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:	160
Acclimatisation period:	7 days
Test containers:	3 l glass beakers
Dose levels:	Control, 125, 250 and 625 g a.i./ha
Loading:	10 worms per 550 g soil
Administration:	Static
Photoperiod:	16 hours light 8 hours dark
Temperature:	18.5 to 24.0 °C
pH:	6.03 – 7.24
Dissolved oxygen:	N/a
Water hardness:	N/a
General observations:	Mortality, health assessments adult group weights at 28 days (adults not returned to system). F_1 assessed after an additional 28 days (56 days treatment) for hatching.

13 Findings

Treatment (g a.i./ha)	Mean No. of dead adult worms (S.D.)	Mean adult weight difference (S.D)	Mean No. of offspring/ adult (S.D.)
Control	2.5 (5.0)	287 (23)	20.7 (4.0)
125	2.5 (5.0)	268 (49)	20.4 (5.1)
250	2.5 (5.0)	293 (31)	19.7 (1.9)
625	0.0 (0.0)	241 (61)	17.8 (2.4)

Other observations:	Mortality data were analysed by Yate's corrected Chi-squared test. Body weights were compared by non-parametric Kruskal Wallis ANOVA.
Results:	No statistically significant differences in mortality were observed at any test concentration. In addition there were no differences in the body weights amongst treatments. There were also no statistically significant differences in the number of young per adult at 56 days.
Conclusion:	No significant effects were observed up and including the highest dose of 625 g a.i./ha.

14	**Statistics**	Significant differences for mortality were analysed by Yate's corrected Chi-squared test. Body weights and number of offspring were compared using a non-parametric Kruskal Wallis ANOVA
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16	**Unpublished data**	None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.	**7.5.2.1/03**	**Reproduction study with other soil non-target macro-organisms**
1.2	**Title**	Propiconazole (CGA64250): Sublethal toxicity of a 155.87 g/L EC formulation (A6780D) to the earthworm Eisenia fetida.
1.3	**Report and/or project N° Syngenta File N° (SAM)**	CGA64250/4592
1.4	**Lab. Report N°**	03 10 48 087
1.5	**Cross reference to original study / report**	-
1.6	**Authors**	Friedrich, S
1.7	**Date of report**	2003
1.8	**Published / owner**	Unpublished / Syngenta Crop Protection AG
2.1	**Testing facility**	BioChem agrar, Labor für biologische und chemische Analytik GmbH, Kupferstraße 6, D-04827 Gerichshain, Germany
2.2	**Dates of experimental work**	27.08.03 to 22.10.03
3.	**Objectives**	To estimate the chronic toxicity of a propiconazole formulation to *Eisenia fetida*
4.1	**Test substance**	Formulation [redacted] containing 155.87 g/L propiconazole
4.2	**Specification**	[redacted]
4.3	**Storage stability**	March 2004
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
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:	W. Neudorff GmbH KG, An der Muhle 3, D-31860, Emmerthal
No. of animals tested:	260
Acclimatisation period:	24 hours
Test containers:	3 l glass beakers
Dose levels:	Control, 750, 1750, 1875, 4700 and 9300 g a.i./ha
Loading:	10 worms per 550 g soil
Administration:	Static
Photoperiod:	16 hours light 8 hours dark
Temperature:	19 to 22 °C
pH:	6.2 – 6.3
Dissolved oxygen:	N/a
Water hardness:	N/a
General observations:	Mortality, health assessments adult group weights at 28 days (adults not returned to system). F_1 assessed after an additional 28 days (56 days treatment) for hatching.

13 Findings

Treatment (g a.i./ha)	Mortality (%) adult worms	Mean adult weight increase per vessel by day 28 (mg)	Mean No. of offspring per vessel
Control	0	160.0	377.3
750	0	160.8	371.8 (99%)
1750	0	151.2	286.0 (76%)
1875	0	184.8	252.3* (67%)
4700	0	187.2	181.5* (48%)
9300	0	161.6	124.3* (33%)

* significantly different from control ($p \leq 0.05$)

