

- 10.1 Certified laboratory** Not specified in the report.
- 10.2 Certifying authority** Not applicable.
- 10.3 GLP** The study was conducted in compliance the US EPA Standards of Good Laboratory Practice.
- 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	3	4	5
Origin of soil:	Alpaugh	Hollister	Lakeland	Lawrenceville	Pachappa
Batch No.:	■	■	■	■	■
Analysis date:	n.a.	n.a.	n.a.	n.a.	n.a.
Classification (USDA):	Silty clay	Clay loam	Sand	Silty clay loam	Sandy loam
Particle size distribution:					
% silt	44	46	0	62	21
% sand	11	26	91	9	62
% clay	45	28	9	29	17
% Organic matter:	1.2	3.0	0.2	1.2	1.4
% Organic carbon**:	0.70	1.74	0.12	0.70	0.81
% Total nitrogen:	n.a.	n.a.	n.a.	n.a.	n.a.
pH:	8.8	6.9	4.8	7.0	6.9
% CaCO ₃ :	n.a.	n.a.	n.a.	n.a.	n.a.
Cation exchange capacity: (meq/100 g soil)	30.5	16.9	1.2	6.6	11.1
Bulk density (g/cm ³)	n.a.	n.a.	n.a.	n.a.	n.a.
Maximum water holding capacity (MWC; pF<0.3):	n.a.	n.a.	n.a.	n.a.	n.a.
Field capacity (FC; pF=2.5):	n.a.	n.a.	n.a.	n.a.	n.a.
Equilibration time:					
adsorption	95 hours				
1. desorption	46 hours				
2. desorption	24 hours				
Soil / solution ratio:	5:1	4:1	2:1	4:1	3:1
Duplicate analysis:	Yes [x]		No []		
Concentrations used:	0.086, 0.043, 0.0085 and 0.0043 mg/l				

** % organic carbon = % organic matter/1.724 n.a. = not available

Test conditions		
Incubation temperature(s)	(°C)	25 ± 1°C
Methods used for analysis	HPLC / LC	Purity of test substance
	TLC	Purity of test substance
	LSC	Aqueous calcium chloride solutions and combusted soil samples.
Methods for identification of degradates	Not analysed	
Reliability of statistics / kinetics	Not applicable.	

13 Findings

Test results						
Soil		1	2	3	4	5
Adsorption	k	0.833	0.748	0.234	0.722	0.719
	K _{om} = Q	69.42	24.93	117.0	60.17	51.36
	K _{oc}	120	43	202	104	89
Desorption step 1	k*	2.130	1.143	0.610	0.816	1.065
	K _{om} = Q	177.5	38.1	305.0	68.0	76.1
	K _{oc}	304	65.69	508.3	116.6	131.5
Desorption step 2	k*	7.93	1.86	7.60	2.04	3.49
	K _{om} = Q	660.8	62.0	3800	170	249.3
	K _{oc}	1133	106.9	6333	291.4	430.9

Summary of findings

The average K_{oc} value for 1,2,4-triazole in the five soils was 112 ± 58, indicating that the chemical has high potential mobility in soil. However, the K_d values for desorption were much higher than those for adsorption indicating that some of the triazole may be irreversibly bound to the soils resulting in a lower mobility than predicted by the adsorption coefficients.

14 Statistics

Calculations were carried out on a computer using the Cricket Graph. The Freundlich adsorption constant k_d was calculated on the basis of the Freundlich equation :-

$$\log(x/m) = \log(k_d) + 1/n \times \log(C_e)$$

where x/m is the equilibrium concentration in soil

C_e is the equilibrium concentration in the aqueous phase and

1/n is the slope of the adsorption isotherm.

The adsorption constants were calculated from the following equations :-

$$K_{oc} = (100 \times k) / \%OC$$

$$K_{om} = (100 \times k) / \%OM$$

15 References (published)

None.

16 Unpublished data

None.

