The main metabolite found with both labels was ¹⁴C-CO₂ amounting after 168 days of incubation to 42.0 and 45.8 % of the dose applied. With both labels, a common transient metabolic fraction was observed. It was identical to a metabolic fraction found in an experiment with the triazole labeled fungicide. It reached 13.8 and 16.9 % of the applied radioactivity after 28 days in the dioxolane- and the phenyl-labeled experiments, respectively, and decreased thereafter to less than 1.5 % after 168 days. It was identified by GLC-MS as a mixture of two compounds (approx.1:1), one found to be CGA 136735, 1-[2-(2',4'-dichlorophenyl)-4-propan-1-ol-1-yl-1,3-dioxolane-2-yl-methyl]-1H-1,2,4-triazole and the other compound hydroxylated probably at the 4- or 5-position of the dioxolane ring moiety. Non-extractable radioactivity increased during the whole incubation period and reached 26.3 and 29.6 %, respectively, after 168 days.

References: Timme, G. and Frehse, H. [1980]. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln I. Pflanzenschutz-Nachrichten Bayer 33/1980,1, p. 47 - 60

Timme, G., Frehse, H. and Laska, V. [1986]. Zur statistischen Interpretation und graphischen Darstellung des Abbauverhaltens von Pflanzenbehandlungsmitteln II. Pflanzenschutz-Nachrichten Bayer 39/1986,2, p. 188 - 204

AK/PP 2.54; MS/AG 7.2; June 1, 1994

Reliability indicator	1
Data Protection Claim	Yes

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>15 May 2007</i>
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>
Results and discussion	<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>
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>