Results:	Exposure to A-6780D concentrations up to 9300 g ai/ha did not have a significant effect on the mortality or growth of earthworms. Similarly the number of juveniles hatched after a further 28 days was not significantly affected by exposure of the parental generation to concentrations of 750 gai/ha. However, concentrations of 1750 g ai/ha and above caused significant reductions in juvenile numbers after 56 days ADDITIONAL COMMENTS (November 2005) For lethal effects and growth the NOEC is 9300, which was the highest rate tested. In this study, spray applications were applied to the soil surface of test vessels with a surface area of 249 cm^2 containing 560 g of dry soil, so these value are use to calculate the rate in mg/kg. Also the data need to be corrected to 3.4% organic matter in wet soil. Therefore the correction factor is rate (g/ha) x (0.00249 x 0.8 x 0.34) / 0.56 = 0.0012092 **The NOEC for lethal and growth effects is 9330 g/ha or 11.2 mg/kg wet soil at 3.4% OM** **The NOEC for reproduction effects is 750 g/ha or 0.907 mg/kg wet soil at 3.4% OM** **At the 4700 g/ha rate or 5.68 mg/kg wet soil at 3.4% OMthere was approximately a 50% reduction in reproduction**
Conclusion:	**Based on mortality and growth, the 56-day NOEC of A-6780 D for Eisenia fetida was 9300 g ai/ha (or 11.2 mg/kg wet soil at 3.4% OM)** **Based on reproduction, the 56-day NOEC of A-6780 D for Eisenia fetida was 750 g ai/ha (or 0.907 mg/kg wet soil at 3.4% OM)**

14	**Statistics**	LC_{50} was calculated by Probit analysis. Dunnett's test was used to compare the control with the independent test item groups in order to detect significant differences (p=0.05) between both.
15	**References (published)**	None
16	**Unpublished data**	None
17	**Reliability Indicator**	1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*13 March 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 7.5.2.2 Long-term test with terrestrial plants
Annex Point IIIA 13.3

Official use only

3 REFERENCE

Reference	Porch J.R., Martin K.H., Krueger H.O., 2009, Propiconazole formulation (LAg 2008 045) – Chronic Toxicity in Higher Plants, Wildlife International Ltd, Easton, MD, USA, Report no: 528-284, February 12, 2009
Data protection	Yes
Data owner	Syngenta Crop Protection AG
Criteria for data protection	[redacted]

GUIDELINES AND QUALITY ASSURANCE

Guideline study	Yes DIN ISO 22030 (2005)
GLP	Yes
Deviations	Yes; - the initial harvest was conducted on Day 16 rather than Day 14, - the total number of emerged seedlings in each replicate was not determined prior to the 7-day thinning, - three replicates were inadvertently thinned to three seedlings per replicate rather than four seedlings per replicate

METHOD

Test material	[redacted] containing nominally 1.22% w/w propiconazole
Lot/Batch number	[redacted]
Specification	[redacted]
Purity	1.30% Propiconazole (w/w) (data provided by sponsor) 1.19% Propiconazole (w/w) (analysed by testing laboratory)
Composition of Product	Not reported
Further relevant properties	Not reported
Method of analysis	HPLC with UV detection for the analysis of propiconazole within the product HPLC with tandem mass spectral detection (LC/MS/MS) for analysis of propiconazole in test soil
Preparation of TS solution for poorly soluble or volatile test substances	See table A7_5_2_2-1
Reference substance	No
Method of analysis for reference substance	-
Testing procedure	
Dilution water	See table A7_5_2_2-2