17 Reliability Indicator

1

Data Protection Claim	Yes
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Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>13 May 2005</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 7.2.3.1
No. **Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**

1. Annex point(s)	7.2.3.1
2. Location in Dossier	Section 7
3. Authors (year) Title Report No., Date Syngenta File N° (SAM) Owner	Adam, D. (2000). Adsorption/Desorption of CGA 118245 in various soils. 99DA09, 11.05.2000 118245 / 0002 Syngenta Crop Protection AG
4. Testing facility	Novartis Crop Protection AG, Basel, CH.
5. Dates of work	November 9, 1999 – May 11, 2000
6. Test substance	CGA 118245 (a metabolite of propiconazole) batch [REDACTED]
7. Test method	Commission Directive 95/36/EC amending Council Directive 91/414/EEC, Annex II: Fate and Behaviour in the Environment; 7.1 Fate and Behaviour in Soil, 7.1.2 Adsorption and desorption, 1995
8. Deviations	None
9. GLP	Yes

Material and methods

Adsorption and desorption of triazole labelled CGA 118 245 was studied according to OECD guidelines (106) and GLP. The test was conducted in three soils (properties of the soils are given in Table 1) at 20 °C. It was performed 48 hours pre-test with one concentration and the final test with five concentrations in duplicates. On the basis of the results from the pre-test CGA 118 245 degraded rapidly; in 5 hours 16.8 % in aqueous phase. The amount of adsorption reached a maximum after 2-5 hours.

Table 1. Properties of the studied soils

	Pappelacker loamy sand soil	Gartenacker silt loam soil	Vetroz loam soil
pH	7.5	7.1	7.2
Organic carbon	1.1 %	2.0 %	4.7 %
Total nitrogen	0.1 %	0.3 %	0.4 %
CaCO ₃	9.8 %	7.4 %	56 %
CEC mmol/z/100 g	5.9	12.7	28.1
Particle size distribution			
- clay	3.1 %	11.9 %	23.3 %
- silt	21.9 %	48.0 %	58.5 %
- sand	75.0 %	40.1 %	18.2 %

Results

The final test was performed with an adsorption time of 2 hours and a desorption time of 5 hours. The recovery of the samples comprising the aqueous phases, the soil extracts and non-extractable residues was between 97.8 and 100.2 % of the radioactivity applied. The amount of radioactivity after adsorption step in aqueous phase was 73.9 %, 72.9 % and 70.1 % in Pappelacker, Gartenacker and Vetroz soils. The corresponding values for the soil extracts were 24.9 %, 25.4 % and 28.7 %. HPLC analysis showed that significant amounts of CGA 118 245 was degraded, 7-14 %, during 2 hours

incubation. 66.9 %, 65.4 % and 56.5 % of the test compound were in aqueous phase and in the extractables of the soils were 21.1, 19.2 and 25.6 %. The results are summarized in Table 2. The results are corrected for the actual amount of the test substance found in the aqueous phases and in the soil extracts

Table 2. Properties of the studied soils

Soil	OC %	l/n	K _{ads} ml/g	K _{oc} ml/g	K _{om} ml/g	K _{clay} ml/g
Pappelacker	1.1	0.898	1.1	100.9	58.5	34.4
Gartenacker	2.0	0.913	2.4	119.7	69.4	20.1
Vetroz	4.7	0.943	7.8	166.2	96.4	33.5

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	<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.	7.3.1	Phototransformation in air, including identification of breakdown products
91/414 Annex Point addressed	II 7.2.2.1	Rate and route of degradation in the air

1. Annex point(s)	7.3.1
2. Location in Dossier	Section 7
3. Authors (year) Title Report No., Date Syngenta File N° (SAM) Owner	Stamm E (1994) Rate estimation of the hydroxyl radical oxidation of propiconazole CGA 6425000DA06, 4.04.2001 64250/2358 Syngenta Crop Protection AG
4. Testing facility	Syngenta Crop Protection AG, Basel, Switzerland
5. Dates of work	May 31, 1994
6. Test substance	ISO common name propiconazole. Company Code: CGA 64250,
7. Test method	Atkinson Method
8. Deviations	None
9. GLP	No

Reliability indicator 1

Data Protection Claim	No
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Results

The half-life of propiconazole in the atmosphere was estimated using the (Q)SAR based AOP program⁴ v1.51 developed from Atkins⁵ it is based on reactions with atmospheric OH-radicals. The half-life was estimated at between 3.4 and 14 hours based on a 12 hour day.

