11.1	**GEP**	Not applicable
11.2	**Type of facility (official or officially recognised)**	Not applicable
11.3	**Justification**	Not applicable

12	**Test system**	Species:	Mysid shrimp (*Mysidopsis bahia*)
		Source:	In-house culture
		No. of animals tested:	120 (20 shrimps/test level)
		Age:	< 48 h
		Test containers:	Glass petri dishes with an attached 15cm high nylon screen collar; 2 petri dishes placed in each 2 sections of an aquarium, filled with appr. 9 l natural seawater, providing 2 true duplicates (A/B)
		Dose levels:	Control/vehicle and mean measured concentrations 0.054, 0.114, 0.205, 0.507 and 0.882 mg/l
		Loading:	5 shrimps/petri dish; 4 replicates/dose level
		Administration:	Intermittend flow-trough system
		Photoperiod:	Not specified in the report
		Temperature:	26 - 28 °C
		pH:	7.8 - 7.9
		Dissolved oxygen:	4.2 - 6.3 mg/l (60 - 90 % of saturation)
		Salinity:	27 ± 2 ‰
		General observations:	Mortality and production of offspring were recorded at 24-hour intervals.

13 Findings

Percentage mortality

Mean measured concentration (mg/l)

Day	Veh. Contr.		0.054		0.114		0.205		0.507		0.882	
	A	B*	A	B*	A	B*	A	B*	A	B*	A	B*
7	0	0	0	0	20	0	10	20	30	40	80	60
14	0	10	0	10	30	0	10	20	50	80	100	60
21	0	10	0	10	30	20	10	20	70	90	100	70
28	0	20	10	10	30	20	10	20	70	90	100	80
	---		---		---		---		---		---	
Average	10		10		25		15		80**		90**	

*** A and B = duplicates; ** Significantly greater than the vehicle control (P □ 0.05)**

Reproduction

Concentration (mg/l)	No. of offspring A	B*	Total offspring	Female with brood pouches	Offspring / female
Vehicle Control	10	19	29	9	3.2
0.054	16	11	27	8	3.4
0.114	21	9	30	9	3.3
0.205	0	5	5	4	1.2
0.507	0	0	0	20	0**
0.882	0	0	0	0	0**

*** A and B = duplicates; ** Significantly greater than the vehicle control (P □ 0.05)**

Other observations: No other toxic effects were observed during the test.

Results: Although the difference between the number of offspring/ female at 0.205 mg/l and the vehicle control and the concentration levels 0.054 and 0.114 mg/l is not statistically significant, it appeared to be biologically relevant. Therefore the LOEC and the NOEC were determined to be 0.205 and 0.114 mg/l, respectively.

14 Statistics

The differences among the percentage mortality of vehicle control and exposed mysids were determined by analysis of variance (ANOVA), after arcsin percentage transformation of binomial percentage to angels of equal information in degrees. Statistical comparison between the vehicle control and each concentration was made by using Williams´method. Significant differences in the number of offspring per female in different treatments were determined by ANOVA and Williams´method.

15 References (published)

Williams, D.A. 1971. A test for differnces between treatment means when several dose levels are compared with a zero dose control. Biometrics 27, 103-117

16 Unpublished data

None

17 Reliability Indicator

1

Data Protection Claim	Yes

AG 7.22/GG/01.03.1995

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*
Remarks	

98/8 Doc IIIA section No.	**7.4.3.5.1**	**Effects on sediment dwelling organisms**