Section 7.5.2.2 Long-term test with terrestrial plants
Annex Point IIIA 13.3

Test plants	*Brassica rapa* CrGC syn Rbr see also table A7_5_2_2-3
Test system	Test type: chronic toxicity in higher plants Test concentrations: 5, 10, 15, 20, 30, 40, and 81 mg formulation/kg Controls: solvent control and a negative control Test Soils: amounts of test substance were weighed out, acetone added to dissolve and added to sand by mixing. The spiked sand was then added to known amounts of soil and mixed to produce the test concentrations. Planting: test soil added to plastic pots (16cm in diameter, 12cm deep) and 10 seeds added to each pot at approximate depth of 6mm Replicates: 10 replicate pots for each treatment group and control groups Observations: Day 1 and 2 after test initiation, 7 days after test initiation, Day 16, regularly throughout flowering and at Day 40 Sampling : Day 16 - shoot fresh weight, Day 40 – shoot fresh weight, shoot dry weight, pod fresh weight, pod dry weight see also table A7_5_2_2-4
Test conditions	Temperature: 13.41 – 33.80°C Humidity: 9.87 – 84.70% 16 hour photoperiod see also table A7_5_2_2-5
Test duration	40 days
Test parameter	Number of seed pods with fertile seeds, fresh and dry weights of plant shoots and seed pods, number of surviving seedlings
Sampling	Day 16: number of live seedlings, mean number of flowers on each plant and shoot fresh weight of half of the replicates were determined in order to assess potential effects on early seedling growth, Day 40: remaining replicates were harvested in order to assess potential effects on reproductive capability via shoot fresh weight, shoot dry weight, pod fresh weight, pod dry weight. Observations were made daily for two days after test initiation at which time at least 50% of the control seedlings were emerged (this was designated as Day 1 of the test). Seven days after planting, the number of emerged seedlings was thinned to no more than four per pot. On Day 16 of the test, five replicates from each treatment group were randomly selected for observations including the occurrence of visible flower buds per plant (noted as present or absent), the number of flowers per plant (counted), the fresh weight of plant shoots, the proportion of live plants (living at Day 16 relative to number present after thinning), and the number of damaged plants, based on qualitative evidence such as chlorosis, necrosis, wilting, or other signs of toxicity. When flowering started, flowers on test plants were hand-pollinated using a paint brush. The pollination procedure was conducted twice each week as long as significant numbers of new flowers were being produced. The in-life portion of the test was terminated on Day 40, at which time the following observations were made: the growth stadium according to the BBCH scheme; the number of seed pods with fertile seeds on each plant (counted); the fresh weights of plant shoots (without

Section 7.5.2.2 Long-term test with terrestrial plants
Annex Point IIIA 13.3

	seed pods); the fresh weights of seed pods for each plant; the proportion of live plants (living at test termination relative to living after thinning).
Method of analysis of the plant material	Plant shoots and seed pods were dried in an oven and weighed. Plant shoot fresh and dry weights were made for each individual plant. All pods collected from a single plant were weighed as a group.
Quality control	Negative and solvent control groups ran in parallel.
Statistics	Dunnett's t-test used to help define the NOEC and LOEC using the DUNNETT option of the GLM (general linear model) procedure of SAS* * SAS Institute, Inc., 1999. SAS Proprietary Software Version 8, Cary, NC, SAS Institute, Inc.
	RESULTS
Results test substance	
Applied initial concentration	Nominal: 5.0, 10, 15, 20, 30, 40 and 81 mg formulation/kg dry weight soil The homogeneity of the test substance in the soil was evaluated after preparation of test soils. Test concentrations of 0.06 ppm a.i. (5.0 mg formulation/kg dry weight soil) and 0.96 ppm a.i. (81 mg formulation/kg dry weight soil) were analytically verified. Recovery rates were 100% and 101% of nominal concentrations (means and standard deviations were 0.06 ± 0.025 ppm a.i. and 0.969 ± 0.346 ppm a.i.).
Phytotoxicity rating	On day 16, damage, consisting of chlorosis or leaf curl, was observed in four seedlings (one each in the 5.0 and 30 mg/kg dry weight soil groups, and two in the 81 mg/kg group). See also table A7_5_2_2-6
Plant height	Not monitored
Plant dry weights	See table A7_5_2_2-7 for shoot fresh weights at day 16, A7_5_2_2-8 for shoot fresh and dry weights at day 40 and A7_5_2_2-9 for pod fresh and dry weights at day 40
Root dry weights	Not monitored
Root length	Not monitored
Number of dead plants	See table A7_5_2_2-7 for measurements at day 16 and table A7_5_2_2-8 for measurements at day 40
Effect data	NOEC = 81 mg formulation/kg dry weight soil corresponding to 0.96 mg a.i./kg dry weight soil EC_{50} > 81 mg formulation/kg dry weight soil corresponding to > 0.96 mg a.i./kg dry weight soil
Concentration / response curve	Not given in the report
Other effects	The seedling survival expressed as the number of live seedlings on day 16 or day 40 in proportion to the number present after thinning is evaluated. Furthermore, the number of flowers and number of pods per plant was monitored. Data are given in table A7_5_2_2-6 (flower number), A7_5_2_2-7 and A7_5_2_2-8.
Results of controls	More than 50% of seedlings were emerged 2 days after planting (see