⁴ Syracuse Research Corporation, Syracuse, New York, USA

⁵ Atkins R (1988), Environmental Toxicological Chemistry 7, 435.

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>4 November 2005</i>
Materials and methods	[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>
Remarks	

PROPICONAZOLE

Dossier for Directive 98/8/EC Document IIIA

Section 7.4 : Effects on Aquatic Organisms

Section 7.5 : Effects on Terrestrial organisms

Section 7.6 : Summary of Ecotoxicological Effects and Fate and Behaviour in the Environment

**From
Tier I - Section 6 - Annex II
of 91/414 dossier**

98/8 Doc IIIA section No.	7.4.1.1 / 06	Acute toxicity to fish
91/414 annex Point addressed	II 8.2.1	Effects on aquatic organisms - Acute toxicity to fish

1.2 Title	Acute toxicity of CGA 64250 to spot (<i>Leiostomus xanthurus</i>)
1.3 Report and/or project N° Syngenta File N° (SAM)	R65 64250/207
1.4 Lab. Report N°	BP-82-6-40
1.5 Cross reference to original study / report	8.2.1 /06
1.6 Authors	[REDACTED]
1.7 Date of report	11.06.1982
1.8 Published / owner	Unpublished / Syngenta Crop Protection AG
2.1 Testing facility	[REDACTED]
2.2 Dates of experimental work	22. - 26.05.1982
3. Objectives	Determination of the acute toxicity of Propiconazole to spot
4.1 Test substance	CGA 64250 technical
4.2 Specification	[REDACTED]
4.3 Storage stability	Not specified in the report.
4.4 Stability in vehicle	Stable under conditions of the test. At the end of the test, the mean measured values ranged from 88 to 112 % of the nominal values.
4.5 Homogeneity in vehicle	Not specified in the report
4.6 Validity	Solutions of the test substance were prepared as required and in conformity with the general laboratory practice.
5 Vehicle / solvent	Acetone, max. 0.3 ml/l
6 Physical form	Liquid
7.1 Test method	EG&G Bionomics Marine Research Laboratory, Test Protocol for Fishes:Static, Acute Marine Fish Toxicity Test. 02/1980, 3pp.
7.2 Justification	The method applied is in conformity with international regulatory requirements for assessing the acute toxicity of chemicals to fish.
7.3 Copy of method	Available on request
8 Choice of method	Not relevant
9 Deviations	Not applicable
10.1 Certified laboratory	Not specified in the report
10.2 Certifying authority	Not applicable
10.3 GLP	No
10.4 Justification	Although the study was not conducted in compliance with the principles of GLP, it complies with sound scientific standards and 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

Species: Spot (*Leiostomus xanthurus*)
 Source: XXXXXXXXXX
 No. of animals tested: 96 (12 fish/dose level)
 Acclimatisation period: 38 days
 Test containers: 19 l glass aquaria, filled with 15 l
 Dose levels: Control/blank, control/vehicle, and mean measured concentrations 0.53, 0.93, 1.52, 2.84 and 5.02 mg/l
 Loading: 0.16 g/l
 Administration: Static exposure
 Photoperiod: Indirect daylight, about 9 hours daily
 Temperature: 22 - 23 °C
 pH: 7.4 - 8.1
 Salinity: 27 - 28 ‰
 Dissolved oxygen: 74 % of saturation in all aerated treatments
 General observations: Mortality and general symptoms of toxicity were recorded 0, 24, 48, 72 and 96 hours after dosing.