1.2	**Title**	Toxicity test of CGA 64250 tech. on sediment-dwelling Chironomus riparius (syn. Chironomus thummi) under static conditions
1.3	**Report and/or project N° Syngenta File N° (SAM)**	64250/4169
1.4	**Lab. Report N°**	983501
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Grade, R.
1.7	**Date of report**	07.05.1999
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection
2.1	**Testing facility**	Novartis Crop Protection AG, Basel, Switzerland
2.2	**Dates of experimental work**	26 Oct. – 22 Apr. 1999
3.	**Objectives**	To determine the effects of propiconazole tech on *chironomus riparius* larvae
4.1	**Test substance**	Propiconazole tech (CGA64250)
4.2	**Specification**	[redacted]
4.3	**Storage stability**	Exp. 07.2000
4.4	**Stability in vehicle**	Stable under conditions of the test
4.5	**Homogeneity in vehicle**	The test substance was dissolved at all test concentrations
4.6	**Validity**	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice.
5	**Vehicle / solvent**	DMF 10 ml – M4-medium
6	**Physical form**	Brown liquid
7.1	**Test method**	OECD Guideline For Testing Of Chemicals, Proposal For Toxicity Test With Chironomidae, May 1998
7.2	**Justification**	The method applied is in conformity with international regulatory requirements for assessing the acute toxicity of chemicals to waterflea.
7.3	**Copy of method**	Available on request
8	**Choice of method**	Not relevant
9	**Deviations**	None
10.1	**Certified laboratory**	Yes
10.2	**Certifying authority**	Not applicable
10.3	**GLP**	Yes
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	Species:	*Chironomus riparius*
	Source:	In house culture
	No. of animals tested:	Water exposure 540
		Sediment exposure 420
	Acclimatisation period:	Water exposure: Test system 8 days, larvae 1 day
		Sediment exposure: Test system 10 days in flowing water, larvae 2 days
	Test containers:	1 l glass beakers
	Dose levels:	Water exposure: control, vehicle, 0.25, 0.50, 1.0, 2.0, 4.0 and 16 mg/l
		Sediment exposure: control, vehicle, 25, 50, 100, 200 and 400 mg/kg dry sediment
	Loading:	Water exposure: 20 larvae per 550 ml
		Sediment exposure: 20 larvae per 500 ml
	Administration:	Static
	Photoperiod:	16 hours light 8 dark 30 minutes transition
	Temperature:	Water exposure: 20.6 – 21.4 °C
		Sediment exposure: 19.9 – 21.1 °C
	pH:	Water exposure: 7.7 – 9.9
		Sediment exposure: 7.9 – 8.5
	Dissolved oxygen:	Water exposure: 5.9 – 8.1 mg/l
		Sediment exposure: 7.5 – 8.0 mg/l
	Water hardness:	Water exposure: 236 – 244 mg/l CaCO3
		Sediment exposure: 232 - 260 mg/l CaCO3
	General observations:	Daily visual inspection, number, time and sex of emerged adults

13 Findings

	EC50	95% CI	NOEC	LOEC
Water Exposure				
Emergence rate	9.5	-	8.0	16
Development rate	35.5	-	4.0	8.0
Sediment Exposure				
Emergence rate	123	91-245	25	50
Development rate	>100	-	50	100

Other observations:	Larval weight 10 days after exposure
	Water exposure: statistically significant effect at 8.0 and 16 mg/l
	Sediment exposure: no clear influence was found

	Conclusion:	Following exposure via the water column, the most sensitive EC50 value was 9.5 mg/l for emergence rate and the most sensitive NOEC was 4.0 mg/l for development. Following exposure via the sediment, the most sensitive EC50 value was 123mg/kg for emergence rate and the most sensitive NOEC was 25 mg/kg for emergence rate.
14	**Statistics**	EC50s and 95% confidence limits were calculated using the logit model. Dunnett tests (α = 5%) was performed to determine NOEC and LOEC values.
15	**References (published)**	None
16	**Unpublished data**	None
17	**Reliability Indicator**	1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*
Remarks	

98/8 Doc IIIA section No.	**7.5.1.1 / 06**	**Effects on other terrestrial non-target organisms**
Annex Point addressed	**II 10.3.5.1**	**Effects on soil non-target micro-organisms - Laboratory testing**

1.2	**Title**	Effects on the activity of soil microflora according to BBA Guideline VI, 1-1 (1990) - Desmel / A 6097 G
1.3	**Report and/or project N°** **Ciba File N° (Desire)**	93 10 49 003 64250/2572
1.4	**Lab. Report N°**	93 10 49 003
1.5	**Cross reference to original study / report**	7.5.1.1/06
1.6	**Authors**	Report: Lang, B. Summary: Görge, G.
1.7	**Date of report**	30.04.1993
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection AG
2.1	**Testing facility**	BioChem GmbH, Labor Cunnersdorf, Cunnersdorf, FRG
2.2	**Dates of experimental work**	09.03. - 06.04.1993
3.	**Objectives**	Examination of the effects of an EC 250 formulation of Propiconazole on the activity of soil microflora, especially the nitrogen turnover and the dehydrogenase activity.
4.1	**Test substance**	ISO common name: Propiconazole Trade name: [redacted] Batch: [redacted] ^{14}C-labelled test substance Yes [ ] No [x] Specific activity of [.....] Mbq/mg (= µCi/mg) Radiochemical purity of the test substance: % (w/w) Formulation used for study: Yes [x] No [ ] Type of formulation (if used): Emulsifiable concentrate (EC) Co-solvent for application (if used): Deionized water
4.2	**Specification**	Not applicable
4.3	**Storage stability**	01/94
4.4	**Stability in vehicle**	The test substance was prepared according to the recommended agricultural practice and therefore it is assumed that stability is guaranteed at least for the time of application.
4.5	**Homogeneity in vehicle**	The test substance was prepared according to the recommended agricultural practice and therefore it is assumed that homogeneity is guaranteed at least for the time of application.
4.6	**Validity**	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice
5	**Vehicle / solvent**	Deionized water
6	**Physical form**	Emulsion