Section 7.5.2.2 Annex Point IIIA 13.3 — Long-term test with terrestrial plants

	table A7_5_2_2-10). All plants of the pooled control were alive at day 16 (see table A7_5_2_2-7) and 98% were alive at day 40 (see A7_5_2_2-8). At days 16 and 40, there were no observed effects resulting from the use of the solvent (t-test, $\alpha = 0.05$), so the negative and solvent groups were pooled for comparison to the treatment groups for all parameters.
Number/ percentage of plants showing adverse effects	One plant (2.5%) of the pooled control showed adverse effects ad day 16. See also table A7_5_2_2-6
Nature of adverse effects	One plant in the solvent control showed signs of necrosis. See also table A7_5_2_2-6
Test with reference substance	Not performed
Concentrations	-
Results	-

APPLICANT'S SUMMARY AND CONCLUSION

Materials and methods	A rapid-cycling variant of rape (*Brassica rapa* CrGC syn Rbr) was tested for effects on seedling growth and reproductive capability according to DIN ISO Guideline 22030. Seeds were planted in soil containing LAg 2008 045, a formulation containing nominally 1.22% w/w propiconazole at concentrations of 5.0, 10, 15, 20, 30, 40 and 81 mg formulation/kg dry weight soil. A negative control group and a solvent control group were maintained concurrently. The test and control groups consisted of ten replicate test pots, with each pot containing ten planted seeds. Half of the replicates were harvested on Day 16 of the test in order to assess potential effects on early seedling growth. The remaining replicates were harvested on Day 40 in order to assess potential effects on reproductive capability. The number of seed pods with fertile seeds, fresh and dry weights of plant shoots and seed pods, and number surviving seedlings were determined at test termination.
Results and discussion	Emergence of the control groups exceeded 50% by two days after planting. At days 16 and 40, there were no observed effects resulting from the use of the solvent, so the negative and solvent groups were pooled for comparison to the treatment groups for all parameters. There was no apparent dose-response, and no treatment group mean was significantly different from the pooled control mean (Dunnett's t-test, $p < 0.05$) for the test parameter proportion of live plants, shoot fresh and dry weight, flowers per plant, proportion of damaged plants and pods per plant. Soil-incorporation of LAg 2008 045 at nominal concentrations of up to 81 mg formulation/kg d wt soil (corresponding to 0.96 mg propiconazole/kg dry weight soil) resulted in no effects. Therefore, the NOEC was determined to be 81 mg formulation/kg dry weight soil, and the EC_{50} was determined to be greater than 81 mg formulation/kg dry weight soil.
NOEC	81 mg formulation/kg dry weight soil corresponding to 0.96 mg propiconazole/kg dry weight soil
EC_{50}	> 81 mg formulation/kg dry weight soil corresponding to

Section 7.5.2.2 Long-term test with terrestrial plants
Annex Point IIIA 13.3

	> 0.96 mg propiconazole/kg dry weight soil
EC_{100}	> 81 mg formulation/kg dry weight soil corresponding to > 0.96 mg propiconazole/kg dry weight soil
Conclusion	The study is considered to be valid as all validity criteria according to ISO Guideline 22030 were fulfilled (see table A7_5_1_3-11). The NOEC was determined to be 81 mg formulation/kg dry weight soil, and the EC_{50} was determined to be greater than 81 mg formulation/kg dry weight soil.
Reliability	1
Deficiencies	No

Data Protection Claim	Yes

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date *6 December 2009*

Materials and Methods [redacted]

Results and discussion [redacted]

Conclusion [redacted]

Reliability [redacted]

Acceptability [redacted]

Remarks -

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7_5_2_2-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	Yes Acetone
Concentration of vehicle	100 mL per 200 g of sand
Vehicle control performed	Yes A solvent control containing 100 mL of acetone which was added to 200 g of sand was included in the study design
Other procedures	Not applicable

Table A7_5_2_2-2: Dilution water

Criteria	Details
Source	Water for seedling growth was supplied by subirrigation with well water from the glasshouse facility.
Alkalinity / Salinity	Not reported
Hardness	Not reported
pH	Not reported
Oxygen content	Not reported
Conductance	Not reported
Holding water different from dilution water	Not suitable for a test with terrestrial organisms

Table A7_5_2_2-3: Test plants

	Family	Species	Common name	Source (seed/plant)
Dicotyledonae	Brassicaceae	*Brassica rapa* CrGC syn Rbr	Turnip rape	Seeds were obtained from Carolina Biological Supply, Burlington, NC, USA