13 Findings

Number of mortalities:

Concentration mg/l	24 h	48 h	72 h	96 h
Control, blank	0	0	0	0
Control, vehicle	0	0	0	1
0.53	0	0	0	0
0.93	0	0	0	0
1.52	0	0	0	0
1.52 (unaerated)	0	0	1	1
2.84	1	3	4	8
5.02	10	12	12	12
LC 50 (mg/l) (conf. Limit)	3.93 (3.73-4.13)	3.11 (2.44-3.66)	3.01 (2.38-3.59)	2.60 (2.19-3.29)

Other observations: In both control groups and in the groups at the concentration levels 0.53 and 0.93 mg/l, no symptoms of toxicity were observed. All fish exposed to the concentration levels of 1.52 mg/l appeared lethargic.

Results: Exposure of spot to Propiconazole resulted in the 96-hour LC 0, LC 50 and LC 100 of 1.52, 2.60 and 5.02/10.0 mg/l, respectively. The EC 0 was 0.93 mg/l.

Conclusion: Propiconazole is classified as toxic to spot.

- 14 Statistics** The LC 50-values were calculated according to the moving average angle method (Stephan, C.E. 1977. Methods for calculating a LC 50. ASTM, Aquatic Toxicology and Hazard Evaluation. (F.L.Mayer and J.L.Hamelink, eds.) pp. 65-84).
- 15 References (published)** None
- 16 Unpublished data** None
- 17 Reliability Indicator** 1

Data Protection Claim	Yes
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AG 7.22/GG/22.02.1995

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	<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>
Remarks	

98/8 Doc IIIA section No.	7.4.1.1 / 09	Acute toxicity to fish
91/414 annex Point addressed	II 8.2.1	Effects on aquatic organisms - Acute toxicity to fish
1.2 Title		Acute toxicity test of CGA 64250 techn. to Rainbow Trout (<i>Oncorhynchus mykiss</i>) under static conditions
1.3 Report and/or project N° Syngenta File N° (SAM)		64250 / 4196
1.4 Lab. Report N°		983986
1.5 Cross reference to original study / report		-
1.6 Authors		██████████
1.7 Date of report		09.08.1999
1.8 Published / owner		Unpublished / Syngenta Crop Protection AG
2.1 Testing facility		██
2.2 Dates of experimental work		11 June – 7 July 1999
3. Objectives		Determination of the acute toxicity of CGA64250 tech. to rainbow trout
4.1 Test substance		Propiconazole tech.
4.2 Specification		██
4.3 Storage stability		Exp. 31 July 2000
4.4 Stability in vehicle		Stable under conditions of the test
4.5 Homogeneity in vehicle		Not specified in the report; 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
6 Physical form		Brown liquid
7.1 Test method		OECD-Guideline for testing of chemicals, No. 203 (Paris 1981)
7.2 Justification		The method applied is in conformity with international regulatory requirements for assessing the acute toxicity of chemicals to fish.
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: Rainbow trout (<i>Oncorhynchus mykiss</i>)

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>4 April 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>
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 04	Acute toxicity to invertebrates
91/414 annex Point addressed	II 8.2.4.2	Effects on aquatic organisms - Acute toxicity to aquatic invertebrates - Acute toxicity to shrimp