7.1	**Test method**	BBA Guideline, Part VI, 1-1 (2.Edition), 03/1990
7.2	**Justification**	The method applied is in conformity with international regulatory requirements for assessing the effects of chemicals to soil microorganisms.
7.3	**Copy of method**	Available on request
8	**Choice of method**	Not applicable
9	**Deviations**	None
10.1	**Certified laboratory**	Yes
10.2	**Certifying authority**	Sächsisches Staatsministerium für Umwelt und Landesentwicklung
10.3	**GLP**	The study was performed in compliance with the "Principles of Good Laboratory Practice (GLP)" (Chemikaliengesetz, März 1990, Anhang 1)
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

System		**1**	**2**
Soil characterisation:		standard 2.1	standard 2.3
Origin of soil:		Rheinzabern, Baron Kandel	Offenbach, Nebel Essingen
Batch-No:		[redacted]	[redacted]
Analysis date:		not specified	not specified
Classification (USDA):		sand	sandy loam
Particle size distribution:	% silt	9	28
	% sand	87	64
	% clay	4	8
Organic matter content (humus):	(%)	1.21	2.31
Organic carbon content:	(%)	0.70 ± 0.07	1.34 ± 0.14
Total nitrogen:	(%)	not specified	not specified
pH:	Kcl	5.9	6.6
$CaCO_3$:	(%)	not specified	not specified
Cation exchange capacity:	(meq/100g soil)	4.9 ± 0.8	9.5 ± 0.9
Bulk density (air dried and sieved soil, 2mm)	(g/ml)	not specified	not specified
Maximum water holding capacity (MWC; pF<0.3):	(ml H_2O/100g dry soil)	26.10	35.30
Field capacity (FC; pF=2.5):	(ml H_2O/100g dry soil)	not specified	not specified
Microbial biomass (mg/100 g dry soil):	at 22 °C	not specified	not specified
Treatment rates (mg/kg based on soil dry weight)		1. Untreated 2. 0.67 3. 6.67	
Soil moisture:		40 % of MWHC	
Test duration:		28 days	
Sampling intervals:		3 h, 14 d and 28 d after application	
Replicates Test temperature:		20 ± 2 °C	

13 Findings

Test results					
		Test system 1		Test system 2	
Deviations from control (%)		**0.67 mg/kg**	**6.67 mg/kg**	**0.67 mg/kg**	**6.67 mg/kg**
Dehydrogenase activity after 28 days	TPF = Triphenylformazan / % deviation from control value	+ 7 %	+ 1 %	- 5 %	- 5 %
	Control TPF unamended: (µg/10 g d.m. soil)	148.2		324.5	
	Control TPF amended with lucerne meal:				
Nitrification after 28 days	NH_4-N unamended:				
	NO_2-N				
	NO_3-N				
	NH_4-N amended with				
	NO_2-N ammonium				
	sulfate:				
	NO_3-N	0 %	0 %	- 12 %	- 12 %
	NH_4-N amended with	0 %	0 %	0 %	0 %
	NO_2-N lucerne meal	- 5 %	0 %	- 2 %	0 %
	(0.5 %):				
	NO_3-N				
Validation of test with Aretit (Dinosebacate):		Yes [x] No [ ]			
Outlier (Dixon's test):		Yes [ ] No [x]			
Significance (Dunnett's test):		Yes [ ] No [x]			

Summary of findings

In a 28-day laboratory test, ´A 6097 G´ (EC 250 Propiconazole) had no negative influence (± 13 %) neither on the nitrogen turnover nor on the dehydrogenase activity in two standard soils up to an equivalent of the tenfold recommended application rate.

14 Statistics None

15 References (published) None

16 Unpublished data None

17 Reliability Indicator 1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*
Remarks	

98/8 Doc IIIA section No.	**7.5.1.1 / 05**	**Effects on other terrestrial non-target organisms**
91/414 annex Point addressed	**II 8.3.4**	**Effects on soil non-target micro-organisms**

1.2	**Title**	The effects of CGA 71019 on soil respiration and nitrification
1.3	**Report and/or project N° Syngenta File N° (SAM)**	CGA71019/0042
1.4	**Lab. Report N°**	763367
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Völkel, W.
1.7	**Date of report**	16.05.2000
1.8	**Published / owner**	None
2.1	**Testing facility**	RCC, Itingen, Switzerland
2.2	**Dates of experimental work**	15 February 2000 to 16 May 2002
3.	**Objectives**	To investigate the influence of the propiconazole soil metabolite CGA 71019 on the functional activity of soil microorganisms under laboratory conditions.