Table A7_5_2_2-4: Test system

Criteria	Details
Test type	Greenhouse
Container type	Plastic pots approximately 16 cm in diameter and 12 cm deep, 1940 cm^3 soil volume
Seed germination potential	Not reported
Identification of the plant species	Not reported
Number of replicates	10
Numbers of plants per replicate per dose	10 seeds/replicate at test initiation, seven days after planting, the number of emerged seedlings was thinned to no more than four per pot
Date of planting	October 10, 2008
Plant density	10 seeds at test initiation/201 cm^2 4 seeds/201 cm^2 after plant thinning at day 7
Date of test substance application	October 10, 2008
High of plants at application	Not applicable, seeds were planted
Date of phytotoxicity rating or harvest	October 27, 2008 and November 20, 2008
Dates of analysis	November 29, 2008 – completion of dry weight measurements

Table A7_5_2_2-5: Test conditions

Criteria	Details
Test type	Long term toxicity test on terrestrial plants
Method of application	Test item was stirred into soil at test initiation
Application levels	Not reported
Dose rates	5.0, 10, 15, 20, 30, 40 and 81 mg formulation/kg dry weight soil (nominal)
Substrate characteristics	The soil used for the test represented a sandy loam soil, and was composed of kaolinite clay, industrial quartz sand, and peat. A slow-release fertilizer was added to provide nutrients essential for plant growth, and limestone was added to buffer the pH. The soil was characterised to consist of 80% sand, 8% silt and 12% clay, with an organic matter content of 1.7%. The soil pH was measured to be 6.2.
Watering of the plants	Seedlings were subirrigated to minimize the potential for the leaching of the test substance through the soil. Subirrigation trays were filled to a predetermined depth to help standardize the amount of water delivered to each tray. Watering dates were 10, 17, 20, 25 and 31 October, 02, 05, 08, 09, 11, 12, 13, 14, 15, 16, 18 and 19 November.
Temperature	October 10 to October 27, 2008: 23.09 °C ± 0.68 (mean ± standard deviation) 17.60 – 33.80 °C (min – max) October 28 to November 20, 2008: 22.08 °C ± 0.88 (mean ± standard deviation) 13.41 – 31.42 °C (min – max)
Thermoperiod	Not reported
Light regime	Minimum 16 h photoperiod
Relative humidity	October 10 to October 27, 2008: 48.63% ± 11.97 (mean ± standard deviation) 14.62% - 82.1% (min – max) October 28 to November 20, 2008: 45.36% ± 16.01 (mean ± standard deviation) 9.87% - 84.70% (min – max)
Wind volatility	Not applicable

Criteria	Details
Observation periods and duration of test	Calendar Day (2008) / Test Day / Study Event 10 October / - / Preparation of test soils and planting 12 October / 1 / First day with > 50% control emergence. 17 October / 6 / Seven days after planting. Pots thinned to no more than four seedlings per pot. 27 October / 16 / Initial harvest of five replicates per treatment level. Hand-pollination of remaining plants begins. 30 October / 19 / Hand-pollination of plants. 03 November / 23 / Hand-pollination of plants. 06 November / 26 / Hand-pollination of plants. 11 November / 31 / Hand-pollination of plants. 13 November / 33 / Hand-pollination of plants. 20 November / 40 / Test termination, shoot fresh weight, pod number, and pod fresh weight determined. 29 November / n/a / Completion of dry weight measurements.
Pest control	Not reported
Any other treatments and procedures	Not reported