1.2 Title	Acute toxicity of CGA 64250 to mysid shrimp (<i>Mysidopsis bahia</i>) in a 96-hour flow-through test
1.3 Report and/or project N° Syngenta File N° (SAM)	R26 BP-81-8-138-R 64250/215
1.4 Lab. Report N°	R26 BP-81-8-138-R
1.5 Cross reference to original study / report	8.2.4.2 /01
1.6 Authors	Report: Hollister, T.A. Summary: Görge, G.
1.7 Date of report	17.07.1981
1.8 Published / owner	Unpublished / Syngenta Crop Protection AG
2.1 Testing facility	EG&G Bionomics, Marine Research Laboratory, Pensacola, Florida, USA
2.2 Dates of experimental work	23. - 27.07.1981
3. Objectives	Determination of the acute toxicity of Propiconazole to mysid shrimp.
4.1 Test substance	CGA 64250 technical
4.2 Specification	[REDACTED]
4.3 Storage stability	Not specified in the report
4.4 Stability in vehicle	Sufficiently stable under conditions of the test. At the end of the test, the measured values ranged from 70 to 89 % of the nominal values.
4.5 Homogeneity in vehicle	Not specified in the report
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	Yellow liquid
7.1 Test method	Not specified in the report
7.2 Justification	The method applied is in conformity with international regulatory requirements for assessing the acute toxicity of chemicals to shrimps.
7.3 Copy of method	Available on request
8 Choice of method	Not relevant
9 Deviations	Not applicable
10.1 Certified laboratory	Not specified in the report
10.2 Certifying authority	Not applicable
10.3 GLP	No
10.4 Justification	Although the study was not conducted in compliance with the principles of GLP, it complies with sound scientific standards and 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

Species: Mysid shrimp (*Mysidopsis bahia*)
 Source: Cultured at Bionomics Marine Research Laboratory
 No. of animals tested: 120 (20 shrimps/dose level)
 Age: 6 - 8 days
 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
 Dose levels: Control/vehicle and mean measured concentrations 0.16, 0.46, 0.75, 1.40 and 2.90 mg/l
 Loading: 5 shrimps/Petri dish
 Administration: Intermittend flow-through system
 Photoperiod: Not specified in the report
 Temperature: 26 °C
 pH: 7.8 - 7.9
 Dissolved oxygen: 4.8 - 5.9 mg/l (□□72 % - □□84 % of saturation)□
 Salinity: 28 - 31 ‰
 General observations: Mortality and general symptoms of toxicity were recorded 24, 48, 72 and 96 hours after dosing.

13 Findings

Mortalities (%):

Concentration mg/l	24 h	48 h	72 h	96 h
Control, vehicle	0	0	5	5
0.16	0	0	10	10
0.46	0	5	20	55
0.75	0	15	45	55
1.40	30	85	90	95
2.90	90	100	100	100
LC 50 (mg/l) (conf. limit)	1.70 (1.5 - 2.1)	1.00 (0.9 - 1.2)	0.67 (0.5 - 0.9)	0.51 (0.4 - 0.7)

Other observations: No other toxic symptoms were specified in the report.

Results: Exposure of mysid shrimp to Propiconazole resulted in the 96-hour LC 0, LC 50 and LC 100 of < 0.16, 0.51 and 2.9 mg/l, respectively.

Conclusion: Propiconazole is classified as very toxic to mysid shrimps.

- 14 Statistics** The LC 50-values were calculated based on the moving average angle analysis (Stephan, C.E. 1977. Methods for calculating a LC 50. ASTM, Aquatic Toxicology and Hazard Evaluation, ASTM STP 634. In: F.L.Mayer and J.L.Hamelink, eds. pp. 65-84)
- 15 References (published)** None
- 16 Unpublished data** None
- 17 Reliability Indicator** 1

Data Protection Claim	Yes
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AG 7.22/GG/28.02.1995

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	<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>
Remarks	

98/8 Doc IIIA section No.	7.4.1.2 / 07	Acute toxicity to invertebrates
91/414 annex Point addressed	II 8.2.4.4	Effects on aquatic organisms - Acute toxicity to aquatic invertebrates - Acute toxicity to water flea