4.1	**Test substance**	ISO common name: Trade name:	1,2,4-triazole Not applicable
		Batch: ^{14}C-labelled test substance Specific activity of [.....] Radiochemical purity of the test substance:	[redacted] Yes [ ] No [x] Mbq/mg (= µCi/mg) % (w/w)
		Formulation used for study: Type of formulation (if used):	Yes [ ] No [x]
		Co-solvent for application (if used):	None
4.2	**Specification**	Not applicable	
4.3	**Storage stability**	Not applicable	
4.4	**Stability in vehicle**	Not applicable	
4.5	**Homogeneity in vehicle**	Not applicable	
4.6	**Validity**	Soil/test substance mixtures were prepared as required and in conformity with the general laboratory practice	
5	**Vehicle / solvent**	Not applicable	
6	**Physical form**	Not specified in the report	

7.1	**Test method**	OECD Draft Guideline 217 "Soil Microorganisms: Carbon transformation Test, August 1999 and OECD Draft Guideline 216 "Soil Microorganisms: Nitrogen transformation Test, August 1999
7.2	**Justification**	The method applied is in conformity with international regulatory requirements for assessing the effects of chemicals to soil microorganisms.

7.3	**Copy of method**	Available on request
8	**Choice of method**	Not applicable
9	**Deviations**	Not applicable

10.1	**Certified laboratory**	Yes
10.2	**Certifying authority**	Swiss
10.3	**GLP**	Yes
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

Origin of soil:		Landwirtschaftliche Untersuchungs- und Forschungsanstalt, Speyer, Germany
Batch-No:		[redacted]
Analysis date:		not specified
Classification (USDA):		Sandy loam
Particle size distribution:	% silt	26.5
	% sand	66.2
	% clay	7.4
Organic matter content:	(%)	not specified
Organic carbon content:	(%)	0.71
Total nitrogen:	(%)	0.09
pH:	Kcl	6.5
$CaCO_3$:	(%)	not specified
Cation exchange capacity:	(meq/100g soil)	11
Bulk density (air dried and sieved soil, 2mm)	(g/1000 ml)	1328
Maximum water holding capacity (MWC; pF<0.3):	(ml H_2O/100g dry soil)	37
Field capacity (FC; pF=2.5):	(%)	not specified
Microbial biomass	(mg C/1000 g dry soil):	203
Treatment rates (mg/kg based on soil dry weight)		1. Untreated 2. 0.035 3. 0.353
Soil moisture:		42 % of MWHC
Test duration:		28 days
Sampling intervals:		Respiration and nitrification: 0-3 h, 7, 14 and 28 days after application
Replicates Test temperature:		20 ± 2 °C

13 Findings

Test results***			
Deviations from control (%)		**0.035 mg/kg**	**0.353 mg/kg**
....Respiration after 28 days	Glucose amended soil	5.5	8.3
Nitrification after 28 days	Lucerne meal amended soil NO_2-N NO_3-N	 n.a. -5.2	 n.a. -1.5
Validation of test with Aretit (Dinoseb acate):		Yes [X]	No [ ]
Outlier (Dixon's test): Significance (Dunnett's test):		Yes [X] Yes [ ]	No [ ] No [ ]

n.a. not applicable

Summary of findings

CGA 71019 at up to the highest rate tested caused less than 25% effect on respiration and nitrification processes in soil, indicating that at 0.353 mg/kg in soil, CGA 71019 is not expected to result in adverse effects on carbon cycles or organic matter turn-over.

14 Statistics Probability analysis

15 References (published) None

16 Unpublished data None

17 Reliability Indicator 1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*

Remarks

98/8 Doc IIIA section No.	**7.5.1.2 / 03**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 annex Point addressed	**II 8.3.3**	**Toxicity to earthworms - Acute toxicity**

1.2	**Title**	Acute toxicity of 1,2,4-triazole (technical) to earthworms
1.3	**Report and/or project N° Syngenta File N° (SAM)**	HBF/Rg 59 71019/21
1.4	**Lab. Report N°**	Rg 14/85
1.5	**Cross reference to original study / report**	8.3.3.1 /03
1.6	**Authors**	Report: Heimbach, F. Summary: Görge, G.
1.7	**Date of report**	24.02.1986
1.8	**Published / owner**	Unpublished / Bayer AG
2.1	**Testing facility**	Bayer AG, Pflanzenschutz Anwendungstechnik, Institut für Ökologie, Leverkusen, FRG
2.2	**Dates of experimental work**	31.01. - 14.02.1986
3.	**Objectives**	Determination of the acute toxic effects of 1,2,4-triazole to earthworm *Eisenia foetida*.
4.1	**Test substance**	1,2,4-triazole (technical)
4.2	**Specification**	[redacted]
4.3	**Storage stability**	Not specified in the report
4.4	**Stability in vehicle**	It is assumed that the test substance is stable throughout the test period of 14 days.
4.5	**Homogeneity in vehicle**	Evenly incorporated directly into soil with a mixing machine.
4.6	**Validity**	Soil/test substance mixtures were prepared as required and in conformity with the general laboratory practice.
5	**Vehicle / solvent**	Water
6	**Physical form**	Brownish, flat pieces
7.1	**Test method**	OECD Guideline 207 (1984)
7.2	**Justification**	Not applicable
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 report was conducted in compliance with the following GLP Standards: - EPA, TSCA 40 CFR Part 792, 29.11.1983 - FIFRA 40 CFR Part 160, 29.11.1983 - OECD C(81)30 (Final, 12.05.1981