Table A7_5_2_2-6: Flower number and damage observations on day 16

Replicate		Negative Control	Solvent Control	Pooled Controls	5.0 mg/kg	10 mg/kg	15 mg/kg	20 mg/kg	30 mg/kg	40 mg/kg	81 mg/kg
	A1	0 / -	1 / -		0 / -	2 / -	0 / -	0 / -	0 / -	2 / -	0 / -
	A2	0 / -	3 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
	A3	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
	A4	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
AVG		**0.0**	**1.0**		**0.0**	**0.5**	**0.0**	**0.0**	**0.0**	**0.5**	**0.0**
	E1	3 / -	1 / -		0 / -	1 / -	1 / -	2 / -	1 / CL	1 / -	1 / -
	E2	1 / -	1 / -		0 / -	2 / -	1 / -	1 / -	0 / -	0 / -	0 / -
	E3	0 / -	0 / -		0 / -	0 / -	2 / -	0 / -	0 / -	0 / -	0 / -
	E4	0 / -	0 / -		0 / LC	0 / -	2 / -	*	0 / -	0 / -	0 / -
AVG		**1.0**	**0.5**		**0.0**	**0.8**	**1.5**	**1.0**	**0.3**	**0.3**	**0.3**
	G1	3 / -	1 / -		4 / -	4 / -	3 / -	1 / -	1 / -	2 / -	1 / -
	G2	1 / -	2 / -		0 / -	1 / -	2 / -	0 / -	1 / -	0 / -	0 / -
	G3	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
	G4	0 / -	0 / N		*	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
AVG		**1.0**	**0.8**		**1.3**	**1.3**	**1.3**	**0.3**	**0.5**	**0.5**	**0.3**
	H1	1 / -	3 / -		2 / -	3 / -	0 / -	0 / -	2 / -	3 / -	3 / -
	H2	0 / -	1 / -		0 / -	1 / -	0 / -	0 / -	1 / -	0 / -	1 / LC
	H3	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / LC
	H4	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	n/a / M	0 / -	0 / -
AVG		**0.3**	**1.0**		**0.5**	**1.0**	**0.0**	**0.0**	**1.0**	**0.8**	**1.0**
	J1	2 / -	1 / -		0 / -	1 / -	0 / -	1 / -	0 / -	0 / -	2 / -
	J2	0 / -	1 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
	J3	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
	J4	0 / -	0 / -		0 / -	0 / -	0 / -	0 / -	0 / -	0 / -	0 / -
AVG		**0.5**	**0.5**		**0.0**	**0.3**	**0.0**	**0.3**	**0.0**	**0.0**	**0.5**
Mean		**0.55**	**0.75**	**0.65**	**0.37**	**0.75**	**0.55**	**0.30**	**0.35**	**0.40**	**0.40**
Std. Dev.				**0.357**	**0.582**	**0.395**	**0.758**	**0.411**	**0.418**	**0.285**	**0.379**
% Reduction					**44**	**-15**	**15**	**54**	**46**	**38**	**38**

Number of open flowers / observed signs of plant damage. n/a indicates that the seedling was not living at Day 16.
CL – Chlorosis, LC – Leaf Curl, N – Necrosis, M – Mortality
* - These replicates contained only 3 seedlings after thinning.

Table A7_5_2_2-7: Day 16 plant measurements

Proportion of Live Plants, Shoot Fresh Weight, Number of Open Flowers, and Number of Damaged Plants at Day 16

Treatment Group (mg/kg)	Proportion of Live Plants (Number Living out of Total)	Shoot Fresh Weight (g) Mean ± SD (% reduction)	Flowers Per Plant (n) Mean ± SD (% reduction)	Proportion of Damaged Plants (Number Damaged out of Total)
Pooled Control	100% (40 of 40)[1]	6.79 ± 1.513	0.65 ± 0.353	2.5% (1 of 40)
5.0	100% (19 of 19)	7.85 ± 1.142 (-16%)	0.36 ± 0.568 (45%)	5.3% (1 of 19)
10	100% (20 of 20)	8.16 ± 1.094 (-20%)	0.78 ± 0.396 (-18%)	0% (0 of 20)
15	100% (20 of 20)	6.22 ± 2.139 (8%)	0.56 ± 0.770 (15%)	0% (0 of 20)
20	100% (19 of 19)	7.14 ± 2.143 (-5%)	0.32 ± 0.409 (52%)	0% (0 of 19)
30	95% (19 of 20)	7.67 ± 1.496 (-13%)	0.36 ± 0.416 (45%)	0% (0 of 19)
40	100% (20 of 20)	6.73 ± 1.716 (1%)	0.42 ± 0.295 (36%)	0% (0 of 20)
81	100% (20 of 20)	5.75 ± 1.422 (15%)	0.42 ± 0.370 (36%)	10% (2 of 20)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p<0.05$).
Mean ± SD = Mean plus or minus one standard deviation.
[1] Survival was 20 of 20 in both control groups.

Table A7_5_2_2-8: Day 40 plant measurements

Proportion of Live Plants, Shoot Fresh Weight, Shoot Dry Weight, and Shoot Water Content at Day 40