1.2 Title	Acute toxicity test of CGA 64250 techn. to the Cladoceran <i>Daphnia magna</i> Straus in the static system
1.3 Report and/or project N° Syngenta File N° (SAM)	64250/4294
1.4 Lab. Report N°	983985
1.5 Cross reference to original study / report	-
1.6 Authors	Grade, R.
1.7 Date of report	21.07.1999
1.8 Published / owner	Unpublished / Syngenta Crop Protection AG
2.1 Testing facility	Novartis Crop Protection AG, Basel, Switzerland
2.2 Dates of experimental work	11 – 28 June 1999
3. Objectives	Determination of the acute toxicity of Propiconazole to <i>Daphnia magna</i>
4.1 Test substance	Propiconazole tech.
4.2 Specification	
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 5 ml; M4-medium
6 Physical form	Brown liquid
7.1 Test method	OECD 202
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: *Daphnia magna* STRAUS
 Source: Derived from a culture originating from Novartis Services
 No. of animals tested: 160 (20 per treatment)
 Acclimatisation period: None
 Test containers: 150 ml glass beakers
 Dose levels: 0, vehicle control, 0.5, 1.0, 2.0, 4.0, 8.0 and 16 mg/l
 Loading: 5 daphnids per 100 ml
 Administration: Static
 Photoperiod: 16 hours light 8 hours dark. 30 minutes transition
 Temperature: 21 ± 1°C
 pH: 8.2 – 8.5
 Dissolved oxygen: 82 – 101% of saturation value
 Water hardness: 261 mg/l CaCO₃
 General observations: Immobilisation and behavioural changes at 24 and 48 hours

13 Findings

Number of daphnids immobilised per replicate

Concentration mg/l	24 hours				48 hours			
	1	2	3	4	1	2	3	4
Blank	0	0	0	0	0	0	0	0
Vehicle	0	0	0	0	0	0	0	0
0.50	0	0	0	0	0	0	0	0
1.0	0	0	0	0	0	0	0	0
2.0	0	0	0	0	0	0	0	0
4.0	0	0	0	0	0	0	0	0
8.0	0	2	1	0	0	2	1	2
16	5	0	3	0	5	4	5	4

EC 50 (mg/l) 48 hours 10.2
(conf. limit) 8.6 – 12.2

Other observations: None

Results: Immobilisation was only observed in the two highest concentrations tested (8.0 and 16 mg/l)

Conclusion: The 48 hour EC50 is 10.2 mg/l.

14 Statistics

The EC50 was calculated using the maximum likelihood method, probit model.

15 References (published)

None

16 Unpublished data

None

17 Reliability Indicator

1

Data Protection Claim	Yes
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Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	<i>4 April 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>
Remarks	

Section A7.4.1.3/10 Growth inhibition test on algae

Annex Point IIA7.3

Official
use only

1 REFERENCE

Reference Höger S, 2011, Propiconazole – Toxicity to *Pseudokirchneriella subcapitata* in a 96-hour algal growth inhibition test, Harlan Laboratories Ltd., 4452 Itingen, Switzerland, D06766, 11 January 2011
Syngenta Study reference CGA064250/10713

Data protection Yes

Data owner Syngenta Crop Protection AG.

Criteria for data protection

[REDACTED]

GUIDELINES AND QUALITY ASSURANCE

Guideline study Yes
OECD 201 (2006)
OPPTS 850.5400 (1996, Public Draft)
761/2009/EC, C.3 (2009)
JMAFF 2-7-7 (2005)

GLP Yes

Deviations No

MATERIALS AND METHODS

Test material CGA64250 tech.

Lot/Batch number

[REDACTED]

Specification

[REDACTED]

Purity

[REDACTED]

Composition of Product

n.a.

Further relevant properties

Method of analysis

HPLC with UV/VIS detection.

Preparation of TS solution for poorly soluble or volatile test substances 50.17 mg CGA64250 dispersed in 500 mL test medium, using 15 minutes of ultrasonication followed by 72 hours of intense stirring on a magnetic stirrer (in the dark). Membrane filtration (0.45 µ pore size).

Reference substance Yes. Potassium dichromate, twice a year.