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**	Species:	Earthworm (Eisenia foetida)
		Age:	> 2 months
		Weight:	mean weight 405 mg/worm (pre-test) mean weight 360 mg/worm (main-test)
		Source:	In-house rearing
		No. of animals:	Pre-test: 120 (20 worms at each test level) Main-test: 80 (40 worms at each test level)
		Test vessels:	Glass container with glass lid, volume 1.5 l
		Loading:	10 worms/test vessel
		Replicates:	Pre-test: duplicate; main-test: quadruplicate
		Test period:	14 days
		Photoperiod:	Continuos lightning; about 400 - 800 lx
		Temperature:	20 ± 2 °C
		Soil composition:	69 % quartz sand, 20 % kaolin clay, 10 % sphagnum peat, ca. 1% CaCO3
		Water content:	Start: about 34 %; end: 32.9 %
		pH:	Pre-test: start - 5.95, end - 6.03; main-test: start - 6.41, end - 6.12
		Dose levels:	Pre-test: Control, 1, 10, 100, 500 and 1000 mg/kg d.w. Main-test: Control and 1000 mg/kg d.w.
		General observations:	Mortality and occurrence of sub-lethal effects were recorded at day 0, 7 and 14. The average net weight of surviving worms was determined at the beginning and end of the test.

13 Findings

Dose mg/kg d.w.		Weight change of survivors at day 14 (%)	Mortality at day 14 (%)	Symptoms day 7	Symptoms day 14
Pre-test*	**Contr.**	+ 1 ± 0	0	n.o.	n.o.
	0.1	0	0	n.o.	n.o.
	1	+ 4 ± 0	0	n.o.	n.o.
	10	+ 6 ± 1	0	n.o.	n.o.
	100	+ 2 ± 0	0	n.o.	n.o.
	1000	- 14 ± 4	0	n.o.	n.o.
Main-test**	**Contr.**	+ 17 ± 5	0	n.o.	n.o.
	1000	- 12 ± 3	0	n.o.	n.o.

*** means from 2 replicates per dose level; **means from 4 replicates per dose level; n.o. = not observed**

	Conclusion:	Exposure of *E.foetida* to 1,2,4-triazole (technical) resulted in the 14 day LC 0 of 1000 mg/kg. No toxic symptoms were observed up to that concentration level. Nevertheless, the living weight of worms at 1000 mg/kg was decreased in comparison to the control and the lower dosage groups. Since no change in living weight occurred at 100 mg/kg in the pre-test, the NOEC can be expected at that concentration level.
14	**Statistics**	None
15	**References (published)**	OECD Guideline for Testing of Chemicals, 207 "Earthworm, Acute Toxicity Tests", 04.04.1984.
16	**Unpublished data**	None
17	**Reliability Indicator**	1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*
Remarks	

AG 7.22/GG/03.03.1995

98/8 Doc IIIA section No.	**7.5.1.2 / 04**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 annex Point addressed	**II 8.3.3**	**Toxicity to earthworms - Acute toxicity**