Treatment Group (mg/kg)	Proportion of Live Plants (Number Living out of Total)	Shoot Fresh Weight (g) Mean ± SD (% reduction)	Shoot Dry Weight (g) Mean ± SD (% reduction)	Shoot Water Content (%) Mean ± SD (% reduction)
Pooled Control	98% (38 of 39)[1]	5.56 ± 1.692	0.791 ± 0.2000	85.5 ± 0.17
5.0	100% (20 of 20)	6.45 ± 1.791 (-16%)	0.910 ± 0.2501 (-15%)	85.9 ± 0.87 (0%)
10	100% (20 of 20)	4.70 ± 0.712 (16%)	0.718 ± 0.1009 (9%)	84.7 ± 0.52 (1%)
15	100% (20 of 20)	5.23 ± 2.236 (6%)	0.738 ± 0.3084 (7%)	85.7 ± 1.57 (0%)
20	100% (20 of 20)	5.10 ± 0.971 (8%)	0.726 ± 0.1553 (8%)	85.8 ± 1.00 (0%)
30	94% (17 of 18)	6.08 ± 2.219 (-9%)	0.872 ± 0.3489 (-10%)	85.7 ± 0.97 (0%)
40	100% (20 of 20)	5.20 ± 1.367 (7%)	0.714 ± 0.1523 (10%)	86.1 ± 1.30 (-1%)
81	100% (20 of 20)	8.15 ± 1.636 (-46%)	1.004 ± 0.1541 (-27%)	87.5 ± 1.17 (-2%)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p<0.05$).
Mean ± SD = Mean plus or minus one standard deviation.
[1] Survival was 18 of 19 in the Negative Control and 20 of 20 in the Solvent Control.

Table A7_5_2_2-9: Day 40 pod measurements

Pod Number, Pod Fresh Weight, Pod Dry Weight, and Pod Water Content at Day 40

Treatment Group (mg/kg)	Pods Per Plant (n) Mean ± SD (% reduction)	Pod Fresh Weight (g) Mean ± SD (% reduction)	Pod Dry Weight (g) Mean ± SD (% reduction)	Pod Water Content (%) Mean ± SD (% reduction)
Pooled Control	19.6 ± 3.75	3.52 ± 0.972	0.650 ± 0.1759	81.5 ± 2.04
5.0	20.4 ± 5.02 (-4%)	3.68 ± 1.240 (-5%)	0.688 ± 0.2392 (-6%)	81.4 ± 0.32 (0%)
10	18.7 ± 8.56 (5%)	3.58 ± 1.798 (-2%)	0.715 ± 0.3505 (-10%)	80.0 ± 0.35 (2%)
15	17.0 ± 7.49 (14%)	3.13 ± 1.591 (11%)	0.572 ± 0.2589 (12%)	81.3 ± 2.23 (0%)
20	20.9 ± 6.24 (-7%)	3.85 ± 1.044 (-10%)	0.751 ± 0.2424 (-16%)	80.7 ± 1.28 (1%)
30	18.5 ± 4.16 (6%)	3.62 ± 1.141 (-3%)	0.711 ± 0.2230 (-9%)	80.3 ± 0.80 (1%)
40	18.3 ± 1.80 (6%)	3.37 ± 0.602 (4%)	0.638 ± 0.1607 (2%)	81.2 ± 2.21 (0%)
81	16.3 ± 3.85 (17%)	3.31 ± 0.707 (6%)	0.574 ± 0.1477 (12%)	82.6 ± 2.75 (-1%)

No treatment group mean is significantly different from the control mean (Dunnett's test, $p<0.05$).
Mean ± SD = Mean plus or minus one standard deviation.

Table A7_5_2_2-10: Seedling emergence in control

Replicate	1 day after planting		2 days after planting	
	Negative Control	Solvent Control	Negative Control	Solvent Control
A	0	0	6	7
B	0	0	9	7
C	0	0	7	9
D	0	0	10	9
E	0	0	5	6
F	0	0	7	8
G	0	0	9	8
H	0	0	9	9
I	0	0	9	8
J	0	0	8	9

Number of emerged seedlings per ten planted seeds in each control replicate pot.

Table A7_5_2_2-11: Validity criteria for terrestrial plant toxicity according to Guideline ISO 22030 (Chronic toxicity on higher plants)

	Fulfilled	Not fulfilled
Emergence rate of the control plants of at least 75% (mean value of all replicates)	X	
Healthy plants develop in the controls: plants do not etiolate and flowers appear during the first three weeks	X	
Not more than one emerged plant per pot has died in the controls during the test	X	

98/8 Doc IIIA section No.	**7.5.5**	**Bioconcentration, terrestrial**

The BCF for propiconazole in earthworms has not been determined experimentally. However, it is possible to estimate this BCF to the following equation :

$$BCF_{earthworm} = (0.84 + 0.012K_{ow}) / RHO_{earthworm}$$

where, for $RHO_{earthworm}$ by default a value of 1 (kgwwt.L-1) can be assumed.