Method of analysis for reference substance

Not described

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Testing procedure

Culture medium	OECD algal test medium. Hardness 24 mg/L as CaCO ₃ Na ₂ EDTA . 2H ₂ O 100 µg/L, pH 8.1.
Test organisms	<i>Pseudokirchneriella subcapitata</i> , Strain No. 61.81 SAG.
Test system	Test vessels – 50 mL Erlenmeyer flasks, containing 15 mL test volumes, with continuous magnetic stirring
Test conditions	Static test Temperature 22 °C pH start 8.2 pH end 8.2 – 8.8 Illumination – mean 5000 lux (range 4520 – 5400 lux)
Duration of the test	96-h
Test parameter	Inhibition of growth (biomass, growth rate and yield), determined from measurements of fluorescence
Sampling	Fluorescence of algal cells measured at 24, 48, 72 and 96-h Analytical samples for determination of propiconazole concentrations taken at start of test (0-h) and at end of test (96-h)
Monitoring of TS concentration	Yes, start of test (0-h) and at end of test (96-h)
Statistics	72 and 96-h EC50s, with 95% confidence intervals, determined using Probit analysis. LOEC/NOEC identified using Williams t-test (one-sided, $\alpha = 0.05$) or Welch t-test (one-sided, $\alpha = 0.05$)

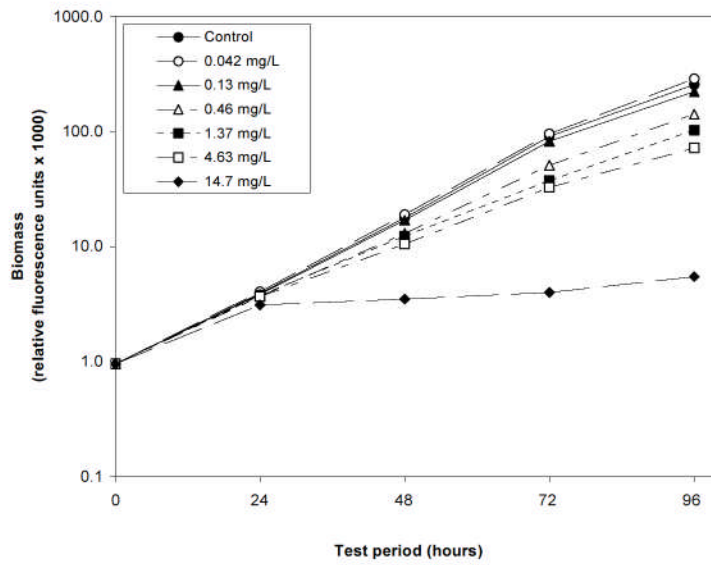
RESULTS

Limit Test	Not performed
Concentration	n.a.
Number/ percentage of animals showing adverse effects	n.a.
Results test substance	
Initial concentrations of test substance	Test start - 0 (control), 0.052, 0.152, 0.527, 1.56, 5.16, 15.4 mg ai/L
Actual concentrations of test substance	Test end - 0 (control), 0.0337, 0.113, 0.393, 1.21, 4.15, 14.0 mg ai/L

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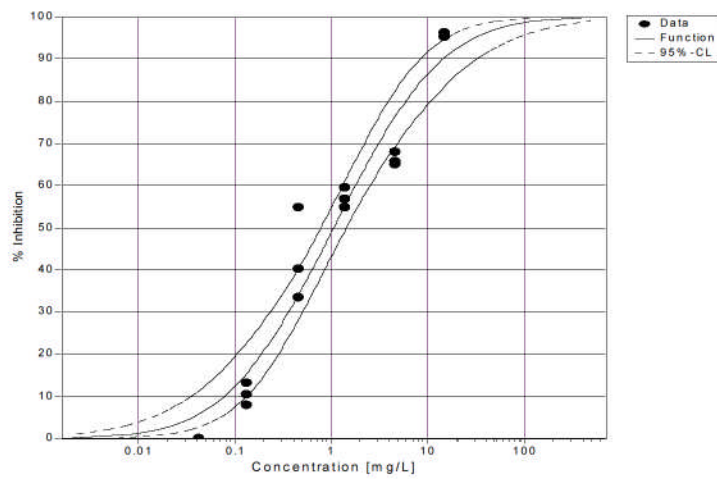
Annex Point IIA7.3