1.2	**Title**	Acute toxicity of CGA 118245 (metabolite of CGA 64250) to the earthworm (Eisenia foetida) in a 14 day test
1.3	**Report and/or project N° Syngenta File N° (SAM)**	118245/0001
1.4	**Lab. Report N°**	747088
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Bätscher, R.
1.7	**Date of report**	13.04.2000
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection
2.1	**Testing facility**	RCC AG, Itingen, Switzerland
2.2	**Dates of experimental work**	
3.	**Objectives**	Determination of the acute toxic effects of CGA118245 to earthworm *Eisenia foetida*.
4.1	**Test substance**	CGA118245
4.2	**Specification**	[redacted]
4.3	**Storage stability**	Exp. 01/2002
4.4	**Stability in vehicle**	Stable under conditions of the test
4.5	**Homogeneity in vehicle**	The test substance was dissolved at all test concentrations
4.6	**Validity**	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice.
5	**Vehicle / solvent**	acetone
6	**Physical form**	liquid
7.1	**Test method**	OECD Guideline 207 (1984)
7.2	**Justification**	Not applicable
7.3	**Copy of method**	Available on request
8	**Choice of method**	Not applicable
9	**Deviations**	None
10.1	**Certified laboratory**	Yes
10.2	**Certifying authority**	Not applicable
10.3	**GLP**	Yes
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**	Species:	*Eisenia fetida*
		Source:	KRAUT & RUEBEN, Germany
		No. of animals tested:	240
		Acclimatisation period:	1 day
		Test containers:	1 l glass beakers
		Dose levels:	Control, 100, 180, 320, 560 and 1000 mg/kg dry soil
		Loading:	10 worms per 556 g dry soil
		Administration:	Static
		Photoperiod:	Continuous illumination
		Temperature:	19 – 20 °C
		pH:	6.1 – 6.5
		Dissolved oxygen:	N/a
		Water hardness:	N/a
		General observations:	Mortality was assessed at 7 and 14 post exposure. Body-weights at the beginning and end of the test.

13 Findings

Percent mortality (average of four replicates)

Dose mg/kg d.w.	**Day 7**	**Day 14**
Control	0	0
100	0	0
180	5	5
320	5	5
560	2.5	2.5
1000	5	5

LC 50 (mg/kg) (conf. limit) **> 1000**

Other observations: Mortality did not exceed the accepted 10% baseline.

Results: No significant mortality or loss of body weight was observed up and including the highest concentration tested (1000 mg/kg dry soil).

Conclusion: The test item is not toxic to earthworms up to and including 1000 mg/kg dry soil. The LC50 is >1000 mg/kg of dry soil

14 Statistics None

15 References (published) None

16 Unpublished data None

17 Reliability Indicator 1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*

Remarks

98/8 Doc IIIA section No.	**7.5.1.2 / 05**	**Acute toxicity test to earthworms or other soil non-target organisms**
91/414 annex Point addressed	**II 8.3.3**	**Toxicity to earthworms - Acute toxicity**

1.2	**Title**	A 14-day acute toxicity test with the Earthworm (Eisenia fetida)
1.3	**Report and/or project N° Syngenta File N° (SAM)**	64250/4258
1.4	**Lab. Report N°**	1047.070.630
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Nienstedt, K.M
1.7	**Date of report**	09.12.1999
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection
2.1	**Testing facility**	Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland
2.2	**Dates of experimental work**	22 Apr. – 7 May 1999
3.	**Objectives**	Determination of the acute toxic effects of propiconazole tech. to earthworm *Eisenia foetida*.
4.1	**Test substance**	CGA64250 tech.
4.2	**Specification**	[redacted]
4.3	**Storage stability**	Not specified in the report
4.4	**Stability in vehicle**	Stable under conditions of the test
4.5	**Homogeneity in vehicle**	The test substance was dissolved at all test concentrations
4.6	**Validity**	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice.
5	**Vehicle / solvent**	Acetone
6	**Physical form**	Liquid
7.1	**Test method**	OECD Guideline 207 (1984)
7.2	**Justification**	Not applicable
7.3	**Copy of method**	Available on request
8	**Choice of method**	Not applicable
9	**Deviations**	None
10.1	**Certified laboratory**	Yes
10.2	**Certifying authority**	Not applicable
10.3	**GLP**	Yes
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

Species:	*Eisenia fetida*
Source:	BBA, Germany
No. of animals tested:	280 (40 per treatment)
Acclimatisation period:	1 day
Test containers:	1.5 l glass beakers
Dose levels:	Control, solvent control, 62.5, 125, 250, 500 and 1000 mg/kg dry soil
Loading:	10 worms per 750 g dry soil
Administration:	Static
Photoperiod:	Continuous
Temperature:	18.5 – 24.0 °C
pH:	5.9 – 6.1
Dissolved oxygen:	N/a
Water hardness:	N/a
General observations:	Borrowing time at 0 and 7 days. Mortality and health assessment at 7 and 14 days.

13 Findings

Percent mortality ± standard deviation (average from four replicates)

Dose mg/kg d.w.	7 day	14 day
Solvent control	0	0
Control	0	0
62.5	0	0
125	0	0
250	0	0
500	0	2.5 ± 5
1000	95 ± 10	100 ± 0
LC 50 (mg/kg)	**686.47**	
(conf. limit)	**500 - 1000**	

Other observations: On days 0 and 7 burrowing time of earthworms was more than 60 minutes in the 500 and 1000 mg a.i./kg dry soil.

Results: On both days 7 and 14 mortality was significantly different from the solvent control in the 1000 mg/kg treatment.

Conclusion: The LC50 is 686.47 mg/kg of dry soil.