Therefore, for propiconazole, with a log Pow of 3.72, the calculated $BCF_{earthworm}$ is

(0.84 + 0.012 x 5248)/1 = **63.8**

RMS comment: [redacted]

98/8 Doc IIIA section No.	**7.6**	**Summary of ecotoxicological effects and fate and behaviour in the environment**

Cross-reference : Document IIA

PROPICONAZOLE

Dossier for Directive 98/8/EC
Document IIIA

Section 8 : Measures Necessary To Protect Man, Animals & The Environment

Section 9 : Classification & Labelling

Section 10 : Summary and Evaluation of Section 2 to 9

Final version

Syngenta Version July 2004 after feedback from preliminary completeness check

8 MEASURES NECESSARY TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

A Safety Data Sheet is enclosed in appendices of Document I.1 (appendix 3)

Personal protective equipment

In General: Change working clothes daily.
Breathing Protection: In case of heavy exposure, wear: Gas mask.
Eye Protection: Goggles
Hand Protection: Chemical-resistant gloves
Body Protection: Heavy duty cotton or synthetic fabric working clothes (e.g. overalls). Heavy-duty shoes or boots.
Precautionary measures after work: Wash thoroughly (shower, bathe, wash hair). Change clothing. Thoroughly clean protective gear. Thoroughly clean contaminated equipment with soap or soda solution.

Hazards identification :	Harmful if swallowed Dangerous for the environment, toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Handling and storage :	Store the product in closed original containers protected from light and humidity. Keep away from food, feed and stimulants.
Transport :	Use unbreakable containers, make sure they cannot fall. Label must be in accordance with regulations.
UN No. 3082	
• Classification Rail / Road RID / ADR :	Class 9 Cipher 11 C Kemmler Index 90 CEFIC No. 90UMW-94 Label 9
Proper shipping name :	environmentally hazardous substance, liquid, N.O.S.
Additional information :	propiconazole
• Classification Sea IMDG-Code :	free
• Classification Air ICAO :	free

Fire

Extinguishing media :	powder, foam, carbondioxide or waterspray (do not use direct jet of water)
Special Hazards during Fire Fighting	Combustion products are toxic and/or irritant. Measures have to be taken to prevent the contaminated

	extinguishing agent from seeping into the ground or from spreading uncontrollably
Protective Equipment for Fire Fighting	Use self contained breathing apparatus. Wear protective equipment

8.2 In case of fire, nature of reaction products, combustion gases, etc.

Combustion gases : Propiconazole contains the elements carbon, hydrogen, oxygen, nitrogen and chlorine.

In the event of fire, the formation of hydrogen chloride, hydrogen cyanide, carbon monoxide and nitrogen oxides must be anticipated.

8.3 Emergency measures in case of an accident

Fire fighting water has to be contained, concentrated and decontaminated by filtration using charcoal. The water can be disposed of in a suitable sewage treatment plant or incinerated. The charcoal can be disposed of in a suitable waste incineration plant in accordance with the official regulations.

First-Aid Measures

General: Remove the affected person from the danger zone to a well-ventilated room or to fresh air, and protect from undercooling. IN CASE OF SUSPECTED POISONING: Immediately call a physician.

Eye Contact: Rinse eyes with clean water for several minutes and immediately call a physician.

Ingestion: Repeatedly administer medicinal charcoal in a large quantity of water. NOTE: Never give anything by mouth to an unconscious person. Do not induce vomiting.

Skin Contact: Remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water, including hair and under fingernails.

Medical Instructions

Antidote: No specific antidote is known! Apply symptomatic therapy.

Experiences Specific to Man: No case of human poisoning is on record.

8.4 Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

The active substance propiconazole can be disposed of safely by incineration in a modern incinerator, licensed to treat special contaminated waste. The ashes have to be disposed of at a suitable approved waste disposal site. Wash water has to be disposed of via a suitable waste water treatment plant.

The halogen content of propiconazole is only 20.7 % and therefore well below the critical limit of 60 %

No other methods are proposed to dispose of the active substance propiconazole.

Where larger quantities are concerned consult the supplier

Environmental Protection Measures following Accidents: Soak up with absorptive material such as sand, soil, diatomaceous earth, etc. Prevent material from spreading, e.g. by damming in with absorptive material. Collect material in specially marked, tightly closing containers. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative. Do not contaminate waters and sewers