Growth curves

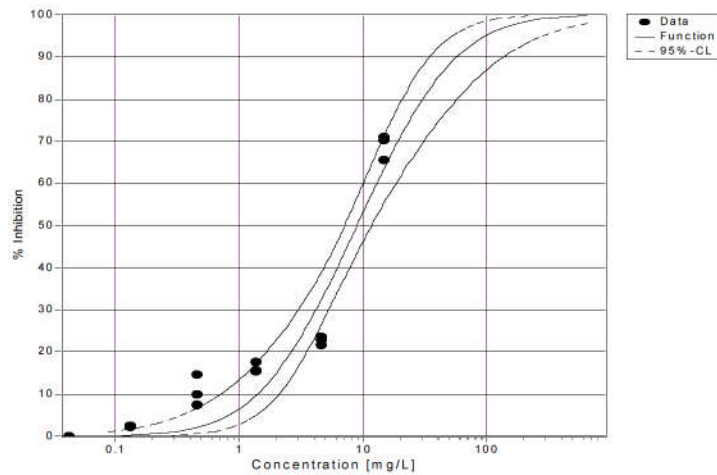


Concentration / response curve

Biomass



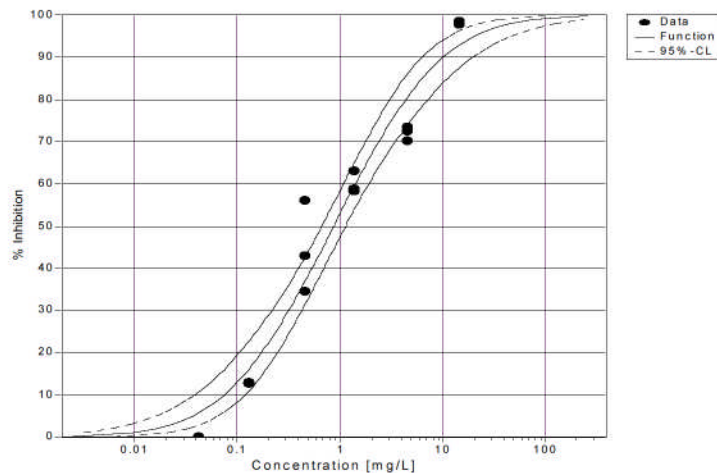
Growth rate



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Yield



Cell concentration data

Treatment / dilution	Mean measured concentration (mg/L)	Rep. no.	Biomass of algae*			
			24 hours	48 hours	72 hours	96 hours
Control	---	1	4.0	19.1	94.3	291.8
		2	4.1	19.5	97.9	272.6
		3	3.4	15.1	91.7	265.9
		4	3.8	17.4	86.2	251.7
		5	3.8	14.8	69.0	224.7
		6	4.4	20.6	102.1	222.1
		Mean	3.9	17.7	90.2	254.8
		SD	0.3	2.4	11.7	27.6
1:1600	0.042	1	3.9	18.8	96.2	270.9
		2	4.1	19.1	95.7	291.2
		3	4.1	18.9	94.2	298.5
		Mean	4.0	18.9	95.4	286.8
		SD	0.1	0.2	1.0	14.3
1:500	0.13	1	3.9	17.1	88.3	222.0
		2	3.8	16.8	75.9	222.8
		3	3.8	16.9	82.7	222.7
		Mean	3.8	16.9	82.3	222.5
		SD	0.0	0.1	6.2	0.4
1:160	0.46	1	3.8	13.8	59.0	167.2
		2	3.7	11.1	38.9	112.1
		3	3.5	14.1	54.3	145.6
		Mean	3.7	13.0	50.7	141.6
		SD	0.2	1.6	10.5	27.7