14 Statistics EC50 value was calculated using the binominal probability method. NOEC and LOEC were calculated using the Yates corrected Chi squared test. Body weights were compared using the non-parametric Kruskal-Wallis ANOVA followed by Tukey's multiple comparison tests.

15 References (published) None

16 Unpublished data None

17 Reliability Indicator 1

Data Protection Claim	Yes

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	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*
Remarks	

Section 7.5.1.3/02
Annex Point IIIA XIII 3.4
Terrestrial plant toxicity

		Official use only
	REFERENCE	
Reference	Maggio RM, 1990. Propiconazole: Tier 2 Seedling Emergence Nontarget Phytotoxicity Study Using Propiconazole Pan-Agricultural Laboratories In, Madera, CA, USA Study number LR90-420	
Data protection	Yes	
Data owner	Syngenta LTD	
Criteria for data protection	[redacted]	x
	GUIDELINES AND QUALITY ASSURANCE	
Guideline study	Yes EPA Guideline No 123-1 – Comparable to the recently revised OECD 208 protocol	
GLP	Yes	
Deviations	None	
	METHOD	
	Tier 2 nontarget phytotoxicity test, using 10 species of plants done according to EPA guideline to assess the effects of propiconazole on seedling survival and emergence. The species used were soybean, lettuce, carrot, tomato, cucumber, cabbage, oat, ryegrass, maize and onion	
Test material	Propiconazole (technical)	
Lot/Batch number	[redacted]	
Specification	[redacted]	
Purity	[redacted]	
Composition of Product		
Further relevant properties	Water solubility – 110 ppm 20 C	
Method of analysis	Means were separated using Duncan's New Multiple Range Test, and the percentage effects values were input into a SAS probitprogramme	
Preparation of TS solution for poorly soluble or volatile test substances	N/A	
Reference substance	No	
Method of analysis for reference substance	N/A	
Testing procedure		
Dilution water	All applications rates are quoted in US Imperial units, so the appropriate conversions are given below: SPRAY CONCENTRATION for US Gallons/acre Max rate (1.5 pounds/acre) x 1120 = g/ha Max rate (1.5 pounds/acre) = (1.5 x 453.592g) / (50gal x 3.785L) = 3.5952 g/L 1 hectare = 2.47 acres	

Section 7.5.1.3/02
Annex Point IIIA XIII 3.4
Terrestrial plant toxicity

Table 1: Conversion from rates in lbs ai/A to spray concentration in g/L

Rates in lbs ai/A	Rates in g ai/ha	Spray Concentration g/L
0.0185	20.72	**0.0443**
0.056	62.72	**0.1342**
0.167	187.04	**0.4003**
0.5	560	**1.198**
1.5	1680	**3.5952**

Test plants

Soybean, Glycine max
Lettuce, Lactuce sativa
Carrot, Daucus carota
Tomato, Lycopersicon esculentum
Cucumber, Cucumis sativus
Cabbage, Brassica oleracea
Oat, Avena sativa
Ryegrass, Lolium perenne
Corn, Zea mays
Onion, Allium cepa

Test system

Ten seeds per species were planted per pot, for soybean, cucmber, oat and maize the seeds were planted at 2.5 cm, for the other species the seeds wee planted at 1.3cm. There were 3 replicates per treatment. After sowing the pots were sprayed with the required rates on propoiconazole on the following day.

Test conditions

Greenhouse temperatures and humidities were recorded by hydrothermographs – Daily temperatures ranges from 68-90 F (=20 – 32 C) and humidity ranged from 45 – 85 % on a natural diurnal cycle

x

Test duration

21 days

Test parameter

Seedling Emergence and Survival

Sampling

Method of analysis of the plant material

Quality control

Statistics

RESULTS

If appropriate, include tables. Sample tables are given below

Results test substance

Non-entry field

Applied initial concentration

x

The soil concentration predicted following a single application of propiconazole is calculated using the following equation:

$$PEC_s\ (\text{mg ai/kg}) = \frac{\text{Application rate (g ai/ha)}}{\text{Soil density (g/cm}^3) \times \text{Soil depth (cm)} \times 100}$$

In addition we need to convert lbs ai/acre to g ai/ha – this conversion factor is 1120. Assuming a standard soil density of 1.5 g/cm^3 and that the product would be incorporated to a depth of 5 cm, gives the PEC_{Soil} values below (to 3 significant figures)..

Rates in lbs ai/A	Rates in g ai/ha	Rates in mg ai/kg soil
0.0185	20.72	0.0276
0.056	62.72	0.0836
0.167	187.04	0.249

Section 7.5.1.3/02
Annex Point IIIA XIII 3.4
Terrestrial plant toxicity

0.5	560	0.747
1.5	1680	2.24

Phytotoxicity rating

Plant height

Plant dry weights

Root dry weights

Root length

Number of dead plants

None

Effect data

x

Seedling Emergence (14 DAT):
At rates of 2.24 mg ai/kg soil propiconazole had no effect on seedling emergence for 8 of the 10 species tested (lettuce, carrot, tomato, cucumber, oat, ryegrass, corn and onion) so this suggests that in general propinacoazole does not have pose a high risk to non target plants. **The NOEC for seedling emergence of the 2 more sensitive species (soybean and cabbage) was 0.5 lb ai/A or 0.747 mg ai/kg soil.**
Generally the effects on seedling emergence was so low that it was not possible to calculate EC50 values for this endpoint, except for the most sensitive species which was cabbage with an EC50 of 4.52 lb ai/A or 6.75 mg/kg soil.

Seedling Survival (21 DAT):
Similarly at rates of 2.24 mg ai/kg soil propiconazole had no effect on seedling survival for 9 of the 10 species tested (soyabean, lettuce, carrot, tomato, cucumber, oat, ryegrass, corn and onion) so this suggests that in general propinacoazole does not have pose a high risk to non target plants.
The NOEC for survival on the most sensitive species (cabbage) was 0.5 lb ai/A or 0.747 mg ai/kg soil.
Generally the effects on seedling survival were so low that it was not possible to calculate EC50 values for this endpoint, except for the most sensitive species which was cabbage with an EC50 of 2.536 lb ai/A or 3.79 mg/kg soil.
Results – No Effect Levels (mg ai/kg soil)

	Seedling Emergence	**Seedling Survival**
Soybean	**0.747**	2.24
Lettuce	2.24	2.24
Carrot	2.24	2.24
Tomato	2.24	2.24
Cucumber	2.24	2.24
Cabbage	**0.747**	**0.747**
Oat	2.24	2.24
Ryegrass	2.24	2.24
Corn	2.24	2.24
Onion	2.24	2.24

Section 7.5.1.3/02 **Annex Point IIIA XIII 3.4**	**Terrestrial plant toxicity**	
Concentration / response curve		
Other effects		
Results of controls		
Number/ percentage of plants showing adverse effects		
Nature of adverse effects		
Test with reference substance		
Concentrations		
Results		
	APPLICANT'S SUMMARY AND CONCLUSION	
Materials and methods	Give guidelines and describe/discuss deviations from test guidelines or, in case of non-guideline study, briefly describe method	
Results and discussion	The levels of damage seen in this test were low in terms of ecological significance, for even at the highest rates tested no plants failed to germinate or grow. The test included 10 species representing 6 different families of dicots and 2 families of monots (onion and 3 grasses). In general across all these data cabbage proved to be the most sensitive species. **Given the breadth of data in this test, across 10 different species of higher plants at a very sensitive growth stage, it is proposed to use the NOEC figure of 0.747 mg ai/kg soil from the final seedling survival assessment as the PNEC for plants in the risk assessment.**	x
EC_{20}		
EC_{50}		
EC_{80}		
Conclusion		
Reliability	1	
Deficiencies	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*8 February 2006*
Materials and methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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*
Remarks	

98/8 Doc IIIA section No.	**7.5.2.1/01**	**Reproduction study with other soil non-target macro-organisms**

1.2	**Title**	A chronic Toxicity and reproduction test exposing the Earthworm Eisenia fetida to CGA 64250 EC 250 (A-6097 K) in OECD artificial soil
1.3	**Report and/or project N° Syngenta File N° (SAM)**	64250/4257
1.4	**Lab. Report N°**	1047.071.630
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Nienstedt, K.M.
1.7	**Date of report**	07.12.1999
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection AG
2.1	**Testing facility**	Springborn Smithers Laboratories (Europe) AG, Horn, Switzerland
2.2	**Dates of experimental work**	15 Apr. – 11 Jun. 1999
3.	**Objectives**	To estimate the chronic toxicity of a propiconazole formulation to *Eisenia fetida*
4.1	**Test substance**	[redacted] containing 250 g/l of propiconazole
4.2	**Specification**	[redacted]
4.3	**Storage stability**	Exp. 10/2001
4.4	**Stability in vehicle**	Stable under conditions of the test
4.5	**Homogeneity in vehicle**	The test substance was dissolved at all test concentrations
4.6	**Validity**	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice.
5	**Vehicle / solvent**	water
6	**Physical form**	liquid
7.1	**Test method**	BBA Guideline VI, 2-2 (1984) and the ISO Draft (ISO/DIS 11268-2)
7.2	**Justification**	Not applicable
7.3	**Copy of method**	Available on request
8	**Choice of method**	Not applicable
9	**Deviations**	None
10.1	**Certified laboratory**	Yes